The impact on patients of pharmacist-conducted domiciliary COPD annual reviews: a qualitative study

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Abstract

Introduction

Globally, Chronic Obstructive Pulmonary Disease (COPD) is one of the most important non-communicable diseases with a progressive downhill course.[1] Guidelines recommend regular review of patients with COPD.[2] In the UK traditionally, annual COPD reviews were held in the GP surgery with no provision for those who could not attend. It was thought that practice pharmacists may be ideally placed to provide annual reviews for COPD patients by providing domiciliary visits.

Aims and Objectives

The objectives of this study were to offer a home COPD annual review conducted by a practice pharmacist to all housebound COPD patients who have not had an annual review in the last 15 months with a secondary review carried out four weeks later to review any changes and to undertake a semi-structured interview to discover patients' thoughts and feelings regarding domiciliary pharmacist led COPD reviews.

Setting

The project was undertaken in the North East Glasgow HSCP where COPD is the fourth highest cause of early death.[3]

Method

A phenomenological approach was taken in this project with mainly qualitative methodology data produced with some baseline quantitative data also being

reported. Thematic analysis was conducted on the data produced by the interviews to identify themes and help develop appropriate services for housebound patients.

Key findings

A one-off domiciliary visit was not found to have a major effect on HRQoL however patient feedback showed that home COPD annual reviews conducted by a practice pharmacist were found to be a positive experience with patients satisfied with the home setting, enjoyed the social contact, and interaction with a health care professional.

Conclusion

This study suggests that pharmacists working within primary care may improve medication outcomes for patients at risk of medication related problems. It also showed that pharmacists conducting domiciliary visits for chronic disease reviews were acceptable to patients.

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This thesis is dedicated to the memory of my dad, Stan Barclay who died suddenly and unexpectedly during the write up. Thank you for always believing in me, even when I did not believe in myself.

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Abbreviations

AC	Adenylate cyclase
ACBS	Advisory Committee on Borderline Substances
ACP	Anticipatory Care Plan
ADR	Adverse Drug Reaction
AR	Adrenergic receptor
ATP	Adenosine triphosphate
BD	Twice Daily
BLF	British Lung Foundation
BMA	British Medical Association
BMI	Body Mass Index
BNF	British National Formulary
BP	Blood Pressure
BTS	British Thoracic Society
cAMP	Adenosine 3', 5'-cyclic monophosphate
CASP	Critical Appraisal Skills Programme
CAT	COPD Assessment Test
CDC	Centers for Disease Control and Prevention (America)
COPD	Chronic Obstructive Pulmonary Disease
CRQ	Chronic Respiratory Questionnaire
DEXA	Dual Energy X-ray absorptiometry
DNACPR	Do Not Attempt Cardiopulmonary Resuscitation
DN	District Nurse
DPI	Dry Powder Inhaler
eGFR	estimated Glomerular Filtration Rate
eKIS	emergency Key Information Summary
FEV1	Forced Expiratory Volume in the first second
FEV1%	Forced Expiratory Volume in the first second as a percentage of normal function
FEV1/FVC	Ratio of the forced expiratory volume in the first one second to the forced vital capacity of the lungs
FIP	Federation International Pharmaceutical
FVC	Forced Vital Capacity
FRAX	Fracture Risk Assessment Tool
GOLD	Global Initiative for Chronic Obstructive Lung Disease

GGC	Greater Glasgow and Clyde
GMC	General Medical Council
GMS	General Medical Services
GP	General Practitioner
GPP	Good Pharmacy Practice
GPhC	General Pharmaceutical Council
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GTN	Glyceryl Trinitrate
H/O	History of
HBA1c	Haemoglobin A1c also known as glycated haemoglobin test
HF	Heart Failure
HRQoL	Health Related Quality of Life
HSCP	Health and Social Care Partnership
ICS	Inhaled Corticosteroids
IV	Intravenous
LABA	Long-Acting Beta-adrenoceptor Agonist
LAMA	Long-Acting Muscarinic Antagonist
LTOT	Long Term Oxygen Therapy
M3	Muscarinic
MDI	Metered Dose Inhaler
MI	Myocardial Infarction
MRC	Medical Research Council
MRP	Medication Related Problems
MUST	Malnutrition Universal Screening Tool
NICE	National Institute for Clinical Excellence
NMP	Non-Medical Practitioner
NHS	National Health Service
OD	Once Daily
OOH	Out of Hours
PEFR	Peak Expiratory Flow Rate
PCO	Primary Care Organisation
PCT	Primary Care Trust
PDE	Phosphodiesterase
PIL	Patient Information Leaflet
PIP	Pharmacist Independent Prescriber

PKA	Protein kinase A
pMDI	Pressurised Metered Dose Inhaler
PSSRU	Personal Social Services Research Unit
PSP	Prescribing Support Pharmacist
PST	Prescribing Support Technician
QOF	Quality and Outcomes Framework
QoL	Quality of Life
RCGP	Royal College of General Practice
RCT	Randomised Controlled Trial
RPS	Royal Pharmaceutical Society
Sa02	Saturation of Oxygen
SC	Sub cutaneous
SGRQ	Saint George's Respiratory Questionnaire
SOB	Shortness of Breath
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristics
STOPP	Screening Tool of Older Persons' Prescriptions
TATT	Tired all the time
TDS	Three times daily
WHO	World Health Organisation
UK	United Kingdom
US	United States of America
UTI	Urinary Tract Infection

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1. Introduction

1.1 Foreword

This thesis presents a qualitative review of housebound COPD patients' views on receiving a home annual review by a practice pharmacist. An overview of a General Practitioner (GP) practice pharmacist role is given in section 1.2 with pharmaceutical care discussed in section 1.3. The Scottish General Medical Service (GMS) contract is discussed in section 1.4 with a definition of COPD given in section 1.5. Treatment options for COPD are detailed in section 1.6. Scotland's population and levels of deprivation are discussed in section 1.7 before the use of medication and adherence is discussed in 1.8. Details of COPD primary care reviews are provided in section 1.9 with information regarding housebound patients explored in section 1.10, and cost burden considered in section 1.11. More information regarding the project pharmacist is provided in section 1.12, with the introduction summary in 1.13, and finally the introduction to the study and organisation of the thesis in section 1.14.

1.2 General Practitioner Practice Pharmacist's Role

Globally, the role of the pharmacist in patient care has changed over the last three decades.[4] Pharmacists are the third largest healthcare profession in the United Kingdom (UK)[5] with a total of 62,525 pharmacists registered with the General Pharmaceutical Council (GPhC) on the 21st of August 2022 of which

5,436 have their home address registered in Scotland.[6] Historically, the pharmacy profession in the UK, like most other countries, comprised two main branches: community and hospital, with smaller numbers of pharmacists employed in industry and academia.[7] This is currently changing in the UK, with primary care becoming a major branch of pharmaceutical employment with practice pharmacists and technicians becoming common-place in General Practice (GP) surgeries across the UK. This is due to the recognition that pharmacists can help towards the increasing demands on general practice caused by demographic changes, more complex health needs, and some care moving out of hospitals, which is contributing to unsustainable pressures on GPs.[8,9]

To support patients with long term conditions and to free up GP time for more complex patient care, the Scottish Government in 2015 announced funding to support pharmacist posts in general practice across NHS Scotland; by 2018 these pharmacists should all be PIPs [Pharmacist Independent Prescribers] with advanced clinical skills.[10] Pharmacists are experts in medicines and their skills in delivering pharmaceutical care is a key component of safe and effective healthcare.[11] Pharmacists process a unique skill set to allow for the assessment of medication tolerance and clinical response to treatment, and are increasingly becoming involved in the GP practice in the regular review of chronically ill patients including clinical decisions to introduce and stop medications.[12,13] Pharmacists have extensive pharmacotherapy knowledge and expertise, and are therefore a logical addition to the general practice team to assist with medication management.[14]

From a global perspective, the US Centers for Disease Control and Prevention (CDC) reported that pharmacists are highly trained yet underutilised health care professionals[15] and there has been growing support in Australia from the Department of Health to extend the role of the pharmacist within the primary health care sector.[16] The movement to include pharmacists as essential members of the primary care setting has gained traction in a number of countries, including Canada, the United States and the United Kingdom.[17] The use of pharmacists in general practice has been noted worldwide with the 2011 FIP/WHO Good Pharmacy Practice (GPP) Guidelines stating that- the aim of pharmacists working in family practices is to "contribute to health improvement and to help patients with health problems to make the best use of their medicines"[18] As pharmacists working within GP surgeries has rapidly evolved in the UK, there is large variability in the day-to-day tasks undertaken and also identification of where pharmacists can best use their expertise to provide best patient care. Not all practice pharmacists are independent prescribers and not all undertake patient facing roles instead focusing on data analysis and cost effectiveness.

1.3 Pharmaceutical Care

Pharmaceutical care has been explained as providing direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life.[19] Pharmacists are uniquely positioned to address the challenges related to medication use. They are also well placed in the healthcare system, to minimise the risk inherent in the transfer

of care between hospitals/healthcare systems and the community, and have the chance to develop their roles further in medication optimisation and adherence, prevention of illness and safety incidents, adoption of best practices, patient self-management and monitoring, and collaborative health care.[18] The unique positioning of pharmacists as healthcare providers with expertise and focus on medications, allows them to educate patients and caregivers on the safe and effective use of medicines to improve patient care outcomes and prevent medication errors. Primary care pharmacists have the time and the access to medical records to be able to use their medical knowledge to conduct medicines reconciliation and communicate medication changes to the patient as well as ensuring titration of medication is organised after discharge from secondary care. Patient safety is becoming increasingly recognised by health boards and patient advocacy groups and the public alike as a top priority for action that requires a collective and coordinated response across all healthcare professions. The pharmacy workforce plays a key role in minimising medication errors thus mitigating the global challenge of patient safety. Pharmacists in primary care practice can conduct clinical pharmacy services that primarily focus on chronic disease management with a multifaceted role including medication therapy reviews, counselling, and medication education. These services can be aimed at patients with a specific chronic condition or a more heterogenous group of patients at risk of drug polypharmacy.[20] Fully integrated non dispensing pharmacists are permanently employed or work within a network or umbrella organisation, they usually have shared access to clinical information systems, working in multi professional teams with face-to-face collaboration with the GP,

have shared education and or support staff for administration functions, and share a vision on patient care with clinicians.[20]

Initially, when pharmacists working in primary care was in its infancy in Scotland in the late nineties, their care roles were focussed on medicines management functions, performing data analysis by identifying prescribing trends, adherence to guidelines, and identifying areas for prescribing improvement. This role evolved over time to include the cost-effective use of medications in the NHS by undertaking therapeutic reviews and switching therapy to the most cost-effective option without being detrimental to patient care. In addition, pharmacists provided prescribing advice to GPs for a plethora of treatments and clinical conditions as well as addressing medication shortage issues and dose related queries where there was multimorbidity present and dose adjustment was necessary. By undertaking these roles, pharmacists helped to improve efficiency and supported medicine optimisation in primary care and contributed towards prescribing incentive schemes and contractual targets from health boards which contributed towards practice incomes and prescribing budgets. Over time, this role evolved to provide patient facing clinics to maximise the benefits of medications and encourage compliance and concordance in patients. The launch of supplementary prescribing and independent qualifications only aided this development to allow pharmacists to independently make changes to patient's medical therapy allowing them to work autonomously alongside their GP and practice nurse colleagues.

This emerging model of care delivery involves utilising the expert knowledge of medicines and health skills of pharmacists in GP practices and moving health systems to a more interdisciplinary approach in primary care.[21] Team-based direct patient care has been identified by American researchers as an important approach to meet patients' needs and improve healthcare quality. Pharmacists working as part of the team in general practice have been shown to make a huge difference to both patients and clinical colleagues.[22] They can consult with and treat patients directly, working closely with GPs to resolve medication issues, enabling GPs to focus their skills where they are most needed, for example on diagnosing and treating patients.[22] The Royal Pharmaceutical Society (RPS) and Royal College of General Practice (RCGP) issued a Joint Policy Statement, initially published in 2012 with an updated version released in 2015, on General Practice based Pharmacists saying that they strongly believed that patient care can be improved through greater synergy between GPs and pharmacists. They stated that they believed that all GP practices would benefit from, and patients should have access to, the expertise of a pharmacist, helping patients to make the best use of their medicines, including minimising avoidable harm, and reducing unplanned hospital admissions as a result.[23]

In 2016, the Pharmaceutical Journal described this new role thus:

> **'***Clinical pharmacists in GP surgeries will resolve day-to-day medicine issues and consult with and treat patients directly. This includes providing help to manage long-term conditions, advising those taking multiple medicines (polypharmacy) and delivering clinical advice about treatments. They will also assist with*

communication across a patient's care pathway, manage medicines shortages by suggesting suitable alternatives where appropriate, and mentor newer pharmacists.' [24]

This involves a model of pharmacy practice which requires pharmacists to work in partnership with patients and other health and social care professionals to obtain optimal outcomes with medicines, including deprescribing as well as eliminating adverse events whenever possible.[11]

Deprescribing is the planned and supervised process of inappropriate medication discontinuation with the aim of managing polypharmacy and improving outcomes.[25] The care of patients with multi-morbidities is one of the greatest challenges now faced by the health service as it can create overly complex health care for some of the most vulnerable in society. The resulting polypharmacy (use of multiple medications) may be inappropriate and the key healthcare aim for the individual patient is to ensure the safe and effective use of their multiple medicines.[26] Older people often have numerous co-morbidities, limited physiological reserves, and are prescribed many medications, thereby increasing the risk of adverse drug events, reduced health related quality of life (HRQoL) and hospitalisation.[27] The Screening Tool of Older Peoples Prescriptions (STOPP), is one useful aide which can be utilised by health care professionals such as pharmacists, to identify possible inappropriate medications and actively look at dose reduction or stopping the medication completely. A medication is considered inappropriate if its potential harms outweigh its potential benefits in

the individual.[28] Deprescribing may provide benefits such as a reduction in falls, fractures, cognitive improvement, and all-cause mortality.[28] The pharmacists' roles as patient educators are known to improve health outcomes and increase patients' satisfaction of which deprescribing can be added as a positive outcome of such educational interventions.[25]

Previous research into pharmaceutical care has demonstrated the following two issues: there is a lack of a GP-pharmacist relationship and opportunity for communication; medication issues identified by community pharmacists do not get actioned as the pharmacist does not have direct access to the patient's medical records.[16] Community pharmacies are able to identify, resolve, and prevent medication-related problems: however, the lack of a formal partnership with physicians and poor access to patients' medical records are limitations.[16] It has been acknowledged that barriers to the uptake and effective delivery of pharmacist medication reviews include the geographical separation of pharmacists from physicians, poor inter-professional communication, limited pharmacist access to patient medical records, time restrictions, and health policies that are not conducive to such collaborative arrangements.[16] Common opinion is that integrated care for patients with chronic diseases may improve patient outcomes, and the presence of non-dispensing pharmacists working in practice along GPs addresses these issues.[20] Evidence of the effect of clinical pharmaceutical services on clinical endpoints, such as mortality, hospitalisation, and HRQoL, is less clear probably due to very heterogeneously defined services, strongly differing study settings (such as general practice versus hospital outpatient clinics) and includes how well integrated the pharmacist is into the

health care team.[20] However, pharmacist-led medication reviews in primary care have been shown to be effective in identifying and resolving medication related problems, improving prescribing quality, and optimising medicine use and costs.[16]

An additional role now undertaken by many general practice pharmacists in the UK is the ability to be able to take responsibility for the decision to prescribe. Prescribing is an area where professionals are able to display their clinical autonomy; their control over the object of their work, the prescription, through autonomous decision making and by implication, the prescribing process and how medicines are used.[29] Pharmacist prescribing is emerging internationally with the UK leading the way having introduced both supplementary (in 2003) and independent models (in 2006) of prescribing.[30] Pharmacists in the UK have had the opportunity to become independent prescribers for 15 years but it is only in the past few years that their contribution to the health service has taken off. Indeed the number of the pharmacists in the UK who are qualified to independent prescriber level has more than tripled since 2016 rising from 2,781 to 8,806 in 2020.[31] Little progress has been seen with independent prescribers working in community pharmacies with problems cited including necessity of having to hire locums to cover clinics causing financial strain. However, the increase in general practice pharmacist numbers has driven the role of the prescribing pharmacist forward and continues to do so, and now pharmacy educational reforms in the UK mean that pharmacists will, from August 2026, register as pharmacists and independent prescribers and not have to undertake a separate qualification.[31] The effectiveness of pharmacist prescribing in terms of outcomes has been found

to be comparable to that of doctors for a number of chronic diseases, including high blood pressure, diabetes and high cholesterol.[32] An improvement in patients' access to medicines, better utilisation of pharmacists' skills, as well as easing the burden of GPs were the main reasons for introducing expanded prescribing for pharmacists in the UK.[30]

As evidenced by the growing body of literature depicting direct patient care services provided by pharmacists in specific health care settings, patient populations, and disease states, the role of pharmacists as members of the health care team has expanded beyond conventional medication dispensing.[33] As the prevalence of chronic disease increases, undoubtedly medication use and demand for pharmacists' expertise will also increase.[33] There is a real opportunity to continue to develop and advance the role of pharmacy in primary care. The British Medical Association (BMA) anticipates a metric of one patient facing pharmacist per 10,000 patients working in GP settings in 2024.[34] As the UK population was estimated at 68,708,659 as of Tuesday June 21st 2022[35], this equates to 6,871 pharmacists in primary care. To put this in perspective, the current number of pharmacists registered to practice currently in the UK stands at 62,525 as of 21st August 2022, with 14,327 registered as prescribers.[6]

Pharmacist have moved into many novel patient-facing roles across the globe, typically delivered through the lens of pharmaceutical care.[36] This includes an assessment of patients' medication needs, identification of all medication-related problems, development of a care plan, and patient follow-up to assess

outcomes.[37] Pharmaceutical care is a key strategy to improve healthcare safety and can help to prevent and correct drug related problems that can lead to adverse drug events.[38] An important concept related to pharmaceutical care is that of evidence-based medicine; the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.[39]

Internationally, pharmacists have been recognised as valued members of speciality clinics including chronic disease clinics e.g. COPD, or therapeutic clinics e.g. anticoagulation[40] however, literature is often limited to pharmacists working in the hospital or community setting. In 2012, Freeman and Cottrell et al published research conducted in Australia that had been carried out to look at the views of GPs, health care consumers, and pharmacists to ascertain their views on practice pharmacists.[40] Responses from GPs were positive recognising the potential benefit of integrating a pharmacist into the medical team with the recognised benefits perceived by the GPs increasing over time.[40] Privacy, access to the patients' medical file, and increased rapport and communication between the GP and the pharmacist were reported as potential benefits to integrating a pharmacist in primary care/general practice.[40] Freeman and Cottrell et al's research also showed that health care consumers are generally supportive of pharmacist involvement in non-dispensing roles, however, some healthcare consumers found it difficult to foresee the benefits potentially offered by a pharmacist in the general practice medical centre setting largely due to being unfamiliar with the clinical roles of a pharmacist.[40]

1.4 Scottish General Medical Service (GMS) Contract

The Scottish General Medical Service (GMS) contract which launched in May 2018, set out to change the face of general practice in Scotland over a three-year period by changing the way GP services were being provided. Pharmacists were attached to all practices to undertake traditional prescribing work to allow GPs to have more time to be 'expert medical generalists' and focus more time on complex chronic disease patients.[41] The roles that practice pharmacists in Scotland were expected to undertake are shown in Table 1.1.

Table 1.1: Scottish GMS contract vision of practice pharmacist roles

Taken from Scottish Government GMS Scottish Contract, 2018

CORE AND ADDITIONAL PHARMACOTHERAPY SERVICES		
	Pharmacists	**Pharmacy Technicians**
Level one (core)	• Authorising/actioning[15] all acute prescribing requests • Authorising/actioning all repeat prescribing requests • Authorising/actioning hospital Immediate Discharge Letters • Medicines reconciliation • Medicine safety reviews/recalls • Monitoring high risk medicines • Non-clinical medication review Acute and repeat prescribing requests includes/ authorising/actioning: • hospital outpatient requests • non-medicine prescriptions • installment requests • serial prescriptions • Pharmaceutical queries • Medicine shortages • Review of use of 'specials' and 'off-licence' requests	• Monitoring clinics • Medication compliance reviews (patient's own home) • Medication management advice and reviews (care homes) • Formulary adherence • Prescribing indicators and audits
Level two (additional - advanced)	• Medication review (more than 5 medicines) • Resolving high risk medicine problems	• Non-clinical medication review • Medicines shortages • Pharmaceutical queries
Level three (additional - specialist)	• Polypharmacy reviews: pharmacy contribution to complex care • Specialist clinics (e.g. chronic pain, heart failure)	• Medicines reconciliation • Telephone triage

Therefore, most GP practice pharmacists in Scotland are employed by the health board rather than directly by the practice, in contrast to the English model. In Glasgow, where I am based, our health board provides us with data analysis of prescribing trends in our practices to allow us to target work appropriately. For example, if a practice is found to have a high number of patients on a non-evidenced based therapy, we can look at these patients in each specific GP practice to audit and review the medication therapy being prescribed. This can

lead to cost savings as well as better, evidence-based therapy being given to patients. In Glasgow, most GP surgeries have access to a practice pharmacist, the majority of which are independent prescribers. This has the added benefit of ensuring any suggested changes to therapy are actioned directly and in a timely fashion.

1.5 COPD

The World Health Organisation (WHO) defines COPD as not one single disease but an umbrella term used to describe chronic lung diseases that cause limitations in lung airflow.[42] This includes emphysema (damage to the air sacs in the lungs) as well as chronic bronchitis (long term inflammation of the airways). WHO further expands this definition to state that COPD is a progressive life-threatening lung disease that causes breathlessness (initially with exertion) and predisposes patients to exacerbations and serious illness. It is a common, preventable, and treatable disease that is characterised by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases.[43] The most common respiratory symptoms include dyspnoea, cough and/or sputum production[44] that mainly affects middle-aged or older adults who smoke although it has been reported that an estimated 25-45% of patients with COPD have never smoked.[45] The pathogenesis of COPD involves gene-related susceptibility, atopy, lung damage, immune regulation abnormalities, and repeated airway infection.[46]

The natural history of COPD is punctuated by exacerbations which have major short- and long-term implications for the patient and the healthcare system.[47] Acute exacerbations of COPD can be triggered by a multitude of factors and persistent exacerbations will aggravate patients' symptoms and seriously affect their quality of life.[46] In 1998, with the cooperation of the National Heart, Lung, and Blood Institute, National Institutes of Health, and the World Health Organisation, the Global Initiative for Chronic Obstructive Lung Disease (GOLD) was implemented. Its goals were to increase awareness of the burden of COPD and to improve prevention and management of the condition through a concerted worldwide effort of people involved in all facets of healthcare and healthcare policy.[44] An important and related goal was to encourage greater research interest in this highly prevalent disease of which approximately three million people in the world die as a consequence each year.[43]

COPD is one of the most common respiratory diseases in the UK, accounting for 10% of unplanned hospital admissions each year.[48] Nearly a third of these admitted patients are re-admitted to hospital within 28 days of discharge.[48] COPD carries a high morbidity and mortality rate and is one of the few chronic diseases where the number of people affected is rising, a trend that looks set to continue,[49] because of the continued exposure to COPD risk factors and the ageing population worldwide. It is predicted by WHO that between 2015 and 2050, the proportion of the world's population over 60 years of age will nearly double from 12% to 22%. Many people suffer from COPD for years and die prematurely from it, or its complications. More than 3 million people died of COPD in 2012 accounting for 6% of all deaths globally.[43] Furthermore, COPD is projected to be

one of the leading causes of mortality and disability by 2030 worldwide. COPD represents an important public health challenge in the UK that is both preventable and treatable, but unfortunately a substantial proportion of patients are diagnosed in advanced stages of the disease.[50] Proactive diagnosis and ongoing multifactorial COPD management, compromising smoking cessation, influenza and pneumonia vaccinations, pulmonary rehabilitation, and symptomatic and maintenance pharmacotherapy according to severity, can significantly improve a patient's HRQoL, reduce exacerbations and their consequences, and alleviate the functional, and financial burden of COPD.[51] Quality of life is lower in patients with severe COPD, but even those with mild disease have HRQoL levels lower than those seen in the general population.[52] This impairment manifests not only as a loss of physical mobility, but also as emotional and sleep disturbances.

The diagnosis of COPD depends upon a clinician thinking of it as a cause of breathlessness or cough.[2] NICE guidelines recommend suspecting a diagnosis of COPD in people over 35 who have a risk factor (generally smoking or a history of smoking) and who present with one or more of the following symptoms: exertional breathlessness, chronic cough, regular sputum production, frequent winter 'bronchitis' or wheeze.[2] COPD can be distinguished from asthma by common clinical signs and symptoms as shown in Table 1.2 and the diagnosis is supported by spirometry.[2]

Table 1.2 Clinical features differentiating COPD and asthma[53]

Taken from Price et al, Difference between asthma and COPD.

	COPD	**Asthma**
Smoker or ex-smoker	Nearly all	Possibly
Symptoms under age 35	Rare	Often
Chronic productive cough	Common	Uncommon
Breathlessness	Persistent and progressive	Variable
Night time waking with breathlessness and/or wheeze	Uncommon	Common
Significant diurnal or day-to-day variability of symptoms	Uncommon	Common

Spirometry assesses the severity of airflow obstruction according to the reduction in Forced Expiratory Volume in the first one second (FEV1). It is well established that chronic airway obstruction, defined as the ratio of the forced expiratory volume in the first one second to the forced vital capacity of the lungs (FEV1/FVC) being below 0.7, has a strong positive correlation with COPD-related hospitalisation and mortality.[54] The degree of severity of COPD can be classified according to the values of FEV1/FVC and FEV1% predicted as shown in Table 1.3. In the UK, the Medical Research Council (MRC) dyspnoea scale should be used with patients to grade their breathlessness according to the level of exertion required to elicit it as shown in Table 1.4.

Table 1.3 Graduation of severity of airflow obstruction.[44]

Taken from GOLD guidelines 2019

Post-broncho-dilator FEV1/FVC	FEV1 % predicted	NICE guideline CG12 (2004) severity of airflow obstruction	ATS/ERS 2004 severity of airflow obstruction (post-broncho-dilator)	GOLD 2008 severity of airflow obstruction (post-broncho-dilator)	NICE guideline CG101 (2010) severity of airflow obstruction (post-broncho-dilator)
< 0.7	80%	Not categorised	Mild	Stage 1 – Mild	Stage 1 – Mild
< 0.7	50–79%	Mild	Moderate	Stage2 – Moderate	Stage 2 – Moderate
< 0.7	30–49%	Moderate	Severe	Stage 3 – Severe	Stage 3 – Severe
< 0.7	< 30%	Severe	Very severe	Stage 4 – Very severe (or FEV1 below 50% with respiratory failure)	Stage 4 – Very severe (or FEV1 below 50% with respiratory failure)

Table 1.4 MRC dyspnoea scale. *Adapted from Fletcher* [55]

Grade	Degree of breathlessness related to activity
1	Not troubled by breathlessness except on strenuous exercise
2	Short of breath when hurrying on a level or when walking up a slight hill
3	Walks slower than most people on the level, stops after a mile or so, or stops after 15 min walking at own pace
4	Stops for breath after walking 100 yards, or after a few minutes on level ground
5	Too breathless to leave the house, or breathless when dressing/undressing

Inadequate management of COPD causes an enormous strain on the health service.[56] It costs the NHS nearly ten times more to treat severe COPD than mild disease, with exacerbations the most common reason that requires hospital admission, and contributes substantially to the related economic impact as shown in Table 1.5.[57] Primary care, as the first level of contact within the health system for many individuals, has to be refocused to emphasise health promotion, illness prevention, and chronic disease management.[58] The increasing burden of chronic conditions on patients, their families, and communities, and the health system, is leading not just the UK but the developed world to investigate new approaches to caring for patients.[58]

Table 1.5. Estimation of cost of COPD care[59]

Unit costs estimated for the resource use categories. *Taken from Puneker et al 2014*

Resource use item	Unit cost	Reference
Moderate exacerbation	£85.29	
Severe exacerbation	£1,263.76	NHS reference costs 2010–2011
Hospital episode	£1,366.88	PSSRU 2011
GP practice in-person visit	£36	PSSRU 2011, Page 149
GP practice nurse visit	£13	(Based on 15.5-minute consultation) × £51 per hour of face-to-face contact
GP home visit	£121	PSSRU 2011, Page 149
G out-of-office visit	£121	Assumed to be the same as home visits
GP practice administrative contact	£22	PSSRU 2011, Page 149; considered equivalent to telephone consultation
GP practice correspondence	£3	Based on 30% of indirect contact of 15.5-minute consultation (0.3 × 15.5) × £39 per hour of non-face to face contact

Abbreviations: GP, general practitioner; NHS, National Health Service; PSSRU, Personal Social Services Research Unit.

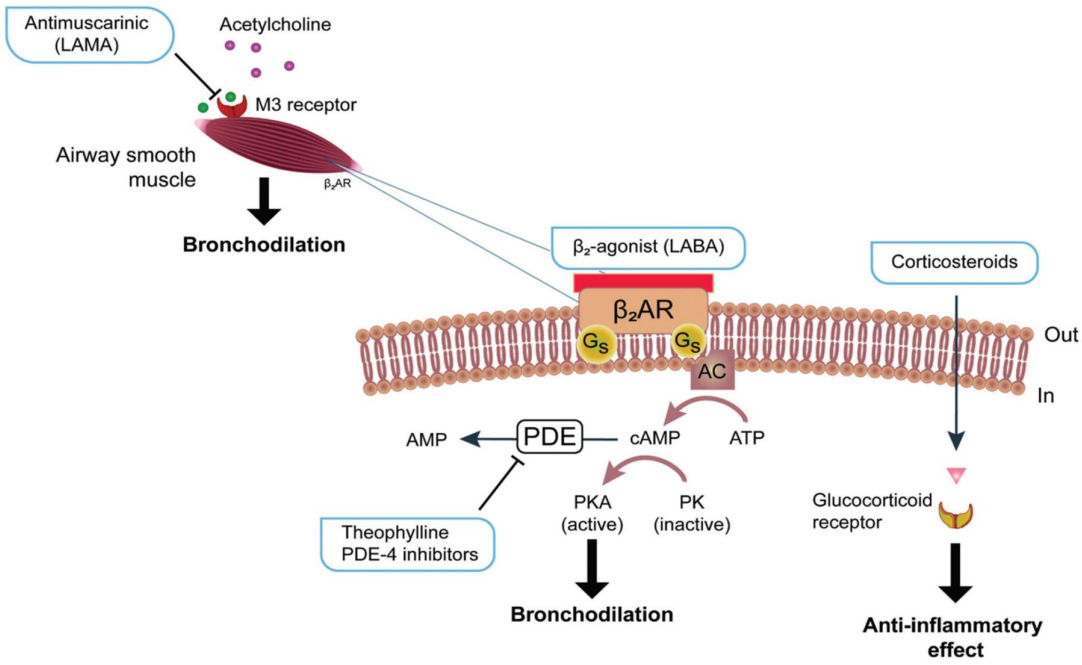
1.6 COPD Treatment

Although COPD cannot be cured, optimal management provides symptom control, slows progression of the disease, and may improve the quality of life.[60] Pharmacological therapy has been shown to alleviate COPD symptoms, reduce exacerbation severity and frequency, and improve patients' health status and exercise tolerance.[61] The primary pharmacological treatments for both maintenance therapy and the treatment of exacerbations of COPD are bronchodilators, including long-acting muscarinic antagonists (LAMAs), long-acting beta-agonists (LABAs), LAMA/LABA combinations, non-selective phosphodiesterase (PDE) inhibitors (such as theophylline) and the newer PDE-4 inhibitors (such as roflumilast).[46]

LABAs stimulate beta 2-adrenergic receptors in airway smooth muscle, triggering cellular pathways that eventually cause relaxation of bronchial smooth muscle and bronchodilation, whereas LAMAs inhibit antimuscarinic receptors, thus reducing contraction of airway smooth muscle as shown in Figure 1.[61] Short acting beta 2 agonists (SABAs) are used for maintenance treatment in patients with mild disease, minimal symptoms, and infrequent exacerbations.[61] For the maintenance of COPD, LAMAs, LAMA/LABAs and inhaled corticosteroids (ICS) in combination with LAMA and/or LABAs could lead to a significantly greater improvement in FEV1 compared with placebo.[46] ICS act in COPD by providing anti-inflammatory effects mediated by activation of glucocorticoid receptors. ICS should not be used as monotherapy in COPD however, when used in combination with a LABA, they do improve lung function and health status, and

reduce exacerbations.[44] In addition, ICS are not used in COPD unless FEV1 <50 and a patient has two or more COPD exacerbations per year, due to potential negative consequences in terms of adverse effects, including risk of pneumonia.[62] NHS Greater Glasgow and Clyde (GGC) Guidelines for COPD are included in Appendix 1. Other therapies including mucolytics, antibiotics and even surgery are used to help improve quality of life in COPD patients with antibiotics, steroids, and oxygen therapy used for acute exacerbations.

Figure 1.1: Mechanism of action of the common pharmacologic agents for COPD *Taken from The Journal of Family Practice 67:10:2018* [61]



Abbreviations: AC, adenylate cyclase; AR, adrenergic receptor; ATP, adenosine triphosphate; cAMP, adenosine 3', 5'-cyclic monophosphate; Gs, stimulatory G-protein; LABA, long-acting β2-agonist; LAMA, long-acting muscarinic antagonist; M3, muscarinic; PDE, phosphodiesterase; PKA, protein kinase A

Bronchodilators are administered via inhalation through devices such as metered dose inhalers (pMDI) or dry powder inhalers (DPI). Inhalers are specifically designed devices for lung drug delivery in COPD which offer several advantages, but require the user's proper mastery.[63] A good inhaler technique is crucial for optimal drug delivery to the lungs indeed, according to a systematic review published in 2016, only 31% of patients are able to use an inhaler correctly, and inhaler technique has not improved over the last 40 years.[64] NICE COPD guidelines recommend that inhaler technique is checked at every interaction with a healthcare professional.[65] It is known that providing education with practical demonstration of inhaler technique and the opportunity for patients to demonstrate their inhaler and receive feedback is associated with improvement of inhaler technique, but is time-consuming and not widespread.[63] Specific educational interventions delivered by healthcare professionals such as teaching effective inhaler technique, have been shown to improve lung function and exercise performance.[66]

As well as pharmacological management options for COPD, there are important non-pharmacological treatment options which have been proven to help increase quality of life, with smoking cessation being the single most effective intervention. Other non-pharmacological treatment options include influenza vaccination, pneumococcal vaccination, pulmonary rehabilitation, oxygen therapy, and lung volume reduction surgery.[65] Previous studies have defined self-management interventions for patients with COPD as structured, personalised, and often multi-component, with goals of motivating, engaging, and supporting patients to positively adapt their health behaviours.[67] Many studies have confirmed that

lifestyle changes and risk factor avoidance such as smoking cessation and increased exercise could help to relieve the symptoms of COPD and reduce the frequency of acute exacerbations of COPD.[46]

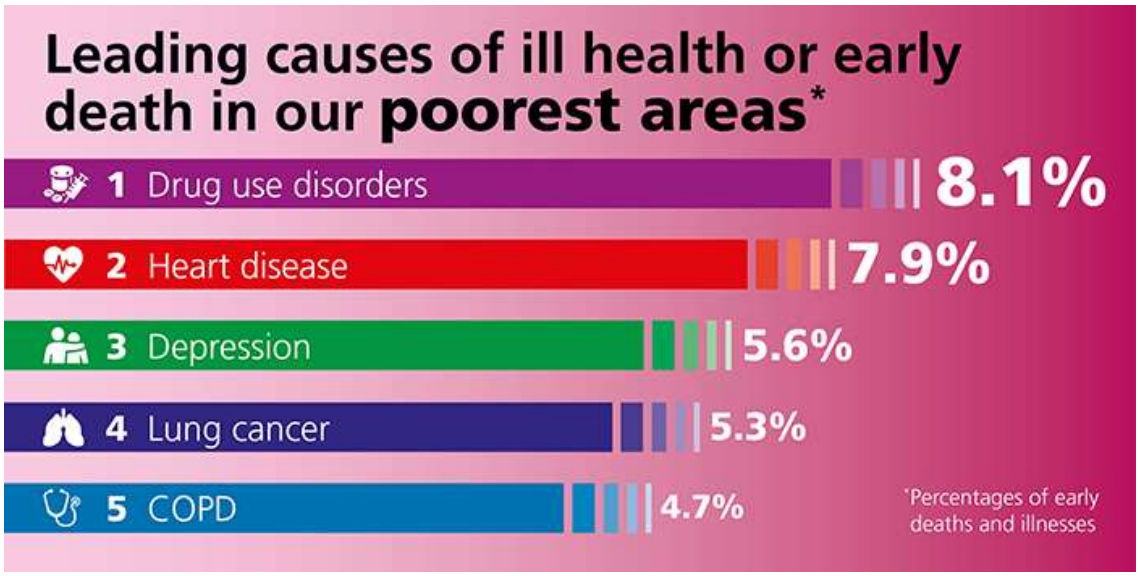
1.7 Scotland's population

In 2017, there were approximately 120,000 people in Scotland living with COPD, with a predicted increase in prevalence of 33% in 20 years.[68] In addition in this year, COPD was the third most common reason for hospital admissions in Scotland.[69] A study in 2016 showed that in Scotland, COPD prevalence was 2.03% (1.96–2.10) in 2011 and estimated that this would increase to 2.20% (1.98–2.40) by 2030.[70] The study also showed that in Scotland, in 2011 there were 9,700 (9,000–12,300) COPD related deaths rising to 13,900 (13,400–14,500) estimated deaths by 2030.[70] While smoking rates are expected to decline,[70] the impact of this will take some time to be reflected in levels of COPD incidence. The changing demography of Scotland with an ageing population, the associated increase in people living with complex and long-term conditions, (multi morbidity) and continuing health inequalities set major challenges for the provision of care in the future.[11] It is estimated that COPD was the fourth most common cause of years of life lost in Scotland in 2015, ranked after ischaemic heart disease, lung cancer, and cerebrovascular disease.[71] The most significant risk factor for COPD is cigarette smoking.

The Scottish Burden of Disease Study (2016) Deprivation Report shows that there are differences in rates of early death and ill health seen across

socioeconomic deprivation groups by age and sex.[72] The report also shows that early death and illnesses associated with mental wellbeing, diet, drug use, tobacco, and alcohol dependency are more common in poorer areas than in richer areas. The leading causes of ill health or early death are drug use disorders, heart disease, depression, lung cancer, and COPD as shown in Figure 1.2.[72]

Figure 1.2. Leading Causes of ill health or early death in Scotland's poorest areas. *Taken from The Scottish Burden of Disease Study (2016)*[72]



Hospital admissions for patients with a diagnosis of COPD are significantly higher for people living in the most deprived areas of Scotland compared to those in the least deprived areas. For males aged 65-84, the most deprived areas have around 2,400 admissions per 100,000 people compared to 340 per 100,000 people in the least deprived areas. Similarly, for females aged 65-84, the most deprived areas have around 3,000 admissions per 100,000 people compared to 46 per 100,000 people in the least deprived areas.[73]

The Scottish Government's Vision for healthcare was that by 2020 everyone would be able to live longer healthier lives at home, or in a homely setting[74] while the Scottish Primary Care Collaborative in 2010 stated the importance of improving care for people with COPD in Scotland.[75] Unfortunately, these aims were complicated by the worldwide pandemic of COVID-19. Patients with a clinical diagnosis of COPD have significantly increased odds of poor clinical outcomes with COVID-19 and are considered a high-risk group of patients and are targeted for aggressive treatment of COVID-19 including vaccination.[76] With this in mind, it is important that we look to address the needs of Scottish COPD patients by examining new ways of delivering care to help manage their condition(s) to maximise their HRQoL.

The associations of long-term conditions like COPD with deprivation, lifestyle risk factors, and wider social health determinants are of importance in Scotland given the country's health inequalities.[72,77] This project was undertaken in NHS Greater Glasgow and Clyde (NHS GGC) in Scotland which is the largest health board within the UK, covering a population of approximately 1.14 million people and employing 39,000 staff.[78] Their aim is to deliver effective and high-quality health services, to act to improve the health of our population, and to do everything possible to address the wider social determinants of health which cause health inequalities. The area of NHS GGC in which this study took place was a large Heath and Social Care Partnership (HSCP) in North East Glasgow in an area of recognised depravation where the health of the public is worse than the average in Scotland.

1.8 Medication Adherence

According to Scottish Government Polypharmacy guidance published in 2018 the proportion of over 75-year-olds in Scotland, who are high users of health and care services and for whom prescribing can be particularly complex, will increase by over 25% in the next 10 years, and the number of over 75s is likely to have increased by almost 60% in the next 20 years.[26] Medication is by far the most common form of healthcare intervention for many acute and chronic conditions in Scotland. Four out of five people aged over 75 years take a prescription medicine and 36% are taking four or more.[26] However, it is suggested by the World Health Organisation that up to 50% of drugs are not taken as prescribed and adverse reactions to medicines are implicated in 5-17% of hospital admissions.[26] Adherence broadly encompasses the decision patients make as to whether health care advice should be initiated, as well as the degree to which the recommended health behaviours, once started, are maintained.[79] Non-adherence has a significant impact on a patient's outcomes, increasing hospitalisations and exacerbation rates.[80]

Although medical treatment of COPD has advanced, non-adherence to medication regimens poses a significant barrier to optimal management.[60] Previous studies in patients with COPD have reported that adherence to maintenance therapy is generally low.[81] Poor medication adherence is a particular concern in COPD, because it has been associated with higher rates of exacerbations, hospitalisations, mortality, and increased health care costs.[82] As multiple studies have shown an association between non-adherence in COPD

and clinical and economic outcomes, it is important that we address this in primary care.[81] Due to the considerable burden of COPD to patients with reducing quality of life with breathlessness, there is a need to improve understanding of the medication adherence of patients at home.

Non-adherence to medications in COPD has been attributed to several factors including use of multiple inhalers, inhaler type, multiple daily doses, cost burden, presence of depression, and patient preferences and beliefs.[82] Medication regimens for patients with COPD are particularly vulnerable to adherence problems because of the chronic nature of the disease, the use of multiple medications or polypharmacy, and the periods of symptom remission.[60] Adherence to medications and its improvement is a challenging issue in the treatment of patients with COPD. In a country where access to healthcare services is good and patients have access to a wide range of effective treatments, any planned improvement of treatment outcomes must address patients' adherence to medication.[83]

1.9 COPD Primary Care Reviews

Recognising the growing burden of long-term conditions on the health system, current NHS policy emphasises a need to move away from the traditional model of care, arguing instead for greater focus on the delivery of preventative care away from hospital, and a concomitant shift in investment from secondary care to primary care and community services.[84] Routine follow up of COPD patient's' breathing condition has been shown to be essential in the GOLD guidelines for

COPD.[43] This is because lung function can be expected to worsen over time, even with the best available care.[43] Symptoms and objective measures of airflow limitation should be monitored to determine when to modify therapy and to identify any complications that may develop. Although a sudden and rapid worsening of symptoms (known as COPD exacerbation) may sometimes necessitate hospital attendance, most clinical contacts with diagnosed patients take place in the primary care setting, presenting opportunities to proactively manage the condition and reduce the risk of hospitalisation.[84] NICE Clinical Guideline (CG) 101 states that patients with COPD should be reviewed in primary care at least once per year, or more frequently if indicated, and the review should cover the points listed in Table 1.6. If patients are not having this regular review due to being housebound, there is the possibility that their condition will deteriorate along with their HRQoL as well, and that this might go unnoticed and not treated appropriately.

Table 1.6 Summary of follow-up of patients with COPD in primary care. *Taken From NICE CG101*[2]

	Mild/moderate/severe (stages 1 to 3)	**Very severe (stage 4)**
Frequency	At least annual	At least twice per year
Clinical assessment	• Smoking status and desire to quit • Adequacy of symptom control: – breathlessness – exercise tolerance – estimated exacerbation frequency • Presence of complications • Effects of each drug treatment • Inhaler technique • Need for referral to specialist and therapy services • Need for pulmonary rehabilitation	• Smoking status and desire to quit • Adequacy of symptom control: – breathlessness – exercise tolerance – estimated exacerbation frequency •Presence of cor pulmonale • Need for long-term oxygen therapy • Patient's nutritional status • Presence of depression • Effects of each drug treatment • Inhaler technique • Need for social services and occupational therapy input • Need for referral to specialist and therapy services • Need for pulmonary rehabilitation
Measurements to make	• FEV1 and FVC • calculate BMI • MRC dyspnoea score	• FEV1 and FVC • calculate BMI • MRC dyspnoea score • SaO2

Research undertaken in the UK in 2005 by Elkington, et al suggested that GPs need to be more active in managing COPD patients, monitoring their condition on a regular basis, rather than responding to acute exacerbations.[85] The same research also noted that GPs may find it difficult to take on the additional tasks

of regularly visiting these housebound patients themselves given their existing workload.[85] The national COPD primary care audit in 2014-15 found clear inconsistencies in the electronic coding, diagnosis, and management of COPD and that many patients may not be receiving care in line with evidence-based guidelines which in part may be due to a limit of resources in primary care.[86] More needs to be done in primary care for COPD patients to ensure best care is implemented equitably for all to reduce exacerbation frequency which is known to deteriorate not only lung function, but also quality of life, work productivity, and increased associated costs.[87] To close the gaps between best practice and usual care will require the collective expertise of doctors, nurses, pharmacists, allied health professionals, social workers, and vested laypersons.[33] NICE CG101 states that COPD care should be delivered by a multidisciplinary team.[65] GP practice pharmacists, as part of that team, are ideally placed to be able to contribute to provide necessary reviews, and reduce variation in prescribing rates for inhaled medications by taking over the care of this cohort of patients to help distribute workload among the health care professionals in the practice.

Under the Quality and Outcomes Framework (QOF) guidance for the General Medical Services (GMS) contract 2014/15 when this study begun, GPs in the UK were remunerated for the percentage of patients with COPD who had a review undertaken by a healthcare professional in the preceding 15 months, including an assessment of breathlessness using the Medical Research Council (MRC) dyspnoea scale as shown in Table 1.2, page 18 (referenced in QOF as indicator COPD003). However, patients who were housebound and could not attend an annual review in the GP practice were often excluded from this by being

‘exemption coded’ by the practice. These patients did not receive such an annual review as there was not remuneration or time for the GP or another healthcare professional to go out to perform such a role at the time. The development of the new GP contract in Scotland in 2018/19 also did not take housebound patients into consideration[41] and while some practices do have health care professionals (usually nurses) who do home visits to housebound patients for chronic disease reviews, these are very far and few between and indeed none in the practices I have worked in over the last 14 years in Glasgow.

Evidence suggests that existing health care provision for patients with severe COPD is reactive and focuses on acute exacerbations.[85] It is noted that COPD often remains undertreated, with a gap between guideline recommendations and real-world practice.[88] NICE CG101 clearly states that COPD patients should receive a review of their condition at least annually.[2] GP practice pharmacists are ideally placed as part of a multidisciplinary team to be able to provide the unmet needs of housebound patients with chronic diseases such as COPD with an aim of providing a holistic review to help increase medication adherence and HRQoL. Regular review of patients who have COPD, as well as the impact of adherence on health care resource use and costs, can inform the design of interventions to improve the effectiveness of healthcare delivery for other long term chronic health conditions. This would allow a cohort of patients who have only received reactive care to now receive regular proactive treatment and care by ensuring housebound patients with long term conditions receive the same equitable assessment, treatment, and health promotion advice afforded to those able to come into the practice.[89]

There is substantial documentation in the literature to support pharmacists' role in medication therapy management, particularly with relation to the management of chronic disease.[12] Having the pharmacist 'in house' in the GP practice rather than remotely in a community pharmacy for example, helps to mitigate known poor communication and connectivity between healthcare professionals that can fragment patient care, and is a significant contributor to the development of drug-related problems resulting in poorer health outcomes and experiences.[17] Pharmacists integrated into interdisciplinary primary care trusts globally demonstrated their significant role in many direct patient care activities, including medication management, identifying adverse or incorrect medication usage, counselling on medications, and effectively optimising a patient's understanding of their own medication regimens to enhance overall quality of life.[17] The skills of pharmacists in primary care include the provision of direct patient care through management of medications, examination and screening, chronic disease management, drug information and education, collaboration and liaison, quality assurance, and research.[17]

1.10 Housebound Patients

Housebound patients are defined as patients who cannot leave their home, owing to either a physical or psychological disability, to attend the surgery or elsewhere other than by ambulance.[90] Housebound patients with a long-term condition do not currently receive the same evidence based proactive management as patients who visit their GP surgery.[91] The United Nations Sustainable Development Goal "Good health and well-being" seeks to achieve universal

health coverage including financial risk protection, access to quality essential health-care services, and access to safe, effective, quality and affordable essential medicines, and vaccines for all.[18] However, increased access to safe and quality health care has to be accompanied hand-in-hand with improvements in service structures, cultures and/or behaviours.[18] It is imperative that we ensure we are providing a service for all patients regardless of their status, in this case the ability to attend a GP practice for annual review. This needs to be embedded at service level to ensure equity of treatment of all housebound patients in the long term especially with the worldwide increase in older population.

While there are many strategies in place in primary care to support the management of patients with long-term conditions, there is a paucity of services for people who are housebound.[89] Housebound patients are a particularly vulnerable group in society, often experiencing inequalities in care through poorly co-ordinated provision for complex health and social needs[92] The Wilson and Barber Review in 2013 highlighted particular concerns about the pharmaceutical care of both residents in care homes and those where care at home services were provided within social care arrangements.[93] The Scottish Government in 2013 stated that "*over the next decade and beyond, advances in health care will continue to accelerate".*[11] In particular it stated that significant changes would occur in medicine and therapeutics which will require new and innovative models of care to enable patients to obtain the maximum benefit.[11] A domiciliary annual COPD review by a practice pharmacist is one such suggested new model of care that may help to break down barriers in accessing care services and provide more regular care for housebound patients with chronic diseases.

While QOF did not discriminate between patients based upon age, it did provide the means for exception reporting for GP practices. This meant that practices were not financially penalised for indicators not achieved in relation to patients who could not attend the surgery. The consequence of this is that housebound patients were potentially disadvantaged by not having the same reviews as those who attended a GP surgery. Policy clearly states that patients regardless of their setting should receive high quality pharmaceutical care.[11] This is particularly important for patients with complex health issues including multi-morbidities and those in care homes.[11] It has also been noted that patient education is key to the management of acute and chronic conditions. However, the majority of such educational interventions have been reported from health-care settings which are inaccessible to the housebound.[94] It is important that we look at services for housebound patients who have long term conditions to ensure that they receive the same equitable assessment, treatment, and health promotion advice afforded to those able to visit GP practices.[89]

Periodic exacerbations of COPD symptoms, such as breathlessness and fatigue, often hamper COPD patients' functional capacity and cause them to become socially isolated, which makes healthcare logistically challenging and not easily accessible.[95] As part of this work, patients who have had a home COPD review by a practice pharmacist were asked what they thought of the review and how they felt about having a pharmacist conduct the review. This has helped give a voice to an inaccessible and isolated group of patients. As the patient is a critical member of the health and social care team, they require to be given enough information to enable them to make informed decisions about their care.

1.11 Cost Burden

An ageing population results in increasingly complex medication-related needs.[20] To sustain the economic viability of health care, the majority of elderly patients should be treated in primary care.[20] Medication review is an important component of the practice pharmacist's role and can lead to improvements in medication use and health outcomes, and reductions in health service utilisation and cost.[16] With the management of patients with a long-term health condition costing the NHS 70% of its health and care budget, any project that leads to an improvement in the management of these conditions is to be embraced.[91] COPD care in Europe equates to almost 56% of the total cost of all respiratory diseases within the healthcare budget.[96]

In Scotland COPD accounts for 122,000 emergency bed days annually with an average inpatient stay lasting 4-8 days and costing £3000.[97] COPD exacerbations and the comorbid nature of the disease pose a significant and increasing economic and social burden.[81] The large cost associated with COPD is frequently due to unplanned inpatient hospitalisations resulting from exacerbations, which occur with all severities of COPD.[98] Coupled with longer life expectancy, the costs of treating COPD in Scotland are expected to increase from £182 million (in 2016) to £207 million a year by 2030, placing substantial financial burden on healthcare provision in Scotland for the foreseeable future.[77] After smoking cessation, preventing exacerbations is the key factor in improving morbidity and mortality for COPD patients.[98] Furthermore, there is evidence to

suggest that treatment outcomes are better and healthcare costs are lower among patients who are adherent with their prescribed medications.[57] The potential demand on community health care services in delivering care to an increasing COPD population is considerable, given that a high percentage of patients may be housebound with high morbidity.[85] Thus, the introduction of a new service whereby practice pharmacists provide domiciliary COPD annual reviews to patients who do not currently receive these may help to improve HRQoL by providing proactive rather than reactive care to this vulnerable group. In addition, one would hope, this could reduce the rate of hospital admissions and hence decrease NHS costs.

There is evidence from work done in America in 2014 to support a significant opportunity and potential return on investment by integrating pharmacist services into the care transition process.[12] The research showed that patients who received follow up from a pharmacist after discharge were less likely to be readmitted to hospital or have an emergency department visit within 30 days of an acute care admission. In addition, patient satisfaction scores also improved in medication-related domains after pharmacist services were implemented. It is therefore important that we assimilate evidence to examine whether this can be extrapolated to pharmacists working in general practice providing annual reviews for chronic conditions in housebound patients. It has been suggested that 10-35% of COPD admissions could be avoided through the implementation of evidence-based care.[48]

1.12 Project Pharmacist

I have been employed as a GP practice pharmacist in Scotland since 2007. The role has evolved dramatically since then with the current role in 2021 being much more patient facing and multifaceted than ever before. I qualified as an independent prescriber in 2008 and actively use my prescribing qualification on a daily basis. My day-to-day role involves a variety of computer-based work combined with face-to-face clinics. I am involved in checking Immediate Discharge Letters (IDLs), making any medication changes, writing the prescriptions for these changes, along with contacting the patient/their representative, and their community pharmacy to relate these changes. I also process any hospital outpatient medication requests including writing and signing these prescriptions. As part of my patient-facing role, I carry out face-to-face reviews in the surgery for patients with chronic diseases such as COPD, asthma, and hypertension. I carry out domiciliary visits to patient that are housebound, who have medication issues, and those who have fallen as part of a 'falls team' review to ensure there are no medications contributing to their falls and carry out post Myocardial Infarction (MI) reviews to ensure patients medications are up titrated and optimised. I am also available to the GPs and nurses in the practice if they need help with any medication queries or to help find alternative medications when there are medication shortages.

One result of my experience of working in primary care, is that I discovered that housebound patients do not receive any routine investigations or annual reviews for chronic diseases. While being aware of the pressures on primary care GPs

and nurses with regards to seeing patients, and with the Prescription for Excellence Guidance from the Scottish Government in supporting the development and utilisation of prescribing pharmacists,[11] it was felt that home visits by practice pharmacists for patients with chronic conditions may be a viable service to help target this deficit. During this work, I was employed by NHS GGC health board and worked within the North East of Glasgow City which has an estimated population of 170,613 and consists of 44 GP surgeries.[99] Glasgow City contains 3 in 10 of the 15% most deprived data zones in Scotland, the highest proportion for any local authority. 116 of these most deprived data zones are in the North East of the city.[99] This is significant as the socioeconomic gradient in COPD has been quoted as being great, if not greater, than any other disease with the clustering of deprivation.[100]

The NHS Vision detailed in the Prescription for Excellence Scottish Government document launched in 2013 stated that in the future all pharmacists providing NHS pharmaceutical care would be NHS accredited clinical pharmacist independent prescribers working in collaborative partnerships with medical practitioners who will continue to have overall responsibility for diagnosis.[11] It has already been noted that areas that will be considered as a priority for increased pharmaceutical care are people who are residents in care homes and those that are being supported by social work or family to live at home.[11] This places housebound COPD patients as a priority group to be looked at with regards to developing new innovative pharmaceutical services to maximise adherence and HRQoL.

1.13 Summary

Research undertaken by nurses in England, published in 2012, highlighted the service gap for housebound patients with chronic disease such as COPD.[89] In light of the considerable social and economic burden of COPD, there is a need to improve understanding of how patients wish to receive care. Therefore, increasing the number of housebound COPD patients who have an annual review, of whom many will be over 75 years of age with complex polypharmacy, means there is more opportunity to provide appropriate care to ensure their adherence and HRQoL are maximised along with reducing health care costs for the NHS.

COPD was chosen as a clinical condition for this project due to high prevalence of COPD in North East Glasgow. Indeed, a 2007 British Lung Foundation project found that in Scotland, GGC and Lanarkshire face the greatest and second greatest challenges from COPD of all PCOs (primary care organisations) in the UK.[101] As there is evidence in national guidelines including NICE CG101 which supports regular review of COPD patients to help improve their quality of life and reduce hospital admissions,[2] it was felt that this clinical condition would be appropriate to review.

Internationally, pharmacists have become increasingly integrated into general practice.[102] They are an important part of the health care team which can contribute to the use of medicines in chronic disease management and consult and treat patients directly. They have a wide breath of knowledge and with the

expansion of pharmacists as independent prescribers, there is now an opportunity to fully examine what benefits having a pharmacist as part of a general practice team can have to improve services to patients, especially a cohort such as the housebound who often miss out on routine health care reviews as they cannot attend the GP surgery.

1.14 Introduction to the Study and Organisation of the Thesis

The premise of this study was to evaluate patients' opinions on receiving domiciliary visits for chronic disease management focusing on COPD. It is known that investigating the views and opinions of key stakeholders on the practice pharmacist model is potentially crucial to the model's success,[40] and that opinions obtained through qualitative inquiry from different perspectives may foster inter-professional development of the potential model.[40] The aim of the study was to provide all housebound patients registered with a diagnosis of COPD with a comprehensive review, which would subsequently take place annually.

The objectives were;

- To offer a home COPD annual review conducted by a practice pharmacist to all housebound COPD patients who have not had an annual review in the last 15 months.
- To visit all identified patients who are agreeable and provide each with a comprehensive COPD review including to review HRQoL via the CAT assessment tool and MRC dyspnoea scale and perform a polypharmacy review including looking at medication adherence.

- To undertake a second review carried out four weeks later to assess any changes and to undertake a semi-structured interview to discover patients' thoughts and feelings regarding domiciliary pharmacist led COPD reviews.

Previous studies reviewing housebound patient domiciliary visits for chronic diseases have shown that further qualitative research would be beneficial to examine how patients and their carers found benefit, if any, from receiving the service.[89] Previous research has also indicated that more needs to be done in the community to support COPD patients and their families as well as carers.[103] Housebound patients do not routinely get annual reviews for chronic illnesses as they cannot attend their doctors' surgery and most general practices do not have the time or resources to be able to perform house visits for routine reviews. This non-randomised qualitative research was designed to investigate if providing a domiciliary annual review for one medical condition (COPD) by a general practice pharmacist was found to be beneficial not only to the patients' HRQoL but also to their medication adherence. It also sought to investigate what patients thought and felt about receiving such a home visit annual review and having it conducted by a pharmacist rather than another health care professional.

This thesis has been introduced with Chapter 1 describing the reasons why this project was chosen. It describes the pathophysiology of COPD and its treatment options, along with information regarding Scotland health where the project is set, and the role of the pharmacist. Chapter 2 goes on to describe the literature

surrounding COPD management, pharmacists' interventions, and housebound patients. It includes a scoping review of the literature evaluating COPD management and the impact this has on patients' HRQoL along with evidence found in the literature regarding pharmaceutical care with regards to COPD and evidence gathered on COPD domiciliary care and house visits by pharmacists. Methodology is covered in Chapter 3 with both qualitative and quantitative data methods discussed. The use of qualitative methods to evaluate patients' thoughts regarding home visits for COPD annual reviews by practice pharmacists is discussed along with the reason some quantitative data has been produced by the project. These consist of demographic information and health-related data gathered with Chapter 4 explaining the theoretical reasoning for the chosen methodology and the methods relating to the project. Chapter 4 also includes information on a previous pilot study conducted to test and finalise the study design along with data collection instruments; ethical considerations, exclusions, and the data analysis of the semi-structured interviews. Chapter 5 presents the quantitative results generated by the home visits. Chapter 6 presents the results of the semi-structured interviews and associated themes generated from the qualitative data. Chapter 7 discusses the quantitative and qualitative data. Chapter 8 concludes the thesis where the strengths and limitation of the study are discussed along with recommendations for future areas of work, and the authors personal journey though the project.

2. Literature Review

2.1 Introduction

This chapter presents a review of the literature gathered around COPD and interventions by pharmacists. The chapter begins with the discussion of the search strategy in section 2.2. An appraisal of the literature with regards to COPD is given in section 2.3 with evidence regarding inhalers in section 2.4. Literature reviewed on medication adherence is presented in section 2.5 with pharmaceutical care discussed in section 2.6. Literature reviewed regarding COPD and pharmaceutical care together is documented in section 2.7 with COPD domiciliary care reviewed in 2.8. The literature surrounding home visits by pharmacists is discussed in section 2.9. Cost effectiveness of domiciliary visits is detailed in section 2.10 before an overall conclusion of the literature is given in section 2.11.

2.2 Search Strategy

A literature search was first conducted in April 2014 prior to the initial study being conducted to retrieve articles describing current services for COPD patients in the community, pharmacist input to COPD patients, and housebound reviews for COPD patient. All current evidence published was reviewed in addition to grey material and previous theses published with the aim to identify gaps in the literature to define the project question further. Initially broad keywords such as 'COPD', 'pharmacist', and 'domiciliary' were utilised to ensure all relevant research was explored. Further keywords used included 'primary care', 'GP', and

'GP pharmacist'. These searches were repeated regularly throughout the doctorate until December 2021. The electronic database searches retrieved 391 articles. An additional 121 articles were identified by a manual search of relevant reviews articles and reference lists. After removal of duplicates, the titles and abstracts of 412 studies were reviewed. Searches were conducted using EBSCO utilising; The Allied and Complementary Medicines Database (AMED), Medline, American Psychological Association's (AA) PsycInfo and PsycArticles, SPORTDiscus, AgeLine, CINAHL Plus and are shown in Appendix 2. Reference lists of studies identified, and the review articles related to pharmacist involvement in general practice, were screened for additional relevant studies. Article results from these searches and relevant references and citations were also included in this review. Current relevant national guidelines were also reviewed to ensure any new service was in keeping with their recommendations.

Very little information was found specifically regarding GP practice pharmacists conducting domiciliary annual reviews for COPD or for patients' opinions on such a service. A scoping review was carried out to ensure a wide body of evidence was collected to provide a broad overview of research studies carried out which would be relevant to this work. A scoping review is a preliminary assessment of the potential size and scope of the available research literature which aims to identify the nature and extent of available research, including ongoing research.[104] A scoping review was chosen as the information produced was broader than that of a traditional systematic review including multiple types of evidence such as primary research, reviews, different research methodologies, and non-empirical evidence.[105] It was felt appropriate as the research question

involved exploring, identifying, reporting, and discussing characteristics across a breadth of evidence sources.

A critical appraisal of the identified studies was carried out as part of the scoping review to allow us to review a variety of types of studies including RCT, observational, and systematic reviews as a way of mapping the evidence in several ways. A critical appraisal involves a careful and systematic assessment of the study's trustworthiness or methodological rigour and continues to assess how confident people can be in the findings of a set of studies. This was particularly useful as there was very limited evidence on GP pharmacists undertaking domiciliary holistic COPD annual reviews. This way we could map separate entities such as practice pharmacists, domiciliary visits, COPD, and chronic disease management, individually or in combinations to allow us to gather a wide evidence base. For example, any healthcare professionals conducting domiciliary visits were reviewed and not just those specifically carried out by pharmacists, any patient feedback on services was reviewed to determine how best to engage and interact with patients for our study, and COPD domiciliary reviews were searched for to review any studies undertaken in this area. While it is acknowledged these were not identical to the piece of work we were looking to review, it was felt important to review all relevant information and papers to determine previous learning which could be applied to our study to help ensure reliability in view of known clinical evidence. Critical appraisal worksheets produced by the Centre for Evidence-Based Medicines and the University of Oxford were utilised to determine each paper's reliability, importance, and applicability of clinical evidence.[106] For each identified study, a critical appraisal

checklist from the critical appraisal skills programme (CASP) was completed, a copy of the one for RCTs is shown in Appendix 3. This was a tool utilised to help provide a structured approach for critical appraisal of each paper.

2.3 COPD Literature Review

COPD affects one-tenth of the world's population and has been identified as a major global unmet health need by the World Health Organisation (WHO).[107] Currently COPD is the fourth leading cause of death across the globe, with WHO predicting that COPD will become the third leading cause of death by 2030.[46] Many studies have confirmed that lifestyle changes and risk factors avoidance could help to relieve the symptoms of COPD and reduce the frequency of the acute exacerbation of COPD.[46]

Current primary care treatment of COPD in Scotland focusses on reactive "rescue care", in which health professionals and patients seldom interact, except during episodes of acute illness such as exacerbations, often neglecting ongoing COPD management to the detriment of patient experience and outcomes.[51] The findings from one Australian study in 2010 of 108,455 patients indicate that regular and proactive 'maintenance' care, as distinct from 'reactive' care, is beneficial to older chronic respiratory disease patients in reducing their risks of hospitalisation and death by an average of 1.45% (global p 0.0279, $p<0.05$).[108]

The natural course of physical decline of patients with COPD can be variable, but overall, it is characterised by a long-term steady deterioration. However, most health care resources are dedicated towards management and prevention of acute events, with significantly less emphasis from physicians and research on palliative and supportive care.[109]

A review of the implementation of chronic care for COPD for improving outcomes conducted by the Department of Family Medicine in the US in 2011 showed that chronic care for COPD must reach beyond primary care practice into patients' lives in the community.[51] It showed that poor maintenance inhaler technique is associated with increased inpatient and emergency care utilisation and a greater need for systemic steroids and antibiotics, and that adherence and persistence with medication are crucial to therapeutic effectiveness.[51] The CAROL study in Switzerland tested whether a primary care COPD care bundle comprising of multiple factors including smoking cessation, pulmonary rehabilitation, inhaler technique, and appropriate vaccinations, would increase quality of care and reduce number of exacerbations.[110,111] However, this intervention was not being delivered by pharmacists but by general practitioners.

Evidence based guidelines published by NICE show that annual reviews of COPD are beneficial and primary care services typically offer these to their patients however the existing service structure only accommodates patient who can attend the GP practice and does not provide an alternative for those with physical restrictions as no alternative options to access essential preventative care are currently routinely available. This gives rise to inequity of services, and

it has been recognised in other studies that this represents a serious gap in service provision.[102]

2.4 Inhaler evidence

COPD patients rely on inhaled medications for disease management as this application method has the advantage of drug delivery direct to the necessary site of action: the lungs. Incorrect use of inhaler devices leads to lack of disease control which is associated with worsened health outcomes, such as increased risk of hospitalisation.[112] Since the correct use of an inhaler by patients is directly related to high drug delivery to the lungs and thereby sufficient disease control, the selection of an appropriate inhaler type taking into account the skills and preferences of the individual patient is an important aspect with regard to therapeutic success.[112] Pharmacist-led interventions have been shown to help educate patients and significantly improve inhaler technique, and thus further improve adherence.[113] As pharmacists have an expert knowledge of the different inhaler devices and drug combinations, they are ideally placed to be able to not only ensure the patient is on the right type of inhaler to suit their needs, but to also provide regular educational interventions to ensure correct inhaler technique and hence improved drug delivery.

A review paper published in 2013 examining a rational, rapid, and effective approach to the prescription of inhalers in asthma and COPD noted the importance of repeat demonstration of inhaler technique.[50] It also noted that reduced adherence and compliance are associated with misuse of inhaler

devices and hence linked to poor asthma control and COPD outcomes.[50] It raised an important issue with regards to patients' ability to use inhalers taking into account other co-morbidities including arthritis.[50] Pharmacists' knowledge of appropriate inhaler technique, competent patient education and demonstration, and follow up assessment have been shown to be instrumental in optimising device competency and medication adherence.[114]

Studies such as the one published by Basheti et al in 2021 show that community pharmacists are ideally placed and accessible to provide a review of inhaler technique and are able to counsel to improve this where necessary.[115] Housebound patients however, do not have access to this service as they typically have family collecting their medications or have their medications delivered to them. No studies were found that detailed inhaler technique education by pharmacists for housebound patients despite it being known to be an important part of COPD management.

2.5 Adherence

Adherence to treatment can be broadly defined as 'the extent to which a person's behaviour corresponds with the agreed recommendations from a healthcare provider'.[116] According to WHO estimates, only 50% of patients receiving long term pharmacotherapy for chronic diseases are adherent to treatment; adherence rates in asthma and COPD have been shown to vary widely from 22% to 78%.[116] The British Medical Association (BMA) published in 2014 a document which stated that non-adherence to medication in COPD is high, with adherence

to inhaled and oral medications between 41.3% to 57%.[117] This wide range of reported adherence rates may be due to the varying definition of 'adherence' with regards to which method and measurements are used to assess this. A lack of gold standard measure of medication adherence and the need for consensus about a uniform measure has been well documented.[118] There are actually very few published studies that focus on adherence to treatment for COPD as shown above, and improving medication adherence among individuals with COPD is critical to optimising patient outcomes.[118] It has been noted that adherence to medication is crucial for patients with chronic diseases and that patient education is an important tool for improving patients' medication adherence.[94]

2.6 Pharmaceutical Care

Pharmaceutical care has been classified by the WHO as a *'complex intervention to improve health'*[119] however this does not begin to cover this multifaceted concept. A popular definition was given by Hepler and Strand in 1990: *'Pharmaceutical Care is the responsible provision of drug therapy for the purpose of achieving definite outcomes which improves a patient's quality of life.*'[120] This was expanded by Strand et al in 1997 who stated that pharmaceutical care is not only a theory but also a philosophy of practice.[120] Pharmaceutical care has been further commented upon by the UK Medical Research Council (MRC), and the UK NHS Executive who have suggested this type of complex intervention in primary care should be assessed vigorously to ensure its effectiveness.[94] Some evaluation has been done by pharmacists in the UK to look at the effectiveness of UK community pharmacist's clinical interventions but there is little to evaluate

the role of practice pharmacists. One research article from Canada published in 2012 did note that the pharmacist's role and contribution to primary health care teams and their expanded role in community pharmacy practice are being discovered as health care reforms unfold in many countries.[58]

Few studies have been undertaken to investigate the patient viewpoint of receiving pharmacist led annual reviews for chronic diseases which would traditionally have been undertaken by other health care professionals. One study undertaken in Iceland in 2017 ascertained that pharmacists were perceived as trustworthy by patients, but unknown as a patient care provider.[4] All participants claimed to think highly of pharmacists as health care professionals, however it was clear from the interviews that participants had almost no experience working with pharmacists, as their responses were rather short e.g.; '*It is just good/…[pharmacists] they are useful and necessary.*' Little knowledge was shown about the exact role pharmacists can play. In addition, GPs' comments on pharmacists were that their interactions were mainly about practice and not clinical issues.[4] They felt that pharmacists were willing to help regarding purely practical issues such as drug package sizes, drug prices, and drug supply problems. Research undertaken by Speirits et al in 2020 investigating patient perceptions of post-MI pharmacist-led clinics in Glasgow, reviewed 12 patients and showed that these patients appreciated and valued the pharmacist clinics especially medical explanations and engagement in dialogue to resolve concerns.[121] It also noted that participants stated that they felt more at ease and reduced stress due to the pharmacist's consultations technique(s).

Pharmacists integrated in general practice teams can perform a variety of roles. These include direct patient care, population management activities, and the provision of expert drug information, and education for other primary care team members.[122] Studies have shown that patient indifference to pharmaceutical care was diminished by having a pharmacist integrated into medical centres compared to out with doctors surgery's in a separate community pharmacy for example.[40] It appears that the co-location of a pharmacist within a medical practice in this case gave patients more faith in the ability of a pharmacist to contribute to their care. A study involving a pharmacists integrated in family practice by Vande et al identified that in addition to patients with diabetes and COPD, patients with cardiovascular disease (especially those with heart failure and/or hypertension) depression, and kidney impairment were more likely to benefit from medication review by an integrated pharmacist.[123]

In the UK in 2016, a pilot project integrating nearly 1500 pharmacists into primary care trusts highlighted the additional roles of pharmacists responding to hospital discharges and prescribing, which, unlike in many other counties, pharmacists have the authority to do in the UK.[17] Despite this study being six years old, the principles still apply to the current practice pharmacist roles. On the other hand, in one study, a focus group consisting of health care consumers and a practice manager discussed the possibility that the pharmacist in the general practice setting could increase demand for services such as more GP appointments being requested as the patient may see the pharmacist as a way to easily get an appointment with the GP rather than make an appointment with a receptionist.[40] Other concerns that GPs voiced in one study were that their patient group is

becoming more complex due to increasing age, multimorbidity, and polypharmacy and that pharmacists may not be able to cope with this level of complexity.[4]

It was noted in a 2014 paper by Ottenbros et al that large-scale and rigorous evaluations of pharmacist-led interventions in community care settings to enhance evidence-based drug treatment in patients with asthma and COPD are lacking and results from studies on pharmacist-led interventions for pharmacotherapy improvements are inconsistent about any benefit they have for respiratory patients.[124]

Pharmaceutical care plays an important role in patient care, as supported by a 2002 American College of Physicians position paper.[125] Studies and several reviews conducted on the subject have shown that physicians in general respond favourably to pharmacist interventions and acknowledge clinical pharmacists as playing a valuable role as medication therapy specialists to improve the clinical status of patients.[126]

In a 2011 paper, the executive director of the Partnership to Fight Chronic Disease, summarised the known benefits of medication therapy management and stated that effective management of medication in primary care has been shown to reduce hospitalisations and emergency department and outpatient visits.[12] Approximately half of all hospital-related medication errors and 20% of all adverse drug events have been attributed to poor communication at the

transitions and interface of care.[12] A systematic review undertaken in Canada in 2020 by Manmeet et al found that emergency room visits decreased and savings in medication and health system costs were realised when pharmacists were integrated into PCTs, even with increased primary care usage.[17] Although it is unclear whether pharmacist-led medication reviews for patients who live in their own homes prevent hospitalisations or improve quality of life, there is evidence that they can improve appropriateness of prescribing, medication adherence, clinical outcomes, and identify and resolve medication related problems (MRP) such as adverse drug reactions, medication errors, inappropriate medication storage, stockpiling, and hoarding.[127]

A study published in 2020 reviewing the impact of pharmacist-led interventions in primary care trusts for elderly patients showed improved medication adherence and reduced emergency room visits and hospitalisations due to drug related problems, as well as improved prescribing appropriateness both in Ontario and globally.[17] These improvements are particularly significant among polypharmacy patients.[17] Pharmacists in Ontario-based primary care trusts also showed improvements for chronic condition management among patients on medications for diabetes and anticoagulation, which is also complemented by additional evidence from the province of Alberta, Canada, for improvements in blood pressure and cholesterol.[128] These studies demonstrate the pivotal and proactive role pharmacists play in optimising patient care, when integrated into the PCT settings around the world.[17] Pharmacists also conduct educational activities not just related to medication management, but also related to disease state management, healthy lifestyle advice, and smoking cessation counselling. These

educational activities showcase the ability of pharmacists to support GPs in providing holistic patient-focussed care.[14] Research from Canada in 2013 by Kelly et al supports that patients prefer to have their care co-ordinated between a physician and pharmacist and recognise that this collaboration is integral to optimising their care.[129] This is an important finding in showing that patients can understand and value the role of the pharmacist alongside the doctor as a healthcare provider.

Pharmacists have been allowed to practice as independent prescribers in the UK since 2006 after passing an accredited course, and there is evidence from a 2013 UK study suggesting that Pharmacist Independent Prescribers (PIPs) prescribe safely and provide patient benefit.[130] Feedback from patients of nurse independent prescribers and pharmacist independent prescribers has shown that longer consultations and more in-depth discussions to address any questions and concerns were especially valued by patients.[131] However, it was noted that some patients still had a preference for seeing a GP rather than a prescribing pharmacist. This may in some part be due to prescribing pharmacists being a relatively new phenomenon in UK healthcare, and that there was a lack of patient familiarity with the role. In the UK, studies looking at the prescribing role of pharmacists have thus far considered the attitudes of the public and patients who had already experienced expanded pharmacist prescribing. These same studies also reported support and benefits from this role.[30] Recent evidence (2021) published by Forsyth et al in the UK highlights the need for system-wide changes to education and support structures to enable the population-level delivery of advanced pharmacist practice.[36]

Meta-analyses and systematic reviews have provided a firm evidence base for pharmacist-led medication optimisation reviews and non-medical prescribing by pharmacists [36] with one study in Australia in 2018 showing that the majority (73%) of pharmacists' recommendations related to changes in therapy, demonstrating the expertise of pharmacists in ensuring that patients receive optimal therapy for their diagnosed conditions.[14]

Freeman et al in 2012, found in one focus group in Australia that having pharmacists embedded in primary care had the benefits of being an integrated service with access to shared patient medical records, improved rapport between the GPs and the pharmacist, and increased communication and collaboration between health care providers.[40] This focus group consisted of pharmacists, general practitioners, health care consumers, and practice managers, leading to a wide range of opinions. GPs who have experience of pharmacists in primary care have found their integration into their service invaluable in providing safe, effective, available, and acceptable rational prescribing, and not solely from a cost effectiveness point of view.[132] This would suggest that although the integration of pharmacists in primary care is still relatively new, once embedded, their worth is seen by both physicians and patients alike.

Physicians attributed many benefits to having a pharmacist integrated into their practice, including having a colleague who is able to provide reliable drug information, optimise medication prescribing, along with improved clinical documentation, services, and recommendations which enhance patient care.[17] Indeed, studies in Australia which explored patients' views on pharmacist

prescribing described how health care consumers recognised attributes such as greater accessibility, medication knowledge, and reduction in costs as benefits to pharmacists prescribing.[40] In addition to optimising outcomes for patients, a literature review by Manmeet et al in Canada in 2020 found that pharmacists in PCTs reduced physicians' workload substantially.[17] The degree of integration of non-dispensing pharmacists into the health care team may be a determinant for its success, but this association has never been properly assessed.[20] Variabilities between pharmacists and practice sites have highlighted the potential benefit of conducting further research investigating how and why the difference between sites and pharmacists occurred.[14] The real-life implementation of such interventions at the population and professional-levels is, however fraught with difficulty; one of the reasons is the skill-set and experience of the pharmacists involved in the original trials are rarely adequately defined and/or are hard to quickly replicate *en-masse*.[36] In the United States, pharmacist-managed clinics act as an opportunity for patients to receive detailed medication information, focused on their specific needs and desires. Patients reported a sense of companionship with the pharmacists, which improved the patient's desire to reach their healthcare goals.

A systematic review carried out by Hayhoe et al in 2019, reviewed the impact of integrating pharmacists into primary care teams. The evidence gathered suggested that pharmacists working in primary care are well-positioned to build relationships with pharmacists working in community and hospital settings and ultimately collaborate to provide patient care that is coordinated across pharmacy settings.[133] The same research also suggested that integrating pharmacists into

primary care may reduce GP workload and emergency department attendance as well as calling for further research to clarify cost effectiveness and long-term impact on health system outcomes. Previous research from Australia published in 2018 demonstrated that activities performed by integrated pharmacists are associated with significant improvements in patient health outcomes.[14] These improvements correlated with pharmacists in primary care identifying and resolving drug related problems and that patients with multiple health conditions and/or medications were those most likely to benefit from a consultation with a pharmacist.

In Malaysia, qualitative research published in 2017 regarding patient perspectives on pharmacist integration, demonstrates that patients believe pharmacists play a substantial role in informing them about the safe and appropriate use of medications, although they struggled to differentiate this from the pharmacists' dispensing role.[134] Additionally, when PCT pharmacists provided medication education and information, many patients felt that the medication-related education, disease-related education, and delivery of education they received was excellent.[17] The PINCER trial, (a pharmacist-led information technology intervention for medication errors), published in the Lancet in 2012, involved pharmacists' interventions that were targeted to the resolution of hazardous medicines management, with the aim of reducing significant medication errors in primary care.[135,136] This differs from our study which targeted a broader general patient population, however the principles are the same by providing a holistic medication review to identify and eliminate prescribing errors and decrease unnecessary polypharmacy.[122]

In a comprehensive systematic review published in 2010 to examine the effects of pharmacist-provided direct patient care on Quality of Life (QoL), no effect and mixed results accounted for more than 80% of studies, suggesting that pharmacists' interventions/services may have little overall statistically significant influence on QoL.[33] Unlike therapeutic or safety outcomes that rely on objective assessment and measurements, humanistic outcomes are generally based on the perspective and perceptions of patients.[33] As it is known that COPD significantly impairs HRQoL,[137] it is important that we focus on what can be done to improve this. In 2006, a US study by Ross found that successful interventions on adherence are often labour intensive and comprehensive, and direct advice to COPD patients from pharmacists may be particularly promising because of their specialised training and knowledge of medications and availability to the patients.[138,139]

2.7 COPD and pharmaceutical Care

A global strategy for the diagnosis, management and prevention of COPD published by the GOLD in 2013 identified pharmacists as key health care professional collaborators in decreasing patient risk.[44] However there are very few studies evaluating the role of pharmacists and COPD.[124] In a 2012 article it was reported that clinical pharmacist interventions to improve clinical and humanistic outcomes in COPD patients had not yet been explored and few randomised clinical trials have been reported to evaluate the impact of pharmaceutical care on health outcomes in patients with COPD.[140] Jia et al published a systematic review and meta-analysis in 2020 that noted that there

were limited number of quantitative synthesis with significant heterogenicity, however, they concluded that pharmacist-led interventions on inhalation technique, and medication adherence in adult asthma and COPD patients were positive.[141] A randomised controlled trial (RCT) undertaken in 2012 in Jordan consisted of a clinical pharmacist in an outpatient setting delivering an educational component as well as medication review along with motivational interviewing with the aim of improving adherence.[140] It reported a decreased hospital admission rate, significant improvement in medication adherence, improvement in disease and medication knowledge, and enhanced positive attitudes towards medication effectiveness in COPD; however these findings are limited by low sample size and recall bias.[140]

Clinical pharmacy services have been shown to positively affect surrogate outcomes such as blood pressure, glycaemic control, and lipid goal attainment. Evidence of the effect of clinical pharmacy services on clinical endpoints, such as mortality, hospitalisations, and HRQoL, is less clear probably due to very heterogeneously defined pharmacy services as well as strongly differing study settings.[20] There is substantial documentation in the literature supporting the role of the pharmacist in medication management in chronic disease states.[12] Previous literature has reported pharmacist participation within primary care specialist clinics such as COPD or therapeutic clinics (anticoagulation) as seen as a positive role of the pharmacist group.[40] Indeed, the NHS in England states that one of the aims of the role of the clinical pharmacist in general practice is to manage patients with long term conditions.[142]

One study published in The Netherlands in 2014 did show that a pharmacist-led intervention in regular primary care had a positive effect on drug treatment in patients with asthma or COPD, with the outcome measurement the prescribing of antibiotics or oral high dose corticosteroids for exacerbations.[124] An RCT published in Indiana in 2002 to review the effectiveness of pharmacist care for patients with reactive airway disease did not show any benefit of a pharmaceutical care plan however, there were several limitations to the trial which may have led to this finding including poor implementation and the use of measuring PEFR as a measurement of COPD.[125]

2.8 COPD Domiciliary Care

Previous studies in the US have shown that home based primary care can be cost effective, reducing average annual cost of health care by up to 24%.[143] It has been shown that COPD patients do not access community-based services for a variety of reasons including perceived barriers of attendance, particularly poor physical health, family commitments, and transport difficulties.[144] Domiciliary visits by clinical pharmacists were evaluated in 2018 in the US focussing on Veterans with complete, chronic disabling disease who have difficulty travelling to a Veterans Health Administration facility.[143] The aim of this service was to provide comprehensive longitudinal primary care in their homes with the goal of maximising the veteran's independence. A large variability in practice in what each pharmacist delivered in terms of level of medication review and a mixture of pharmacists that could and could not prescribe were found

however overall, it was felt that the service increased access for veterans to trained clinicians delivering healthcare.

A service development project in Sunderland in 2006 noted that for a cohort of patients with COPD who were chronically ill and disabled, and often too sick to access routine GP or other clinic-based services which contributed to lack of access to proactive chronic disease management, compromised effective illness management and increased uptake of urgent care services.[145] This project noted that to firmly establish the business case, the role of the practice pharmacist in housebound chronic disease annual reviews needs to be defined to highlight the unique contributions that a pharmacist provides within a multidisciplinary, collaborative care model.[145]

In one English study in 2014, three COPD patients received home respiratory nurse visits. While this was only three patients, it was felt they performed a valuable role in giving advice, spending time with patients, and liaising with secondary care.[146] Skilbeck et al concluded in 1998 that respiratory nurse specialists may be best placed to respond to the unmet needs of these patients which includes an holistic approach to patient care, in attending to their social and psychological as well as physical needs.[146,147] It could be argued that practice pharmacists are now in an ideal position to be able to fulfil this role similarly to the respiratory specialist nurses and in addition will be able to use their clinical knowledge to tackle other medication polypharmacy and another chronic diseases or clinical decisions. Practice pharmacists are also ideally placed with working in GP practices, with the benefits this brings with access to

medical records and awareness of local services such as money advice, smoking cessation, and support groups. It has been noted in previous studies that GP practices need to provide additional resources to regularly visit housebound patients but appreciate that it is difficult to incorporate this in to their existing workload.[85] Primary care pharmacists are equipped with knowledge and clinical skills to be able to deliver chronic disease management services to the housebound.

2.9 Home Visits by Pharmacists

A variety of care transition models exist and several published models which have included pharmacists have generally shown decreased hospital admissions, readmissions, and ED visits.[12] A care transition model is one utilised to improve outcomes and reduce readmissions, usually with a focus on maintaining patients in their home. In 2014, a US case study examined the benefit of a post-discharge, home-based medication management service delivered by pharmacists which proved beneficial in enhancing patient care.[148] The study showed that the home setting provides the opportunity to explore what medications the patient is actually taking in the outpatient setting and to identify barriers to a patient's medication adherence. However, it was observed that home visits can be time consuming for the pharmacist.[148] While this study does not focus on patients discharged from hospital, it does relate to a pharmacist being involved with a medication review in a patients home and the benefits this brings. Pharmacists were chosen to deliver this care transition care in several studies due to their extensive education on evidence-based use of medicines and

their clinical counselling skills. As one of the aims for both services is to keep patients out of hospital where possible, it is useful to review previous work done in this area to utilise what is already known about pharmacists and home visits, albeit not in the same context.

Research from Australia in 2012 showed that a home medication review for older people by a pharmacist was useful with clinicians reporting that it enabled a medication review for clients who don't see a GP regularly.[127] The study also found that there appeared to be an unmet demand from patients and carers for medication information and advice, with 41% expressing a desire for this.[149] In addition it concluded that additional problems that were detected during the pharmacist home visit could not be detected through a review of patient medical records, a finding that is consistent with other studies.[149] It should be noted, however, that home medication visits by GPs are routinely available in Australia whereas in Scotland GP home visits are only for acute emergency medical reasons.

Although it has been acknowledged in a case study from America in 2014 that home visits take more time and are therefore more costly, home visits have proven beneficial in the past for a number of reasons including being able to elicit more drug-related problems as all medicines are available at the home.[148] Moreover, deploying home visits instead of a telephone call is more beneficial due to the personal touch of face-to-face encounters.[94] Patients might feel more comfortable at home and therefore more likely to share their experiences and

concerns about their medicines and even be more receptive to pharmacists' counselling.[94]

One study in England in 2004 reviewing care of COPD patients in their last year of life reported that only three carers mentioned a respiratory nurse specialist who visited at home but in each case this contact was valued.[146] Having someone (whether a GP or other health care professional) who cared about and was interested in the patient and was willing to spend time with them was appreciated. The lack of active monitoring, in the form of regular review was criticised;

'To my mind that doctor shouldn't have kept writing those prescriptions out. He should have had her down the surgery or come down here to have a look at her, to see does she really need all those tablets, does she really need all that oxygen?'[146]

2.10 Cost Effectiveness of Home Visits

There is evidence that pharmacist home medication reviews can be cost effective.[148] However, some of these studies compare this with a GP home review rather than with no review. It was acknowledged in one of these trials that the cost-effectiveness ratio for the intervention based on cost savings, reduced adverse effects, and improved health outcomes, was small.[150] Sufficient time must be allowed for the pharmacist to ensure they can conduct a comprehensive medication review including but not limited to, prescribing, adjusting medication,

stopping medication, as well as providing patient and caregiver education. An American home visit pharmacist study in 2018 found that an initial medication review took an average of 83 minutes to complete with subsequent reviews 48 minutes.[148] The future of this service development and indeed the expansion of it to other long-term conditions will rely on the cost effectiveness of the services, the provision of appropriately trained pharmacists, and acceptability to patients. It has been acknowledged in previous studies that where major savings can be made is in preventative strategies for patients, which help avoid the use of secondary services when crises arise.[89]

Limited information is available on cost effectiveness of pharmacist domiciliary visits. One previous study in Malaysia, published in 2016, showed that pharmacist-led home-based interventions significantly increased disease-related knowledge and medication adherence in patients with type 2 diabetes mellitus. This study estimated time taken by the pharmacist to help manage type 2 diabetic patients was approximately one hour undertaking each home visit.[94]

2.11 Literature Review Summary

It was established that there was little published work undertaken in the UK with regards to current services for housebound COPD patients. This is despite the evidence clearly demonstrating the benefit that ongoing multi-factorial care provides to these patients in improving a patient's HRQoL, reducing exacerbations and their consequences, and alleviating the functional, utilisation, and financial burden of COPD.[51] Approximately 5% of women and 3% of men in

Scotland have been diagnosed with COPD,[151] and with this expected to rise by a third over the next twenty years, it is essential that healthcare services are tailored to the needs of patients and that there is investment in pro-active preventative healthcare.

The patient's perspective differs greatly from the organisational perspective and only a handful of studies have attempted to describe or evaluate disease management programs of the concept of integrated care from the perspectives of patients and relatives.[95] Previous studies among patients with chronic conditions revealed they experience a number of problems with health care services relating to appropriate and timely care, communication, and coordination between settings, relational continuity and patient information, among other issues.[95] Previous studies have shown that older patients and those living with chronic disease often experience problems with access to, and fragmentation of, continuity and quality of care. Therefore, as the population ages and the proportion of individuals living with one or more chronic diseases continues to grow, we need to listen to patients' experiences and use these to potentially inform strategies to improve health care services.[152]

There is also little published research to show the role the practice pharmacist can perform in primary care in the UK. Those studies that have been conducted have either been limited by small sample size or by choice of primary endpoints. The majority of studies have concentrated upon services provided by community pharmacists, who do not have the same access to patients and their medical records as practice pharmacists. This is important because access to records is

of significant help when performing a clinical role. If there is no record, there is no continuity of care. As the pharmacist's role increases, it becomes much more critical to be able to read and write records.[153] It is also of great patient safety importance as information is key to reducing medication errors, improving medicines adherence, and delivering safe and more effective care to patients.[154] As the role of the independent pharmacist prescriber evolves, evidence of whether a practice pharmacist led home COPD annual review is of benefit would be invaluable and may help to contribute towards the design of future service arrangements for this vulnerable patient group.

In August 2007, Audit Scotland published a report entitled 'Managing Long Term Conditions'.[68] While this is not a recent publication, the suggestions for practice are still relevant today. It suggested that increased community care for COPD may reduce numbers of admissions, outpatient appointments, and GP consultations (based on the experience of Scottish health boards), but the report also suggested that the cost implications appear to be much less understood.[68] However in contrast, it has been noted in a report from the Lung UK society in 2012 that the economic costs associated with manging the incapacity and disability that result from untreated or poorly-managed COPD far exceed the direct healthcare costs of treating the condition.[101] There would appear, therefore, to be a need to investigate the financial feasibility of such an intervention as cost effectiveness is a very important question especially with the current economic status of the NHS in the UK.

Lung UK state in their 'Time for a Breather' document that the main priorities in the treatment of COPD are controlling symptoms as well as reducing both the frequency and severity of exacerbations.[101] The correct prescription and effective administration of inhalers play a vital role in achieving that. Regular reviews of medication and inhaler technique are crucial to this. The document also states that a well-managed review is an excellent opportunity not only to assess the patient's current condition but to maximise the chances of maintaining or improving that condition.[101] Ensuring that all COPD patients receive such reviews not only prevents waste and reduces costs but, crucially, allows patients and carers to report the extent to which the prescribed therapy is relieving symptoms. Therefore, an evaluation of the usefulness of a practice pharmacist in performing this intervention is required.

The plethora of inhalers available for COPD patients is substantial and constantly growing with a selection shown in Appendix 4. A pharmacist is well placed to have knowledge of all the current devices as well as the medication combinations of inhalers available. This knowledge can be utilised to ensure the patient receives effective pharmacological management that not only treats their condition but suits their needs and preferences. Pharmacists can also review current treatment to ensure it is appropriate. As a recent evaluation of the use of ICS in primary care patients revealed that up to 30% of the patients did not have a clear indication for this medication,[60] this can help to ensure patients are not put at risk of over or under medicalisation.

3. Methodology

3.1 Introduction

This chapter discusses the methodology of the project with section 3.2 providing an overview of the aims. Sections 3.3 and 3.4 respectively discuss the choice of methodology, discussing the differences between qualitative and quantitative research with mixed methodology and professional context demonstrated in section 3.5 and 3.6. Limitations and mitigation of potential bias are discussed in Section 3.7 with the philosophical perspectives underlying the methodology choice discussed in section 3.8. Section 3.9 concludes this chapter by describing the data analysis.

3.2 Overview

The main aim of this research project was to provide all housebound COPD patients a comprehensive domiciliary review by a pharmacist. The objectives included measuring patient's satisfaction with care and with the pharmacist home visit annual review process as a whole as NICE guidelines for COPD note that treatment and care should take into account patient's needs and preferences.[2] It also looked to investigate whether a COPD domiciliary annual review by a practice pharmacist increased adherence and/or HRQoL and if the project resulted in a reduction in COPD exacerbations or a reduction in the number of hospital admissions for breathing related conditions.

3.3 Qualitative research

Qualitative research includes a diverse set of interpretative methods which aim to explore, understand, and explain people's experiences using non-numerical data.[155] Qualitative researchers aim to study things in their natural setting, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them, and they use a holistic perspective which preserves the complexities of human behaviour.[156] Qualitative projects that are descriptive in nature and serve to organise and summarise respondent perspectives can make a useful contribution to the literature and help build an understanding on new processes and phenomena.[157] An advantage of using qualitative methodology is that it generates rich, detailed data that leave the participants perspectives intact and provide multiple contexts for understanding the phenomenon under study.

Qualitative research interviews are 'attempts to understand the world from the subjects' point of view, to unfold the meaning of peoples' experiences, to uncover their lived world prior to scientific explanations.'[158] One of the overarching purposes of qualitative research is to illuminate the depth and richness of social phenomena or populations in their natural settings.[159] The patient perspective is justified not only for its intrinsic value, but also for its positive association with patient safety and clinical effectiveness. This research paradigm emphasises the voice of participants, delving into the complex meaning, experiences, attitudes, and motivations behind various human behaviours.[159] Limitations of qualitative methodologies include the non-generalisation of data due to small sample sizes which mean broad policy recommendations cannot be based upon the

findings.[160] However the data derived are still valuable and can be used to determine the feasibility and direction of further research in the area. It should also be acknowledged that larger sample sizes do not necessarily produce greater applicability, and that depth may be sacrificed to breadth or there may be too much data for adequate analysis.[161]

Pharmacy practice researchers are increasingly employing qualitative research techniques to understand complex social problems.[162] This is as a result of the value of qualitative researching exploring peoples' experiences, behaviours, and emotions, and in understanding a phenomenon from the participants' perspectives.[162] Qualitative research allows a researcher to provide an interpretation of observed experiences and actions of individuals and groups in different contexts. It lends itself to health services research in general and social pharmacy research in particular, where an in-depth understanding of the participants experiences is needed.[163] Qualitative methods can also be used for the 'democratisation' of research through carrying out studies that are more inclusive, collaborative, and involving partnerships.[163] This is particularly important, especially with increasing calls for increased patient involvement in health services research.[163] As the practice of modern medicine moves towards patient-centred care, involving patients in research is becoming critical. Qualitative approaches afford an opportunity to explore new areas, provide greater depth with rich data collection (e.g., open-ended questions, stories, interviews), and address complex problems when quantitative approaches are inadequate, and create a holistic picture.[159]

Contextualisation is an integral component of qualitative analysis as it is important to visualise the data. I chose not to use analytical software because one of the main limitations of using computer software is that the user is bound to the software context. This can restrict the researcher's capacity for creative expression and free thought which have proven so essential in effective learning contexts.[164]

3.4 Quantitative research

Qualitative methodology lends itself to understanding participants perspectives, to defining phenomena in terms of experienced meanings and observed variations, and to developing theory from field work.[149] In contrast, quantitative data lends itself to testing hypothesised relationships or causal explanations. Evaluating the reliability, validity, and measuring degree of generalizability across samples.

Quantitative studies emphasise the measurement and analysis of causal relationships between variables, not processes.[160] Qualitative methods are used to answer questions about experience, meaning, and perspective, most often from the standpoint of the participant.[161] It can be argued that qualitative research is weak in understanding the context or setting in which people talk. It can also be seen as deficient due to the difficulty in generalising to a large group due to its limited sample size. In contrast, the voices of participants are not directly heard in quantitative research. Furthermore, quantitative researchers are in the background, and their personal biases and interpretations are seldom discussed.

To some quantitative researchers, qualitative methods are not seen as gold star research to be compared with RCTs for example. They dismiss qualitative methods are inferior and not good enough quality to be able to prove a theory. However, the application of qualitative research has expanded in the health profession and is increasingly accepted by journals and funding agencies.[157]

A solely quantitative methodology was not deemed appropriate for this study as it could not explore patients' feelings and perceptions of their review. In addition, the small sample size of this study would mean that quantitative data would not be generalisable. Quantitative data alone would not be able to understand the nuances of human thoughts and feelings and any new patient service needs to take these into account. A central critique of quantitative research is that some quantitative research models are statistic dependent, inflate the importance of mathematical averages, and cannot capture the complexity associated with human behaviour.[39] By focussing solely on numeric information, some approaches miss the depth and detail that are assigned phenomena by participants themselves.[39] As non-numerical questions such as 'what do patients think about a domiciliary COPD annual review by a pharmacist?' are being asked, and as we were looking for causes and themes which are based on human behaviour that are non-quantifiable, quantitative methods such as an RCT would not be able to extract the necessary data. Qualitative data is a process of real-life inquiry that aims to understand social phenomena but focusing on the 'why' and 'how' rather than the 'what'. As we are not dealing with numerical data or data that can be broken down into meaningful categories along with a small

sample size, statistically relevant quantitative findings are not possible and would not be a true reflection of the data gathered in this project.

Surveys are a potential method of quantifying perceptions but are only useful for big sample sizes. Surveys were not chosen as a study method as it was felt this would be unsuitable for the chosen cohort of patients. It was felt that patients may be unable to respond due to possible eyesight or manual dexterity problems, or that illiteracy or language barriers may prohibit participation. In addition, surveys do not allow for prompting to provide further information and to allow participants to elaborate on answers given. Free text questions on surveys can easily be left blank and scale answers (such as Likert scales rating) do not allow for the depth of answer needed to address human behaviour. Small group discussions were also not chosen as a suitable method due to the housebound nature of the patient cohort chosen. It was felt unethical to ask participants to travel to a central location to undertake this when the patients are known to be housebound and need domiciliary care.

3.5 Mixed Methodology

Although the main methodology chosen for this project was qualitative in nature, quantitative data was also produced from the baseline demographics collected. Quantitative data measurements included age, gender, weight, smoking status, as well as measures of patient adherence, exacerbations, and HRQoL scores; while the qualitative data used semi-structured interviews to explore participants' views about the intervention, its outcome, and the acceptability of the pharmacist

home visit COPD review. While both qualitative and quantitative data was produced, the project was not deemed a mixed methodology but a mainly qualitative one as more emphasis was placed on patient perspective of the service being provided. Mixed methodology traditionally sets out to incorporate both quantitative and qualitative methods to balance out perceived weaknesses of the individual methods when used alone. Triangulation is one such popular mixed methodology design whereby the purpose is to use the strengths of both methods with the aim of comparing and contrasting the result to build one complete picture whereas in this project, the quantitative data gives us information on medical impact whereas the qualitative data gives us information on patient's thoughts and feelings. In addition, the individual methodologies are not undertaken sequentially to build upon data previously generated at one stage in the project which again demonstrates the parallel nature of the data developed rather than mixed methodology.[165]

3.6 Professional Context

Qualitative research attempts to develop an understanding of a phenomenon based as far as possible on the perspectives of those participating in the research. However, in qualitative research it is impossible to completely set aside one's own perspective, and it is important to be explicit about what interests, values, and assumptions, and the role that these play in the understanding of the data.[149] With regards to professional context, I am a practice based independent prescribing pharmacist who has worked in six out of the 44 GP practices across the North East of Glasgow since 2007 and have a good working relationship with

these practices. I am currently employed by NHS GGC health board and have some awareness of the cultural nuances that exist such as Scottish slang. I am asthmatic myself, so have always had an interest in respiratory conditions as I know what it feels like to struggle to breathe. I am passionate about finding out what roles the pharmacist can undertake in primary care to help develop patient care, especially for those who struggle to access routine care.

3.7 Limitations

Qualitative researchers are often embedded in the culture and experiences of others which increases the opportunity for conscious or unconscious bias. Bias can occur at any stage of the research process, and it is therefore necessary to acknowledge the lead researcher in the study as a pharmacist with an interest in advancing the pharmacy profession. Actions were taken to try to minimise this known bias. Self-description and self-reflections are very important in qualitative research to acknowledge and reduce researcher bias, a common criticism of qualitative research.[155] In order to monitor the researchers' own developing interpretations and constructions, reflective journaling was conducted throughout the process.[164] Selection bias was minimised by not omitting age groups or ethnicities from the project. The NHS has an excellent 'language line' interpreter service which can be used remotely in patient' homes. All patients eligible for the project were invited not only using written material but also with phone calls to enable those with literacy issues to receive information about, and participate in, the study if they wished. Potential participants were also encouraged to have

family members or close friends involved as well to reassure patients regarding the authenticity of the project.

Interview questions were reviewed by the project supervisors to check for bias and for any potential leading questions as well as closed questions which would not enable a patient to elaborate on their thoughts. Interviewer bias is very hard to avoid; however, both pharmacist interviewers were aware of this as well as response bias and tried to ensure that body language was kept neutral and that participants were encouraged to give the true answers they wished to and not the answers they felt were 'correct' and also to reassure them they would not cause offence. Open questions were utilised to try to allow information to flow more freely and by not forcing a limited set of answers. Procedural bias was reduced by ensuring that participants had ample time to answer questions and that their responses were not rushed.

Meticulous records of interviews and observations were kept and the process of analysis was documented in detail to increase retest reliability and to try to mitigate bias.[166] The researcher also kept a log book throughout the project. This provided researcher perspective and identified any issues whereby researcher influence might have affected data. It was also used for the documentation of field notes such as non-verbal aspects of the interviews such as facial expressions, body language, the setting, and patient/researcher interactions, as these may affect the interpretation.[154]

The audio-recorded interviews were transcribed independently of the lead researcher to minimise bias being introduced at this stage of the research process. Generated themes from the data were checked with supervisors and peers to ensure they were a true representation of the transcriptions. Thematic analysis was undertaken on the transcribed semi-structured interviews. All patients who agreed to be interviewed were included in the study.

It is noted that semi-structured interview results may not produce results which are generalisable beyond the sample group, however- they provide a more in-depth understanding of the participants' perceptions, motivations, and emotions. As healthcare should be patient centred, it is vital that we ensure that any services we plan to introduce are acceptable to the patient cohort they are designed for. The semi-structured interviews were rooted in a constructivist worldview that argues there is no absolute truth or valid interpretation.[159] The aim of this piece of work was to explore the complexity of perspectives and views offered by patients.

The tools used in the project such as the CAT score and MRC score are specific for this patient cohort and are validated measurement aides in COPD. It was decided that the most comprehensive disease-specific HRQoL or health status questionnaires such as the Chronic Respiratory Questionnaire (CRQ) and St George's Respiratory Questionnaire (SGRQ) were too complex to use in routine practice[43] therefore the CAT which is a validated 8-item one-dimensional measure of health status impairment in COPD was utilised instead.[43] The GOLD

guidelines for the management of COPD distinguish patients that have a CAT score of ≥ 10 with those that have <10 as being more symptomatic and less symptomatic as a result of their COPD respectively.[131]

PEFR was not measured in this study due to the lack of sensitivity of PEFR with regards to COPD. It was not considered to be an adequate measure of change to be used as a clinical endpoint in this study. MRC score was measured during the study however it was not used as an indication of condition change due to the natural fluctuation of COPD as a condition. MRC scores can indicate changes in the severity of COPD and when other medical changes should be made, for example NICE CG 101 recommends that pulmonary rehabilitation should be offered to those with an MRC score of greater or equal to three.

3.8 Underpinning Methodology

A phenomenological approach was taken in this project as it was exploring how a phenomenon (annual domiciliary review by a practice pharmacist) was experienced by patients. It sought to describe the 'lived experiences' of several individuals around a particular concept of phenomenon.[159] A grounded theory approach would not have identified potential changes needed e.g., what could be done to provide appropriate services for housebound patients but rather to generate a theory. A phenomenological viewpoint was deemed appropriate for this study as this takes into account variations in individuals and their views and ideas. The phenomenologist is one who tries to understand social phenomena or human activity from the viewpoint of the person being studied.[31] This is a useful

viewpoint to take to help us understand if the patients find the intervention beneficial.[32] It is very much an exploratory research question as it is general in nature and seeks to build theory.[31] As we are trying to understand human behaviours with regards to adherence and also HRQoL, methods have to include a qualitative methodology to capture this. Qualitative work can reach aspects of complex behaviours, attitudes, and interactions which quantitative methods cannot.[33] The methodology also has a few subtle aspects of a new paradigm research design called action research in that the research is *with* and *for* people, rather than *on* people.[31] This paradigm also makes room for the human, emotional, and intuitive elements of everyday life.[31]

This recursive method will allow the patients to be given the opportunity to discuss the topic freely using their own terminology and drawing from their own experience; the length of time and amount of information obtained is largely dependent on the relative importance of that issue to the patient.[31,34,] A semi-structured interview will also allow the researcher to probe particular comments and to ask and encourage patients for further elaboration or increased depth.[34] Since the intention in this form of interview is to gain insight into a topic from the perspective of the informant, it is important that the agenda for the interview is not imposed by the interviewer, but is negotiated between interviewer and interviewee.[31] Conducting these reviews as home visits should help to contribute to the ecological validity of the data collected due to the natural and comforting surroundings which will hopefully put the patient at ease.[35]

Open questions were chosen to give respondents an opportunity to raise the issues that were important to themselves, which may not be those that the researcher would have anticipated.[167] The qualitative data produced will not have external validity and will therefore not be able to be applied to the whole population however this is acceptable for this evaluation as we wish to find out what is happening within this specific group of patients. Qualitative data was chosen as the main method as it was felt this was the most suitable to help us understand social phenomena in natural settings, giving due emphasis to the meanings, experiences, and views of all the participants.[166]

3.9 Analysis of Data

A grounded theory inductive approach was taken to analyse the qualitative data produced by this project. In this approach, data collection and analysis are iterative, i.e. the researcher moves back and forth between the two, rather than collecting and analysing data in sequence.[31] The semi-structured interviews were transcribed verbatim and a thematic approach was used for analysis with themes being coded to provide an accurate reflection of the views raised by respondents using open and then conceptual coding.[34] Smagorinsky warns that impressionistic data reports often involve selectively chosen data designed more to confirm a researcher's preconceived thesis.[168] Therefore, time was taken to ensure thematic codes were relevant to the data produced including comparing and contrasting interview participants answers. It is noted by Glaser and Laudel that to find explanations linking conditions, effects, and mechanisms, we need to

systematically reduce complexity and bring our data in a form that supports pattern recognition which can introduce researcher's bias.[169]

4. Method

4.1 Introduction

This chapter presents a review of the methods used in this study beginning with section 4.2 describing the pilot study which was undertaken. Section 4.3 onwards, discusses the main study with sampling strategy discussed initially and then ethical considerations described in section 4.4. Section 4.5 documents the target population with the exclusion criteria in Section 4.6. Section 4.7 goes into detail on the first domiciliary visit undertaken with section 4.8 describing visit two. Section 4.9 describes the specifics of the semi-structured interviews with section 4.10 documenting the data analysis, with a summary of the methods provided in section 4.11.

4.2 Pilot Study

The pilot project was conducted by the project pharmacist to develop and trial the paperwork for a home COPD annual review by a practice pharmacist as well as to gauge initial patient feedback as to their experience of this. Non-probability sampling using purposive sampling was undertaken as the number of patients with COPD who had not received an annual review in the last 15 months was expected to be a small number based on QOF reported figures. The initial project involved patients from one GP practice in the North East Sector of Glasgow City.

The information gathered from this service evaluation was utilised to focus the clarity of the questions and the design and style of the way the questions were

presented for the main study. It was also used to streamline data collection forms for the main research project to ensure consistency throughout the rest of the GP practices in the North East Glasgow sector for the main project. All paperwork was checked by the other pharmacists in the team as well as the project supervisors to ensure clarity of the questions and usability of the forms to collect all the relevant data, and also to ensure the paperwork was appropriate and understandable and simple to use. Copies were passed to the GGC Managed Clinical Network (MCN) for respiratory to ensure they were happy with the content.

Only one domiciliary visit per patient was undertaken as part of the pilot study as the main purpose was to ascertain suitability and feasibility of the domiciliary review and to ask for patient feedback at this point. The initial pilot was undertaken as a service evaluation, with feedback from patients gathered using a one-page feedback form (Appendix 5) that the patients completed themselves and returned to the practice after the visit. It was noted during the pilot that the self-administered feedback form was difficult for a couple of patients to complete due to co-morbidities such as poor eyesight or dexterity issues due to arthritis. It was therefore decided that instead of a feedback form a semi-structured interview with patients would be used in the main study.

The only changes between the pilot study and the main study were that the main study consisted of two domiciliary reviews approximately four weeks apart and that the second domiciliary review included a semi structured interview by a

different pharmacist than the first visit to ascertain patients' thoughts and feelings regarding a domiciliary COPD review by a practice pharmacist. The semi-structured interview in the main study was chosen specifically as the self-completed feedback forms by the patients in the pilot study were not completed in enough detail nor where enough returned to make the study viable.

The semi-structured interview was derived of questions constructed by the project pharmacist with the aim of finding out the patients' thoughts and feelings of having a pharmacist perform domiciliary COPD reviews. The framing of questions was guided by studying semi-structured interview techniques such as those set out by DeJonckheere et al in their 2019 paper semi structured interviewing in primary care research: a balance of relationship and rigour.[170] The initial question was chosen to make participants feel comfortable and set them at ease**.** Attention to detail was undertaken to ensure no leading questions were used and that questions were as neutral as possible to enable capture of a broad range of opinions.[171] Interviewers were trained in active learning and probing techniques to use during the interview.[172] Potential follow up questions were prepared to try to make sure the best was obtained out of each interview and to allow the interviewers to delve deeper into the participants responses and hone in on the most important themes.[171] Planning possible follow up questions also aided the interviewer in case they felt stuck or needed a prompt. Data collection design was undertaken using papers recommended by pharmacy peers and textbooks from established qualitative researchers such as John Creswell. [165,173] The interview schedule was then appraised by peers and academic supervisors for suitability.

4.3 Sampling for the Main Study

NHS GGC health board is the largest in the UK, providing care for approximately 1.14 million patients in the West of Scotland.[174] Glasgow's North East Locality is historically where health is most challenging due to severe levels of poverty, even compared to Glasgow city as whole. The North East Locality where this study took place is committed to responding to the significant challenges faced by people living in the area. The high levels of poverty and multiple health problems experienced by local residents seriously impacts both on their quality of life and their life expectancy.[175]

Non-probability sampling using purposive sampling was undertaken and therefore all housebound patients aged 18 and over with COPD who were exemption coded from their annual COPD review in all GP practices in North East Glasgow in the last 15 months were invited to participate in this project by telephone and written invitations. This included those patients who were receiving palliative care as an annual review was still relevant and could be beneficial in helping to produce symptomatic relief. Those not using inhalers were also included in the project as it was important to ascertain adherence and conduct a review before their condition declines. Those who did not wish a home visit were offered a surgery COPD annual review with the pharmacist (or practice nurse if they preferred) and were excluded from the evaluation. This was to ensure patients were not put at a disadvantage by not wishing to participate in research. Patients who did want a home visit COPD annual review but did not wish to participate in the evaluation also still received a home visit. As access to

translation services was available, there was no need to exclude those who could not speak English.

4.4 Ethical Considerations for Main Study

Ethical approval was not deemed necessary for the full research project as it was considered to be a service evaluation project. This was clarified and confirmed by both NHS GGC NHS Ethic Committee (Appendix 6) and Keele University. As this is a service evaluation, formal ethical approval was not required as evaluations of service are viewed as an essential part of service delivery. Meticulous records of interviews and observations were kept, and the process of analysis was documented in detail to increase retest reliability.[42] The project pharmacist also kept a logbook throughout the project. This provided project pharmacist perspective and identified any issues whereby project pharmacist influence might have affected data. It was also used for the documentation of field notes such as nonverbal aspects of the annual review such as facial expressions, body language, the setting and patient/researcher interactions, as these may affect the interpretation.[37] It also provided an audit trail of data collection and analysis to enhance validity. Only data without confidential or patient identifiers were allowed to be removed from the practice and was kept on a secured flash drive in accordance with NHS data security regulations.

The need to gain informed and valid consent is both good practice and essential.[176] For this reason, patients included in the project were advised that

the visit was optional both in advance and during the visits and semi-structured interview. Written information regarding the ability to withdraw at any point was left with the patient to allow any family to be involved in the decision to consent.

Informed consent was obtained from each patient and written material was left with them which they were encouraged to share with family members. The patient's ability to refuse to take part and also to withdraw at any time without any detriment to their health care or relationship with their health care professionals was emphasised. Email and telephone numbers were left as a contact for both the investigator and the lead pharmacist for patients or their family to contact if they had any concerns or questions. Confidentiality and anonymity were ensured throughout the evaluation and quotes used in this report have been anonymised to remove any personal information and prevent any participants being identified via deductive disclosure. In the eventuality that a risk of harm may develop as a natural consequence of a social situation, the research pharmacist decided whether or not to intervene as it has been argued that a health care professional researcher should respond in terms of his or her clinical responsibility.[31] This was communicated to the patient as part of the informed consent process and if this was the case then they were excluded from the project.

Security and safety of the practice pharmacists were paramount as were the security and safety of the patient. The pharmacists all followed local NHS lone working policy guidelines and ensured patients checked their NHS ID badges before allowing them entry to their house. Participants were sent a letter

confirming the visit on practice headed note paper and encouraged to have family members present at the review if they wished- especially if someone else helped them deal with their medications. Visits could also be co-ordinated with carers if that was felt to be of benefit.

A guiding framework for ethical dilemmas was adopted; [40]

- Be available to explain the research to the participant before, during, and after the data collection stages
- Put people first above all other considerations
- Do unto others what you would like others to do unto you
- Participant centred research

As the pharmacists in the North East Locality who carried out part of the research project were colleagues of the research pharmacist, ethical issues needed to be framed and considered in terms of the wider relationships that go beyond friends and colleagues. There was a need to develop a critical research stance whilst at the same time maintaining allegiance to the institution and colleagues. Acknowledgement was paid to managing marginality in which the project research pharmacist had to try to counteract the balance between insider and outside roles.[153]

4.5 Target Population for the Main Study

All patients with a diagnosis of COPD and who had not had an annual review in the last year were identified by a search using practice software (EMIS/VISION and DOCMAN). Purposive sampling was undertaken and therefore all housebound (or mobility restricted) patients aged 18 and over with COPD who were exemption coded from their annual COPD review in all 44 GP practices in the North East Glasgow Locality in the last 15 months were invited to participate in this study by telephone and written invitations. The invite with details regarding the project sent to patients is included in Appendix 7 with the ethical consent form in Appendix 8. Patients who were receiving palliative care were included as it was considered that an annual review was still relevant and could be beneficial in helping to produce symptomatic relief in this cohort of patients. Those not using inhalers were also included in the study as it was felt important to ascertain adherence and conduct a review before their condition declines. Those who did not wish a home visit were offered a surgery COPD annual review with the pharmacist (or practice nurse if they preferred) and were excluded from the evaluation. This was to ensure patients were not put at a disadvantage by not wishing to participate in research. Patients who did want a home visit COPD annual review but did not wish to participate in the evaluation also still received a home visit. As access to translation services was available, there was no need to exclude those who could not speak English. All patients who consented were screened for suitability and baseline data including age, smoking status, any co-morbidities, and current medication therapy, was noted.

4.6 Exclusions for the Main Study

The main reasons for participants being exempt from this project are given below with more detail included in Appendix 9;

- those with a terminal illness diagnosis where a home visit may be inappropriate (as determined via their status (i.e.- if end stage or in distress) and via GP discussion)
- those with severe dementia where it would be detrimental to review their condition (- i.e., cause upset or confusion by asking questions)
- Households where violence towards others or physically or verbally abusive behaviours were present (if recorded in patients notes)

There were two trials in Glasgow that were being conducted, involving patients with COPD, at the same time as data collection was being undertaken for this service evaluation. Patients in the North East area who were participating in these trials were excluded from this study to prevent bias as it would not be possible to state that any change in these patients was solely due to this project's intervention. All other patient involvement with other healthcare professionals for breathing conditions, such as early supported discharge nurses or secondary care appointments was recorded, and patients excluded if these interventions could have introduced confounding factors to the study.

4.7 Domiciliary Visit One

Prior to the first consultation the pharmacist reviewed each patients' medical records and, in some cases, dispensing histories from the patient's community pharmacy. The patients' medical records were reviewed in practice with the patient's computer medical records (and paper if still used by the practice) and the following information was gathered from their file prior to the initial visit using the COPD workup form (Appendix 10):

- Most recent blood pressure, pulse, U&Es and any other relevant lab results
- Complete medical history recording COPD therapy, out of hours attendance, and hospital admissions secondary to COPD within the past year
- Complete medial history recording of all other co-morbidities
- Record of all repeats and acute prescriptions issued in the last 15 months
- Last COPD annual review or any review on file to assess the history of COPD symptoms (cough, wheeze, dyspnoea) including noting any CAT or MRC scores recorded on file
- Review practice records for any previous pulse oximetry readings
- COPD medications will be initiated, discontinued, or adjusted as needed
- Record any information on medical records regarding social history, work/environmental exposure, and functional status

- Review if records state patient is a smoker and if they have had recent vaccines such as ‘flu or pneumococcal and note if these are outstanding
- Note any mention in medical records regarding inhaler technique and compliance and whether good/poor etc
- Assess compliance of other medications

These items provided the pharmacist with background information on the patient’s current condition(s) and HRQoL burden of COPD. It also provided information to enable the pharmacist to ensure holistic care was given by paying attention to all current medical and social issues as appropriate tailored to each patient’s individual circumstances. Blood pressure and pulse give an indication of cardiovascular health and were measured as they may help provide the pharmacist with information on differential diagnoses of breathlessness such as concurrent heart failure. Review of the patients’ medication provided currently prescribed medications and a list of those previously tried and why they were changed (such as allergic reaction, intolerable side effects, poor inhaler technique, or non-adherence). Knowledge about the number of COPD related hospital admissions and out of hours attendance provided insight into how stable each patients’ COPD had been over the last year and informed decisions about changing therapies as recommended by NICE COPD CG101.

Patients received a face-to-face consultation, lasting approximately 30-60 minutes with the pharmacist in their home to review their COPD. The pharmacist

interviewed the patient to compile a full accurate medication history, discussed their medication management, and reviewed their medication regimen. An audit form to record this information is included in Appendix 11. Even though this was classed as a COPD review, if there was something in the medical history related to another condition which could be reviewed to help the patient and was within the pharmacist's area of expertise, it was undertaken. An example of this was increasing blood pressure medications if blood pressure was raised or changing a medication to an alternative due to side effects. Indeed, this is one of the benefits of having primary care pharmacists undertake this work as they are generalists who can help with all medical conditions and are not restricted to just one medical condition. A polypharmacy review was of benefit to patients with opportunities to deprescribe any unnecessary medication to reduce the medication burden. An example of this was stopping antihistamine therapy which was started years previously for a rash which had long since resolved. Medication was also assessed holistically to check for interactions or contraindicated combinations; these were addressed if found.

During the visit, the pharmacist fully described the study being undertaken and asked for the patient's permission to use their data and for them to undertake a second home visit by a different practice pharmacist (to prevent bias) who would conduct a progress review of the patients COPD and a semi-structured interview. Patients were then asked to sign a consent form and informed of their right to decline to participate at any time; this would not have any influence on their care or relationship with their health care providers. An information sheet about the study was left with the patient to provide written information and remind them of

their right to decline to participate at any time after the visit and whom to contact to do so. A copy of this is included in Appendix 8.

During the visit, measurements including pulse oximetry were taken and two validated assessment tools- the MRC Dyspnoea Scale and the CAT score were administered. The MRC and CAT score both provide information regarding the patients HRQoL and how their condition affected their daily life and are described in Chapter 1, Table 1.4 on page 18, and Appendix 12 respectively. The MRC score was measured to classify COPD severity using COPD staging classification and to help the pharmacist determine whether it is appropriate to signpost the patient to pulmonary rehabilitation, as NICE guidelines state that pulmonary rehabilitation should be offered to all patients who consider themselves functionally disabled by COPD (usually MRC grade 3 and above).[2] Pulse oximetry was recorded as NICE CG101 recommends that pulse oximetry should be available in all healthcare settings to ensure that all patients eligible for Long Term Oxygen Therapy (LTOT) are identified. Inhaler technique was checked using the relevant Patient Information Leaflet (PIL). Nutritional status was also reviewed as recommended in NICE CG101 using the validated Malnutrition Universal Screening Tool (MUST).[41]

Reviewing pulse oximetry enabled the pharmacist to determine if onward referral to secondary care for oxygen therapy was appropriate. Having access to the full medical record was of use as it allowed the pharmacist to determine trends and understand what level of oxygen saturation was ‘normal’ for each individual

patient. The number of COPD exacerbations in the last year as well as Out of Hours (OOHs) attendances and hospital admission for breathing related conditions were gathered to help identify how stable patients' COPD had been over the previous year. An exacerbation was defined as having been treated with antibiotics and/or oral steroids for their breathing condition and not for any other unconnected medical reason.

The pharmacist also assessed medication adherence and knowledge including using the Morisky 8-point adherence questionnaire (Appendix 13). Adherence to prescribed medications, both in research trials and in clinical practice, is crucial to the success of the pharmacological interventions.[177] However, there is no accepted standard method of assessing adherence, both as a cross-sectional measurement and for measurements across time.[177] Adherence to all medications was recorded using the eight item Morisky Medication Adherence Scale (MMAS-8) as discussed in Chapter 1, page 96. Morisky et al developed a self-reported scale with four items regarding common medication taking behaviours leading to omission of drug which has been used widely especially in RCTs.[178] Later an additional four items addressing circumstances surrounding adherence behaviour were supplemented to the original version to overcome some of its limitations. It is one of the most widely used instruments to measure adherence in patients with chronic diseases, including COPD.[179] A systematic review was carried out by Moon Sun et al in 2017 to look at the accuracy of the Morisky Medication Adherence Scale.[178] It concluded that the MMAS-8 had acceptable internal consistency and reproducibility.

The MMAS-8 scale comprises eight questions related to medication use as prescribed by the physician. Items one–seven are Yes/No questions; “Yes”, is scored as zero and “No” as one, except for Question five where “Yes” is scored as one point and “No” as zero. Item eight is a ranked question similar to a Likert Scale with the range of zero to four. The total score for a patient ranges from zero to eight. A COPD annual review intervention which covered all points set out in NICE CG101 (as shown in Table 1.6 one page 29) was also undertaken by the pharmacist at this visit. After the visit, the pharmacist returned to practice and processed any changes and/or referrals necessary.

Reviewing all medications, not just those prescribed for COPD allowed the patients’ illness(es) to be treated collectively and not in isolation. Patients’ thoughts and feelings were gathered on all their medications and changes were made to increase compliance, if necessary, say for example from tablet to capsule or liquid if appropriate for swallowing difficulties. Having the review face to face also allowed the pharmacist to check inhaler technique which is paramount to providing the necessary medications to the lungs in respiratory conditions. Social history and functional status knowledge allowed the pharmacist to consider any external factors which might affected their health such as family members who smoke in the same household, or if the patient worked in a factory setting which may exacerbate their condition, or works outside, or subjected to allergic components. Patient’s weight was also checked, and the possibility of sleep apnoea considered in case this was present and negatively affecting a patient’s breathing.

As smoking cessation is the single most important action that can be taken to improve outcomes in COPD, it is important this is discussed with patients regularly in a non-threatening respectful manner. This was undertaken if the patient was a current smoker. Appropriate vaccinations (including annual influenza and pneumococcal) were also reviewed, and patients were referred for vaccination where necessary. Information was given both verbally and in written form to help educate patients regarding COPD (as shown in Appendix 14), inhaler technique, how to get the best from their medicines, and measures to increase compliance if necessary, such as aide memoirs. The pharmacist altered medication regimens as appropriate with a follow-up visit conducted four weeks later where possible.

Non-pharmacological disease management, non-drug issues related to disease management, or social factors that were identified by the pharmacist (e.g., the need for weight and diet management, exercise, money mattes or counselling) were addressed during the home visit(s). When necessary, the pharmacist;

- referred the patient to the GP or other health professional as required for management of other patient issues identified during the appointment (e.g., social, psychological, medical issues).
- liaised with the patient's community pharmacist to start a dosette box or medication adherence aid as appropriate.
- referred the patient for immunisation and/or pulmonary rehabilitation

4.8 Domiciliary Visit Two

Follow up visits were undertaken by a different clinical pharmacist to the first visit to try to reduce bias. Only two pharmacists conducted visit two to reduce differences in conducting the semi-structured interviews. The four weeks lapse between visits was to try to ensure the patient remembered the initial visit and to minimise any other health issues or care interfering with the second visit data; the longer the time gap between the visits, the more time for other factors to exacerbate control. However, it is still acknowledged that any changes to COPD control between visit one and two with regards to COPD control may have been affected by other factors, such as seasonal variability or interventions by other health care professionals, as well as the relapsing and remitting nature of COPD.[180]

During the second visit, the following were conducted and assessed;

- Obtain an updated medication history, including both COPD and non-COPD medications.
- Frequency of signs and symptoms of COPD.
- MRC and CAT scores repeated to look for change
- Pulse oximetry and blood pressure re-checked
- History of COPD exacerbations - had there been any in the last 4 weeks?
- Pharmacotherapy - effectiveness, adverse effects, compliance,
- COPD medications– if any changes had been made- have they made a difference to breathing control?
- Review inhaler/spacer technique; have patient demonstrate technique

- Polypharmacy- any changes since visit one with regards to any medications will be discussed with the patient and adjusted as needed

In addition to the same parameters as visit one, visit two also reviewed if any changes made since visit one had any impact on the patient's HRQoL either positively or negatively. After the COPD follow-up review had been completed, the pharmacist then went on to audio record a semi-structured interview in the patient's house after checking again for consent. The participants were informed of the nature and the purpose of the interview and the importance of being honest, with the interviewer striving to put the patient at ease throughout.[181] It was noted that the interviewer may have to steer participants back to the questionnaire if they were moving off the point, without being impolite, and the importance of the interviewer avoiding being judgmental or revealing any personal bias as this could skew the data.[182]

4.9 Semi-structured Interviews

A semi-structured interview using open ended questions (Appendix 15) was used as this is more relaxed than a structured interview and encouraged patients to share their views and to build rapport with the interviewer. Semi-structured in-depth interviews are commonly used in qualitative research and are the most frequent qualitative data source in health services research.[170] The questionnaire was formulated during the pilot work and altered based on the feedback from patients to produce the final version. Questions were developed based on researchers' knowledge of COPD and what questions where thought to help elicit

opinions of the patients regarding the domiciliary COPD review and having a pharmacist providing the service. Questions when formulated to be participant-orientated and not leading, and clearly worded, single-faceted, and open-ended.[183] The aim of the questionnaire was to generate answers from participants that were spontaneous in-depth, unique, and vivid which reflected the patients personal feelings and stories.[183] This method typically consists of a dialogue between researcher and participant, guided by a flexible interview protocol and supplemented by follow-up questions, probes and comments. A semi-structured interview schedule enables interviewers to ask additional questions as necessary; semi-structured interviews combine elements of structured and unstructured interviews, giving the advantages of both.

The patients were given the opportunity to discuss topics freely in their own terminology drawing from their own experience and the length of time and amount of information obtained was dependent largely on the relative importance of that issue to the patient.[167] Notes were also taken by the interviewers during the interviews to capture the interpersonal, interactional, communicative, and emotional aspects of the interview such as facial and bodily expressions.

Only two pharmacists conducted the semi-structured interview to minimise bias and to ensure pharmacists with awareness of undertaking semi-structured interviews were conducting the reviews. No second visit was carried out by the same pharmacist who undertook visit one to minimise bias and prevent patients feeling uncomfortable about discussing treatment given by the same person as undertaking the interview.

The first question asked was *'what breathing condition(s) do you have?'* Although the pharmacist was aware of what breathing conditions that patient had, the question was posed as an ice breaker to help the patient to relax and ignore the recording device. After the first few interviews, the two interviewers learned that it was best to place the recorder out of sight of the patient as they found that this helped the patient forget they were being recorded more quickly. The sequence and framing of questions were also taken into consideration to allow easier and less threatening non-controversial questions to be addressed earlier in the interview to put respondents at their ease.[182] A total of 13 questions were asked. The length of the interview was guided by what was felt to be acceptable to the patient. There was conscious effort not to overload the participants with too many questions. The questions were initially piloted in the initial doctorate study and were found to be acceptable to patients however they were asked in written format which was quickly found to be undesirable to patients and negatively affected return rates and did not allow us to delve deeper into issues/information raised. For these reasons, it was decided to conduct the reviews in person and audio record them to allow further depth to the answers to be given and increase participation rates.

Other questions that were asked included asking participants what they thought about the pharmacist who visited about a month ago to conduct a review of their breathing. This was further analysed by asking the participants what their perceptions about having a pharmacist conduct the review rather than, say a nurse or a doctor were. Questions were also asked regarding if the pharmacist had helped with their breathing medications and this was further built upon by

asking if they had helped with any other medications and indeed with any other issues, whether pharmacological or non-pharmacological.

All interviews were transcribed verbatim by an independent contractor. Transcripts were then checked for accuracy by the investigator. Notes taken by the researcher during the interviews, such as nonverbal behaviour, were added to the transcripts at this point for completeness of data before analysis. A brief thematic analysis was conducted after each transcript was received to make any necessary iterative adjustments to the interview guide as themes were identified. This was undertaken to ensure any relevant issued identified were able to be addressed in more detail in later interview.

4.10 Data analysis

4.10.1 Quantitative data

The general practice computer systems, EMIS/VISION along with DOCMAN, as well as paper notes, were utilised to extract data relating to patients who had not attended an annual COPD review in the last 15 months. Data relating to patients' COPD treatment and demographics, as shown in Table 4.1, were also extracted, and entered into a password protected Excel spreadsheet, including minimum patient identifying characteristics. Data was reported as descriptive statistics, such as percentages and frequencies.

Table 4.1 Quantitative data collected

Patient age	Living status (alone/cohabiting)
Gender	Respiratory medication ordering figures
Smoking status	Number of hospital admissions or Out of Hours (OOH) attendances in the last 12 months for respiratory exacerbations
Diagnosed respiratory condition (s)	Number of courses of oral corticosteroids for respiratory exacerbations during last year
FEV1 (and date of spirometry)	Smoking status
Pack years (if applicable)	If currently attending secondary care for respiratory
If on Long Term Oxygen Therapy (LTOT)	Previous breathing exacerbations in the last 12 months

4.10.2 Qualitative data

Qualitative data were produced from the semi-structured interview at the second home visit. Due to the small sample size, any quotations from patients will be provided in the results section of the project for validation, authenticity. These are confidential and anonymous to ensure they contain no patient identifying markers and will provide the reader with first hand examples of encountered viewpoints.

Thematic analysis was used to interpret the data into broad themes. Through its theoretical freedom, thematic analysis provides a highly flexible approach that can be modified for the needs of many studies, providing a rich and detailed, yet complex account of data.[184] An inductive approach was used by allowing the data to determine themes. A latent approach was undertaken by reading into the subtext and assumptions underlying the data. Transcripts were analysed using

Braun and Clarke's six steps as show in 4.2.[185] The interview analyses were coloured coded into clusters of similar entities and the identifications of themes and relationships between themes undertaken using Microsoft Word and Excel. Transcriptions and themes were checked by the lead supervisor for accuracy.

Table 4.2 Braun and Clarke (2006) 6-step guide to good thematic analysis.

Phase	**Examples of procedure for each step**
1. Familiarisation	Transcribing data; reading and re-reading noting down initial codes
2. Generating Initial Codes	Coding interesting features in the data in a systematic fashion across the data set, collating data relevant to each code
3. Searching for Themes	Collating codes into potential themes gathering all data relevant to each theme
4. Involved Reviewing Themes	Checking the themes work in relation to the coded extracts and the entire dataset; generate a thematic map
5. Defining and Naming Themes	Ongoing analysis to refine the specifics for each theme; generation of clear names for each theme
6. Producing the Report	Final Opportunity for Analysis selecting appropriate extracts; discussion of analysis; relate back to the research questions or literature; produce report

The interview transcript was printed out on A4 sheets of paper with plenty of space between the lines of text and a wide margin for coding. Line-by-line coding was conducted manually using pens, coloured markers, and post-it notes displayed on large magnetic display boards. The researcher highlighted in the text lines/phrases relating to possible themes and ascribed codes in the margins. The process of coding was continued until all transcripts were coded. During the process, newly emerging codes were compared with previous codes and amended as necessary to capture process and understanding. All interviews were gone through at least three times by the researcher to check for accuracy and ensure data was not missed. Codes were then gathered into groups in a sequential coding session with advisor input to ensure accuracy. This was a slow process to allow themes to be developed which captured words of the participants and individual and collective processes. Microsoft Word and Excel were utilised to store the transcripts and codes with correlated patient quotes to demonstrate and verbalise themes. The advantage of this was that it ensured the researcher stayed close to the actual interview transcripts and maintained a clear data trail.

4.11 Summary of Method Chapter

This chapter outlined the methods used in this project. The overall aim of the study was to evaluate the impact on patients of pharmacist-conducted domiciliary COPD annual reviews. This was achieved using qualitative methods with some quantitative baseline data collected and analysed alongside this. Both the pilot study and the ethical considerations of the project were discussed along with what each domiciliary visit entailed. Semi-structured interviews were then

discussed before data analysis was reviewed. A grounded theory inductive approach was taken with regards to the analysis of the qualitative data produced by this project which was coded and analysed using thematic analysis as described by Braun and Clarke in Table 4.2. [185]

5 Results and Discussion of Home Visit

5.1 Introduction

Section 5.2 details what data was collected prior to the home visits as well as data derived from the COPD annual reviews conducted at home visit one and two along with discussion as to the significance of this, with section 5.3 reporting the general demographics collected of all participants. Smoking status is reported in section 5.4 with the severity of COPD of participants catalogued in section 5.5 along with a discussion as to the implications of this data. Co-morbidity data is reported in section 5.6 with medication adherence data in section 5.7. Pulmonary rehabilitation results are detailed in section 5.8 with secondary care input in section 5.9. Section 5.10 reports data gathered around the number of breathing exacerbations and hospital admission in the previous 12 months with section 5.11 detailing the results of the actions undertaken by the pharmacist during the first home visit. Section 5.12 documents the information gathered on referrals made by the pharmacist to other healthcare professionals including the reasons why these referrals were made. Pharmacist time to conduct an annual COPD domiciliary review is detailed in section 5.13 with data collected during the pharmacists second COPD visit documented in section 5.14. Comparisons between data collected during the first visit versus the second visit is reported in section 5.15 including any change in CAT and MRC scores. Section 5.16 details recorded medication adherence at visit two and whether there had been any

change in this since the intervention(s) of the pharmacist during visit one with key points summarised in section 5.17.

5.2 Home visit COPD annual review

One of the service developments objectives was to determine if undertaking an annual review in COPD housebound patients improved HRQoL and breathlessness. To achieve this, data was collected at visit one and again four weeks later at visit two. A reduction in MRC and/or CAT scores at visit two, would be an indicator of a reduction in breathlessness and improved HRQoL. The MRC score is a measurement scale used to assess a patient's disability caused by breathlessness with a score of one being minimal and five severe (as shown in Table 1.4 on page 18). The CAT score adds to this data by grading the impact that COPD has on a patient's life, a score which has been shown to be responsive to changes in treatment and exacerbations and is explained by the CAT Assessment Guide, as shown in Appendix 16. This section presents the quantitative data collected in relations to patients' demographics, comorbidities, COPD status, and medication.

Each patient was visited by one member of a team of trained practice pharmacists. The following data were recorded for each patient:

1. Age
2. Weight and Body Mass Index (taken from last recorded in GP notes)
3. Smoking status
4. Living status - whether with family or alone

5. Palliative care status and whether an emergency care summary (eKIS) was in place
6. Comorbidities
7. Repeat Medications
8. If any aides such as dosette boxes are used to aid medication adherence
9. FEV1 and FEV1/FVC ratio
10. Disease severity according to GOLD guidelines
11. Last MRC and CAT score if recorded on GP computer system
12. Pulmonary rehabilitation attendance
13. Whether any other healthcare professionals are currently involved in their respiratory care.
14. Number of exacerbations of COPD and hospital/out of hour's attendance in last 12 months for respiratory related issues.

5.3 General demographics

A total of 43 housebound patients were recruited to the project. All patients received an initial pharmacist COPD annual review conducted in their house by one of eight experienced practice pharmacists employed in the North East Glasgow prescribing team. Reviews were carried out between November 2015 and January 2016. 31 of the 43 patients were female (72%) with the remaining 12 patients (28%) patients male. The age range of all patients is shown below in Table 5.1. 12 patients (28%) reviewed were current smokers at the time of the first pharmacist visit. A further 28 patients (65%) were recorded as ex-smokers with three patients (7%) reporting that they had never smoked.

Table 5.1 Age of patients in study

Age Range (in years)	Number of Patients
51-60	2
61-70	7
71-80	15
81-90	16
91-100	3

33 of the 43 patients (77%) had an established diagnosis of COPD recorded in their notes with nine additional patients (21%) having a recorded diagnosis of 'mixed disease' of both asthma and COPD. The one remaining patient was being treated for COPD but with no formal diagnostic testing found in the notes. Four patients (9%) had known lung cancer including asbestosis-related lung cancer.

In participants with available spirometry data or pulmonary function test results, the presence of airflow limitation was assessed based on the ratio of forced expiratory volume in one second to forced vital capacity (FEV1/FVC). 32 patients (74%) had spirometry results recorded in their medical record in the practice. As NICE guidelines and GOLD guidelines both state that spirometry is necessary to confirm the diagnosis of COPD,[2,44] this is an interesting finding. It should be noted that patients may refuse to undertake spirometry and that some spirometry results may be missing from patients records for reasons unknown.

As weight can play a factor in the morbidity and mortality of COPD as discussed in Chapter 4, page 102, the latest recorded value on the computer system in the

GP practice for each patient was noted (Table 5.2). NICE CG101 recommends that each COPD patient has their BMI calculated and recorded. These are shown in Table 5.3.

Table 5.2 Last recorded weight of patients in kilograms*

Weight range (kg)	Number of Patients
40-50	9
51-60	5
61-70	8
71-80	13
81-90	5
91-100	4
101-110	1
111-120	1

**(patient 43 has no recorded weight on file)*

Table 5.3 Body Mass Index of each patient*

BMI Range	BMI category	Number of Patients
<18.5	underweight	5
18.5-24.9	health weight range	15
25-29.9	overweight range	9
30-39.9	obese range	11
>40	morbid obese range	1

**(two patients had no recorded BM on file)*

19 patients (44%) were living alone at the time of the initial pharmacist visit. 22 patients (51%) lived with family members and two patients (5%) were resident in sheltered housing accommodation. While living with other members may help

medication compliance and adherence, if the other members in the household are smokers, this can have a negative effect on the patient's breathing condition even if they themselves are not smoking.

The management of breathlessness in advanced COPD remains an important element of a palliative care approach in this population.[186] Two patients (5%) were recorded as being palliative on their medical record. This did not exclude them from this service development as there may be things that the pharmacist could alter to make it easier for patients to take their medications or improve symptom control.19 patients (44%) were noted to have an eKIS recorded in their medical record. eKIS is an electronic Key Information Summary which NHS Scotland introduced to allow a shared medical record between healthcare professionals. It allows selected elements of the GP electronic patient record to be shared electronically with other part of the NHS, using a template within the GP clinical system. Patients are selected by their GP as those with the most complex health and/or social care needs. The level of detail contained on an eKIS will depend on the complexity of the patient's clinical condition(s), and can include such things as emergency contacts, triggers for deteriorations and DNACPR (Do not attempt cardiopulmonary resuscitation) status as to whether the patient has expressed wishes to be resuscitated or not.

5.4 Smoking status

The World Health Organisation (WHO) estimated that 1.1 billion people smoke worldwide and it is known to play a significant role in the pathophysiology of

COPD as well as coronary heart disease, stroke, and peripheral vascular disease.[187] Cigarette smoking is among the most important known risk factors for COPD and is estimated to account for 69% of the global burden of disease.[188] It was noted that 12 of the 43 patients reviewed were current smoker with 28 patients classified as ex-smokers as shown in Table 5.4. Six of the twelve patients who were current smokers at the time of the first visit (50%) were given both oral and written information regarding local smoking cessation services and the benefits of smoking cessation.

Table 5.4 Smoking status

Smoking Status	Number of Patients
current smoker	12 (28%)
ex-smoker	28 (65%)
never smoked	3 (7%)

5.5 Severity of COPD

Disease severity according to NICE and GOLD guidelines, as shown in Table 5.5 below, were calculated for patients when spirometry values were available in the GP record. Spirometry in Glasgow is carried out mainly by a hospital clinic and the results, especially from spirometry which was carried out several years ago, are not always communicated to the GP practice but to the respiratory consultant who the patient was seeing at the time. Consultants may therefore alter therapy but not inform the GP practice of WHAT the spirometry values were when doing so. Three patients were in the ‘mild’ COPD category with 14 in ‘moderate’; nine in ‘severe’ and three as ‘very severe’. Unfortunately, spirometry data for the

remaining 14 patients was not available so they could not have their level of COPD categorised in this way.

Table 5.5 Severity of COPD classification[2]

Classification of airflow obstruction in COPD		
	Postbronchodilator FEV1/FVC	**FEV1% predicted**
Mild * (Stage 1)	<0.7	>=80%
Moderate (Stage 2)	<0.7	50-79%
Severe (Stage 3)	<0.7	30-49%
Very severe ** (Stage 4)	<0.7	<30%
1.NICE CG101 (2010) 2. Global Initiative for Chronic Obstructive Lung Disease, GOLD (2008) * must also be symptoms to diagnose COPD (NICE) ** or FEV1<50% with respiratory failure (NICE, GOLD)		

5.6 Comorbidities and their Implications

COPD often co-exists with cormorbidites that may have a significant impact on prognosis, and comorbidites are comon in all stages of COPD. These comorbidities include hypertension, cardiovascular disease, diabetes, and cancer, and the proportion of patients with at least one cormobidity is in the range of 70-97%.[189] It is also important to note that mortality in COPD with comorbidities is observed to be higher than the mortality in COPD alone.[189] It is thought that advanced age and exposure to toxic gases and dust, and especially cigarette smoke, are considered as the general risk factors for the development of the higher rates of co-morbidities in COPD.[189] As some studies have found that there is a higher number of episodes of hospitalisation in COPD patients with a higher

comorbidity index,[189] the number of co-morbidities each patient had listed as a diagnosis within the GP medical system were recorded. All patients reviewed had at least one other co-morbidity, as shown in Table 5.6, with one patient having 19 co-morbidities recorded in their GP notes. It was noted that this data was not a true represenation of the number of co-morbidities recorded but actually the number of significant issues highlighted in the GP record as significant which varies by patient as to whom has recorded each issue and what significance they placed on it. For example, one practitioner may code an admission with an acute kidney injury in the year 2001 as significant and this will then show up in the list of active significant problems indefinately unless removed by someone. In addiiton, another practitioner may not record this as a significant problem or indeed not record at all. This raised the issue of practice coding which will be addressed in the discussion chapter.

Table 5.6 Number of concurrent medical conditions recorded for each patient

Range of number of concurrent medical conditions	Number of patients
1-5	11
6-10	20
11-15	8
16-19	4

The number of repeat medications each patient was receiving was recorded and is shown in Table 5.7. An example of a repeat list for someone who has 30 items is shown in Appendix 17 for illustative purposes. It is worth noting that some of these items on repeats may be sundries and not medicines *per se* such as blood

gluose testing strips and lancets, as well as dressings, colostomy bags, and catheters.

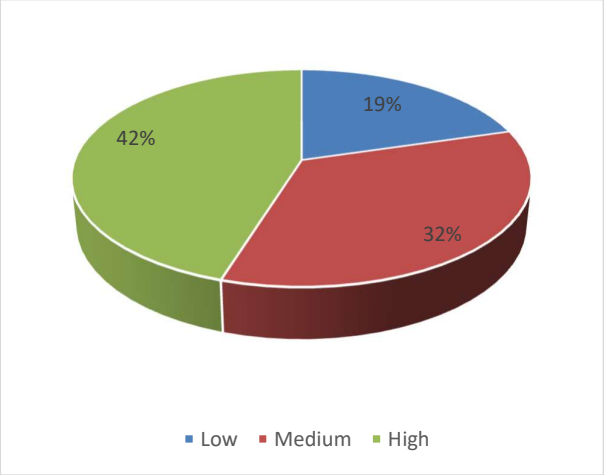
Table 5.7 Number of repeat medications each patient received

Number of repeat medications	Number of patients
0	1
1-5	3
6-10	13
11-15	13
16-20	8
21-25	4
26-30	1

5.7 Medication adherence

In this study, patient adherence was classified into three categories based on the MMAS-8 scale: high adherence (score= 8), medium adherence (score= 7–6), and low adherence (score= <6).[190]

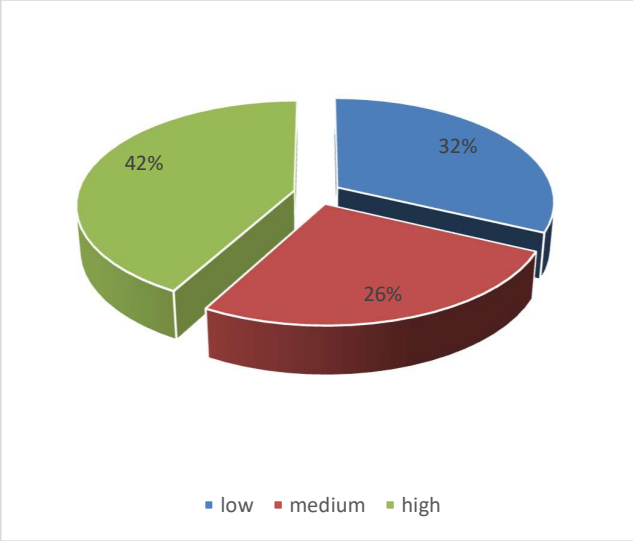
Figure 5.1 Patient adherence with prescribed medication(s)



Adherence	Number of patients
Low	8
Medium	17
High	18

Figure 5.2 Patient's adherence specifically with inhalers

Adherence specially with inhalers	Number of patients
Low	14
Medium	11
High	18



As adherence to medication has significant implications on health and important ramifications for disease control and quality of life, it was decided to compare adherence level across several different demographic characteristics as shown in Table 5.8 below. Statistical values such as p-value and odds ratio were not carried out due to the small sample size.

Table 5.8 Association between demographic characteristics across adherence levels

Adherence Categories	Low Adherence Score <6 (%)	Medium Adherence Score 6-7 (%)	High Adherence Score 8 (%)
Age			
80 years and under	7 (29)	10 (42)	7 (29)
Above 80 years	1 (5)	7 (37)	11 (58)
Sex			
Male	1 (8)	8 (67)	3 (25)
Female	7 (22)	9 (29)	15 (49)
Number of Medications *			
15 or less	3 (10)	11 (38)	15 (52)
Above 15	4 (31)	6 (46)	3 (23)
Living Status			
Lives alone	2(11)	8 (42)	9 (47)
Lives with family	6 (26)	9 (37)	9 (37)
Hospital admissions in last year			
1 or less	6 (16)	16 (42)	16 (42)
2 or above	2 (40)	1 (20)	1 (40)

** It was unknown how many repeat medications one patient was on.*

5.7.1 Dosette boxes

It is known that medication adherence in the elderly is one of the most significant public health challenges of the current age with this burden set to increase as the population ages and more people suffer from multiple long-term conditions.[191] One of the ways to help medication adherence is to supply medication in a dosette box. A dosette box, an example of which is shown in Figure 5.3, is designed to help simplify medication regimens by providing multiple compartments divided by time and day which clearly show a patient, or their carer, which medicines need to be taken at what time of day every day. Each

dosette box typically holds medicine for one week and each patient receives a new box weekly which are typically provided free of charge from community pharmacies. It some cases, it is known that if a patient has a social work appointed carer helping them, then medicines must be in a dosette box to allow the carer to prompt the patient to take their medicines. 26 patients (60%) in this project utilised a dosette box to help with their medication administration and adherence**.** Six patients (14%) had carer help with their medication noted on their medical record file, however this does not take into account family helping with medications, nor is this type of information routinely recorded in patients records in the majority of practices.

Figure 5.3 Example of a dosette box

Taken from the Pharmaceutical Journal [192]

5.8 Pulmonary rehabilitation

Three patients (7%) who participated in the pharmacist COPD annual review home visit had evidence of having attended a pulmonary rehabilitation course in their medical files. Despite a clear evidence base and guidelines recommending pulmonary rehabilitation, it is grossly underutilised in practice worldwide.[193] The national COPD audit programme for 2013/14 for England and Wales noted that only 15% of normative need were referred of whom only 69% attended an initial assessment (10% of normative need).[193] Pulmonary rehabilitation has been found to be integral in managing patients with chronic respiratory disease and is recommended in all guidelines, based on grade A evidence.[194] Pulmonary rehabilitation was explained and offered to all patients with an MRC score of three or more as recommended by NICE CG101. Two patients agreed to be referred for this. A further five were left further information and who to contact if they wished to participate.

5.9 Secondary care input

Seven of the 43 patients (16%) were recorded as currently receiving secondary care input with regards to their respiratory condition. This included patients who were seeing respiratory consultants in hospital, those under the respiratory specialist physiotherapy team, and those receiving input from the community respiratory team. This did not exclude them from the review but was noted to ensure that any changes made were communicated to all health care professionals involved in the patients' care. It was also to acknowledge that any

changes in a patient's respiratory condition between visit one and visit two by the practice pharmacist may also be due to other respiratory healthcare intervention.

5.10 Exacerbations and hospital admissions in last year

The number of admissions to hospital for respiratory related issues in the 12 months prior to the pharmacist visit are shown in Table 5.9. The length of each hospital admission was not obtainable. 17 patients (39%) were admitted to hospital for respiratory-related reasons during this time period with one patient being admitted five times in the last year. In the 12 months prior to the pharmacist visit, one patient had one GP out of hours (OOH) contact for a respiratory condition, one patient had two, and a third patient had three OOH contacts for a respiratory condition. GP out of hours services are for people who need urgent medical treatment but cannot wait until their doctor's practice opens. They are available 6pm on weekdays until the GP practice opens the next morning and 24 hours on Saturday, Sunday, and public holidays. Requiring either an unplanned hospital admission or OOHs for COPD related breathing issues can be seen as potentially avoidable with timely and effective community care. The Taskforce for Lung Health's five-year plan published in 2018 in England highlights that avoidable hospital admissions can be prevented through the effective implementation of evidence-based interventions for COPD and asthma, such as pulmonary rehabilitation and new technology, including smart inhalers.[195] It would be useful to consider a longitudinal study to see if a home based domiciliary pharmacist review reduced OOHs and hospital admission in the long term.

Table 5.9 Number of hospital admissions in the last 12 months

Number of admissions in last 12 months	Number of patients
1	
2	2
3	1
4	1
5	1

The number of patients with an exacerbation of COPD documented in their medical record in the 12 months preceding the first pharmacist visit was recorded and is shown below in Table 5.10. An exacerbation of COPD was classed as one which resulted in treatment with either an antibiotic and/or steroid treatment specifically for breathing related conditions and not for other conditions. It is known that prior exacerbations of COPD have an impact on the long-term course of the disease[196] and in addition it has been noted that exacerbations are an important medical and healthcare problem; it is evident that severe exacerbations of COPD are related to a significantly worsening outcome for patients.[196]

Table 5.10 Number of exacerbations in the last 12 months

Number of exacerbations in last 12 months	Number of patients
1-2	10
3-4	7
5-6	2
7-8	3
9-10	1
11-12	1
13-14	1

5.11 Actions undertaken by the pharmacist at the first home visit

Patient inhaler technique was checked and recorded by the pharmacist at the first home visit as shown in Table 5.11 using each inhaler's PIL as a guide**.** As there is no standardised tool validated to check inhaler technique, this is a subjective measure and therefore just a guide however guidelines do recommend that inhaler technique should be checked at every meeting with a healthcare professional to emphasise and encourage correct technique to ensure maximal drug deposition to the lungs.[2]

Table 5.11 Patient's inhaler technique at first visit

Inhaler technique	Number of patients
Good	10
Moderate	21
Poor	9
n/a as not using or refused	3

Each intervention made by the pharmacist as part of the COPD annual review home visit was recorded. The number of interventions per patient ranged from zero to nine as shown in Table 5.12 with each patient receiving an average of five interventions during visit one. Interventions were not restricted to solely respiratory medications but included all medications and conditions as part of a holistic medication review. An example of an intervention is to change inhaler or alter a medication therapy with a list of all the interventions and the rationale for their change documented in Appendix 18.

Table 5.12 Number of interventions by patient numbers

Number of interventions received	Number of patients who received x number of interventions
0	2
1	3
2	3
3	5
4	8
5	4
6	6
7	3
8	2
9	5

The 2011 GOLD strategy document recommends that COPD management and treatment should consider both disease impact, determined by assessment of symptoms and activity limitation, and future risk of exacerbations, determined from airflow limitation or exacerbation history and recommends the MRC as one tool for assessing symptoms.[197] While COPD severity is commonly staged by lung function, the MRC dyspnoea scale has been proposed as a more clinically meaningful method of quantifying disease severity in COPD. The MRC Score (as shown in Table 1.4 page 18) gives an indication of how breathless the patient currently feels from grade 1 - 'not troubled by breathlessness except on strenuous exercise', to grade 5 - 'too breathless to leave the house, or breathless when dressing or undressing.' MRC scores recorded at the first visit are shown in Table 5.13. The COPD Assessment Test (CAT) is an assessed instrument associated with levels of physical activity of daily living in patients with COPD. As low physical activity in daily life reduces quality of life and increases the risk of exacerbations and number of hospitalisations, it is considered the strongest predictor of mortality in patients with COPD.[198] The CAT score is a useful tool to undertake with patients. CAT score values recorded for patients during the first

visit are documented in Table 5.14 with Appendixes 12 and 16 showing the CAT test and user guide on how to interpret the values provided respectively. Table 5.15 gives a brief explanation of the significance of the CAT score.

Table 5.13 MRC score recorded at first visit

MR Score	Number of patients
1	1
2	1
3	8
4	20
5	13

Table 5.14 CAT score recorded at first visit

CAT score ranges	Number of patients
Less than 10	4
10 to 20	12
21 to 30	20
Greater than 30	7

Table 5.15 CAT score implication

CAT score	Impact level	Broad clinical picture of the impact of COPD by CAT score	Possible management considerations
>30	Very High	Their condition stops them doing everything they want to do and they never have any good days. If they can manage to take a bath or shower, it takes them a long time. They cannot go out of the house for shopping or recreation, or do their housework. Often, they cannot go far from their bed or chair. They feel as if they have become an invalid.	Patient has significant room for improvement In addition to the guidance for patients with low and medium impact CAT scores consider: • Referral to specialist care (if you are a primary care physician) Also consider: • Additional pharmacological treatments • Referral for pulmonary rehabilitation • Ensuring best approaches to minimising and managing exacerbations
>20	High	COPD stops them doing most things that they want to do. They are breathless walking around the home and when getting washed or dressed. They may be breathless when they talk. Their cough makes them tired and their chest symptoms disturb their sleep on most nights. They feel that exercise is not safe for them and everything they do seems too much effort. They are afraid and panic and do not feel in control of their chest problem.	
10-20	Medium	COPD is one of the most important problems that they have. They have a few good days a week, but cough up sputum on most days and have one or two exacerbations a year. They are breathless on most days and usually wake up with chest tightness or wheeze. They get breathless on bending over and can only walk up a flight of stairs slowly. They either do their housework slowly or have to stop for rests.	Patient has room for improvement – optimise management In addition to the guidance provided for patients with low impact CAT scores consider: • Reviewing maintenance therapy – is it optimal? • Referral for pulmonary rehabilitation • Ensuring best approaches to minimising and managing exacerbations • Reviewing aggravating factors – is the patient still smoking?
<10	Low	Most days are good, but COPD causes a few problems and stops people doing one or two things that they would like to do. They usually cough several days a week and get breathless when playing sports and games and when carrying heavy loads. They have to slow down or stop when walking up hills or if they hurry when walking on level ground. They get exhausted easily.	• Smoking cessation • Annual influenza vaccination • Reduce exposure to exacerbation risk factors • Therapy as warranted by further clinical assessment.
5		Upper limit of normal in healthy non-smokers	

5.12 Referral onwards to other healthcare professionals

While pharmacists can work with clinical autonomy as prescribers, there will still be areas out-with their expertise that require referral to other healthcare professionals. In addition, there are health care professionals who may be more suited to the patients' needs such as a social worker for housing issues, domiciliary phlebotomy for bloods, and smoking cessation services for counselling, and it was important for the pharmacist to signpost to these agencies as appropriate to ensure the patient gets the right care from the right person at the right time. As a result of the pharmacist home visit, 15 patients (35%) were referred to other health care professionals/agencies due to issues identified by the pharmacist during the visit. These are listed in Table 5.16 below. It should be noted that these issues would have gone untreated/unnoticed if it had not been for the pharmacist home visit identifying them and while not a main objective, it is a useful finding of the study ensuring holistic care.

Table 5.16 Reasons for onwards referral

Patient	Referred to	Reason
1	District Nurse	Recheck blood pressure
2	GP	Recurrent urine infections and swollen stomach
3	Dietician	Poor diet and low weight
4	Nurse	Bloods needed for chronic disease management
5	Bone Metabolism	Referred for DEXA scan
6	District Nurse	Review a sore on the foot
7	GP	To refer to the community respiratory service for more intensive support
8	British Lung Foundation (BLF) nurses	Regarding current pulse oximetry
9	District Nurse	Regarding frequency of hydroxocobalamin injections and for up-to-date cholesterol and HBa1c bloods
10	GP	Patient feels has a chest infection
11	District Nurse	For ‘flu vaccination
12	GP	As patient refusing to use inhalers

5.13 Pharmacist time commitment

To enable cost effectiveness to be reviewed, each pharmacist recorded the time it took them to undertake the first review. This included time to review each patient's record in the practice prior to the visit, travel time, visit time, and post visit write up. Time spent with each patient in their home ranged from 25 to 80 minutes as shown in Table 5.17 The break down and combined total time taken from start to finish including work up, travel, and write up is shown in Table 5.18 and ranges from 75 minutes to 370 minutes. It should be noted that as this was the first time for the pharmacists providing this role; with practice and experience, these timings would be expected to go down. The cost per hour of the pharmacist providing this service would be between £16.37 to £25.06 based on a band 7 or band 8A pharmacist in Scotland conducting the review under the NHS agenda for change bandings in 2015/16 when these reviews were carried out. Mileage has to be included on top of these costings but would be the same for any health care professional undertaking house visits under the NHS.

Table 5.17 Time in minutes for home visit by number of patients. *

Time of visit (minutes)	Number of patients
25	4
30	4
35	2
40	2
45	11
50	5
55	1
60	7
70	3
80	3

**Only 42 patients reported as times were not recorded for 1 patient*

Table 5.18 Breakdown of timings shown in minutes*

Patient	work up	by	travel to	visit time	travel from	changes time	total time
1	45	PSP	20	60	5	20	150
2	90	PSP	15	45	15	45	210
3	120	PSP	10	70	10	60	270
4	50	PSP	5	60	5	50	170
5	60	PSP	10	70	10	60	210
6	25	PSP	5	45	5	15	95
7	60	PSP	5	45	5	60	175
8	20	PSP	10	50	10	20	110
9	70	PSP	10	45	10	60	195
10	35	PSP	10	35	10	30	120
11	65	PSP	10	40	7	15	137
12	25	PSP	5	45	5	15	95
13	45	PSP	10	30	10	10	105
14	50	PSP	10	30	10	10	110
15	50	PSP	5	45	5	30	135
16	65	PSP	5	30	5	10	115
17	25	PSP	5	25	5	15	75
18	60	PSP	20	45	20	90	235
19	30	PSP	5	45	5	15	100
20	45	PSP	5	55	7	55	167
21	80	PSP	5	60	5	30	180
22	60	PSP	10	60	10	20	160
23	90	PSP	25	80	10	120	325
24	105	PSP	5	80	5	150	345
25	40	PSP	10	45	10	15	120
27	90	PSP	10	80	10	25	215
28	45	PSP	3	25	3	20	96
29	50	PSP	5	40	5	5	105

Patient	work up	by	travel to	visit time	travel from	changes time	total time
30	50	PSP	10	60	10	20	150
31	80	PSP	5	50	5	120	260
32	90	PSP	20	70	10	180	370
33	Not recorded						
34	90	PSP	25	50	5	60	230
35	55	PSP	10	45	10	15	135
36	19	PSP	10	25	10	15	79
37	90	PSP	10	50	10	120	20
38	50	PSP	20	50	10	30	160
39	90	PSP	5	60	5	120	280
40	60	PSP	5	30	5	10	110
41	90	PSP	10	60	10	60	230
42	120	PSP	10	35	10	50	225
43	20	PSP	10	45	10	10	95

**Only 42 patients reported as times not recorded for one patient*

5.14 Second pharmacist COPD visit

A second home visit was conducted by a different pharmacist approximately four weeks after the first visit. Four weeks was chosen as an arbitrary amount of time to ensure the patient did not forget the first visit, as there were concerns that leaving it any longer than this may negatively affect the quality of data provided during the semi-structured interviews if patients could not remember the first visit clearly. The second visit had a dual purpose: to review the patient after the first visit and to conduct a semi-structured interview to seek patient perceptions of having a pharmacist perform a home annual review for their breathing condition(s). The results of the semi structured interview will be presented in a later chapter.

For the semi-structured interview after visit two, all patients who were willing to be interviewed were included. It had originally been planned that interviews with patients would be conducted until thematic saturation occurred- i.e., the point at which no new thematic information was gathered from participants of interest,[158] however as the number of patients who agreed was a relatively small number of twenty, it was decided all patients who were agreeable would be interviewed.

Each patient was visited by either the project pharmacist or one other pharmacist who was trained in semi-structured interview techniques. The same pharmacist did not conduct visit one and visit two to reduce bias. The following data were recorded for each patient at visit two:

- Review of all current medications
- Review of any changes to medication which occurred during the first visit
- Review of medication adherence using the Morisky adherence questions
- Inhaler technique
- MRC and CAT score
- If experienced any exacerbations, OOHs or hospital admissions since the first visit

39 patients participated in a second visit out of the initial 43 who had a first home visit (91%). Two patients declined without giving reasons, one was in hospital and one patient died in between the first and second visits. MRC scores and CAT scores from the second visit are shown in Table 5.19 and 5.20 respectively. Eight patients did not have the CAT score undertaken at the second visit. The

pharmacist forgot to undertake for two patients, three patients did not have the test undertaken due to dementia, and one patient struggled to answer therefore it was abandoned to prevent causing distress. It was noted that one patient had the CAT score omitted although no reason was specified as to why and one patient had severe deafness and was struggling to hear the questions therefore it was not felt possible to complete.

Table 5.19 MRC Score calculated during the second home visit

MRC score	Number of patients
1	1
2	0
3	6
4	16
5	13

Table 5.20 CAT score recorded at second home visit**

Cat score ranges	Number of Patients
Less than 10	2
10 to 20	4
21 to 30	19
Greater than 30	4

***missing data for eight patients.*

The number of interventions carried out during the second visit was recorded and is documented in Table 5.21 with the average of one intervention per patient carried out during visit two. A summary of the interventions are listed in Table 5.22 with the full details provided in Appendix 19. As expected, there were fewer interventions carried out at the second visit however it was important to review

the changes made at the first visit to ensure patients were managing satisfactorily with new inhalers and that any new medications were reviewed for side effects with these rectified if necessary.

Table 5.21 Number of interventions carried out during the second home visit

Number of interventions undertaken at 2nd visit	Number of patients
0	14
1	10
2	7
3	7
4	1

Table 5.22 Summary of pharmacist interventions during visit two

Intervention	Rationale
Add in aero chamber	improve inhaler technique
Change other medication out with COPD	Help patient with other co-morbidities
Change in inhaler device	simplify regimen for patient and aid compliance
Inhaler technique counselling	improve technique to benefit more from inhaled therapy
Encouraged compliance with inhalers	improve drug delivery and symptomatic benefit to patient
encouraged pulmonary rehabilitation attendance	patient thinking about attending but had lost leaflet
medication stopped or changed	patient felt like getting side effects
referred to other health care professional	To help with issued raised out with pharmacist remit

5.15 Data comparison of values between first and second visit

Symptom burden was measured by means of CAT and MRC scores at visit one and then at visit two four weeks later. Table 5.23 below shows patients split by their MRC score recorded at the first visit. The MRC value demonstrates the severity of the patient's breathlessness at the moment of recording with 1 being the least severe and 5 the most. The majority of patients scored either 4 or 5 which correlates with patients who are severely affected by breathlessness and are either unable to walk more than 100 yards on the level without rest or are breathless on talking or undressing, or unable to leave the house because of breathlessness.

Out of the 39 patients who had both a first and second visit, only five patients (13%) demonstrated a difference in MRC score between the first and second visit. Of the five patients who did have a change in MRC score, four had an increase in their MRC score which would indicate a worsening of the COPD and one patient had a decrease in their MRC score which would indicate an improvement of their COPD symptoms. This shows that the vast majority (87%) did not experience a change in the breathlessness symptoms over a four-week period.

Table 5.23 Documented MRC value changes between first and second visits

Patient	MRC at 1st visit	MRC at 2nd visit	Change
1	4	4	0
2	5	5	0
3	4	4	0
4	2	3	1
5	3	3	0
6	4	4	n/a
7	4	5	1
8	3	3	n/a
9	5	5	0
10	5	5	0
11	4	4	0
12	4	4	0
13	4	4	0
14	3	3	0
15	4	4	0
16	3	4	1
17	3	3	0
18	4	4	n/a
19	3	3	n/a
20	5	5	n/a
21	3	4	1
22	4	3	-1
23	4	4	0
24	5	5	0
25	5	5	0
26	4	4	0
27	5	5	0
28	4	4	0
29	5	5	0
30	5	5	0
31	4	4	0
32	5	5	0
33	4	4	0
34	5	5	0

Patient	MRC at 1st visit	MRC at 2nd visit	Change
35	4	4	0
36	4	4	0
37	4	4	n/a
38	5	5	0
39	5	5	0
40	4	4	n/a
41	3	3	0
42	1	1	0
43	4	4	0

Of the 39 patients who had both visit one and visit two, a total of 31 patients (77%) had their CAT score calculated at both visits as shown in Table 5.24. 21 of these 31 patients (68%) had a change in their CAT score recorded between the first and second visits. Ten of the 31 patients (32%) had a decrease in their CAT score which would indicate that their COPD quality of life had improved with 11 of the 31 patients (35%) reporting an increase in their CAT score indicating less control of their COPD. The CAT data is different from the MRC data as the CAT data shows more people worsened with regards to HRQoL whereas most patients had static MRC scores, showing that the CAT score maybe more sensitive to small changes in HRQoL compared to the MRC score.

Table 5.24 Differences between CAT scores between visit one and two

CAT score 1st visit	CAT score 2nd visit	Change in CAT score?	Actual numerical change in CAT score between 1st and 2nd visit
15	14	yes	-1
32	32	no	n/a
26	26	no	n/a
39	35	yes	-4
22	22	no	n/a
17	10	yes	-7
28	30	yes	2
21	23	yes	2
5	8	yes	3
23	25	yes	2
30	31	yes	1
10	28	yes	18
27	28	yes	1
27	24	yes	-3
25	25	no	n/a
29	24	yes	-5
33	22	yes	-10
19	25	yes	6
34	32	yes	-2
26	29	yes	3
23	24	yes	1
36	27	yes	-9
24	26	yes	2
17	17	no	n/a
25	22	yes	-3
27	27	no	n/a
33	25	yes	-8
8	8	no	n/a
13	13	no	n/a

5.16 Medication adherence at visit two

Following pharmacist intervention, the proportion of patients who were adherent of their medication regimens improved according to the Morisky questions as shown in Table 5.25. A copy of the Morisky questions and scale are shown in

Appendix 13. The project also ensured that the GP practice record was up to date with an accurate list of medications that the patient was actually taking. The practice pharmacist identified a median of two medication related problems per patient. This aligns with the findings of other studies assessing pharmacist medications reviews undertaken in clinical settings.[16]

Table 5.25 Morisky adherence results between visits one and two

Morisky adherence level visit one	Morisky adherence level visit two	Change?
medium	medium	no
medium	medium	no
high	high	no
low	medium	yes- improved
high	high	no
medium	medium	no
high	high	no
medium	high	yes- improved
low	low	no
medium	high	yes- improved
high	high	no
medium	high	yes- improved
high	high	no
high	high	no
high	high	no
high	high	no
medium	medium	no
high	high	no
high	high	no
medium	medium	no
medium	medium	no
high	high	no
low	low	no
low	low	no
low	medium	yes- improved
medium	medium	no
medium	medium	no
medium	high	yes- improved
medium	high	yes- improved
high	high	no

Morisky adherence level visit one	Morisky adherence level visit two	Change?
medium	high	yes- improved
low	high	yes- improved
medium	medium	no
high	high	no
high	high	no
high	high	no
high	high	no
medium	medium	no
low	high	yes-improved
high	high	no
medium	medium	no
low	medium	yes- improved
high	high	no

5.17 Chapter Summary

This chapter documents the results generated by the COPD annual reviews from the data collected from GP practice computer and paper records (if applicable) before the first visit, through to results generated during both the first and second home visit. This included general demographics of the patients who participated in the project showing the majority of patients were between the age of 71-90 with 72% of participants female. 77% of patients had a documented diagnosis of COPD with a further 21% recorded as having 'mixed disease' of both asthma and COPD concurrently. One patient did not have any recorded diagnosis of COPD but was being treated as such. 28% of participants were smokers with a further 65% ex-smokers. 14 patients did not have a FEV1/FVC and FEV1% value recorded making categorisation of severity of COPD difficult. From the remaining patients who did have these values recorded, only three patients were classified

as mild with 14 moderate and the remaining 12 patients categorised as severe or very severe COPD.

As all patients in our cohort had at least one co-morbidity recorded, this shows that this is an important area to review. The number of repeat medications each patient had documented in their record was discussed with 26 patients recorded as having between 5-15 repeat items. Calculating adherence with these medications using the Morisky scale showed that only 18 of the 43 patients (42%) recorded as high adherence specifically with inhalers, which are the mainstay of COPD treatment; it is evident that this is an important area to review. Pulmonary rehabilitation was shown to have a low uptake with 7% of patients reviewed having received this to date, which is in line with past studies documenting low update of this service. Two patients agreed to be referred for pulmonary rehabilitation as part of this project with a further five left information about it. Only 16% of patients were recorded as currently receiving secondary care input to their respiratory condition which may be related to the patients' housebound status. 39% of patients had a hospital admission for their breathing condition recorded in the last year with one patient recording a total of five admissions over the last 12 months. This, combined with the data showing 25 patients had at least one COPD exacerbation recorded in the last 12 months shows that impact COPD can have not only on the patient and their family, but also the burden on the health care resources.

The importance of good inhaler technique has been reported in numerous studies as vital to helping improve symptomatic control of COPD. With only 10 out of the

43 patients (23%) having inhaler technique recorded as ‘good’ during the first pharmacist visit, this is an area where vast improvement could be made to the benefit of the patient’s HRQoL. The number of interventions each pharmacist undertook per patient were recorded with only two of the 43 patients not needing some sort of action undertaken at visit one. At the other end of the spectrum, five patients received a total of nine interventions each during visit one as shown in Table 5.11. Monitoring MRC and CAT scores to review HRQoL with MRC score recorded at visit one shows 33 patients (77%) recorded as 4 or 5 which correlates with the two most severe restrictions of breathing, showing this cohort of patients has a high HRQoL burden from COPD. CAT scores also demonstrated the impact COPD has on the health with the majority of patients sitting with a medium or high level of impact with regards to their COPD as shown in Tables 5.13 and 5.14.

The second pharmacist visit showed a lower number of interventions carried out by the pharmacist which would be expected after the initial review four weeks previously however, one patient still had a further four interventions carried out at the second visit as documented in Tables 5.20 and 5.21. Data comparisons between the first and second pharmacist visit show only 13% of patients demonstrated a difference in MRC score with 4 of the 5 patients showing an increase in MRC score which would indicate a worsening of their breathing conditions. 68% of patients showed a difference in their CAT score between visit one and two with 32% showing an improvement in their CAT score which would reflect an improvement in their COPD HRQoL and 68% showing an increase in their CAT score which reflects a worsening of their HRQoL. Morisky adherence

scores, as shown in Table 5.25, show that 35 of 43 patients (81%) were recorded as medium or high adherence at visit one with this increasing to 40 out of 43 patients (93%) at visit two. Results from the semi-structured interviews, which took place at the end of the second home visit to understand patients' perceptions of a pharmacist domiciliary annual review of their COPD, are presented and discussed in the next chapter, Chapter 6.

6. Semi Structured Interview Results

6.1 Introduction

From the initial 43 patients recruited to the project, four second visits were not undertaken as one patient died, one was hospitalised, and two declined a second visit. The remaining 39 patients were asked, on visit two, if they wished to participate in an audio recorded semi-structured interview to explore their perceptions of home visits conducted by a practice pharmacist to review their COPD. A total of 20 patients (51%) agreed to participate in an interview, 12 of which were female (60%) with the remaining eight male (40%). The main reason for non-participation in the semi-structured interview was that due to undiagnosed cognitive issues, the patient did not remember the initial visit.

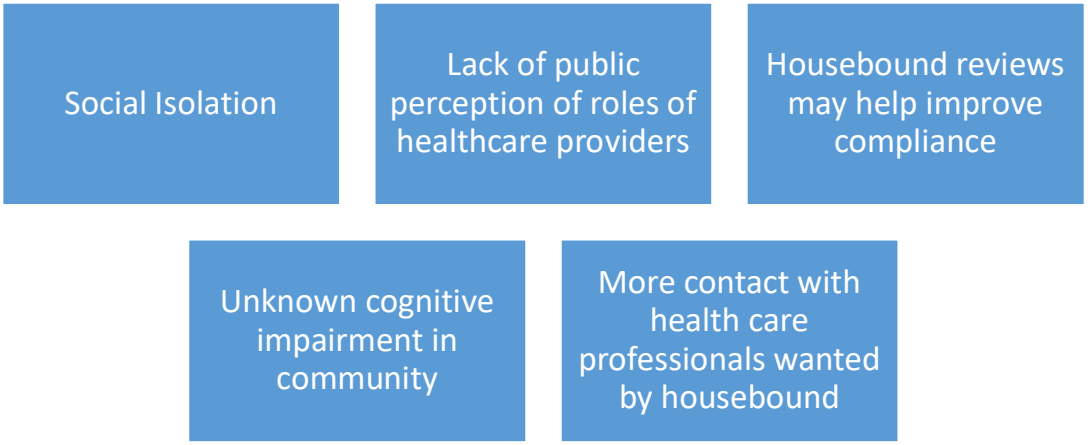
Family members or carers were encouraged to participate in the interviews with the patients to increase participation. 18 of the interviews (90%) included a carer or family member present. This is noted as a slightly different set of data than was originally designed for, however, it was felt that this was overall beneficial and would add to the knowledge of what patients and their families thought about chronic disease management in the housebound. A total of 13 questions were asked during the semi-structured interview as shown in Appendix 15. The first two questions *'Can I ask what breathing condition it is you have?'* and *'How long have you had it for?'* were introductory questions to help put the participants at ease after the recorder had been started and to encourage them to relax and speak freely.

This chapter will report the analysis of the qualitative data obtained from the semi-structured interviews undertaken at the end of home visit two. The thematic analysis conducted is described in section 6.2 with the main five themes identified. Section 6.2.1 discusses the social isolation theme in detail with section 6.2.2 discussing the theme regarding the lack of public perception of roles of healthcare providers. The theme 'housebound reviews may help compliance' is discussed in section 6.2.3 with unknown cognitive impairment in the community discussed in section 6.2.4. Section 6.2.5 details the theme of more contact with healthcare professionals being wanted by housebound patients with the overall findings from the semi-structured interview discussed in section 6.3 and a summary of the chapter is provided in section 6.4

6.2 Thematic Analysis

Thematic analysis was undertaken as discussed in the methodology chapter 4, page 103. Qualitative research is intended to generate knowledge grounded in human experience and has established a distinctive place in research literature.[184] Thematic analysis is a method for systematically identifying, organising, and offering insight into patterns of meaning (themes) across a dataset.[199] A theme captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set [199] Five main themes were identified from the semi-structured interviews as shown in Figure 6.1 below.

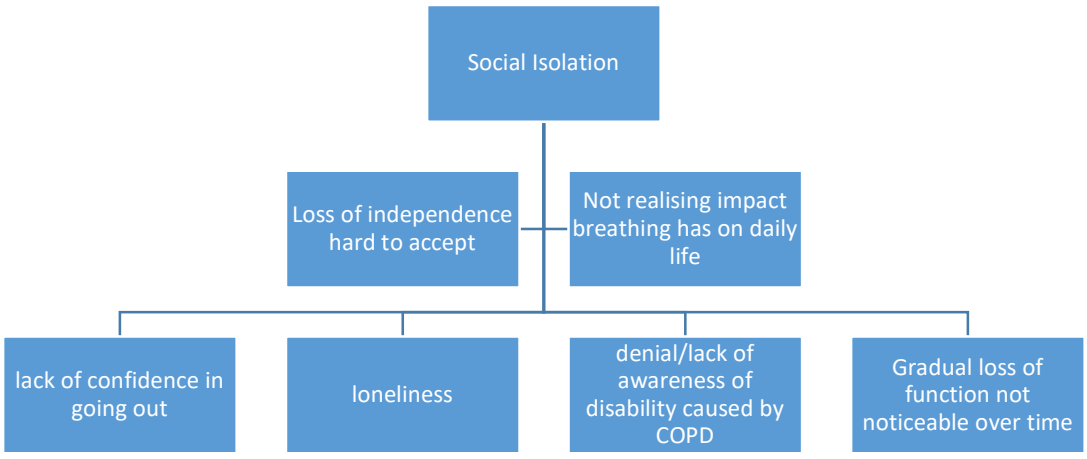
Figure 6.1 Main themes identified



6.2.1 Social isolation theme

The first main theme identified was that of social isolation. This included isolation caused by physical disability caused by illness, whether COPD related, or from another co-morbidity. A breakdown of the sub-themes which were linked to the main theme of social isolation is shown in Figure 6.2.

Figure 6.2 Social Isolation sub themes



Acceptability of disability or loss of function caused by COPD and/or other co-morbidities was variable among the patient group. Some of this was acknowledged by patients whereas some was prompted by family members, regarding how their breathing condition affected their daily living. It was felt that some patients confused gradual deterioration of their disease with the normal aging/degenerative process.

'It doesn't really affect me at all, I just, I get out of breath, I just slow down and then start over again you know so it really doesn't affect me at all'

Patient 11

'"Well it doesn't stop me now in fact, not really, that's about it'
Family Member- 'Yeah but you don't, you don't manage to get out?' 'No.'

Patient 2

'It's just the thought of being that active all your days. And now when you are slowed right down like a snail you know what I mean.'

Patient 9

However, other patients commented that they didn't feel their breathing condition(s) have had a negative effect on their daily living.

'No my breathing is not that bad.'

Patient 18

However, with further questioning to encourage participants to elaborate on their answers, four patients who had denied that their breathing condition(s) affected their life, did admit it had some effect. This may indicate that there is an apparent level of 'acceptance' of limitations. Indeed, some felt their breathlessness and decreased quality of life were 'just part of the ageing process'. This finding has been shown in other research work such as one published in 2011 in Scotland which stated that it was 'apparent throughout the patients' interviews that there was a sense of "acceptance" in the face of severe disease and social difficulties.[200] COPD was something that had to be coped with "as best you can"'.[200] For others it was difficult to tell if limitations were due to a breathing condition or another comorbidity. One patient who was adamant that his breathing condition didn't affect his daily living was contradicted by their partner who commented that it did have an effect as well as social consequences caused by the deconditioning of the patient.

'No it doesn't, no I mean I'm 82 years of age so I've got home helps in 4 time a day so that's all.'

Patient 13

'He, he can't to be honest with you, it's lack of not being out all the time, that goes against him and when he's walking, he's, his walking, he's really out of breath to be honest with you, really bad.'

Partner of Patient 4

Reactive services, especially secondary care may only see people with COPD when they are ill or exacerbating.[201] Slow insidious development of COPD does not cause the sudden disruption, which is described as triggering an active process of learning to cope with the symptoms, developing strategies to mobilise support and adapting a culturally appropriate style of living with their illness.[201] People with COPD may consider COPD as a health problem and not an illness except during exacerbations.[201]

When participants were asked about if they felt the pharmacist review was useful, several patients answered positively as they felt the social interaction was a major benefit of having the pharmacist conduct the home COPD review rather than specifically any input they had with regards to their medical condition(s). The theme of social isolation and how domiciliary visits overcome this was evident in several interviews and was an unexpected but valuable finding in this important cohort of patients.

'Aye aye, nice to have a visitor'

Patient 16

'You are my only company during the day.'

Patient 1

Maintaining a sense of independence was found to be very important to some patients who wished to try to manage themselves at home with their medical condition(s) as much as possible. Some mentioned that they didn't wish to be a burden on their family, some of whom were working long hours and/or had a family of their own to look after. The feeling of 'not wanting to bother anyone' was also conveyed towards seeking help for their breathing conditions.

'That's, maybe we're a wee bit, I don't know if it means you want to prove to yourself you can do it you know.'

Patient 5

'I don't want to bother the doctor because there are people more ill than what I am and I mean you are only taking up time and space you know what I mean?'

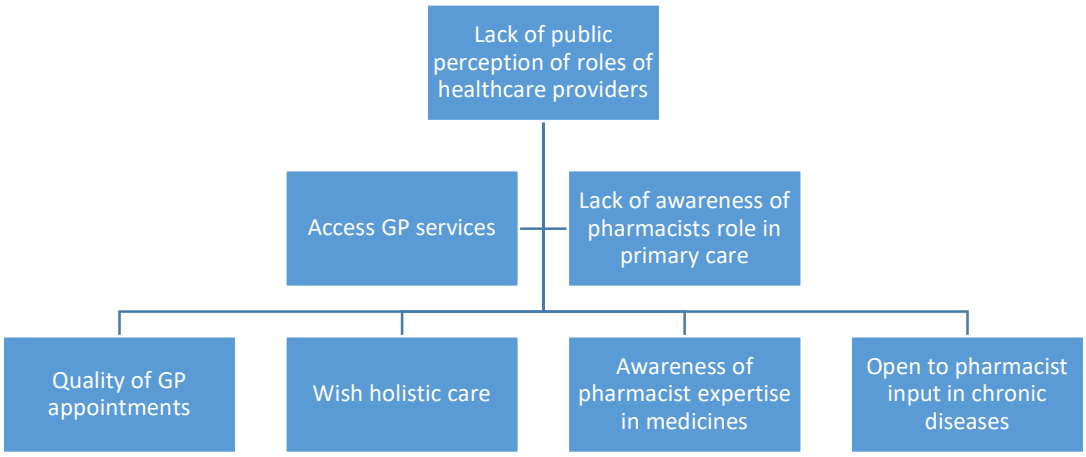
Patient 9

6.2.2 Lack of public perception of roles of healthcare providers

A second theme was discovered concerning the lack of public perception of roles of healthcare providers with the breakdown of sub-themes shown in Figure 6.3**.** The introduction of new health professional roles, such as that of the nurse practitioner and pharmacist prescriber in primary health care, led to changes in health service delivery. Patients, after encountering these new roles, often report

high satisfaction. However, there is limited knowledge of how patients position nurse practitioner and pharmacist prescriber roles within existing practice structures.[202] Patients were therefore asked for their thoughts about a pharmacist carrying out the review rather than another health care professional, such as a doctor or nurse, who would traditionally have carried out this role in practice.

Figure 6.3 Lack of public perception of roles of healthcare providers



On answering this question, it became apparent to the interviewers that not all patients were aware that it was a pharmacist who had conducted the reviews with patients quoting they thought the pharmacist who undertook the reviews was actually a nurse or a doctor. Some patients seemed unclear regarding the exact role of the pharmacist, and some were ambivalent as to which health care professional conducted the review viewing them as all similar health care providers.

'I don't know, I don't, I'd never think of it, to me a nurse or a doctor are there to help me so why should I be complaining.'

Patient 5

'Aye alright, aye ok, I don't care now, anybody's coming to see me I'll be here to be seen.'

Patient 8

There were many patients who commented that they weren't aware that pharmacists were part of the GP practice team and thought they only dealt with medicines in hospitals and chemist shops. Some patients thought the pharmacist who conducted the visit was from their own usual community pharmacist and did not know that their GP practice had an attached pharmacist nor what actions they could take, such as undertake chronic disease reviews or sign prescriptions.

You know because I mean I would never think to say to myself I'll make an appointment and go and see pharmacists or anything like that. You would just keep going on.'

Patient 7

'I just take you all, you're all doctors so if they tell me to do something I'll do it and that's, it's not failed yet anyway.'

Patient 8

'The pharmacist, what about them laughter? (laughter).

Interviewer- [NAMEs] a pharmacist.

Aye well that's fine.'

Patient 4

'No the pharmacist was excellent, he was actually excellent. I would rather I spoke to the pharmacist than the doctor. Because he was so easy to talk to. And he listened. Sometimes Dr X has got no time'.

Patient 17

'The pharmacist aye. You are better, you know what you are dealing with, you know what you need to set up. Aye. The doctor doesn't have too much time anyway. He just up and go on to another patient. [sic] Aye doctors are too busy'.

Patient 1

Some patients were positive regarding the pharmacist undertaking annual home visits for chronic diseases and mentioned the reason for this being that they had previous positive experience in interacting with pharmacists.

'All right aye [sic] all right. I think its good eh I had a pharmacist that came out a long time ago because I had so many pills'

Patient 20

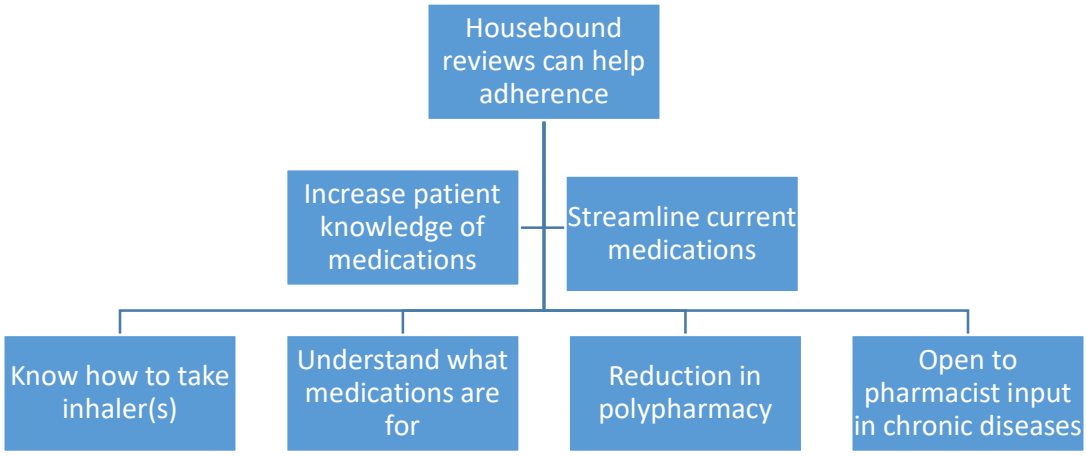
Patients were frustrated by the lack of joined up care and wished they could receive more holistic care whereby one professional came and completed all necessary medical tests and reviews rather than for example, a different nurse for a blood test, another nurse to inject insulin, and a doctor to attend for an infection for example as shown in the quote below.

> *'But if you say to the nurse you are to take blood today the doctor said, I wasnae [sic] told so they don't do it but if the nurse is there and the doctors are needing nurses why not just use the nurse she is giving you your insulin injection she can she can take your blood?'*
>
> *Patient 20*

6.2.3 Housebound reviews may help adherence

The third theme identified was that housebound reviews may help adherence with a breakdown of sub-themes shown in Figure 6.4.

Figure 6.4 Housebound reviews can help adherence



Patients were questioned on their views of the pharmacist input with regards to their breathing condition(s) specifically during the home visits. A common view among patients was that they felt the review had helped with regards to their breathing condition(s).

'Oh it definitely helped aye, it helped. And not feeling like you were getting that much. Like I was getting it aye.

Interviewer-Yeah so swapping to the Fostair you found beneficial?

Oh aye definitely.'

Patient 11

'Oh definitely, definitely. Definitely and that other thing as well. That's an inhaler too but it's just, it was brilliant, absolutely brilliant. He explained about my inhaler and he changed them right there and then. He wrote me out a prescription. I got three new inhalers.'

Patient 17

'It was just my breathing and checking what medication I was on so she helped to take me off the things that I didn't need to take, well it was quite good as well.'

Patient 18

Patients were then asked if they felt the review had changed how they used any of their medications in general and if so, how? Some patients felt the review had made a benefit to how they used their medications, with improved inhaler technique, less constipation, and more awareness of the indications of their medications mentioned as examples. Other patients commented that they didn't really feel it had changed the way they used their medications as they have always taken them the way they were instructed to, or always took what was in their box. This may in part be due to the older age group of the housebound patients and the more historical view point that doctors' orders are to be strictly followed, with other patients reporting that family members helped them remember all their medications.

(with regards to their inhalers)

'Aye well I'm more, as I say I take my time now, it's not a case of I feel I just grab it and go. You know I take well I'm taking my time now.'

Patient 12

Well, I'm more aware of it definitely. More aware of it. Definitely, Definitely because he had the time to make me understand that.'

Patient 17

'Interviewer- You were saying since the last review you've been taking your sachets for your bowels more often?

Oh aye I take it once every week.

Interviewer- and that's helping?

That helps it, I don't have to get anybody to…I couldn't go through that again.'

Patient 15

'See I was always using the brown one and forgetting all about the grey one, when I did use them it was only the brown one that I used. Aye I'll start using that more often.'

Patient 4

Some patients reported that they had found the specific addition of a spacer device (referred to by patients as ‘bottles’ or ‘chamber’) during the first home visit was beneficial to help using their inhalers. A spacer device, an example of which is shown in Figure 6.5, is one which can be used with Metered Dose Inhalers (MDIs) to aid delivery of the inhaler medication to the lungs by decreasing oropharynx deposition and increasing the proportion of the drug which reaches the lungs. They are particularly beneficial in those who have poor coordination between activation of the MDI with inhalation. This includes the elderly and infirm, and those with compromised comprehension or manual dexterity.[203] As it is known that incorrect inhaler technique can have serious consequences for patients in terms of disease control and quality of life,[204] it is important we address this where possible especially as national and international guidelines recommend that MDIs should be used with a spacer. [203]

Figure 6.5: Example of spacer device

Taken from Asthma UK

'And I've got the wee bottle of it. Perfect yes. Well, I find that a difference, there is a difference.'

Patient 3

'Aye it has helped aye. Oh aye, I like that wee one, it goes right to my chest (family member: because your, the wee chamber, because when you were using it you weren't using it properly, now you've got that wee chamber) I can feel it going to my chest when I take it (family member: see the last time we had [NAME] up he didn't actually say you had asthma I think you're doing too much, he still gave you an inhaler) oh it's better, it's good to have'

Patient 15

'It was more you talking about the breathing and she showed me all the inhalers and that wee bottle makes some difference, you know you are getting, you are getting the good of what you are, sometimes I was pressing it and my mouth and didn't know if it was going in you know I just didn't know if it was in the right place but the wee bottles are good.'

Patient 1

As part of the first review, the pharmacist conducted a general polypharmacy review to identify any medications no longer needed or indicated. Patients were

asked if they felt the review had helped with any other medical condition or medication they were taking, including any non-pharmacological interventions that the pharmacist recommended or undertook. Patients were generally positive regarding this and responded favourably when their medication burden was able to be safely reduced.

'Aye she was, aye she had a look through because there is times that you, you think I don't know if maybe they should take them off now, because I'm on too many so, she reduced 2 of them.'

Patient 19

'Aye she went into everything. Aye she was really good. Aye especially when you get into a panic you know she told you to sort of slow down and you know. Aye.'

Patient 1

'Yeah I thought it was all right, it was a good idea to keep in touch with the medication you were on. Because to be honest with you I just take my medication. I don't know what half of it's for and so honestly you could go into the hospital and when you come back out of hospital you can bet your bottom dollar you've got another.'

Patient 7

'I don't know he took a lot of stuff away that I didn't want or that he didn't want me to have any way you know (other speaker; aye he went through all your medications) aye he went through it all and sent a bundle of it away but you're asking the wrong one because I just take what I get and that's it done. If he said take it, take it and that's it. They're not there to put me down, they're there to cure me or help me.'

Patient 8

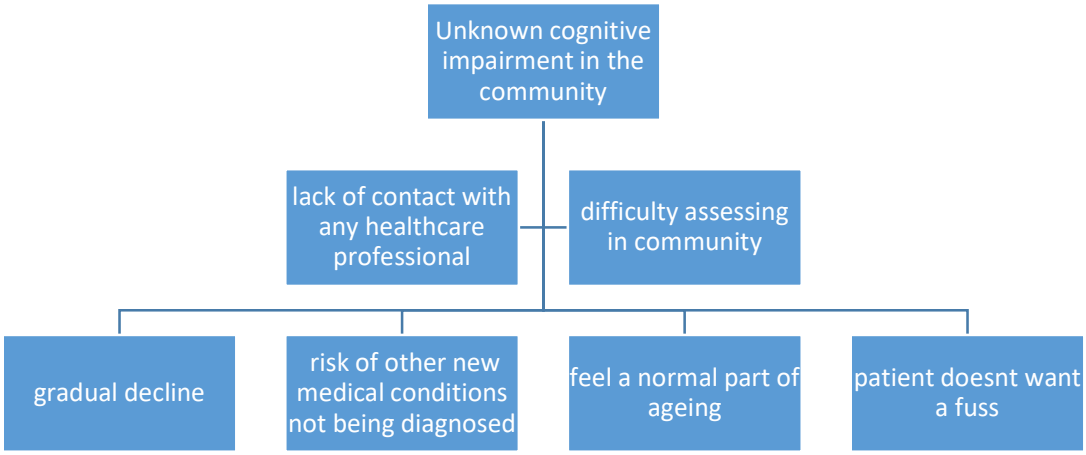
6.2.4 Unknown cognitive impairment in the community

Patients were asked to divulge their perceptions of the pharmacist home visit they had received one month prior. It became evident at this point in the questioning that some patients could not remember the prior visit even though they did not have a diagnosis of cognitive impairment in their medical records. Unknown cognitive impairment in the community was therefore identified as a theme with the sub-themes shown in Figure 6.6. In four cases the interview had to be terminated at this point as it was felt that continuing would cause the patient upset or distress. The cognitive impairment noted in these patients was fed back to the general practitioner to allow them to decide whether referral to onwards services were appropriate. There is a real risk of undiagnosed new conditions for housebound patients due to a lack of regular contact with any health care professionals.

It was good aye she was nice, very nice I can't even remember who she was like but as I say it was very nice, she's a very nice person. [sic]'

Patient 4

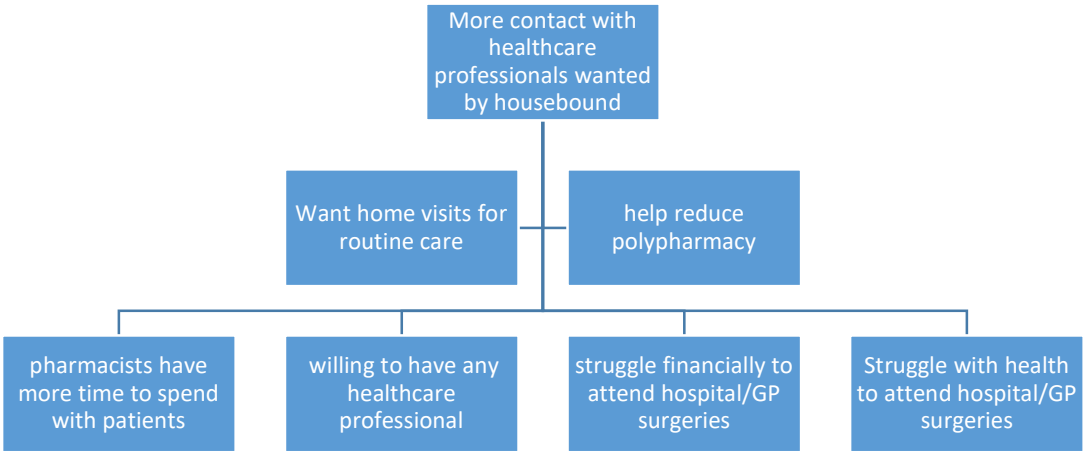
Figure 6.6 Unknown cognitive impairment in the community



6.2.5 More contact with healthcare professionals wanted by housebound

Patient were asked for their thoughts on having the review in their home instead of in the doctor's surgery where traditionally such annual reviews of chronic diseases would take place. This question generated the most comments of any question in the semi-structured interview and seemed to be one that they felt most strongly about. Therefore, more contact with healthcare professionals for the housebound was identified as a major theme with sub-themes shown in Figure 6.7.

Figure 6.7 More contact with healthcare professionals wanted by housebound patients.



'Oh it was a lot better here. It was more relaxing you can tell her anything, in the surgery you are waiting and by the time you get in you have forgot what you wanted to say. You know what I mean, you do, here you feel you can talk about it.'

Patient 1

'Well I can't get out [laughter] I'm not going down the stairs then yes, yes, so it's great. It was comfortable and more reassuring. Relaxed I am yes, I'm more comfortable.' *Patient 6*

‘Aye it was, aye it was good it's more, it was, you know when you’re talking to somebody face to face and you’re not in a hurry, you’re not timed and it's, you know and the doctors timing you, you know. And anyway, I can’t get up to the doctor, he’d need to, he's got to come to me you know because I can’t walk, it's away to Shettleston. I don’t walk anyway I would take a taxi.’

Patient 10

‘Oh well it's a lot easier here you know than going up to the surgery you know because it's, not that it's that far away but I find it difficult see where I park the car to walk in and see if I get shouted right away I'm completely shattered you know, I can’t even, by the time I get to the desk I can’t even give my name because I've not got a, I've not got a breath you know so this is a lot easier for me. I think you are aye because you’re uptight because you can’t breathe and you’re not wanting people to see that you can’t breathe do you know what I mean you’re, it's quite embarrassing when you’re going, huffing and puffing you know and then carrying that tank of oxygen you know I've got to carry that about with me. And then people look at you when you’ve got that tank of oxygen you know so it is easier definitely.’

Patient 11

‘A lot better in the house. It was more kind of relaxed. Relaxed and more face to face instead of being away at a surgery and sitting.’

Patient 18

'Oh I prefer this aye. I mean even in the doctor's surgery you are only allowed so many minutes, I know, 7 minutes or 10 minutes or you know.'

Patient 12

Only one patient responded that they did not feel it mattered whether it was a home visit or in the GP surgery although did go on to mention the cost of having to attend the surgery.

'It's immaterial, it doesn't matter. It doesn't matter. Whatever is the best and whatever one is the quickest because I tend [HOSPITAL NAME] you know the diabetic clinic. I was £16 in taxis, that was just for [HOSPITAL NAME] and then I was £6 from [HEALTH CENTRE NAME] down to here so I was £22 in taxis you know.'

Patient 9

'[PHARMACIST NAME] he had the time to make me understand that. He was here nearly an hour. You know yourself when you go into the surgery you've got 10 minutes.'

Patient 17

'Aye I think it would be good for them aye, because they're, they're at ease and they've got your time and you've got the time for them you know whereas in the, you go to a surgery you're, you know your doctors only got so much for each patient so you're not going to be there for long [laughter] you know.'

Patient 10

‘No I think it's different because I can never remember things I would want to say and forget to tell the doctor and that would be it you wouldn’t bother again, whereas you’re getting, you’ve got your time, you’ve got my time and, nothing hurrying us.’

Patient 10

‘Aye it was, aye it was good it's more, it was, you know when you’re talking to somebody face to face and you’re not in a hurry, you’re not timed and it's, you know and the doctors timing you, you know.’

Patient 10

‘And anyway I can’t get up to the doctor, he’d need to, he's got to come to me you know because I can’t walk, it's away’

Patient 10

‘I mean I know there are lot of people that don’t want anybody coming to their house but if it helps you and it helps you with your medication, I think it's a good idea.’

Patient 7

'I prefer the house aye, or when I was fit it would be no bother, now you, it's slow my walking [laughter] but well I don't like to moan anyway, I've nothing to moan about, I've a great family you know, even the great grand weans have a rare time.'

Patient 5

'Aye no problem at all, it's always a good thing, why complain if somebody's going to see if you're alright.'

Patient 5

'And coming to the house I think that was quite a good idea and as I say it makes me. If I want to ask any questions or I'm more likely to ask you.'

Patient 7

'It was just my breathing and checking what medication I was on so she helped to take me off the things that I didn't need to take, well it was quite good as well.'

Patient 18

6.3 Overall findings from semi-structured interviews

Patients were asked if they thought that annual reviews for all chronic diseases should routinely be offered to all patients who are housebound. The interviewer was allowed to elaborate on what a chronic condition was, such as hypertension or diabetes. All patients who commented on this question indicated that they thought that this would be a good idea. One patient was concerned that it might be abused, and the same patient also commented that it would cost a lot of money and therefore might not be possible to offer this service on the NHS. This was an isolated finding throughout the study regarding costs of service and potential abuse of services. One patient thought that an exercise programme should be offered to housebound patient to allow them to stay mobile as well as maintain some independence.

> *'Oh yes. Yes because they might, they can't get out to see the doctor, the doctor would need to come up but if somebody specialises and sees these people yes that would be good.'*
>
> *Patient 6*

> *'People that just can't get out. I mean it shouldn't be abused the system you know but you always get somebody that would abuse it'.*
>
> *Patient 12*

> *'Oh aye. Definitely. Aye. I don't know if would be possible money wise again isn't it. It all comes down to money but that would be ideal'.*
>
> *Patient 12*

'Well I think, actually I think they should do, have a programme for the likes of us for exercise, think exercise is about the best thing you know.'

Patient 11

Not all patients felt the review was of benefit though with one patient reporting he did not find it promising. Whether the patient was expecting a dramatic change in his breathing condition because of the review is unclear. Patient expectation of improvement or change as a result of one pharmacist visit is something that needs to be taken into account. This could relate to the short interval period of one month between visit one and visit two.

The penultimate question asked patients if they wished to share any other comments or thoughts on the visits they had received from the pharmacist and allowed patients the opportunity to add any further comments regarding the medical care that they wished to discuss while bringing the interview to a natural conclusion. Only four patients commented on this question and were all of a positive nature. Several patients enquired if the pharmacist would be visiting again or if they could contact them if they had any questions. All patients who asked were encouraged to contact their practice pharmacist if they had any queries.

6.4 Chapter Summary

This chapter has presented the major themes identified from the semi-structured interviews conducted with patients after the second house visit. While we were focused on what patients thought about receiving housebound COPD reviews conducted by a pharmacist, we had not anticipated social isolation nor the lack of awareness/understanding of different healthcare professionals among patients. The positive findings surrounding the pharmacist reviews focussed on the domiciliary nature of the review and having time to listen and spend with the patient rather than a doctor who was perceived by many to be ‘very busy’ and ‘short of time’. It was acknowledged that those patients who had previous experience of working closely with pharmacists, were the most positive in receiving care from a pharmacist and it can be hoped that this will increase over time with more patients being seen by a practice pharmacist routinely rather than as an exception.

The finding of unknown cognitive impairment in the community was unexpected and raised concerns that there may be other medical conditions experienced by patients which have not been diagnosed and/or treated due to the lack of healthcare involvement due to the patient’s housebound status. This compounds with the finding that housebound patients wish more contact with healthcare professionals showing that multiple benefits of regular healthcare involvement with this cohort of patients would be beneficial for a wide variety of reasons and not just chronic disease management but also health and social reasons.

7.0 Overall Discussion

7.1 Introduction

This chapter focuses on the findings of the work undertaken throughout this project and its contribution to current pharmacy research. The key findings for this thesis in relation to the objectives set out in the methods chapter are discussed in section 7.2. The results in relation to the COPD home visit results are discussed in section 7.3 with the semi-structured interview results in section 7.4. Confounding factors for the study are reviewed in section 7.5 with convenience sampling discussed in section 7.6. The thoughts from health care professionals surround the service are reviewed in section 7.7 with the benefits of pharmacists providing reviews detailed in section 7.8, with details of the researcher's personal journey in section 7.9, and a discussion summary in section 7.10.

The overall aim of this project was to evaluate whether a practice pharmacist working in a GP practice could provide an annual review of COPD to housebound patients who would not receive a review otherwise. The objectives were to examine any changes to HRQoL that may result from this, and to elucidate patients' thoughts and feelings regarding such a service. It has been noted in primary care in the UK, and indeed throughout the western world, that house visits by GPs are on the decline.[205] This is thought in part to be due to increased work load and the declining number of practicing GPs.[206] Routine annual reviews

for chronic disease management are not carried out for domiciliary dependent patients who typically only receive house calls from a health care professional when acutely unwell or for routine vaccinations.[146] It was felt by the researcher that practice pharmacists who work in GP practices in Scotland could be in a position to fulfil this role for chronic disease patients to provide more routine care and less 'firefighting' when patients traditionally only came into contact with health care professionals during an exacerbation or worsening of their condition or co-morbidity.

Prior to 2018, the General Medical Services (GMS) Contract in Scotland stated that a certain percentage of patients must have received an annual review for their COPD (and other medical conditions) in return for the practice to be paid a certain percentage. 9 points were available in achieving between 50-90% of patients on the COPD register who had received a review, undertaken by a healthcare professional, including an assessment of breathlessness using MRC dyspnoea scale in the preceding 15 months. In 2018, each QOF point had a value of £179.26.[207] This contract allowed general practices to 'exclude' housebound patients from these counts as it acknowledged that there was not capacity in primary care to carry out these reviews with housebound patients. From 2018, this GMS contract was replaced with a new one which did not specify targets for conditions including COPD to be achieved to receive payment. Neither contract made any mention or requirement for GP practices to provide routine reviews for housebound patients therefore this work remains relevant despite the change in GMS contract.

COPD is a major cause of mortality and morbidity in the United Kingdom with estimates of over 3 million people living with COPD, yet only 900,000 diagnosed.[2] Over 25,000 people die from COPD each year in the UK and it is the second highest cause of emergency hospital admissions. Data from the World Health Organization shows that UK premature mortality from COPD in 2008 was nearly twice as high as the rest of Europe[42] with the UK among the top 20 countries for COPD mortality worldwide.[208] COPD was chosen as the chronic disease for this project due to the high incidence of COPD in the local Scottish area as well as the knowledge that COPD poses a substantial healthcare burden. Indeed, the Global Burden of Disease Study 2010 showed that COPD is now the third leading global cause of death.[1] In one study looking at geographical distribution of COPD prevalence in Europe, Glasgow was the fifth highest with 24% with only one other region (Manchester) in the UK higher.[209]

Interventions to improve chronic disease management by patients can produce positive outcomes including better monitoring of a condition, fewer symptoms, enhanced physical and psychosocial functioning, and reduced health care use.[210] Indeed, the NICE quality statements for COPD shown in Table 7.1, include five out of 13 which pharmacist domiciliary COPD annual reviews could achieve or sign post towards.

Table 7.1 NICE quality standards for COPD[2]

Number	Quality statements
2	People with COPD have a current individualised comprehensive management plan, which includes high-quality information and educational material about the condition and its management, relevant to the stage of disease
3	People with COPD are offered inhaled and oral therapies, in accordance with NICE guidance, as part of an individualised comprehensive management plan
4	People with COPD have a comprehensive clinical and psychosocial assessment, at least once a year or more frequently if indicated, which includes degree of breathlessness, frequency of exacerbations, validated measures of health status and prognosis, presence of hypoxaemia, and co-morbidities
5	People with COPD who smoke are regularly encouraged to stop and are offered the full range of evidence-based smoking cessation support
6	People with COPD meeting appropriate criteria are offered an effective, timely, and accessible multidisciplinary pulmonary rehabilitation programme

7.2 Design Objectives

The study objectives related to measuring patient's satisfaction with care and with the pharmacist home visit annual review process as a whole, as NICE CG101 states that treatment and care should take into account patient's needs

and preferences.[2] It also investigated whether a COPD domiciliary annual review by a practice pharmacist increased adherence and/or HRQoL and if the project resulted in a reduction in COPD exacerbations, or a reduction in the number of hospital admissions for breathing related conditions.

It is often necessary to measure the structure and process of primary care general practitioner services for all groups of patients in order to interpret the outcomes of care, and to ensure services are constantly developing to fit the needs of all of its patients. For example, the collection of quantitative and qualitative descriptive data about the process and structure is essential if the investigator wishes to address the question of whether - and how - the outcome was caused by the activity itself, and/or by variations in the structure or the way it was organised or delivered.[211]

Health systems research has been defined fairly broadly as being ultimately concerned with improving the health of a community, by enhancing the efficiency and effectiveness of the health care system as an integrated part of the overall process of socio-economic development.[211] The focus is generally on the relationship between the population's need and;

- demand for health services
- the supply, use, and acceptability of health services
- the processes and structures, including the quality and efficiency of health services.

It is also focussed on the appropriateness and effectiveness of care services being offered by the NHS, including patients' perceptions of the outcome in relation to the effects on their HRQoL and their satisfaction with the outcome. HRQoL as an outcome measure broadens the outcome towards considering 'the impact of the condition and its treatment on the persons emotional, physical, and social functioning and lifestyle'.[211] It provides a more subjective, patient-led baseline against which the effects of the interventions can be evaluated. It is imperative that the needs and wishes of all patient cohorts are considered when planning service changes aimed at improving their care. Indeed, the initial idea for this piece of work was conceived during a discussion between other health care professionals in general practice who themselves felt frustrated and concerned that housebound patients may not be receiving routine care, but only receiving medical help when their conditions deteriorated significantly and required urgent medical care.

This project aimed to undertake a pharmacist domiciliary COPD review to patients who could not attend their local GP surgery for one due to their housebound status and evaluate the service and review any changes in compliance to medication or improvement in HRQoL, and also to try to understand patients' thoughts and feelings regarding annual domiciliary reviews for chronic diseases by pharmacist and if they felt this would be acceptable.

7. 3 COPD Home Visit Results

7.3.1 Gender

The Global Burden of Disease organisation estimates that the number of COPD patients in the world exceeds 328 million, including 168 million men and 160 women.[212] The majority of COPD patients in the study population were female at 72%. Previous studies have shown that for many years, COPD was considered a disease of men, with higher global prevalence in men than women.[213] In the UK in 2012, about 10 per cent more males than females were living with a COPD diagnosis.[101] Throughout the years 2004–12, proportions of the population with diagnosed COPD were always higher among males than females.[208] The physiological changes of COPD affect women and men differently in terms of both symptoms and quality of life. In the Confronting COPD International Survey, women were more likely to report severe dyspnoea (OR, 1.30; 95%CI 1.10-1.54) despite significantly fewer pack-years of smoking, while reporting similar degrees of cough (OR, 84%; 95% CI, 0.72-0.98) and less sputum (OR, 0.84; 95% CI, 0.72-0.98).[214] It is unknown if more women with COPD are housebound but it is known that more women are hospitalised with COPD each year than men[208] and this project certainly would suggest that this may be the case.

The population from which the sample was taken conforms with known trends in the incidence and symptomology of COPD. Recent evidence suggests that the prevalence and mortality of COPD have increased more rapidly in women than

in men which would correlate with our data, in that more than 50% of participants were women. Between 1990 and 2016, the proportion of deaths attributable to COPD in Scotland among those aged 70 years or greater rose for females by 1.58% and fell for males by 1.12%.[215] It can be argued that this is because the female COPD patients have outlived male ones in the population and thus form a larger proportion of this older age group. Although increasing tobacco consumption among women during the past several decades is linked to the rising prevalence of COPD in women, the relationship may be more complex, including additional factors such as differential susceptibility to tobacco, greater exposure to indoor air pollution, anatomic and hormonal differences, as well as behavioural differences in response to available therapeutic modalities. However, the extent of the differences in prevalence of COPD between men and women is not well understood and may vary by geography or other factors. Unfortunately, population-based estimates of COPD prevalence by region are problematic since the disease is progressive, measurement tools and definitions vary among studies, and implementation of spirometry is often not feasible in developing regions.[216]

7.3.2 Cohabitations and carer status

Cohabitation status has been shown to have influence on health status and can also affect medication adherence as can having a carer who can provide medication prompts. A total of 56% of patients in this study either lived with family or were resident in sheltered housing which may influence not only disease

progression and recognition of disease progression but also on medication adherence. Patients who have family or carers to help them with aspects of daily life such as washing and cooking may be less likely to appreciate fully whether their COPD has had a negative effect on their ability to carry out day to day tasks.

7.3.3 Age Range

The data collected showed that 72% of patients were aged between 71-90 years of age with no patients below the age of 51. This finding correlates with previous studies that have shown that in the UK, a COPD diagnosis is rare among those aged under 40 years and becomes more common with age, affecting 9% of those aged over 70 years.[215] Worldwide figures also show that people living with a COPD diagnosis are mostly over the age of 40 and that the proportion of people living with COPD increases markedly with advancing age.[208] Understanding the features of COPD in older patients is important in order to introduce effective interventions and to inform efforts for health resource allocation.[217] An example of this is that many studies have shown that the elderly population with lung disease do not understand the role of each inhaler and the purpose of taking inhalers. In addition, 40% of patients who were prescribed metered-dose inhalers(s) for an average of four years were reported to have been found incompetent in using them.[217] As there is evidence that a patient having an understanding of how their COPD effects their lives and how to cope with their symptoms has been shown to reduce avoidable admissions, it is important that this cohort of older patients receive annual COPD reviews and are not penalised due to their housebound status.[218] In addition, pharmacists have a wide

knowledge of inhaler devices and can ensure that patients have the most suitable inhaler for not only their degree of COPD, but also one that they can use. This is especially important if, for example, they only have a carer in once a day to help them then a once-a-day inhaler can be given to ensure the full dose is received or, if there are manual dexterity problems, a user-friendly inhaler can be prescribed rather than one which involves adding capsules and several steps to administration.

7.3.4 Weight

It has been noted that malnutrition adversely affects pulmonary function, decreases HRQoL, and increases the risks of exacerbations, length of hospital stays, and healthcare costs.[219] Previous analysis has indicated that being underweight significantly increases the risk of all-cause mortality by 40%.[220] The prevalence of malnutrition in outpatients with COPD is 10-45%.[219] In our project, five patients were known to be underweight with 21 overweight or obese/ morbidity obese with only 15 in the healthy weight range and two patients did not have a weight on file. It is unknown why there is such a wide range of BMIs in COPD. It has been shown in meta-analyses of COPD clinical trials that low BMI is a risk factor for accelerated lung function decline, while high BMI has a protective effect.[221] The relationships may be due to common but as-of-yet unknown causative factors. Weight loss is not an inevitable part of the disease progression in COPD, but is instead an independent factor influencing survival.[222] This makes maintaining a healthy weight an important part of COPD management especially as previous studies have shown that nutritional

interventions can result in significant improvements in functional capacity and quality of life as well as decreasing mortality and morbidity for COPD patients.[219] Therefore it can be suggested that signposting to dietetic care is one potential benefit of domiciliary chronic disease reviews.

Some studies have suggested that being overweight or obese has a protective effect against mortality but the pathophysiological basis for this apparent obesity paradox is unknown.[223] In both community-dwelling and hospitalised patients with COPD, several studies have reported a significant protective factor effect of obesity on all-cause mortality.[224] The 'Obesity Paradox' in COPD patients is more evident for subjects with severe bronchial obstruction while in mild-moderate conditions, the weight-related mortality shows a behaviour similar to that observed in the general population.[224]

Weights were sought for all patients from the GP medical records. NICE guidelines for COPD recommend that BMI is recorded for all COPD patients due to the effect a patient's weight can have on the condition.[2] BMI was calculated and categorised according to the standard of the World Health Organisation (WHO) into four subgroups, underweight (<18.5 kg.m2), normal (>18.5-<25 kg.m2), overweight (25-29kg.m2) or obese (>= 30 kg.m2).[225] The range of weights and BMIs recorded were noted as varying widely between 14 and 44, which correlates with data gathered in other studies that shows there is a wide variation of BMIs seen within COPD patients.[188] Obesity and COPD are linked with each other in several ways. Breathing difficulties characteristic of COPD can

make it hard to maintain a healthy weight, and conversely excess weight can exacerbate COPD symptoms.[224] Being very underweight on the other hand is associated with a higher risk of COPD-associated mortality, so weight also seems to have a protective effect in some cases.[224,226]

The prevalence of obesity in COPD patients is variable, and it seems that obesity is more common in COPD patients compared with subjects who do not have COPD. However, it is noted that further studies are encouraged in this area due to observed inconsistencies in the current data, as there is still no consensus as to whether obesity has a negative or even a positive effect on dyspnoea in COPD patients. It is hypothesized that obese COPD patients might benefit from favourable respiratory mechanics (less lung hyperinflation), however, despite less hyperinflation, obesity seems to have a negative influence on exercise capacity measured with weight-bearing tests.[226] This negative influence is not seen with weight-supported exercise such as cycling. With respect to severe exacerbations, obesity seems to be associated with better survival[226] which resonates with other COPD studies that have shown that those with higher BMI (overweight and obesity) had better pulmonary function, lower inflammation level and less exacerbations.[227]

One study carried out in China on the effects of weight and BMI on COPD has shown that in patients with COPD, BMI was positively correlated with pulmonary function and negatively correlated with inflammation levels and acute exacerbations markedly.[227] This finding was shared in a UK paper in 2016 which stated that underweight adults have higher rates of respiratory death than the

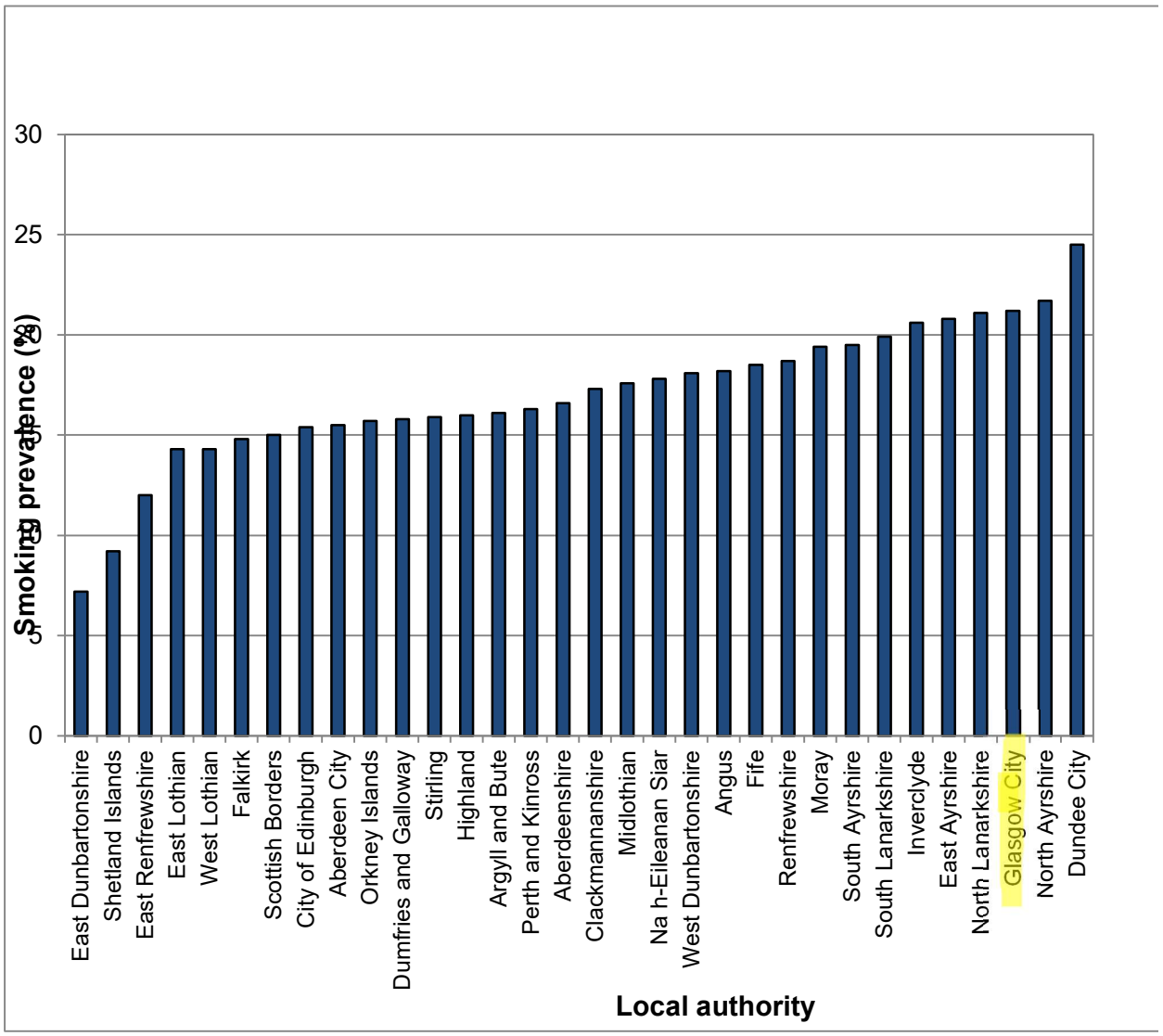
normal weight but noted it is unclear whether this association is causal or reflects illness-induced weight loss.[228] Some studies have demonstrated that higher mortality in underweight COPD patients was partially due to the accelerated decline of FEV1.[227] It is generally accepted that improving nutrition status, enhancing respiratory muscle strength, and reducing inflammation level are effective on long term management of COPD. Therefore, all patients in this study who were under or overweight were highlighted, and action taken depending on individual factors. For example, brief health/dietary advice was given by the visiting practice pharmacist, British Lung Foundation leaflets regarding weight and COPD were given, and/or referral to a dietician could be arranged depending on what help was felt beneficial based on individual circumstances. Indeed, in one case, a social work referral was undertaken as the patient was struggling to afford and access necessary nutritious food and was living solely on tinned goods. It was noted that some patients did not have a weight recorded on their general practice record for a number of years due to non-attendance at the practice due to their housebound status. This can have implications for medications for other medical conditions including paracetamol and apixaban doses as an example both of which rely on a recent weight to be able to prescribe doses appropriately and safely.

7.3.5 Smoking

Cigarette smoking is by far the most dominant cause of COPD with 90% of all COPD causes caused by it.[229] NICE guidelines recommend that the smoking status of all COPD patients is recorded at every opportunity.[2] This is due to smoking being the biggest preventable risk factor for COPD exacerbations. With 28% patients in this study being current smokers, it is important that we engage these patients at every opportunity possible and provide a range of materials, written and oral, to explain the benefits of stopping smoking at any age, along with the resources available in the local area to help with this and how they can be accessed. In the UK, smoking is considered an important modifiable determinant of Socioeconomic (SES) inequalities of COPD and is therefore important to address with patients as tobacco use is a major contributor to health inequalities, with some of the highest rates of smoking and smoking related diseases found in the most disadvantaged communities.[215]

Figure 7.1 Smoking prevalence among adults in Scotland[71]

Take from Scottish Surveys Core Questions (SSCQ) 2018



North East Glasgow, the area where the study was conducted, has in the past been associated with a higher smoking rate than this with the last estimate in 2010 to be 32% which is significantly higher than the overall Glasgow City value. The correlates with a higher level of lower socioeconomic status (SES) in the North East population of the city with both male and female life expectancy significantly lower than the Scottish average, and the lowest of all the local areas

in Scotland. In addition, mortality rates from all causes are also significantly higher than the Scottish average. With regards to COPD, figures for the North East area of Glasgow from 2010 show that the number of patients hospitalised with COPD was statistically significantly 'worse' than the Scottish average with 2,290 over 3 years compared to 158.6 as the Scottish average hence why ensuring all patients have access to an annual COPD review in this area would be beneficial.

7.3.6 Socioeconomic Issues

Low socioeconomic status (SES) is associated with a high risk of developing COPD.[215] The influence of SES on treatment success and clinical outcomes, including adherence to therapeutic management, exacerbations, admissions and mortality once COPD has developed is poorly understood. The Tottenburg study found that COPD severity was higher among patients with lower education, lower income, pensioners, and those living alone.[230] North East Glasgow City, where this study was undertaken, has a high level of deprivation therefore it is important to acknowledge that this may also have an impact on COPD trajectory. While there is nothing that can be done by health care professionals to change risk factors such as gender, age, or where patents live, those with modifiable risk factors such as weight, smoking, and medication adherence can still be targeted.

7.3.7 Comorbidities

The majority of people with COPD also have other medical problems; most commonly ischaemic heart disease which occurs in some 25% of patients.[48] This multi-morbidity means that managing patients' healthcare needs is challenging. Cardiovascular diseases are perhaps the most important co-morbidities in COPD and carry an increased risk of death and hospitalisation.[88] Our project showed that 11 patients had between one and five concurrent medical conditions with 20 patients having between 6-10 co-morbidities listed. 12 patients had 11 or more co-morbidities listed with one patient having 19 listed. On examination of this data, it became apparent that this was due to how GP computer systems list co-morbidities as 'active problems' which can contain any information from 'Myocardial Infarction' to 'given dietary advice' therefore this is not a true reflection on the number of co-morbidities that each patient had. Unfortunately, the GP practice data was not of sufficient quality to allow the researcher to go back and identify true co-morbidities from other recorded 'active problems'. It would be beneficial for any future work for this data to be captured. This also raises the issue of accuracy of computer GP patient records, an issue which was documented in the British Journal of General Practice in 2010 who advised that standardised protocols for deciding which patients are included and excluded from major disease groups was required.[231,232]

7.3.8 Compliance Aids and Medication Adherence

Socioeconomic Status (SES) is also an important factor for medication adherence. It has been noted in a nationwide prospective cohort study of COPD that patients shared socioeconomic differences in adherence to inhaled maintenance medications, exacerbations, acute admissions, and all-cause mortality with the socioeconomically disadvantaged disproportionately affected.[233] Glasgow's North East Locality, is historically where health is most challenging due to severe levels of poverty, even compared to Glasgow city as a whole. The Scottish Index of Multiple Deprivation (SIMD) measures deprivation by neighbourhood every four years and produces a ranking of deprivation by housing neighbourhood areas. An analysis of Glasgow's 56 neighbourhoods using information from the 2004, 2008, and 2012 SIMD data showed that of the 25 neighbourhoods with the worst position (in child poverty, income deprivation, and lowest levels of male and female life expectancy) ,11 were in the North East Locality.[175]

Previous COPD studies have reported up to 84% of patients have sub-optimal adherence to their medication regimen.[230] Studies have shown that adherence to long term treatment in chronic illness is unequally distributed across SES with poorer adherence among patients of lower SES, although this finding has not been shown in other studies.[234] Poor adherence has also been found in those with milder disease, those who were younger, unemployed, immigrants, and those who lived alone[230] however, anyone can have poor adherence to medications in COPD and this should be considered in all patients. As poor

adherence has been found to cause disease exacerbations and affect mortality in patients with COPD, it is imperative we do all we can to address this.[235] If patients are to participate fully in their care and in the management of a long-term condition such as COPD, good communication is essential. However not all patients are able to use the written word and this needs to be taken into consideration when planning services. As a result of this, patients were invited by letter and phone call as well as given oral and written information regarding COPD to try to ensure no patients were penalised as a result of illiteracy. In addition to a general limitation of their ability to recall information, patients with reduced health literacy may inherently have more difficulty comprehending medical information.[233] This makes an annual (or more often) health care professional visit all the more important to re-emphasise information.

As part of the management of stable COPD, GOLD recommends close monitoring of the patient's pharmacotherapy, including patient's adherence and inhalation technique.[43] Indeed, in many COPD patients, inhalation technique and medication adherence have been shown to be suboptimal.[5] RCTs have shown that regular treatment with inhaled maintenance medications including LAMA, LABA, ICS and fixed dose combinations of ICS and LABA (ICS/LABA) reduces symptoms, decreases exacerbations, and improves quality of life.[230] Concurrently, suboptimal education adherence has been associated with increased hospitalisation and health care expenses.[230] As 17 of our patients had medium adherence and eight with low adherence with their prescribed medication, this is an area where annual COPD reviews could be beneficial in encouraging patients to take their medications. One of the benefits of having

prescribing pharmacists carrying out these reviews is that they have a wide knowledge of medications and formulations including inhaler devices and, as part of polypharmacy review, can simplify or reduce medication burden if appropriate to increase adherence.

7.3.9 Inhalers compliance versus oral medication compliance

Inhalation therapy is of paramount importance in the treatment of respiratory conditions, including COPD. However, problems related to poor adherence and inhaler technique among respiratory patients are widely and historically reported in the literature and still represent a challenge for healthcare professionals and healthcare systems to date.[236] 19% of patients in this study had low medication adherence. This increased to 32% when specifically asked about inhalers. Eight patients reported an improvement in medication adherence after visit one with four patients reporting improved inhaler adherence. As poor adherence and inhaler technique are two aspects that significantly contribute to poor disease control leading to prescribing unnecessary higher doses, increased frequency of exacerbations and hospitalisations, high mortality, low quality of life, and loss of productivity, it is important we review these on a regular basis.[236] This adherence issue could be exacerbated in our subject group due to their housebound condition leading them to have less contact with healthcare professionals at the GP surgery and community pharmacy. There is evidence that suggests correct inhaler technique is fundamental for effective therapy and that inhaler device type and mastery play important roles in improving adherence, clinical outcomes, HRQoL, and use of health care resources in patients with asthma and/or

COPD.[237] Pharmacists, with their in-depth knowledge of all inhaler devices and combinations, as well as their knowledge of correct inhaler technique are ideally placed to be able to deliver an intervention to patients, including those who are housebound. Indeed, patients commented during the semi-structured interview that they felt this to be the case when asked if they would rather have a nurse or a doctor undertake the review. This has been previously reported in other studies that some health care consumers did report that pharmacists have a great depth of medication knowledge and might be a suitable alternative to a GP prescribing.[40]

7.3.10 Pulmonary Rehabilitation

Pulmonary rehabilitation combines exercise training, psychological counselling, and social support to improve outcomes such as levels of daily physical activity, exercise capacity, HRQoL, dyspnoea, and duration of hospital admission.[144] Pulmonary rehabilitation programs are considered to be a mainstay of treatment in COPD.[238] Therefore the fact that only three patients in our entire cohort had participated in pulmonary rehabilitation in the past shows that this is an area where improvement should be focussed. Pulmonary rehabilitation does have a history of poor uptake and the reasons for this are multifaceted including symptom severity, acute exacerbations, lack of energy, and disruption to daily routines.[239] Indeed the use of pulmonary rehabilitation in COPD patients is globally estimated to be around 2-5% of patients.[240] Additional factors for the poor uptake of pulmonary rehabilitation in this cohort of patients include the housebound nature of the patients who may not feel able to attend even though

transport can be provided (although this fact may not be well known) as well as lack of interaction with healthcare professionals to be offered this service. As there is evidence to suggest that pulmonary rehabilitation can improve healthcare utilisations during the first 12 months post programme,[241] it is important we look at increasing the uptake for not only our housebound cohort of COPD patients, but all our COPD eligible patients. As part of this project, two patients agreed to be referred for pulmonary rehabilitation, with a further five left information leaflets about it. It was felt that previous poor uptake may have been due to a lack of understanding by patients of the terminology 'pulmonary rehabilitation' and found it daunting. As part of this annual review, the pharmacist took time to explain what pulmonary rehabilitation was and reassure that it would not be overly strenuous or out-with their levels of capability as well as the fact that transport would be provided for them. Indeed, previous studies including one published in 2020 in the UK found that poor continuity of GP–patient relationships and limited consultation time made it harder to discuss pulmonary rehabilitation in a meaningful way.[242]

7.3.11 Palliative care and COPD

The natural course of physical decline for patients with COPD can be variable, but overall, it is characterised by a long-term steady deterioration.[109] However, most healthcare resources are dedicated towards management and prevention of acute events with significantly less emphasis from physicians and researchers on palliative and supportive care.[109] It is worth noting that there is no commonly accepted definition of 'end-stage COPD', however this has been suggested as

having very severe airflow obstruction on spirometry (FEV1<30%).[243] Patients frequently express difficulty coping with COPD's unpredictable trajectory, and in these situations, palliative care initiated early has the potential to provide significant quality of life benefits for patients and their care partners.[243] Palliative care provides comprehensive support delivered by an interprofessional team to provide physical, emotional, spiritual, social, and respite care.[243] Only 5% of patients in our study were recorded as being palliative in their medical records when it is possible a substantial number of patients may benefit from receiving palliative care. Previous studies have indicated that palliative care for COPD is inadequate.[109] Globally COPD prevalence is on the rise and is the only disease that continues to have an increasing age- adjusted mortality rate.[109] In the UK, 5.2% of all deaths are secondary to COPD, which is approaching the proportion (6.2%) of deaths that are due to lung cancer.[109] Patients with advanced COPD have a burden of disabling physical symptoms that are often compounded by multiple co-morbidities, psychological distress, and isolation.[109] There is a noted lack of palliative care support for patients with COPD, despite evidence that it improves their HRQoL.[109] At least 9% of patients in this study could have been classified as palliative based on their FEV1 alone.

Palliative care is not just synonymous with end-of-life, but also centres on symptom management, improving a patient's quality of life, and psychological support for the patient and their family.[109] Indeed, modern palliative care approaches are more needs based rather than prognosis based, appropriate for COPD patients in whose life expectancy is difficult to predict.[109] NICE CG101 states that patients with end-stage COPD should have access to the full range of

services offered by palliative care teams.[2] These include; palliation for breathlessness and other symptoms, advance care planning, addressing emotional and social needs, and end of life care.[2] Previous studies have noted that there is poor access for COPD patients to palliative care studies, alongside limited provision of patient information.[109]

7.3.12 Cost Effectiveness

The total annual direct healthcare costs for caring for people with COPD in Scotland were projected to increase from £159 million in 2011 to £207 million by 2030.[1] This model did not consider any changes in the cost of treatment, therefore as a result, the current projections of COPD-related healthcare cost are also likely to be conservative as, in general, healthcare costs increase over time. Meanwhile, these projections should be considered for planning for the increased numbers, costs, and care needs of people with COPD. This will be in the context of Scotland and England facing an increasing elderly and frail population with high rates of multi-morbidity.[34]

Although costly, and some patients might be reluctant to welcome their pharmacist into the privacy of their own home, home visits have proven beneficial in the past for several reasons, including being able to elicit more drug-related problems as all medicines were available at the home. Moreover, deploying home visits instead of a telephone call is more beneficial due to the personal touch of face-to-face encounters.[94] Previous research has shown that patients might feel more comfortable at home,- a finding which correlates with the results

of this study, and therefore are more likely to share their experiences and concerns about their medicines and even be more receptive to pharmacists' counselling.[94] In this instance, a practice pharmacist domiciliary visit annually would help to ensure that inhaler technique is correct, with the known benefits of increased compliance and disease control.

Practice pharmacists are also ideally placed in the GP practice as this brings access to medical records and greater awareness of local services such as money advice, smoking cessation, and support groups. It has been noted in previous studies that GP practices need to provide additional resources to regularly visit housebound patients but appreciate that it is difficult to incorporate this in to their existing workload[146] Primary care pharmacists are equipped with knowledge and clinical skills to be able to deliver chronic disease management services to the housebound as shown by this study.

Home visits are not the only option to undertake chronic disease management with housebound patients. Self-management interventions, which are increasingly supported by mobile apps, may improve disease management in patients with COPD and may decrease hospital admissions.[67] However not all patients can access this because of reasons such as socioeconomic status, internet access, and skills. As the North East Glasgow is a known area for deprivation, it was felt that face-to-face would be more acceptable for an elderly cohort of patients who might also not be computer literate. It has also been noted in other studies that further research and analysis on relevant apps to support patients with COPD is necessary as evidence is limited.[67]

There is a lack of evidence surrounding the cost effectiveness of domiciliary annual reviews for chronic disease, whether carried out by a pharmacist or other health care professionals. Some studies have shown that even the proven effective but less comprehensive disease management and chronic care programs struggle to demonstrate their economic benefits, and because more comprehensive programs are likely to come at an even higher opportunity cost than the less comprehensive ones, the need for rigorous studies and timely economic evaluations can hardly be underestimated.[244]

With regards to the cost effectiveness of this study, rough estimates conclude that it cost on average £72 to deliver one home COPD pharmacist review taking work up, travelling time, and actioning any changes into account. This does not include any cost savings that were made during the visit itself, such as deprescribing, or any costs of additional medications which may have been prescribed. It has been noted that where major savings can be made is in preventative strategies for patients, which help avoid the use of secondary services when crises arise.[91] Further work should be undertaken to look at the utilisation of practice pharmacists for domiciliary chronic disease patients. This would allow a cohort of patients who previously only had their healthcare addressed at a time of acute illness, would instead be provided with a holistic comprehensive polypharmacy review annually to prevent, or decrease the rate of decline.

It is beneficial to perform annual reviews of COPD patients to try to prevent exacerbations and to reduce their severity by ensuring patients know how and

when to report symptoms which may be a sign of an exacerbation to ensure prompt treatment. One previous study published in 2016 recorded a moderate exacerbation, defined as one needing antibiotic therapy plus or minus steroids, cost approximately £118 and the cost of a severe exacerbation, classified as one requiring hospital admission, cost approximately £3,329 in Scotland.[70] This value will only increase over time due to the increasing ageing population as well as inflation.

7.4 Semi-Structured Interview Results

The qualitative findings of the semi-structured interview indicate that the topic area chosen was useful, as patients as well as their carers and families in some incidences, reported finding a home COPD visit carried out by a pharmacist as beneficial. While it appeared that patients were not overly concerned about which health care professional carried out the home review, it was noted by several participants that doctors were too busy and don't have the time to visit. Those patients who had previous experience dealing with a pharmacist in their care, reported it as a positive interaction mentioning that the pharmacist was 'an expert in medications' so was well placed to carry out reviews.

It became evident during the interviews that patients did not always associate having COPD with causing a restriction on their lifestyle. Some patients felt that any functional decline was part of the normal ageing process, and some felt that COPD did not negatively affect their way of life despite admitting they were housebound and needed help at home to undertake daily routines due to their

condition(s). This in part may be caused by patient acceptance of their decreasing health, perhaps enhanced by the relative decline in COPD in that patients have adapted to their condition as time has gone on. It may also be that some patients were fiercely protective of their independence and may not have wished to acknowledge their increasing disability caused by breathlessness. Previous studies investigating COPD patients' thoughts regarding their condition have found 'weary resignation' after years of futile attempts to improve their circumstance, and/or a recalibration of expectations as an adaptive coping strategy contributing to an undemanding acceptance of their circumstances.[201]

7.4.1 Needs of COPD patients

There is a substantive body of literature acknowledging that people with COPD have extensive unmet needs.[201] Indeed, GPs have previously raised concerns that the patient group is becoming more complex due to increasing age, multimorbidity, and polypharmacy.[4] Recently there has been interest into the observation that people with COPD tend not to actively seek help for these unmet needs, variously interpreted as 'the silence of people with COPD', 'passive acceptance of their situation' or resignation/contentment.[201] Coping with the help of family of neighbours was more aligned with remaining 'normal' and not in 'need.'[201] An additional challenge to providing appropriate care to those with COPD is the recognised tendency for this older age group of patients to remain 'silent' about their physical and social disabilities, tending to 'normalise' their limitations as the result of 'old-age', about which 'nothing can be done'.[201] The patients who were included in the pilot are some of those most likely to be

admitted to hospital as 40% of all emergency admissions are accounted for by those over 65 years of age.[91] Work in England in 2006 hypothesised that COPD patients who were housebound with no proactive care led patients to perceive themselves to be low priority for professionals.[145] This was a similar finding to some of the patients in this study as shown by the quotes below.

> *'I think it's a good idea. It's not that, it's been a long haul. It's been five years or maybe even more so and nobody has actually bothered with him. do you know what I mean?'*
>
> *Partner of Patient 1*

> *'they're just sitting there waiting to die you know it's a sin.'*
>
> *Patient 11*

7.4.2 Housebound patients

It is important to continue to increase patient outreach programmes. One such recent model has been the use of a mobile self-management app after hospital discharge for COPD patients however so far use has only been found to be feasible for a small number of patients with patients satisfied with the service but use of the app decreased over time.[67]

7.4.3 Undiagnosed cognitive impairment

Undiagnosed cognitive impairment was an unexpected finding of this work. As housebound patients in North East Glasgow GP practices generally do not receive regular reviews of their health unless acutely unwell, many of the patients visited as part of this service evaluation had not been in contact with a health care professional for a significant period of time. For some patients, this was several years. This lack of health care contact meant that a decline in cognitive impairment has gone unnoticed by any health care professionals unless flagged to them by relatives or carers. This has significant consequences for the patients of this study, for two reasons. Firstly, patient's may not be taking their mediations correctly leading to an increased risk of COPD exacerbations and secondly, patients may not recognise when they are having an exacerbation and when to seek medical help. A delay in diagnosing any cognitive impairment can also lead to a delay in treatment options, many of which require early identification for best results, as well as a delay in providing the patient and their family with the necessary support to try to minimise the impact cognitive impairment has on their lives.

7.4.4 Social isolation

A large body of research shows that social isolation and loneliness have a serious impact on older people's physical and mental health, quality of life, and their longevity, with the effect of social isolation and loneliness on mortality comparable to that of other well-established risk factors such as smoking,

obesity, and physical inactivity.[245] Lack of social contact might hinder the maintenance of health promoting behaviours; for instance, marital partners, family members, or friends might be likely to encourage each other in an effort to influence health habits. Social isolation of elderly people has been noted in literature with subsequent social as well as medical conditions uncovered which required referral onto other agencies including social work, physiotherapy, and General Practice.[246] This could be because a number of these housebound patients had not been to the GP surgery for a number of years and were therefore not being regularly reviewed by a health care professional. Previous work has detailed the importance COPD patients feel on maintaining a sense of independence and autonomy, considering themselves as ageing rather than ill.[201] Previous research regarding health care professionals who look after COPD patients noted that they felt people with severe COPD have substantial unmet needs and in addition, have a loss of self-confidence describing example patient statements as; 'scared to go out' 'lots of social issues.' [247] This certainly seemed to match our findings with patients reporting inability to go out and if they can get out, that it is a challenge health wise as well as financial wise with cost of taxis. Embarrassment of not being able to breathe was also mentioned as a factor as shown by the quotes below.

> *I think you are aye because you're uptight because you can't breathe and you're not wanting people to see that you can't breathe do you know what I mean you're, it's quite embarrassing when you're going, huffing and puffing.'*
>
> *Patient 11*

'The nurse, the reception asked and how can you not come down? I said I can't I'm in a wheelchair and I've got no feet. What?! How can you not come down I said I can't come down.'

Patient 16

One reason identified as to why patients responded positively to pharmacist home COPD visits was felt to be due to patients enjoying the social interaction. Several patients noted that apart from carers or family visiting when they were able, they did not have any other visitors and found being housebound contributed significantly to their social isolation and loneliness. This showed that the pharmacist home visit provided a social benefit to this cohort of patients. It may be argued that a pharmacist is an expensive provision to provide companionship to lonely housebound patients however this is only one part of the role that a practice pharmacist can provide during an annual review process, and it is important that we address both medical and social factors as both can affect health and HRQoL.

7.4.5 Awareness of the pharmacist role in primary care

Patients responded positively to having a pharmacist conduct a visit however it is unclear whether patients were aware that the health care professional visiting them was a pharmacist (and not a nurse or a doctor for example) despite this being clearly said on numerous occasions. This was in part felt to be down to the lack of public understanding of the pharmacy professional role in primary care and is not an issue limited to housebound COPD patients but to the public as a

whole. This raises an importance issue in that the profile of practice pharmacists needs to be raised with the public so they fully understand what the pharmacist can offer and make sure that pharmacists are regarded as important members of the health care multidisciplinary team. One previous study undertaken in Iceland ascertained that pharmacists are found to be trustworthy by patients, but unknown as a patient care provider. All participants in this study claimed to think highly of pharmacists as health care professionals, however, it was clear from the interviews that participants had almost no experience working with pharmacists, as the responses were rather short as exemplified e.g.; It is just good/…[pharmacists] they are useful and necessary.' Little knowledge was known on the exact role pharmacists can play. As the patients responded positively to the review being undertaken, despite not knowing in some cases that the health care professional carrying out the review was a pharmacist, it may not seem important to raise the role of the practice pharmacist in the public. However, it is important that this role is raised among the public, so they have confidence in the health care professional looking after their care (or a member of their families care). In addition, the role of the practice pharmacist should be raised with other health care professionals so that they are aware of the significant role pharmacists can play as part of a general practice team and signpost patients to them where appropriate.

One major finding that emerged during this work was the identification of the role of the pharmacist and what exactly they did within 'the doctors' surgery'. Most patients were only aware of pharmacists working in hospitals or working in their local community pharmacy where they get their prescriptions from as

demonstrated by the quote below. Not one patient interviewed was aware that their own GP surgery had a pharmacist attached to it from the health board, nor what role they played, or that they could prescribe medications. The role of practice pharmacist was introduced in Greater Glasgow in the early 1990s and was funded by the health board in Scotland rather than by individual practices as was the initial mode of employment in England. Each GP practice had the option of pharmacist time in their practice initially to look at cost-effective prescribing by conducting medication switches and running clinics for health board priorities which changed annually. The role has vastly changed for practice pharmacists since then, leading to them becoming much more of an integrated part of the GP practice although this does vary across GP practices to what level of integration has been achieved.

'Are you out the pharmacy? are you out the chemist?'

Patient 15

GP practice pharmacists tend to be generalists although some also have an area of expertise. For the project pharmacist this is respiratory disease, although it is noted that not all pharmacists in the North East Glasgow locality who carried out the domiciliary COPD reviews had the same speciality, they were all experienced pharmacists practising at Agenda for Change band 8a, with a wealth of knowledge to bring to the project. The typical key responsibilities of a practice pharmacist in 2015 when the domiciliary visits were undertaken were;

- Providing clinical expertise and being an educational resource for colleagues in relation to medicines such as doses, side-effects, and alternatives whilst helping to address the public health and social needs of patients within SIGN/NICE and other evidence-based guidelines and local formularies.
- Liaising with and proactively developing relationships with a multidisciplinary team (including colleagues, NHS professionals, and other local HSCPs) and acting as the main point of contact for medicines.
- Managing, auditing, and reviewing prescription and repeat prescription policies to improve the quality, safety, and cost-effectiveness of prescribing.
- Reduce wasteful polypharmacy and seek to reduce inappropriate prescribing of medicines (deprescribe).
- Proactively seek to reduce medicine-related hospital admissions and readmissions by identifying medicine-related issues and supporting patients to get the best outcomes from their medicines.
- Handling patients and health care professionals' prescription queries and providing remote support where needed.
- Research and identify patients that require medication reviews including patient's clinical condition(s), blood monitoring, and care arrangements.
- Perform regular patient reviews to identify and address any medicines-related issues and ensure patients get the best outcome from medicines prescribed.

- Make appropriate recommendations to GP and other healthcare professionals for patients' ongoing treatment and for the management of referrals.
- Undertake domiciliary reviews to patients identified by the falls service whose polypharmacy may be contributing to their falls risk.

In 2018, the Scottish government released a new GMS contract, which sought to address the fundamentals challenges faced by general practice, not least the growing workload and increasing risk.[41] They removed the QOF framework and invested £12 million in the GP pharmacy fund in Scotland 2017/18 to allow more pharmacists and pharmacy technicians to work in general practice to reduce GP workload and improve patient care. Pharmacists and pharmacist technicians were recognised as expert medical generalists and it was expected that by increasing their use in primary care, that the workload would be distributed more appropriately with the pharmacists and technicians undertaking prescribing improvement work, and providing medication reviews, and specialist clinics.[248] As part of this, a new pharmacotherapy service was developed called the 'core and additional pharmacotherapy services' as discussed on page 12 but is also shown again here as Figure 7.2. While this shift towards a different model of pharmacists working in primary care in Scotland, it is hoped that pharmacists undertaking domiciliary reviews for chronic disease management could still be an important and viable service coming under level two or level three services.

Figure 7.2: Core and additional pharmacotherapy services

Taken from GMS Scottish Contract 2018 [41]

Core And Additional Pharmacotherapy Services		
	Pharmacists	**Pharmacy Technicians**
Level one (core)	• Authorising/actioning all acute prescribing requests • Authorising/actioning all repeat prescribing requests • Authorising/actioning hospital Immediate Discharge Letters • Medicines reconciliation • Medicine safety reviews/recalls • Monitoring high risk medicines • Non-clinical medication review Acute and repeat prescribing requests includes/authorising/actioning: • hospital outpatient requests • non-medicine prescriptions • instalment requests • serial prescriptions • Pharmaceutical queries • Medicine shortages • Review of use of 'specials' and 'off-licence' requests	• Monitoring clinics • Medication compliance reviews (patient's own home) • Medication management advice and reviews (care homes) • Formulary adherence • Prescribing indicators and audits
Level two (additional - advanced)	• Medication review (more than 5 medicines) • Resolving high risk medicine problems	• Non-clinical medication review • Medicines shortages • Pharmaceutical queries
Level three (additional - specialist)	• Polypharmacy reviews: pharmacy contribution to complex care • Specialist clinics (e.g., chronic pain, heart failure)	• Medicines reconciliation • Telephone triage

The publication of the Advanced Practice Framework by the Royal Pharmaceutical Society (RPS) in 2013 was ground breaking for UK pharmacists.[36] In 2021, the RPS developed and launched a UK Core Advanced Curriculum and credentialling process.[249] This has the potential to revolutionise the standardisation of advanced practice skills development and is an exciting development to assure pharmacists have the capabilities to practice at an advanced level.

Most patients reported that they felt the pharmacist had helped with their breathing condition(s), with the amount of time spent explaining their medical treatment(s) being specifically appreciated. The comparison between the pharmacist having time to discuss health related issues and medications compared to the doctor who is seen as 'very busy' and 'doesn't have much time' was evident. This may show one advantage of having a practice pharmacist conducting chronic disease reviews as they are seen as more available and associated with having more time for patients in comparisons with other health care professionals.

Some patients mentioned that they appreciated having a general medication review as they wanted to know if they still needed to take all their medication. Being able to provide a general polypharmacy review as part of a domiciliary chronic disease review shows another benefit of having a pharmacist undertake this role compared to other health care professionals such as a nurse who may not have such a wide range of knowledge regarding medications and their pathophysiology. With the additional change from August 2026 onwards, where

all pharmacists will qualify as prescribers as part of their undergraduate course, this will allow all pharmacists to carry out any prescribing changes autonomously, leading to a quick turn around on medication changes and less workload for GPs having to read, check, and authorise changes for pharmacists before any changes can be made.

The home setting for the reviews was preferred by most patients. They reported finding it a more relaxed atmosphere without having to worry about travelling anywhere due to health deconditioning or transport concerns or costs. Patients felt they were less likely to forget what they wished to say or feel rushed or pressurised for time during a house visit which reflects that for this cohort of patients, domiciliary visits are beneficial and appreciated by patients.

It has been noted that a home setting for patient education may have enabled patients to be able to receive and interpret information on their chronic disease in a non-clinical and unrushed environment.[94] Previous research undertaken in England whereby nurses provided domiciliary COPD annual reviews has also shown that COPD patients were elderly, socially isolated, and dependent on family, friends, or professionals to support them during their illness. This was matched by our findings which showed patients preferred the home setting as felt more time was spent with the health care professional and patients felt they were less rushed. They also commented that it helped them understand their condition(s) as shown in quotes below.

'Oh I prefer this aye. I mean even in the doctor's surgery you are only allowed so many minutes, I know, seven minutes or ten minutes or you know.'

Patient 12

'Aw it was fine, aye. I mean it's the first time I've ever had anybody really talking about my condition. I mean you just went to the doctor and once you. You were left to, right that's it, take that you know what I mean.

That's what I feel as if.'

Patient 12

Sufficient time must be allowed for the pharmacist to ensure they can conduct a comprehensive medication review including but not limited to, prescribing, adjusting medication, stopping medication, as well as providing patient and caregiver education. An American home visit pharmacist study in 2018 found that an initial medication review took an average of 83 minutes to complete with subsequent reviews 48 minutes,[143] with one study in Malaysia which helped managed type 2 diabetic patients spent approximately one hour undertaking each home visit.[94] This study had an average of 49 minutes per review not including preparation or travel time. In totality including work up, travel, and time taken to make any necessary changes or referrals, the average time equated to 173 minutes. However, it must be acknowledged that this would be expected to decrease with time and the number of reviews each pharmacist conducted. It

should be noted that this was the first time this group of pharmacists had provided COPD domiciliary annual reviews.

7.5 Confounding factors

Research is not value-free and investigators cannot be divorced from the cultural, social, and political context of their topics.[211] The researcher remained aware that researchers' attitudes influenced design, data collection, and analysis, and used a multidisciplinary professional team and lay advisors to ensure a balanced interpretation of the data.

The internal validity of a study depends greatly on the extent to which biases have been accounted for and necessary steps taken to diminish their impact. It should be noted that both the initial visit and the second visit were conducted within the winter period where 30% more COPD exacerbations requiring hospitalisation are known to occur compared to the summer months, [250] which may have affected the results. The winter season may be a confounding factor in the results such as CAT score and HRQoL, however it should not affect the semi-structured interview answers regarding what the patient thought and felt about the review. While undertaking this project in spring or summer may have produced more positive results with regards to COPD symptoms, it also shows real life data as in real life, as annual COPD reviews would be undertaken all year round to be able to review all housebound patients and not just during one season. In addition, an annual review would typically only be once a year whereas our study involved two visits, four weeks apart. While this was

necessary for our study to be able to get feedback regarding visit one, it also means that our study is not a true representation of a once yearly review, and this needs to be taken into consideration when planning future research and services.

Different pharmacists undertook the home visits with each pharmacist in the North East Glasgow prescribing team reviewing patients attached to their GP practices that they were assigned to at the time of the study. This did result in some pharmacists seeing more patients than others based on the demographics of their practices. All pharmacists who were part of the North East prescribing team at the time of the study were asked if they were happy to deliver the domiciliary COPD reviews and were able to decline if they felt this was out-with their area of competence. None of them did so. It was ensured that each second visit was not conducted by the pharmacist who undertook the first visit to reduce bias of the patient feeling they had to give a positive review as it was the same pharmacist asking the questions, however it is noted that having a number of different pharmacists undertaking the annual reviews may affect the data. Again, this is relevant to real life practice as in real life, it would be different pharmacists undertaking each review. Therefore, while standard operating procedures were used to ascertain each patient's individual inhaler technique, there may be variance between what one pharmacist classified as moderate inhaler technique compared to another pharmacist who might classify the same as poor technique.

Though this service development revealed the advantage of having a pharmacist with a higher grader of skill carrying out the visit, the financial implications of this are not insignificant. It must be acknowledged that in practice now, due to the aforementioned increase in primary care pharmacists in general practice as part of the Scottish GMS pharmacotherapy contract introduced in 2018 as discussed in Chapter 7, page 221, that Bands 6, 7, and 8a pharmacists are now currently employed in primary care. This means there is opportunity to undertake further research to ascertain if it would be feasible for other bands of practice pharmacists to undertake domiciliary COPD annual reviews more cost effectively, if they felt it was within their area of competency. Indeed, there is no reason why this would not be feasible although it is important to consider the benefits of a prescribing pharmacist undertaking the reviews autonomously and the benefits that brings.

Semi-structured interviewing can be a powerful tool for family physicians, primary care providers, and other health services researchers to use to understand the thoughts, beliefs, and experiences of individuals. Due to the vulnerability of the elderly housebound cohort we wished to interview, we decided to allow family members and/or carers to be present during the reviews and semi-structured interviews. It is noted that having a family member present can make the interview more complex, including;

- Family concerns
- Additional concerns or questions about the patient's health from the family member
- Ethical dilemmas involving confidentiality and privacy

One study found that a third person in an examination room decreased the amount of time the patient spoke to the physician. While our situation was somewhat different for the semi-structured interview, it is important to acknowledge the fact that most patients had someone present during the semi-structured interview which may have introduced bias into the results. We found that the family member and/or carer was a valuable source of information and indeed helped give a more accurate picture of the effects COPD had on the patient's HRQoL, especially when the patient was uncomplaining and may not have noticed the gradual decline in heath. Bias from this factor was attempted to be mitigated by allowing both the patient and their representative time to speak, recognising and acknowledging feelings, respecting privacy, and maintaining confidentially while avoiding taking sides. [251]

7.6 Convenience sampling

The results are not generalisable to the wider population due to the non-random method of selection that was used for this project. Convenience sampling was chosen as we wished to initially see what housebound COPD patients thought about domiciliary annual reviews for COPD before considering a larger trial involving other chronic diseases such as diabetes or hypertension. Patients were chosen for this project because they had a recorded COPD diagnosis on their GP practice records and were also recorded as being housebound. In addition, only patients who were accessible to the researcher, e.g., in the North East Glasgow HSCP were invited to participate as she worked in this local area**.** While convenience sampling lacks external validity because it does not represent the

characteristics of the whole population, the aim was to understand complex phenomena rather than apply the findings to a wider population. Convenience sampling is appropriate in this case as we are looking in primary care at something that would be used in the primary care setting. It is essential for the investigator to estimate the extent to which the accessible population which has been included in the study deviates in important ways from the excluded but relevant population. While this may limit the study generalisability of the results, there were actions taken to try to improve the dependability of the data produced by;

- recruiting as many participants as possible
- not using probability tests
- including quotes to confirm the accuracy of themes chosen
- collecting data in a diversified manner- at different days or different times
- validating data by using two pharmacists undertaking the interviews

The least burdensome method for housebound patients was felt to be a face-to-face interview as this only required the respondent to speak the same language in which the questions were asked and to have basial verbal and listening skills. A friendly, motivated interviewer is also known to increase response and item response rate.

7.7 Thoughts of service from other health care professionals

There was some concern from GP colleagues that by undertaking this piece of work, that a can of worms of issues could be raised, leading to the GPs having to undertake more tasks to care for their patients; sustainability of the service was a concern. However, the majority felt that this was a good piece of work to do to identity any issues in community and provide proactive care rather than reactive. In response to GP concerns, while it was acknowledged that issues may be raised that will need a GP referral, the study showed that they weren't that many onwards referrals to GPs with only four patients needing a referral to a GP because of the pharmacists visits one and two combined. In addition, with pharmacist prescribers being embedded in practice and their increasing role in primary care, they are in an advantageous place to be able to action or follow up any tasks as necessary autonomously without having to refer to GPs thus freeing them up to focus on acute illness diagnostics.

It has also been shown that direct contact and intensive collaboration between pharmacists and clinicians improves the uptake of the recommendations given by the pharmacist.[94] Having pharmacists based in GP practices helps to cement this relationship. Access to the patient's medical file and increased rapport/communication between the pharmacist and GP were also commonly considered the benefits to integrating pharmacist services within the general practice environment.[40]

7.8 Why pharmacists?

A number of countries, including the UK, Australia, Canada, and the US, have introduced multidisciplinary allied-health clinics, nurse practitioner, and nurse-led clinics into routine practice in primary care.[252] Under certain circumstances, available evidence shows that this model of care delivery has the potential to reduce health costs without compromising quality of care.[252] It has been noted in past studies that it is not always clear what benefits pharmacists could provide compared with other health care providers, including nurses with expertise in the target of chronic disease, who would also be reviewing medications.[12]

However, it can be argued that with pharmacists being increasingly placed in primary care and upskilling as well as an increase in pharmacists prescribing, that this evidence may change in the future. Indeed, many previous studies investigate the role of pharmacists based in community pharmacies, who do not have access to clinical records or were not able to directly action changes, thus having to refer issues onwards to the GP practice, where a GP had to review any suggested change(s) and decide whether to action or not.

In the Netherlands, non-dispensing pharmacists in primary care conduct clinical pharmacy services that primarily focus on chronic disease management.[20] Clinical pharmacy services are usually multifaceted, including medication therapy reviews, counselling, and medication education. These services can be aimed at patients with a specific chronic condition such as diabetes, cardiovascular disease, or COPD, or at a more heterogeneous group of patients at risk of drug

related problems, such as patients with multimorbidity and polypharmacy.[20] Disease specific clinical pharmacy services focusses on evidence-based protocolled care, while patient centred clinical pharmacist services entail a more non-standardised and holistic approach. [20]

Research involving healthcare consumers found that patients are generally supportive of a pharmacist involvement in non-dispensing roles.[40] However, some healthcare consumers found it difficult to foresee the benefit potentially offered by a pharmacist in the general practice setting largely due to being unfamiliar with the clinical roles of a pharmacist.[40] Previous research work has shown that lack of identity of pharmacists in general practice is a common issue where further work is needed to be conducted to address this.[253] This was identified as a significant finding in this study as well, with the majority of patients struggling to understand who the pharmacist was, and what actions they could take, for example being able to prescribe. Several patients, despite it being clearly stated that the member of staff was a pharmacist, nevertheless thanked them as the 'doctor' or 'nurse' at the end of the visit. It has been noted in other studies that to strengthen the successful integration of pharmacists into primary care settings, it is critical to ensure there are opportunities and support available for the increased visibility of pharmacists as primary care team ambassadors.[17]

It has been noted in past studies that it is not always clear what benefits pharmacists could provide compared with other providers, including nurses with expertise in the target of chronic disease, who would also be reviewing medications.[12] However, it could be argued that pharmacists are not confined to

one specialist area but are generalists and can provide a full holistic review rather than just a one disease review. It has previously been reported in other studies that some healthcare consumers did report that pharmacists have a great depth of medication knowledge and might be a suitable alternative to a GP prescribing. '*I think it's a bit like we're saying the pharmacist knows medicines best but the doctor knows bodies best and diseases best*.' [40]

There is growing evidence that high quality care leading to desirable and sustainable outcomes for chronic diseases (i.e., clinical makers, cost savings, care experience, care quality, etc) is positively impacted by "care that is respectful of, and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions.[254] Patient centred care is also viewed as a moral and desirable end in and of itself, regardless of the clinical outcomes or savings it produces.[255] It has been noted that unless a medication review is tailored to suit an individual's needs, it will be unlikely that the patient will receive maximum clinical benefit.[256]

The general perception among health care professionals in literature was that severe COPD patients' needs are poorly addressed compared to people with (say) cardiac disease or cancer.[257] This was felt to be due to low profile of respiratory disease, stigma of smoking, and low expectations or cultural norms of people affected by COPD. Indeed, it was a practice nurse who suggested that I review COPD housebound patients as she was worried that they missed out on routine reviews but noted that she did not have capacity or time to be able to perform these herself.

In one English study, three COPD patients received home respiratory nurse visits. While this was only three patients, it was felt they performed a valuable role in giving advice, spending time with patients, and liaising with secondary care.[147] Skilbeck et al concluded that the respiratory nurse specialists may be best placed to respond to the unmet needs of these patients. The value of the respiratory nurse appears to be in the holistic approach to patient care, and in attending to their social and psychological, as well as physical needs.[146,147] It could be argued that practice pharmacists are in an ideal position to be able to fulfil this role similarly to the respiratory specialist nurses and in addition will be able to use their clinical knowledge to tackle other medication polypharmacy and any other chronic diseases or clinical decisions.

An English study in 2018 has demonstrated that a specialist respiratory pharmacist visiting a general practice could reduce asthma exacerbations and associated costs.[142] Findings from this study included comments that the practice pharmacist was a generalist and not asthma specialist. However, this can be perceived as advantageous, being more representative of likely future models and can also ensure a holistic overview of all the patient's comorbidity and polypharmacy are undertaken.[142] A Belgian study in 2014 has shown that a pragmatic pharmacist care programme can improve the pharmacotherapeutic regimen in patients with COPD and could reduce hospitalisation rates.[258] While this study focussed on community pharmacists rather than primary care pharmacists, there are some common themes such as improved inhaler technique and medication adherence which are applicable to both.

It has been previously noted in literature that it is difficult to determine if a single provider type of intervention has a direct impact on the outcome. However, pharmacist interventions have been shown to have a positive effect on the clinical outcomes of asthma and COPD.[141] Evidence of the effect of clinical pharmacy services in clinical endpoints, such as mortality, hospitalisations, and HRQoL, are less clear probably due to very heterogeneously defined clinic pharmacy services as well as strongly differing study settings.[259] Further research is needed into this field to ensure that the integration of pharmacists into general practice is beneficial to patients both with regards to clinical endpoints and patient acceptability. There is a limited amount of literature data focussed on exploring the attitudes of one of the key stakeholders involved in pharmacist prescribing, that is, patients. Comprehensive pharmacy disease management services (e.g., asthma), which use a patient-centred approach, can improve self-management and adherence to therapy, as well as clinical outcomes.[260] When considering service developments for patient care, it is important that patient acceptability and preference are taken into account.

7.9 Personal Journey

As a researcher, I have been humbled by listening to the patient stories and hardships they have endured, and I have also shared their frustration at the lack of access to healthcare for housebound patients. They have kindly welcomed us into their homes and shared their experiences of their medical conditions and care they have received so gracefully, and I hope I have been able to give them a voice. All service developments should keep the patient at the forefront of their

plans, and I strongly believe this is vitally important. Pharmacists have a vast clinical knowledge, and it is important we utilise their skills as part of a general practice team. I have been very grateful for the whole team of pharmacists in the North East Glasgow prescribing team taking on this project and wanting to help housebound patients with chronic diseases, when they already had a current full workload and I am grateful to the GP practices in the area for supporting us with this endeavour and working together with us to improve patient access to services.

7.10 Discussion Summary

COPD affects more than 900,000 people in the UK and has been recognised as a neglected medical and social problem in relation to both the provision of health care services, and research.[261] It is known that effective interventions for COPD include; inhaled medications, inhaler device technique training, smoking cessation and pulmonary rehabilitation. It has also been shown that community pharmacists are well placed to provide medication reviews and inhaler technique training as well as to support general practitioners.[236] Practice pharmacists are therefore in an ideal role to be able to provide a similar service to their patients both in the GP surgery and to those who are housebound such as our cohort in our study. Practice pharmacists can leave the surgery to conduct these house visits during routine working hours whereas the community pharmacists in the UK currently are only allowed to leave the premises for a maximum of 30 minutes otherwise the shop must shut. In addition, during this time, no prescriptions or 'P' licensed pharmacy only medications can be given out. If a community pharmacy

has a second pharmacist, then home visits can be achieved, however there is a substantial cost associated with this and there are limited payment schemes in place for community pharmacies in Scotland at present to be able to recompense for this. In addition, practice pharmacists are also currently more likely to be trained independent prescribers and able to issue their own prescriptions for any necessary changes for prescribed medications which further enhances the service that practice pharmacists can provide. As the current roles of pharmacy changes in the UK, with future plans that pharmacists come out of university with a prescribing qualification as part of their undergraduate degree, this will open up further opportunities for not only primary care pharmacists but also community pharmacists to be able to suggest and action changes autonomously although currently there is no plan to allow community pharmacists full access to patients notes but this may come with time.

The intervention in this study did not have a significant effect on patients HRQoL, and this finding is consistent with other medication review studies. Follow up duration may not have been long enough to detect changes in these parameters. While this study was for a small cohort of patients, the design was such that it has the potential for application to housebound patients with other long-term conditions.

Following pharmacist intervention, the proportion of patients who were adherent to their medication regimens improved significantly, according to the Morisky (from 81% versus 93% of patients recorded as medium or high compliance as per Table 5.25). Aside from medication related problems, pharmacists identified

a wide range of non-drug issues including bloods or blood pressure needing checked, influenza vaccination outstanding, patients reporting low mood and/or poor sleep, smoking cessation needed, and weight management, for both under and overweight patients.

This service development has shown that housebound patients are an important cohort of patients who are currently missing out on routine chronic disease reviews due to their domiciliary setting. While this service development focussed on COPD as a chronic disease, there is no indication that this benefit could not be associated with other chronic diseases such as diabetes and hypertension. Providing annual reviews for housebound patients for chronic disease management provides both a medical and social benefit. While it is acknowledged that pharmacists are an expensive resource if being used solely for a social interaction role, it should be noted that a holistic review including a full polypharmacy medication review, may help lead to a decrease in hospital admissions as well as improved HRQoL however, further studies on a larger subset of patients is needed before this can be directly correlated.

8.0 Conclusion

8.1 Introduction

COPD is a progressive lung disease with a high symptom burden which is a leading cause of death in Scotland and the world.[71] COPD is a common disease that, if not managed appropriate, causes an enormous strain on health services.[56] COPD is one of several ambulatory care sensitive conditions identified by the NHS as having effective management and treatment options in primary care that should prevent emergency admission to hospital.[215] It is predicted that by 2033, Scotland's population will increase by 50% in the over 60 years age group.[71] With this increase in age there is also an increase in chronic medical conditions and associated medication use.[14] The ageing of the population is resulting in increasingly complex medication-related needs.[20] To sustain the economic viability of health care the majority of elderly patients should be treated in primary care.[20] Within Western Europe, Glasgow is known to have poor health outcomes, with average life expectancy more than six years below the UK average for men and more than four years below for women with poor respiratory health outcomes, with particularly low lung cancer survival rates.[215] Half of Glasgow City population lives in the lowest quintile of deprivation[215] and a systematic review of studies found that for a range of COPD outcomes, individuals living in the lowest socioeconomic strata were at least twice as likely to have poor health outcomes than those from the highest.[215]

Rates of COPD emergency admissions did not change significantly between 2002 and 2013 in Scotland, despite several initiatives being directed at managing COPD symptoms in the community.[215] It has been noted that adherence to medication is critical for patients with chronic diseases and that patient education is an important tool for improving patients' medication adherence.[94] Patients who adhere to treatment have a lower risk of exacerbating their medical condition when compared to those with poor adherence.[56] Adherence to therapy in COPD is complex. Patients with COPD require adequate education on the disease process, comorbidities, and also on the use of different medications and devices.[60] Effective management of medications has been shown to reduce hospitalisations and emergency department and outpatient visits.[262] While medication is an integral component of the effective management of COPD, contemporary studies report that more than half of all people who are prescribe medication for the management of their COPD do not adhere to therapy.[56]

Research has previously shown that COPD patients do not access community-based services for a variety of reasons including poor physical health, family commitments, and transport difficulties.[144] Primary care needs to develop programmes that will reduce the requirement for crisis intervention for patients with long-term conditions. Equality and diversity are important priorities for all organisations, and it is important we ensure that housebound patients with chronic diseases are given the same opportunity for preventive care as those patients who are able bodied who can attend their GP practice for reviews. Practice pharmacists are ideally placed to be able to provide these services direct to patients. GPs who have experience of working with pharmacists in primary

care have found their integration into primary care invaluable in helping to provide safe, effective, available, and acceptable rational prescribing, and not solely from a cost effectiveness point of view.[132]

8.2 Pharmacists

Unplanned hospital admissions place a large and growing burden on healthcare resources; primary care plays an important role in reducing these by ensuring that patients receive high-quality disease management, timely treatment or advice, and appropriate referral.[263] It is acknowledged that the proportion of hospital admissions is greater among the elderly in the UK due to a higher proportion of multi-morbidity, frailty, and polypharmacy than younger patients, therefore it is important that this cohort of patients has their medication reviewed regularly to maximise their HRQoL and address any arising health issues. Approximately half of all hospital related medication errors and 20% of all adverse drug events have been attributed to poor communication and the transitions and interfaces of care.[12] Practice pharmacists are ideally placed to be able to provide annual chronic disease reviews to correct any errors as well as address adverse drug reactions. Pharmacists are viewed as highly trained yet underutilised and there is growing support to extend the role of the pharmacist within the primary health care sector.[40]

Changing demographics across the UK with an ageing population has led to general practitioners managing increasing numbers of older patients with multi-

morbidity and resultant polypharmacy.[264] The UK government has stressed the need for transformational change in workforce development and also voiced a warning about the critical need to ensure that staff with the correct level of confidence and skills are being trained to safely deliver care.[36] Through UK government led initiatives within the NHS; an increasing number of GP practices employ pharmacist support. Pharmacists have extensive pharmacotherapy knowledge and expertise and are therefore a logical addition to the general practice team to assist with medication management.[122]

Advanced pharmacist practice is a growing professional phenomenon across global healthcare systems.[36] In 2021, the Royal Pharmaceutical Society launched a UK 'entry-level' advanced practice curriculum and credentialling process.[249] This has the potential to revolutionise the standardisation of advance practice skills development.[36] In the past two decades, the movement to include pharmacists as essential members of primary care teams has gained traction in a number of countries including Canada, the US, the UK, Australia, Malaysia, and Brazil.[17] The skills of pharmacists in primary care include the provision of direct patient care through management of medications, examination and screening, chronic disease management, drug information and education, collaboration and liaison, quality assurance and research.[17] With the role of the practice-based pharmacist ever increasing, and the newly launched Standards for the Initial Education and Training of Pharmacists that from 2026 all pharmacists registered with the GPhC will have completed their training with prescribing qualifications, this research shows that pharmacists are ideally placed to undertake routine chronic disease management for a cohort of patients

who routinely do not receive such reviews. Previous research has supported a significant opportunity and potential return on investment by integrating pharmacy services into the care transition process.[262] This thesis enhances the overall literature base regarding practice-based pharmacists in Scotland and adds in particular value to the under-researched area of housebound chronic disease patients.

A previous home-based medication management service in New York published in 2014 was shown to be of limited benefit as it relied upon the physician implementing the recommendations of the pharmacy and nurse team.[148] Only 18% of their recommendations were acted upon. With practice pharmacists being based in the practice itself and also being independent prescribers, this should not be an issue. Practice pharmacists are ideally placed to be able to independently review patients both in practice and in the patients home and can also implement any changes themselves with the added advantage of already having a working relationship with the patient's general practitioner for any issues that are raised which need further discussion.

To my knowledge, this is the first study to explore and gather information on patients' perceptions of domiciliary visits conducted by practice-based pharmacists. Investigating the views and opinions of key stakeholders on a practice model is potentially crucial to the model's success. This research has identified which services would be of value and the primary barriers and facilitators to service provision as identified by stakeholders. This research was done in a real-life setting with readily available clinical tools that can be easily

obtained and used in clinical practice. Opinions obtained through qualitative inquiry from different perspectives may foster inter-professional development of the potential model. The power of this work relies less on a pharmacological approach to COPD than on understanding of patient-related determinants of access to health care services. This may then facilitate a greater opportunity for the model to be implemented successfully.[40] Qualitative methods can provide an in-depth understanding of why patients are admitted to hospital and the role healthcare professionals could play in averting this.[263]

Limitations of most models of GP-pharmacist collaborations in primary care include geographical isolation, poor communication, and lack of time, and remuneration for team activities.[265] The co-location of pharmacists with GPs in primary care settings has been shown to enable greater interprofessional communication and the development of collaborative working relationships.[265] Good healthcare teamwork by using pharmacists as part of a multi-disciplinary team in non-acute settings has been linked with better patient impact to increase symptom control in chronic disease.[142] Literature also suggests that patient indifference to pharmaceutical care was diminished by having a pharmacist integrated into the medical centre compared to a community pharmacy.[40] At an international level, there is evidence to support the benefits to patients with the addition of pharmacists to general practice teams.[122,265] At a UK level, this includes NHS England in 2016 investing £100 million with the aim of integrating pharmacists in 40% of all NHS general practices by 2021 following a successful pilot integrating 491 pharmacists in general practice sites.[14] Known benefits of pharmacists working in general practice with doctors include access to the

patients' medical files and increased rapport/communication between the pharmacist and GP.[40]

In previous studies in Australia, it has been noted that pharmacists have not historically been included in multidisciplinary general practice teams and that it would take time to develop and build relationships to allow true collaboration to develop.[14] As pharmacists have been present in general practice in Scotland since the late 1990s, this is less of an issue for this study and shows that this synergistic relationship is of definite benefit to all- GP, pharmacist and patient. Most previously published studies of pharmacists input into general practice discussed thoroughly the issue of how many of the pharmacists' recommendations were agreed with by the GP and actioned. As pharmacist independent prescribers, this issue is irrelevant in this study and demonstrates the holistic benefit of having a prescribing pharmacist onsite. This shows that having practice prescribing pharmacists in general practice can overcome some of the barriers and drawbacks experienced and mentioned in previous studies investigating whether pharmacists can help with chronic disease management by eliminating the need for a GP to check, agree, and action any suggested changes.

As health boards across the UK and wider afield are using more and more practice-based pharmacists to help deliver contract specifications, it is imperative that the profile of pharmacists is raised with the general public, so they understand and have confidence in who they are seeing and what actions and skills (including prescribing) that a practice-based pharmacist has to offer. The data gathered during this work shows that patients, while not fully understanding

the pharmacist's role in general practice, appreciated receiving visits from healthcare professionals**.** Indeed, not only did patients struggle with understanding a pharmacist's role in primary care, with previous studies having identified that hospital administration struggled to understand the benefits pharmacists could provide compared to other providers, including nurses with expertise in chronic diseases[262], more needs to be done to help educate the public as to the role the pharmacists play in primary care.

An important role is emerging for pharmacists with direct patient-care responsibilities[36] with the role, impact, and value, that pharmacists contribute to primary care being recognised as significant.[17] Over the last 30 years, pharmacists have developed novel non-technical patient-facing roles across the globe.[36] The NHS in England states that one of the aims of the clinical pharmacist in general practice is to manage patients with long-term conditions.[266] Practice pharmacists have a range of functions including administrative and clinical duties related to their expertise in medication use and safety.[265] There is evidence that non-dispensing or clinical services provided by pharmacists in the outpatient setting may result in improved patients' outcomes and prescribing patterns.[265] This gives encouragement that the setting for this study is appropriate and that practice pharmacists can improve care for patients in the community as well as prescribing habits.

The themes identified within this research demonstrate that chronic disease management by the practice pharmacist was acceptable to housebound patients

and further work should be undertaken to ascertain a wider audience view so we can further develop this service and ensure it is suitable for patient's needs.

> *'The pharmacist aye. You are better, you know what you are dealing with, you know what you need to set up. Aye. The doctor doesn't have too much time anyway. He just ups and go on to another patient. [sic] Aye doctors are too busy. '*
>
> *Patient 1*

Whilst current literature is uncertain whether pharmacist-led medication reviews for community dwelling patients prevent hospitalisations or improve quality of life, such services have been effective in identifying and resolving medication-related problems, improving prescribing quality, and optimising medicine use and costs.[16] One of the advantages of having practice-based pharmacists undertake these domiciliary COPD reviews is their ability to be able to review the patient holistically and be able to address any other medication needs for other medical conditions. This is an important issue seeing as how the majority of patients in the study had one or more comorbidities ranging from cardiac to endocrine. While it has been acknowledged that community-based pharmacists could also undertake this role, studies have shown that having an integrated pharmacist in the general practice surgery aide's communication and integrated working to ensure any necessary interactions such as any changes to prescribing are actually carried out without adding to the GPs workload.[265] On the other hand, being able to access GP help easily, is also an advantage for a practice-based

pharmacist, in that if they felt they needed to run something by a GP or refer a patient onto another health professional, then there is an easily accessible route for doing this.

This study demonstrates that pharmacists acting as part of the general practice team can be effective at making recommendations to improve COPD patient's pharmacotherapy and with conducting activities to support patient education and disease management. As we know previous evidence suggests that existing health care provision for COPD patients is reactive and focuses on acute exacerbations,[146] it is important that we continue to strive to provide regular care for our housebound patients. COPD not only impacts on patients' physical wellbeing but also their social and psychological health.[146] Future use of this analysis may assist with standardisation of the primary care pharmacist role and development of future services and may aid in the development of a new model of integrated primary health care services involving a pharmacist practitioner looking after a cohort of patients with chronic disease.

Previous research has noted that the role, impact, and value that pharmacists contribute to primary care is significant.[17] However, this piece of work showed that patients and their carers do not have a good understanding of the role of a practice pharmacist and what kind of skills they can bring to the role. In order to address this finding, it is important that we increase the visibility and credibility of the role of pharmacists in primary care to the general public. This finding has been shared in other work which felt that to strength the successful integration of

pharmacists into PCTs practice settings, it is critical to ensure there are opportunities and support available for the increased visibility of pharmacists as PCT ambassadors.[17]

The intervention did not have a significant effect on patients self-reported HRQoL, and this finding is consistent with other medication review studies.[265] Follow up duration may not have been long enough to detect changes in these parameters. The visits to the housebound patients revealed many issues that may not have otherwise been identified. It was recognised in an English study published in 2012 regarding housebound annual reviews by nurses that no one intervention, no matter how well it is executed, will be enough by itself to prevent hospital admission.[89]

8.3 Covid 19

As health care responded to the new restrictions due to the Covid-19 pandemic, more virtual ways of undertaking chronic disease management were looked at. One emerging model which could be considered as suitable to help housebound patients such as those in this study is Virtual Group Visits (VGVs). VGVs have emerged as a viable alternative care delivery model for safely and effectively managing chronic diseases via telehealth.[267] This model involves seeing multiple people at the same time in the same place (in this case using telehealth remotely) to allow the sharing of education and peer support in addition to individual care.

To date though, there is a lack of evidence of cost effectiveness and generalisability to different settings and populations such as COPD patients.[267]

The increased risk to COPD patients with the identification of the Covid-19 virus in 2020 led to NICE releasing a Covid-19 rapid guideline: community-based care of patients with chronic obstructive pulmonary disease (COPD).[268] At a time where both secondary care and primary care were stretched beyond capacity, practice pharmacists were in a prime position to be able to help the overall healthcare response to the crisis. Part of this role entailed myself and several other pharmacists in Glasgow explaining to patients with COPD and their families and carers that they are at increased risk of severe illness from Covid-19 and to advise them on isolation measures brought in by the government. This also involved the prescribing of rescue packs of steroids and/or antibiotics as deemed appropriated on a case-by-case basis. As an independent prescriber, I was able to undertake this role autonomously and take workload off the doctors who were themselves stretched due to colleagues having the virus, having to isolate, or being redeployed to hospital or the Covid-19 Assessment Centres. I also trained as a vaccinator and helped vaccinate as well as secure the cold chain as did several of my pharmacy colleagues in Scotland during the pandemic. While these circumstances were less than ideal, it has shown that pharmacists can play an important role in primary care.

8.4 Future Work

Further work should be undertaken to look at the utilisation of practice pharmacists for domiciliary chronic disease patients. This would allow a cohort of patients who previously only had their healthcare addressed at a time of acute illness to be provided with a holistic comprehensive polypharmacy review annually to prevent or decrease their rate of decline. While COPD was chosen as the one disease state to focus on for this project, it is acknowledged that other chronic diseases may also be applicable for receiving a domiciliary visit from a practice pharmacist and indeed this is an area of extension of this project which should be developed further. It would also be interesting to examine whether HRQoL results from domically visits varied by which chronic disease state the patient received the review for. Currently, where care including health related care for the elderly is receiving a lot of attention from the media, as well as the health boards throughout the UK due to our ever-increasing elderly population, it is imperative that we look at what services and packages of care we can put in place to enable our elderly to have the best level of HRQoL possible while dwelling in their own homes.

It is known that health and social care budgets must work harder and harder, year on year, leading to conversations within the NHS about which initiatives provide the best value for money or even safe public money.[269] There are some main building blocks that are required when undertaking any economic evaluation including;

- Effectiveness
- Time period of effectiveness
- Cost of the intervention
- Perspective of the analysis[269]

Economic evaluations show that pharmacotherapy for COPD is cost effective, therefore it is important that patients are on the right medications for COPD and using them correctly to reduce exacerbations and hospitalisations.[270] While this does not directly relate to pharmacists conducting domiciliary COPD visits, there is a case to be made for the ensuring that COPD patients are on the right medications regardless of whether they are housebound or not. The NHS also has a duty of care to all patients and to ensure they are not penalised by their inability to attend the GP practice for review of chronic conditions. With this said, it is important, that as a public service, that best use of finances and resources are utilised. It would therefore be beneficial to conduct further reviews for house bound patients with different bands of pharmacists and to record and itemise medication changes for each patient to determine any cost benefit of each visit. In addition, a longitudinal study would be beneficial to see if exacerbations and hospital admissions are reduced over the year after an annual review. Each COPD domiciliary review conducted by a pharmacist cost £72 in this study which is less than a GP home visit costing £121 and a severe COPD exacerbation costing £1263.76, as shown in Table 1.5 on page 18. This shows that pharmacists are cost effective to perform COPD domiciliary reviews although it is acknowledged more research is needed into the effectiveness of these visits in reducing hospital admissions and HRQoL.

The COPD populations in England and Scotland are projected to increase substantially over the coming years to 2030.[70] In those with established COPD there is a probability to profess to the next level of COPD severity as time progresses.[1] It is also known that lung function declines with exacerbations. There will also be increases in the healthcare costs of COPD patients and the number of deaths among COPD patients. These increases need to be taken into account by policy makers when planning healthcare deployment and resource allocation for the future.[1] It has been noted that due to the growing prevalence of elderly patients with multi-morbidity living at home, that there is an increasing need for primary care professionals from different disciplinary backgrounds to collaborate within primary care teams.[271]

It was acknowledged back in 2001 by the Department of Health that service developments or new services need to be innovative, creative, and very different, redesigned around the needs of the patient.[145] Future work on the topic of housebound patients receiving pharmacist led reviews for any chronic disease, not just COPD, is invaluable to be able to provide a vulnerable group of patients with the routine healthcare they deserve. While common opinion is that integrated care for patients with chronic conditions may improve patients' outcomes,[20] further evidence on a wider scale is necessary to show whether pharmacist annual reviews can provide an increased HRQoL as well as reduce hospitalisations.

Past literature has reported that patient indifference to pharmaceutical care was diminished by having a pharmacist integrated into the medical centre compared

to a community pharmacy.[40] As practice pharmacists are embedded in the GP practices, this shows our setting is appropriate for this project and for services going forward being provided by pharmacists in GP practices however, further work should also be undertaken on a nation-wide scale to help educate the public as to the role of practice-based pharmacists. This issue will be raised locally within the GGC health board to see if we can put measures in place locally to try to raise the profile of practice-based pharmacists.

The outcome of the professional activities undertaken by a pharmacist is often done without the patient in front of them. In addition, during a consultation with a pharmacist, the person may not be manipulated physically as during a consultation with the family doctor or physiotherapist.[272] The outcome of the professional activity, therefore, may not be obvious to the person. In this context there is a potential danger that the pharmacy professionals, as a silent partner in healthcare and, as such, reinforce a possible belief that it does not contribute greatly to health outcomes.[272] Hopefully as the UK has now launched a new advance pharmacist practice curriculum and credentialing process to support advanced skills development for pharmacists,[36] there will be further opportunities for pharmacists in primary care to be involved in housebound patients with chronic diseases as a cohort of patients.

8.5 Final Remarks

Health systems research has been defined fairly broadly as ultimately concerned with improving the health of a community, by enhancing the efficiency and effectiveness of the health care system as an integrated part of the overall process of socio-economic development.[211] The focus is generally on the relationship between the populations' need and demand for health services, and the supply, use, and acceptability of health services; the processes and structures, including the quality and efficiency of health services.[211] It is also focussed on the appropriateness and effectiveness, including patients' perceptions of the outcome in relation to the effects on their HRQoL and their satisfaction with the outcome.

Higginson stated that quality of care needs to include humanity, as well as effectiveness, acceptability, equity, accessibility and efficiency.[273] Disease-specific HRQoL scales are needed not simply for greater brevity, but to ensure sensitivity to sometimes small, but clinically significant changes in health status and levels of disease severity.[211] This service provided routine care to housebound patients who would usually have been offered a review of their chronic disease annually only if they were able to attend the GP surgery. While no significant change in HRQoL or change in MRC was noted over the short duration of time of the project, the impact of the pharmacist review both medically and socially was noted.

The project was aimed to evaluate the impact of a practice pharmacist providing a domiciliary COPD review, to find out whether it represented an improvement in service provision for housebound patients, and so guide improvement and development of the service for other chronic diseases. This work has shown that there is opportunity for health and social care partnerships to explore and establish new social networks of support.

A number of effective strategies have been developed to improve the quality of life in patients with COPD however, few have been implemented in patients with COPD at all stages in a community setting.[274] Practice pharmacists are ideally placed to support the national outcomes strategy for COPD by providing appropriate management of those with moderate/severe COPD by supporting shared decision-making regarding treatment, which minimises progression, and on-going unscheduled care, and risk of death.[275] The European Active and Healthy Ageing Innovation Partnership recognised the need to increase the pharmacist's role in improving the health of the older population through multi-disciplinary working.[11] Shifting interventions from acute and reactive care for COPD to a more equitable, proactive, rehabilitative, and preventative nature, may overall provide better service to patients, reduce hospitalisations, and improved outcomes for patients. While this study was for a small cohort of patients, the design was such that it has the potential for application to housebound patients with other long-term conditions.

Previous studies have shown that general practice pharmacists can play an integral role in reducing medication burden by facilitating dose reduction and

cessation of medications.[276] Meta-analyses and systematic reviews have provided an evidence base for pharmacist-led medication optimisation reviews and non-medical prescribing by pharmacists.[36] By making recommendation to optimise therapy in patients with chronic diseases, pharmacists have demonstrated their ability to support GPs in the complex treatment of patients taking multiple medications.[122] Previous research has also noted that to firmly establish the business case, the role of the practice pharmacist in housebound chronic disease annual reviews needs to be defined to highlight the unique contributions that a pharmacist can provide within a multidisciplinary, collaborative care model.[12]

This study sheds light on an isolated and inaccessible group of patients who regularly do not routinely receive preventative care for chronic diseases. The intervention did not have a significant effect on patients' self-reported general health or health service utilisation, and this finding is consistent with other medication review studies.[16] In listening to patients accounts of their experiences, a mismatch between patients' needs and the current primary care services received has been shown. The recent pandemic of Covid-19 has only compounded this fact. Breathlessness can restrict patients' freedom by impairing their mobility and their ability to get out of their home. This deprives patients of their independence, with some becoming housebound and isolated. It is important that this cohort of patients is provided with appropriate care. This is also true for other housebound patients with chronic diseases and not just limited to COPD patients. This study suggests that pharmacists co-located within primary care clinics may improve medication outcomes for patients at risk of

medication related problems and that these services are acceptable patients. With our ever-increasing elderly population and plans to keep patients in their own homes as long as possible, it is vital that we ensure we provide the same level of care to housebound patients with chronic diseases as those who can attend GP practices.

Setting up a service for housebound patients to provide an annual review for long-term condition(s) has the potential to identify and manage chronic diseases in a cost effective and timely fashion to prevent reactive management.[91] Pharmacists can work within primary care collaboratively but autonomously as advanced practice practitioners assisting with the holistic pharmacological managements of many chronic diseases as well as addressing non-pharmacological management such as smoking cessation, exercise, and diet. General practice pharmacists can play an integral role in reducing medication burden by facilitating dose reducing and cessation of medications by deprescribing. By not only recommending but also actioning recommendations to optimise therapy in patients with chronic disease, pharmacists have demonstrated their ability to support GPs in the complete treatment of patients taking multiple medication.[122]

8.6 Overarching Points for Future Practice

This thesis has shown that there is a need for housebound patients to be able to access routine health care resources to benefit patient care and medication adherence. It is important that patients are not penalised due to their housebound

status and still receive proactive care for chronic diseases in a format that is acceptable for them. Further work now needs to be done with a larger number of patients for a wider range of chronic diseases to see if these findings can be replicated. In addition, a longitudinal study would be beneficial to determine if HRQoL improves, and hospital admissions and number of exacerbations reduce, over time. While the NICE guidelines indicate that this would be the case, undertaking a longitudinal study would give us a wider breadth of data and may help to provide additional cost saving data in relation to reduced admissions. While this initial piece of work has shown the feasibility and acceptability of a pharmacist led domiciliary chronic disease service, it has also highlighted a lack of patient knowledge of what activities a pharmacist can undertake. This has raised the need for the public to understand the value and role pharmacists can play across all healthcare sectors. The public would benefit from an educational campaign as to the roles and responsibilities of pharmacists within the UK to provide patients with confidence in their healthcare provider as well as raise the profile of pharmacists as valuable qualified professionals that provide expert medicines advice for a multitude of chronic diseases while also providing holistic patient centred care for all patients in all walks of life.

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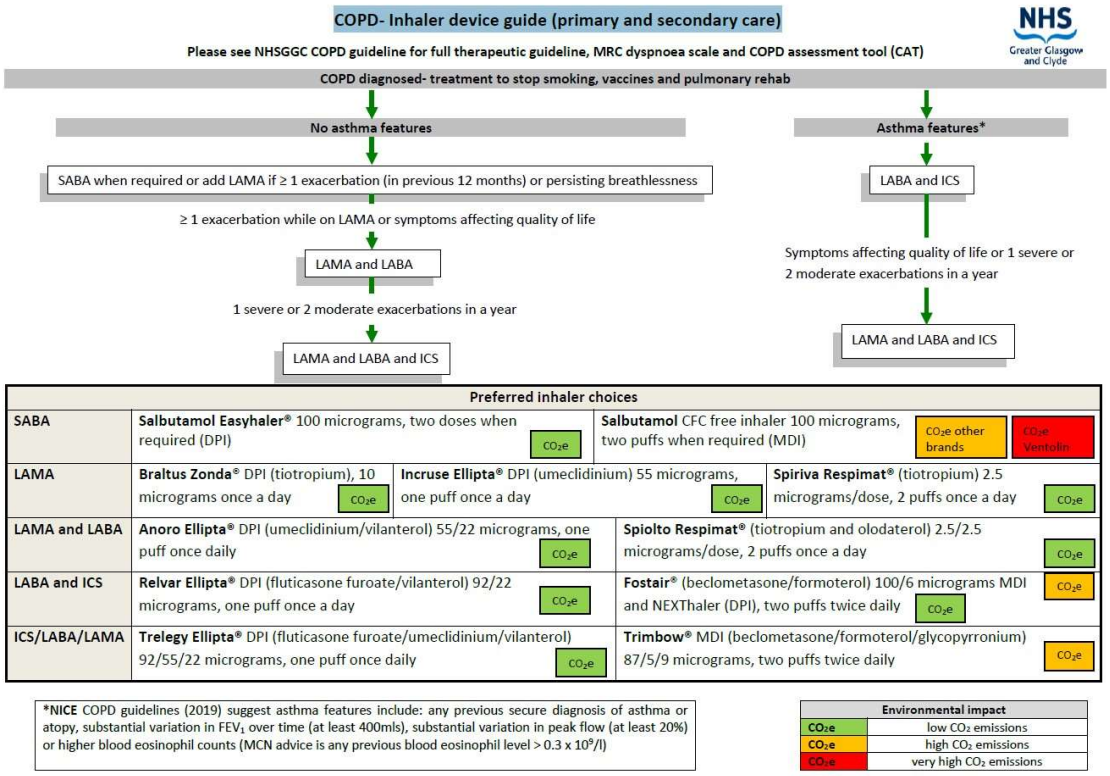
Appendix 1. NHS Greater Glasgow and Clyde Guidelines for COPD



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Appendix 2. Literature Search Results

The Allied and Complementary Medicines Database (AMED), Medline, American Psychological Association's (APA) PsycInfo and PsycArticles, SPORTDiscus, Ageline, CINAHL Plus

Search Terms	Total number of results
(COPD OR 'chronic obstructive pulmonary disease') AND pharmacist AND ('primary care' OR 'general practice' OR 'PCT' OR 'CHP')	27
((COPD OR 'chronic obstructive pulmonary disease') AND pharmacist AND ('primary care' OR 'general practice' OR 'PCT' OR 'CHP')) AND pharmacist AND ('home visit' OR domicill*)	24
(COPD OR 'chronic obstructive pulmonary disease') AND pharmac* AND ('primary care' OR 'general practice' OR 'PCT' OR 'CHP')	309
pharmacist AND ('primary care' OR "general practice' OR 'prescribing support pharmacist' OR 'PSP') AND (copd or chronic obstructive pulmonary disease or chronic bronchitis or emphysema or chronic obstructive airway disease or coad or airflow obstruction or centriacinar emphysema or panacinar emphysema or distal acinar emphysema or paraseptal emphysema)	31

Appendix 3. Critical Appraisal Skills Programme

CASP Randomised Controlled Trial Standard Checklist:
11 questions to help you make sense of a randomised controlled trial (RCT)

Main issues for consideration: Several aspects need to be considered when appraising a randomised controlled trial:

- Is the basic study design valid for a randomised controlled trial? (Section A)
- Was the study methodologically sound? (Section B)
- What are the results? (Section C)
- Will the results help locally? (Section D)

The 11 questions in the checklist are designed to help you think about these aspects systematically.

How to use this appraisal tool: The first three questions (Section A) are screening questions about the validity of the basic study design and can be answered quickly. If, in light of your responses to Section A, you think the study design is valid, continue to Section B to assess whether the study was methodologically sound and if it is worth continuing with the appraisal by answering the remaining questions in Sections C and D.

Record 'Yes', 'No' or 'Can't tell' in response to the questions. Prompts below all but one of the questions highlight the issues it is important to consider. Record the reasons for your answers in the space provided. As CASP checklists were designed to be used as educational/teaching tools in a workshop setting, we do not recommend using a scoring system.

About CASP Checklists: The CASP RCT checklist was originally based on JAMA Users' guides to the medical literature 1994 (adapted from Guyatt GH, Sackett DL and Cook DJ), and piloted with healthcare practitioners. This version has been updated taking into account the CONSORT 2010 guideline (http://www.consort-statement.org/consort-2010, accessed 16 September 2020).

Citation: CASP recommends using the Harvard style, i.e., *Critical Appraisal Skills Programme (2021). CASP (insert name of checklist i.e. Randomised Controlled Trial) Checklist. [online] Available at: insert URL. Accessed: insert date accessed.*

Appendix 4. List of Inhalers available for COPD

Respiratory Inhaler Identification Chart

NHS Greater Glasgow and Clyde

Examples of different inhaler devices are illustrated to aid identification. Please note different strengths may be different colours from those illustrated. Some of these inhalers may not be included in the NHSGG&C formulary. See http://www.ggcprescribing.org.uk/ for formulary status, inhaler device guidance and NHSGG&C Guidelines. Refer to BNF and SPC for full product information.

Appendix 5. Pilot Feedback Form

Feedback Form

It would be really helpful for us to get your feedback on this home review by the pharmacist in order to develop it for the future. Please spend a few minutes completing this short feedback form. Forms are anonymous and any comments good or bad will be taken into consideration to make this as useful as possible going forward.

		1 ***Very unsatisfied*** 	2	3	4	5 ***Very Satisfied*** 
1	**How satisfied are you with the pharmacist review of your breathing condition today?**					
2)	**How satisfied are you with the pharmacist taking to you about your other**					

	medications and medical conditions?					
3)	**How satisfied are you with receiving this review in your home?**					
4)	**How satisfied are you with having this review conducted by a pharmacist?**					

Are there any other comments you would like us to take into account with regards to your pharmacist visit and review today?

……

……

……

……

Thank you

Appendix 6. NHS Ethical Approval Email

Advice on research

GJ

Godden, Judith

To:

- Ballantyne Susan (NHS GREATER GLASGOW & CLYDE - SGA20) <susan.ballantyne@nhs.net>

Fri 21/08/2015 11:20 AM

Dear Susan

I think this makes it clearer that the study is a pilot of a possible service development. A service development will need to inform the service therefore you require the relevant permission within the service. If that is Respiratory MCN then that would be appropriate.

Thanks

Judith

From: Ballantyne Susan (NHS GREATER GLASGOW & CLYDE - SGA20) [mailto:susan.ballantyne@nhs.net]
Sent: 18 August 2015 14:13
To: Godden, Judith
Subject: RE: advice on research

thank you so much for taking the time with this. I have tried to reword a bit to go forward as a proposed service development and have attached the revised document.

You mention having to check with the clinical department whose area this is in- sorry for my ignorance- but do you mean the respiratory MCN?

many thanks

Susan
Susan Ballantyne
Prescribing Support Pharmacist

North East Sector Prescribing Team - Glasgow City CHP
Parkhead Health Centre Room 43
101 Salamanca Street
Glasgow
G31 5BA

(off Thursdays)

alternative email for social work-

From: Godden, Judith [Judith.Godden@ggc.scot.nhs.uk]
Sent: 12 August 2015 09:48
To: Ballantyne Susan (NHS GREATER GLASGOW & CLYDE - SGA20)
Subject: RE: advice on research

Dear Susan

There are aspects of both research and service development in the study. The population though are being selected because they are in need of routine care, ie an annual review and therefore I would suggest this is part of a service development. You will need to be able to state that this is a pilot of a proposed service development.

Your title is a research question but I am not sure if the methodology would be able to answer the question as there is no control. Are you using the patients as their own controls?

Alternatively you are piloting a service which fulfils current NICE guidelines and looking at acceptability of a pharmacists' review to patients.

My overall opinion would be that the project is better described as a service development but may need some rewording to make this clear. The project if it is not defined as research does not require NHS ethical review but may require to be reviewed within your University REC. R&D does not approve service development projects but instead the Clinical Department would need to approve the project going ahead in their area and would want to see the outcome of the study.

Kind regards

Judith

From: Ballantyne Susan (NHS GREATER GLASGOW & CLYDE - SGA20) [mailto:susan.ballantyne@nhs.net]
Sent: 11 August 2015 15:45
To: Godden, Judith
Subject: RE: advice on research

thanks for your help- I have gone through the tool a couple of times and I am afraid I am still a bit undecided. As you have kindly suggested, I have attached a one page summary of my study to see what you think.

COPD annual reviews have been carried out by general practices routinely for years- the difference with this is it is domiciliary in nature and carried out by practice pharmacists rather than nurses or GPs. It also involves a semi-structured interview to examine patients thoughts and feelings about this.

many thanks for your help,

Susan
Susan Ballantyne
Prescribing Support Pharmacist
North East Sector Prescribing Team - Glasgow City CHP
Parkhead Health Centre Room 43
01 Salamanca Street
Glasgow
G31 5BA

(off Thursdays)

alternative email for social work- Susan.Ballantyne@ggc.scot.nhs.uk

---

From: Godden, Judith [Judith.Godden@ggc.sot.nhs.uk]
Sent: 07 August 2015 09:14
To: Ballantyne Susan (NHS GREATER GLASGOW & CLYDE - SA20)
Subject: RE: advice on research

Dear Susan

I would advise that you check whether your project will be classed as research. If you follow the link then you will find a useful tool to help you decide o this. Any problems you can send me a short summary of the man aims of your project and the methodology.

http://www.hra-decisiontools.org.uk/research/

Once you have checked that the project is research then you can get in touch with R&D in GG&C through one of the R&D Coordinators. I have listed Dr Maureen Travers as she has responsibility for your disease area Maureen.travers@ggc.scot.nhs.uk but she may pass you over to another member of the R&D team.

The R&D Department will decide whether GG&C will act as sponsor for the study.

Kind regards

Judith

Dr Judith Godden
Manager/Scientific Officer
West of Scotland Research Ethics Service
Tennent Institute
Western Infirmary
Glasgow G11 6NT

Tel: 0141 211 2126
e-mail: judith.godden@ggc.scot.nhs.uk

From: Ballantyne Susan (NHS GREATER GLASGOW & CLYDE - SGA20) []
Sent: 31 July 2015 16:09
To: Godden, Judith
Subject: advice on research

Hi there- I am a prescribing support pharmacist in the North East and I am currently working towards a doctorate with Keele University. As part of this, I am looking to conduct a research project into practice pharmacist domically reviews for housebound COPD patients using mixed methodology and semi-structured interviews to try to find out what patients think of these reviews as well as gathering data on their health related quality of life and adherence levels etc

I have started (tyring) to fill out an IRAS form and uni have been very helpful They have advised me to contact my local R&D team to discuss if its going to be possible for them to act as a sponsor.

I would be very grateful if you could point me in the right direction of who (and how!) to ask this question.

many thanks for your help,

kind regards,

Susan
Susan Ballantyne
Prescribing Support Pharmacist
North East Sector Prescribing Team - Glasgow City CHP
Parkhead Health Centre Room 43
101 alamanca Street

Glasgow
G31 5BA

(off Thursdays)

alternative email for social work- Susan.Ballantyne@ggc.scot.nhs.uk

Appendix 7. Participation Information Sheet

Review of patients receiving a home Chronic Obstructive Pulmonary Disease (COPD) annual review

Invitation

You are being invited to take part in a study about receiving a home COPD review. This study is being conducted by a Greater Glasgow and Clyde prescribing support pharmacist, Susan Ballantyne as part of a doctorate study at Keele University to try to make our services suit patients needs better and improve their health related quality of life.

What is the purpose of this study?

We are undertaking this study because we are aware that some patients do not manage to attend annual reviews for their medical conditions because they cannot get to the surgery. This study is to look to see if a home visit by a pharmacist to undertake an annual review would be beneficial and whether it would be worthwhile rolling out this service for more people across Glasgow and beyond.

Why have I been chosen?

You were selected as a possible participant in this study because you have COPD or a similar breathing problem.

Do I have to take part?

It is up to you whether or not to take part. If you choose to take part you will first be asked to confirm your consent and you can still withdraw at any time. You do not need to give a reason. Your decision whether or not to participate in this study will not affect your medical care. If you would like to receive a pharmacist home annual review but NOT take part in the study that is absolutely fine and will be arranged.

What will happen to me if I take part and what do I have to do?

If you decide to take part you will be invited to have a practice pharmacist visit you at home to conduct an annual review of your breathing condition and ask about how you are getting on with your medications. This can take between 30 minutes and 60 minutes depending on how many medications you are on and how stable your condition is. They will also check your blood pressure using an automatic machine on your arm and measure your oxygen level by using a device which fits on your finger.

A second home visit approximately a month after your first visit will also be conducted by a different qualified practice pharmacist to see how you are getting on since your initial visit and will recheck your blood pressure and oxygen level. This second visit will also consist of a 30 minute digitally recorded interview of what you thought of the review and what you thought of a pharmacist carrying out the review rather than say, a nurse or doctor. The interview is anonymous. No one will be able to identify you or your answers.

What are the possible disadvantages and risks of taking part?

We are not aware of any disadvantages or risks to you in taking part in the study.

Who will have access to information about me?

All of the information collected as part of the COPD annual review will be recorded on the computer system within your medical practice so that it can be used to help inform future treatment decisions however all information from the interview during the second visit will NOT be made available to anyone within your doctors surgery. This digitally recorded information will be stored on password-protected media that only the pharmacist who is conducting the study will have access to. Hardcopies of data and other documentation containing personally identifiable information about you will be kept secure and at the end of the study all of the data and documents from the interview will be destroyed. You will not be able to be identified in any reports or publications.

How will information about me be used?

The results (including anonymised short direct quotes) will be included in a report as part of a Doctorate in Pharmacy at Keele University, and may subsequently be published as research papers in academic journals and presented at conferences. No individual person will be identifiable in any direct quotes, reports, papers, presentations or summaries. The results of the study might also be used for subsequent research.

What if I have a question?

If you have a concern or query about any aspect of this study, you may wish to speak to the pharmacist undertaking the study who will do their best to answer your questions. You should contact her (Susan Ballantyne) at susan.ballantyne@nhs.net or you can phone the North East prescribing team administrator on 0141 277 7452 who will put you in touch with someone who can assist you. You can also discuss with the practice manager at your doctors surgery.

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time. You are also free to decline to answer any particular question you do not wish to answer for any reason.

Appendix 8. Patient Ethical agreement letter

System Date Long

PRIVATE AND CONFIDENTIAL

Title Forenames Surname,

Dear Title ,

Review of patients receiving a home Chronic Obstructive Pulmonary Disease (COPD) annual review

You are being invited to take part in a study about receiving a home COPD review. This study is being conducted by our prescribing support pharmacist, Susan Ballantyne as part of a postgraduate course at Keele University to try to make our services suit patients' needs better.

We are undertaking this study because we are aware that some patients do not manage to attend annual reviews for their medical conditions because they cannot get to the surgery. This study is to look at if a home visit by a pharmacist to undertake an annual review would be beneficial and whether it would be worthwhile rolling out this service for more people across Glasgow and beyond.

You were selected as a possible participant in this study because you have COPD or a similar breathing problem. If you agree to this study Susan will visit

you in your home to conduct a review of your breathing condition. She will then ask you to fill in a short (4 questions) questionnaire. The questionnaire is anonymous. No one will be able to identify you or your answers. They will be included in a report as part of course at Keele University, and may subsequently be published as research papers in academic journals and presented at conferences. No individual person will be identifiable in any direct quotes, reports, papers, presentations or summaries. The results of the study might also be used for additional or subsequent research.

Your participation in this study is entirely voluntary. Your decision whether or not to participate in this study will not affect your medical care. If you would like to receive a pharmacist home annual review but NOT take part in the study that is absolutely fine and will be arranged.

If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time. You are also free to decline to answer any particular question you do not wish to answer for any reason.

If you have any questions about the study, please contact Susan Ballantyne at susan.ballantyne@nhs.net or via the practice.

Alternatively you may also contact the Practice Manager, Mrs AA, if you wish any further information on this project on 0141 xxx xxxx.

CONSENT SLIP

I consent to participate in this evaluation and understand that I have the right to withdraw from the project at any time without in any way affecting my medical care.

Print Name of Participant: Title Forenames Surname

Signature of Participant _____

Date of Birth_____

(Day/month/year)

Date _____

(Day/month/year)

Appendix 9. Exclusion Criteria

1) Those with a terminal illness diagnosis who had less than 2 months expected to life (as determined via their status on the palliative care register and via GP discussion). Please use your professional judgement or ask the patients regular GP. The reason for this is to prevent causing upset or disturbing a patient unnecessarily. If you feel they could benefit from a review by looking at their paper notes i.e., you could reduce the number of inhalers, you can still go ahead. Palliative patients are still included in this service development as they could still get symptomatic benefit or relief from a COPD annual review.

2) Those with dementia or where lacking capacity where it would be detrimental to review their condition (i.e., cause upset or confusion by asking questions). Please use your own professional clinical judgement here as to whether include or not. Err on the side of caution. If you start the visit and then find that the patient would struggle with visit two then just complete the first visit and don't ask them to be part of the study.

3) Households where violence towards others or physically or verbally abusive behaviours were present (if recorded in patients notes). Please ensure your own safety- this is paramount. As well as referring to the lone working policy, please ask practice staff to see if they have any local knowledge. 2 person visits can also be conducted if deemed necessary- do not put yourself at risk.

Appendix 10. Patient Data Collection Form

Pharmacist COPD Review **Completed:**

Patient details					
Name **Address**		**Age** **&** **DOB**		**GP**	
Telephone Number					
CHI					
History					
Medical Conditions ***Include date of diagnosis***					

Living status ***Alone? With family? etc***				
Any family to contact /carers? ***include contact details if appropriate***				
ADR's				
ADR's **Medicines-** **Repeats**	**Form**	**Weight** ***& date recorded*** **BMI**		
		Dose	**Quantity**	**Date last issued**
Medicines- Acutes	**Form**	**Dose**	**Quantity**	**Date last Issued**

Clinical information				

Housebound?					
On Dosette box?		**Problems with sight?**		**Problems with hearing?**	

Who is pharmacy?			
Blood Pressure			
Pulse		**Date taken**	
Spirometry ***FEV1 and FEV1/FVC ratio***	**FEV1=** **FEV1/FVC=**	**Date taken**	
Disease Severity ***as amended by NICE, 2010***	**□ Mild: FEV1 >80% predicted (if symptomatic).** **□ Moderate: FEV1 50-79% predicted.** **□ Severe: FEV1 30-49% predicted.** **□ Very severe: FEV1 <30% predicted.**	**Date taken**	
CXR *last on file* ***- record any findings***			
Pulse oximetry		**Date taken**	

Last MRC grading		**Date taken**	
Influenza vaccine?		**Date last given**	
Pneumo vaccine?		**Date last given**	
Smoker?	**Current / Ex-smoker / Never smoked**	**Date last given**	
If so- pack years ***(daily smokes x years of smoking divided by 20).***			
Daily inhaled steroid dose? ***in mcgs***			
BTS current step			
Previous inhalers tried? ***(and reason for discontinuation)***			
Currently seeing any sec care respiratory?			
Current Nebuliser?			
LTOT? ***If yes- how many litres per ay***			

Date of last COPD annual review			
Number of breathing related hospital admissions in last 12 months			
Number of exacerbations in last 12 months needing oral steroids +/or antibiotics		**Number of breathing related OOHs admissions in last 12 months**	
Attended pulmonary rehab If so when last			
Receiving palliative care?			

Appendix 11. Visit One Paperwork

Notes for Review	
Risk assessment carried out for home visit?	
MRC scoring *Breathlessness assessment*	
Pulse Oximetry	
Medication Review	
Overall compliance with all meds	
Compliance with inhalers	
Adherence questionnaire *(separate)* **Total score**	□ <6= low adherence □ 6-<8= Medicine adherence □ 8= high adherence
Inhaler technique? *(good, moderate, poor)*	

Include visual check	
CAT score?	
Smoking cessation?	
Nutritional status? *Consider MUST tool*	
Signs of anxiety/depression?	
Osteoporosis assessment? *Use WHO FRAX*	
Referred for pulmonary rehab?	
Respiratory for consideration of LTOT?	
Notes	
GP	
Occ Health	
Dietician	
Spacer given	
Inhaler device changed	

Inhaler changed	
COPD info given	

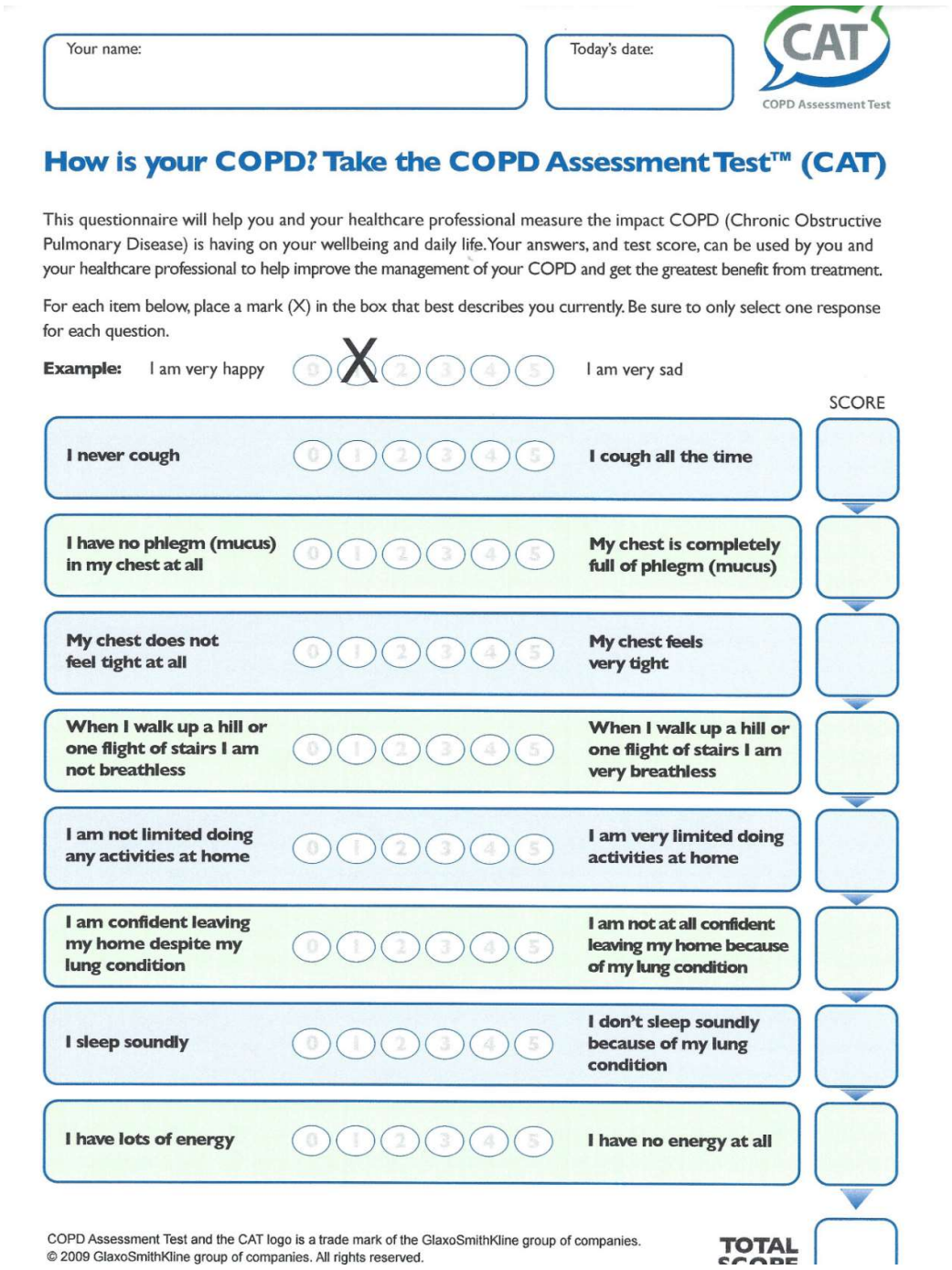
Distance travelled and Time taken	
Time taken for work up in practice	
Time taken to travel to home visit	
Time taken for actual visit	
Time taken to travel back to practice	
Time taken by pharmacist/technician to action and complete any changes in practice	

Pharmacist Name……...……

Date…….

Signature……..…….

Appendix 12. CAT Score



Your name:

Today's date:

CAT
COPD Assessment Test

How is your COPD? Take the COPD Assessment Test™ (CAT)

This questionnaire will help you and your healthcare professional measure the impact COPD (Chronic Obstructive Pulmonary Disease) is having on your wellbeing and daily life. Your answers, and test score, can be used by you and your healthcare professional to help improve the management of your COPD and get the greatest benefit from treatment.

For each item below, place a mark (X) in the box that best describes you currently. Be sure to only select one response for each question.

Example: I am very happy 0 X 2 3 4 5 I am very sad

			SCORE
I never cough	0 1 2 3 4 5	**I cough all the time**	
I have no phlegm (mucus) in my chest at all	0 1 2 3 4 5	**My chest is completely full of phlegm (mucus)**	
My chest does not feel tight at all	0 1 2 3 4 5	**My chest feels very tight**	
When I walk up a hill or one flight of stairs I am not breathless	0 1 2 3 4 5	**When I walk up a hill or one flight of stairs I am very breathless**	
I am not limited doing any activities at home	0 1 2 3 4 5	**I am very limited doing activities at home**	
I am confident leaving my home despite my lung condition	0 1 2 3 4 5	**I am not at all confident leaving my home because of my lung condition**	
I sleep soundly	0 1 2 3 4 5	**I don't sleep soundly because of my lung condition**	
I have lots of energy	0 1 2 3 4 5	**I have no energy at all**	
		TOTAL SCORE	

Appendix 13. Morisky 8-point adherence questionnaire

Table 2. The Morisky 8-Item Medication Adherence Scale

1. Do you sometimes forget to take your medicine?	No=1, Yes=0	
2. People sometimes miss taking their medicines for reasons other than forgetting. Over the past 2 weeks, were there any days when you did not take your medicine?	No=1, Yes=0	
3. Have you ever cut back or stopped taking your medicine without telling your doctor because you felt worse when you took it?	No=1, Yes=0	
4. When you travel or leave home, do you sometimes forget to bring your medicine?	No=1, Yes=0	
5. Did you take all your medicine yesterday?	Yes=1, No=0	
6. When you feel like your symptoms are under control, do you sometimes stop taking your medicine?	No=1, Yes=0	
7. Taking medicine every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	No=1, Yes=0	
8. How often do you have difficulty remembering to take all your medicine? (A) Never/rarely (B) Once in a while (C) Sometimes (D) Usually (E) All of the time	(A)=4, (B)=3, (C)=2, (D)=1, (E)=0	Divide score by 4
Score: <6=Low adherence; 6-<8=Medium adherence; 8=High adherence		

Appendix 14. COPD Leaflets

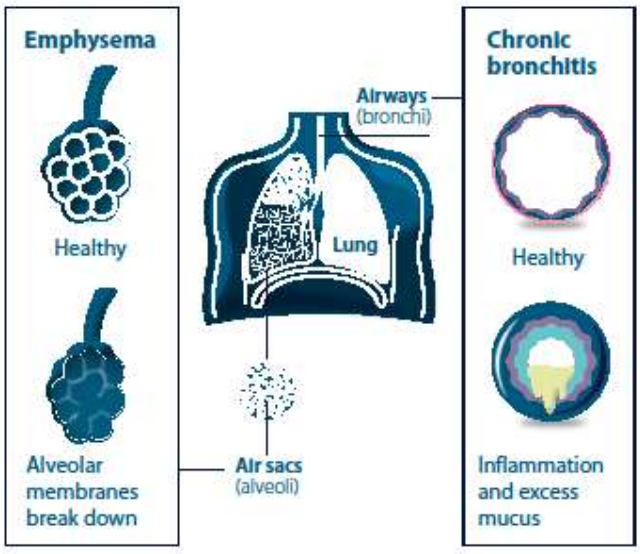
Living with COPD

This information is for people with chronic obstructive pulmonary disease (COPD), their families, friends and carers. It provides advice and information about COPD, including what the symptoms are, how it can be treated and what steps you can take to manage your condition and look after yourself. It also offers advice on how to take care of your emotional well-being and where you can turn for further information and support.

What is COPD?

COPD stands for chronic obstructive pulmonary disease. This is the name used to describe a number of conditions including emphysema and chronic bronchitis. Emphysema affects the air sacs in your lungs (alveoli), and chronic bronchitis affects your airways (bronchi). If you have COPD, you might have just one of these conditions, or you might have more than one.

COPD is a condition where the airways become inflamed and the air sacs in your lungs are damaged. This causes your airways to become narrower, which makes it harder to breathe in and out. Therefore, people with COPD have breathing difficulties, and this can affect many aspects of your day-to-day life. Unfortunately, there is no cure for COPD, but there are lots of treatments available to help you manage your condition, improve your symptoms and live an active life.



Chronic Obstructive Pulmonary Disease

Chronic obstructive pulmonary disease (COPD) is an umbrella term for people with **chronic bronchitis**, **emphysema**, or both. With COPD the airflow to the lungs is restricted (obstructed). **COPD is usually caused by smoking**. Symptoms include cough and breathlessness. The most important treatment is to stop smoking. Inhalers are commonly used to ease symptoms. Other treatments such as steroids, antibiotics, oxygen, and mucus-thinning (mucolytic) medicines are sometimes prescribed in more severe cases, or during a flare-up (exacerbation) of symptoms.

What is chronic obstructive pulmonary disease?

Chronic obstructive pulmonary disease (COPD) is a general term which includes the conditions **chronic bronchitis** and **emphysema**. COPD is the preferred term.

- Chronic means persistent.
- Bronchitis is inflammation of the bronchi (the airways of the lungs).

Emphysema is damage to the smaller airways and air sacs (alveoli) of the lungs. Pulmonary means 'affecting the lungs'.

Chronic bronchitis or emphysema can cause obstruction (narrowing) of the airways. Chronic bronchitis and emphysema commonly occur together. **The term COPD is used to describe airflow obstruction due to chronic bronchitis, emphysema, or both**.

How common is chronic obstructive pulmonary disease?

COPD is common. It is estimated that about three million people in the UK have COPD. However, in many of these people, the condition has not been formally diagnosed (normally these would be mild cases). This is because in the early stages, many people put up with a cough or mild breathlessness without seeing their doctor. They may only see see their doctor when symptoms get worse. COPD mainly affects people over the age of 40 and becomes more common with increasing age. The average age when it is formally diagnosed is around 67 years. It is more common in men than in women.

COPD accounts for more time off work than any other illness. A flare-up (exacerbation) of COPD is one of the most common reasons for admission to hospital (1 in 8 admissions are due to COPD).

What causes chronic obstructive pulmonary disease?

Smoking is the cause in the vast majority of cases. There is **no doubt** about this. The lining of the airways becomes inflamed and damaged by smoking. About 3 in 20 people who smoke one packet of cigarettes (20 cigarettes) per day, and 1 in 4 40-per-day smokers, develop COPD if they continue to smoke. For *all* smokers, the chances of developing COPD are between 1 in 10 and 1 in 4.

Air pollution and polluted work conditions may cause some cases of COPD, or make the disease worse. The combination effect of occupational exposure to air pollutants *and* smoking increases the chances of developing
COPD.

A small number of people have a hereditary (genetic) risk of COPD due to very rare protein deficiencies that can lead to lung, liver and blood disorders. (The condition is called alpha-1-antitrypsin deficiency). Less than 1 in 100 cases of COPD are due to this.

However, people who have never smoked *rarely* develop COPD. (Passive smoking remains, however, a *potential* cause.)

What are the symptoms of chronic obstructive pulmonary disease?

- **Cough** is usually the first symptom to develop. It is productive with phlegm (sputum). It tends to come and go at first, and then gradually becomes more persistent (chronic). You may think of your cough as a 'smokers cough' in the early stages of the disease. It is when the breathlessness begins that people often become concerned.
- **Breathlessness (shortness of breath) and wheeze** may occur
- only when you exert yourself at first. For example, when you climb
- stairs. These symptoms tend to become gradually worse over the years if you continue to smoke. Difficulty with breathing may eventually become quite distressing. **Sputum** - the damaged airways make a lot more mucus than normal. This forms sputum. You tend to cough up a lot of sputum each day.

Chest infections are more common if you have COPD. A sudden worsening of symptoms (such as when you have an infection) is called an exacerbation. Wheezing with cough and breathlessness may become worse than usual if you have a chest infection and you may cough more sputum. Sputum usually turns yellow or green during a chest infection. Chest infections can be caused by germs called bacteria *or* viruses.

Bacteria (which can be killed using antibiotic medicines) cause about 1 in 2 or 3 exacerbations of COPD. Viruses (which cannot be killed with antibiotics) are a common cause of exacerbations too, particularly in the winter months. The common cold virus may be responsible for up to 1 in 3 exacerbations.

- Other symptoms of COPD can be more vague. Examples are weight loss, tiredness and ankle swelling.

Chest pain and coughing up blood (haemoptysis) are not common features of COPD. It is possible to have slightly blood-streaked sputum when you have a chest infection. However, chest pain, blood in the sputum or coughing up just blood, should always be reported to a doctor. This is because other conditions need to be excluded (like angina, heart attack or lung cancer).

What's the difference between chronic obstructive pulmonary disease and asthma?

COPD and asthma cause similar symptoms. However, they are different diseases. Briefly:

- In COPD there is permanent damage to the airways. The narrowed
- airways are fixed, and so symptoms are persistent (chronic). Treatment to open up the airways is therefore limited.

In asthma there is inflammation in the airways which makes the muscles in the airways constrict. This causes the airways to narrow. The symptoms tend to come and go, and vary in severity from time to time. Treatment to reduce inflammation and to open up the airways usually works well.

- COPD is more likely than asthma to cause an ongoing cough with phlegm (sputum).

Waking at night with breathlessness or wheeze is common in asthma and uncommon in COPD.

COPD is rare before the age of 35 whilst asthma is common in under-35s.

There is more likely to be a history of asthma, allergies, eczema and hay fever (so-called atopy) in people with asthma.

Both asthma and COPD are common, and some people have both conditions. (See separate leaflet called Asthma for more information.)

Do I need any tests?

COPD may be suspected by your doctor because of your symptoms. Examination of your chest can be normal in mild or early COPD. Using a stethoscope, your doctor may hear wheezes in your chest, or find signs of a chest infection. Your chest may show signs of being over-inflated (hyperinflation). This is because the airways are obstructed and, as well as it being difficult for air to get into your lungs, it is also difficult for it to escape. Your symptoms (history) and physical examination will help your GP decide if COPD is likely.

Spirometry

The most common test used in helping to diagnose the condition is called spirometry. This test estimates lung volumes by measuring how much air you can blow out into a machine. Two results are important:

- The amount of air you can blow out in one second (called forced
- expiratory volume in 1 second FEV1)

  The total amount you can blow out in one breath (called forced vital capacity - FVC).

Your age, height and sex affect your lung volumes. So, *your* results are compared to the average predicted for your age, height and sex.

A value is calculated from the amount of air that you can blow out in one second divided by the total amount of air that you blow out in one breath (called FEV1/FVC ratio). A low value indicates that you have narrowed airways. The FEV1 compared with the predicted value shows how bad the COPD is.

COPD is divided into mild, moderate and severe groups, depending on the level of airflow obstruction. The airflow obstruction is the FEV1, measured with spirometry.

- **Mild (stage 1) COPD** is an FEV1 at least 80% of predicted value.
- **Moderate (stage 2) COPD** is an FEV1 between 50% and 79% of predicted value.

  Severe (stage 3) COPD is an FEV1 between 30% and 49% of predicted value. **Very severe (stage 4) COPD** is an FEV1 less than 30% of predicted value.

Other tests

A chest X-ray may show signs of COPD and can be used to help exclude other serious conditions (including lung cancer). Occasionally, a special CT scan of the chest - high-resolution CT - is needed. A blood test to make sure you are not

anaemic is often helpful. If you are anaemic, you have a tendency to be lacking in iron, and anaemia can lead to breathlessness. Sometimes a blood test can show changes (called polycythaemia) that suggest you have chronically low levels of oxygen (hypoxia).

A pulse oximeter is a device which can be clipped on to your finger. It measures your heart rate (pulse) and the amount of oxygen in your circulation (oxygen saturation). Lower levels than normal tend to be found in people who have COPD, especially if you have a flare-up (exacerbation) of your symptoms.

What is the progression and outlook?

Symptoms of COPD typically begin in people aged over 40 who have smoked for 20 years or more. A 'smoker's cough' tends to develop at first. Once symptoms start, if you continue to smoke, there is usually a gradual decline over several years. You tend to become more and more breathless. In time your mobility and general quality of life may become poor due to increasing breathing difficulties.

Chest infections tend to become more frequent as time goes by. Flare-ups (exacerbations) of symptoms occur from time to time, typically during a chest infection.

If the condition becomes severe then heart failure may develop. This is due to the reduced level of oxygen in the blood and changes in the lung tissue which can cause increased pressure in the blood vessels in the lungs. This increase in pressure can put a strain on the heart muscle, leading to heart failure. Heart failure can cause various symptoms including worsening breathlessness and fluid retention.

(**Note**: heart failure does not mean the heart stops beating (that is called cardiac arrest). Heart failure occurs when the heart does not pump blood very well.)

Respiratory failure is the final stage of COPD. At this point the lungs are so damaged that the levels of oxygen in the blood are low. The waste product of breathing, called carbon dioxide (CO_2), builds up in the blood stream. People with end-stage COPD need palliative care to make them more comfortable and ease any symptoms.

At least 25,000 people die each year in the UK from the end stages of COPD. Many of these people have several years of ill health and poor quality of life before they die.

Depression and/or anxiety affect at least 6 in 10 people with COPD, and can be treated if recognised.

How can the course of the disease be altered?

Stop smoking. This is the single most important piece of advice. If you stop smoking in the early stages of COPD it will make a huge difference. Damage already done to your airways cannot be reversed. However, stopping smoking prevents the disease from worsening. It is never too late to stop smoking, at any stage of the disease. Even if you have fairly advanced COPD, you are likely to benefit and prevent further progression of the disease.

Your cough may get worse for a while when you give up smoking. This often happens as the lining of the airways 'comes back to life'. Resist the temptation to start smoking again to ease the cough. An increase in cough after you stop smoking usually settles in a few weeks.

The National Health Service (NHS) provides free help and advice for people having difficulty in stopping smoking. Medication (such as varenicline, brand name Champix® and bupropion, brand name Zyban®) and nicotine replacement

therapy (such as patches and chewing gum) can be prescribed, and counselling offered. You could see your GP or practice nurse for further advice, or visit the NHS Smokefree website (see under 'Further help & information', below).

What are the treatments for chronic obstructive pulmonary disease?

Stopping smoking is the most important treatment. No other treatment may be needed if the disease is in the early stage and symptoms are mild.

If symptoms become troublesome, one or more of the following treatments may be advised

(**Note**: treatments do not *cure* COPD. Treatments aim to ease symptoms. Some treatments may prevent some flare-ups (exacerbations) of symptoms.)

As a general rule, a trial of 1-3 months of a treatment will give an idea of whether it helps or not. A treatment may be continued after a trial if it helps, but may be stopped if it does not improve symptoms.

It can be helpful to consider treatments for three separate problems.

- Treatments for stable COPD
-
- Treatments for exacerbations of COPD

Treatments for end-stage COPD

Treatments for stable chronic obstructive pulmonary disease

The main treatments are medications given in devices called inhalers. The medicine within the inhaler is in a powdered form which you breathe in (inhale). Some people find inhalers more difficult than others do to use. The medicines in standard inhalers reach the lungs better if used with a spacer device. (See

separate leaflet called Inhalers for Chronic Obstructive Pulmonary Disease for more information on the different inhaler medicines and devices.)

Short-acting bronchodilator inhalers

An inhaler with a bronchodilator medicine is often prescribed. These relax the muscles in the airways (bronchi) to open them up (dilate them) as wide as possible. The same inhalers may be used if you have asthma. People often call them relievers.

They include:

- **Beta-agonist inhalers**. Examples are salbutamol (brand names include Airomir®, Asmasal®, Salamol®, Salbulin®, Pulvinal Salbutamol® and Ventolin®) and terbutaline (brand name Bricanyl®). These inhalers are often (but not always) blue in colour. Other inhalers containing different medicines can be blue too.
- **Antimuscarinic inhalers**. For example, ipratropium (brand name Atrovent®). These inhalers work well for some people, but not so well in others. Typically, symptoms of wheeze and breathlessness improve within 5-15 minutes with a beta-agonist inhaler, and within 30-40 minutes with an antimuscarinic inhaler. The effect from both types typically lasts for 3-6 hours. Some people with mild or intermittent symptoms only need an inhaler as required for when breathlessness or wheeze occurs. Some people need to use an inhaler regularly. The beta-agonist and antimuscarinic inhalers work in different ways. Using

two, one of each type, may help some people better than one type alone.

Long-acting bronchodilator inhalers

These work in a similar way to the short-acting inhalers, but each dose lasts at least 12 hours. Long-acting bronchodilators may be an option if symptoms remain troublesome despite taking a short-acting bronchodilator.

- **Beta-agonist inhalers**. Examples are formoterol (brand names Atimos®, Foradil®, and Oxis®), salmeterol (brand name Serevent®, Neovent® - a green-coloured inhaler) and Indacaterol (brand name Onbrez Breezhaler®). You can continue your short-acting bronchodilator inhalers with these medicines.
- **Antimuscarinic inhalers**. The only long-acting antimuscarinic inhaler is called tiotropium (brand name Spiriva®). The inhaler device is green-coloured. If you start this medication, you should stop ipratropium (Atrovent®) if you were taking this beforehand. There is no need to stop any other inhalers.

Steroid inhalers

A steroid inhaler may help in addition to a bronchodilator inhaler if you have more severe COPD or regular flareups (exacerbations) of symptoms. Steroids reduce inflammation. Steroid inhalers are only used in combination with a long-acting beta-agonist inhaler. (This can be with two separate inhalers or with a single inhaler containing two medicines.) The main inhaled steroid medications are:

- Beclometasone. Brands include Asmabec®, Beclazone®, Becodisks®, Clenil Modulite®, Pulvinal Beclometasone® and Qvar®. These inhalers are usually brown and sometimes red in colour.

  Budesonide. Brands include Easyhaler Budesonide®, Novolizer Budesonide® and Pulmicort®.

  Ciclesonide. Brand name Alvesco®.

  Fluticasone. Brand name Flixotide®. This is a yellow or orange coloured inhaler. Mometasone. Brand name Asmanex Twisthaler®.

A steroid inhaler may not have much effect on your usual symptoms, but may help to prevent flare-ups. In the treatment of asthma, these medicines are often referred to as preventers. Side-effects of steroid inhalers include oral (in the mouth) thrush, sore throats and a hoarse voice. These effects can be reduced by rinsing your mouth with water after using these inhalers, and spitting out.

Combination inhalers are available, usually containing a steroid medication and either a short-acting or longacting beta-agonist.

Combination inhalers are useful if people have severe symptoms or frequent flare-ups. Sometimes is is more convenient to use just one inhaler device. Examples of combination inhalers are:

- Fostair® (formoterol and beclometasone).
- Seretide® (salmeterol and fluticasone). This is a purple-coloured inhaler. Symbicort® (formoterol and budesonide).

Because there are lots of different coloured inhalers available, it is helpful to remember their names, as well as the colour of the device. This might be important if you need to see a doctor who does not have your medical records (such as in A&E, if you are on holiday, or outside the normal opening hours of your GP surgery).

Bronchodilator tablets

Theophylline is an oral bronchodilator (it 'opens' the airways) medicine that is sometimes used. It is used in stable COPD rather than in an acute exacerbation. Brand names of theophylline are Nuelin SA®, Slo-Phyllin® and Uniphyllin Continus®. Aminophylline is a similar medicine (usually given by injection in hospital) but there are tablets (Phyllocontin Continus®).

The body breaks down (metabolises) theophylline in the liver. This metabolism varies from person to person. The blood levels of the medicine, therefore, can vary enormously. This is particularly the case in smokers, people with liver damage or impairment, and in heart failure. In some conditions, the breakdown is reduced, and blood levels increase. In other conditions, the breakdown is increased and so blood levels of theophylline fall. This is very important, as the dangerous (toxic) dose for theophylline is only just above the dose that is needed for the medicine to work well.

Blood tests are done to measure the amount of theophylline in the blood, to check it is neither too high nor too low. Theophylline interacts with lots of other medicines too, so sometimes it cannot be prescribed, due to other medicines that you take. Theophylline commonly causes side-effects. These include:

- A thumping heart (palpitations).
- Feeling sick (nauseated).

Headache.

Occasionally, an abnormal irregular heartbeat (arrhythmia), or even fits (convulsions).

Mucolytic medicines

A mucolytic medicine such as carbocisteine (Mucodyne®) and erdosteine (Erdotin®) makes the phlegm (sputum) less thick and sticky, and easier to cough up. This may also have a knock-on effect of making it harder for germs (bacteria) to infect the mucus and cause chest infections. The number of flare-ups (exacerbations) of symptoms tends to be less in people who take a mucolytic. It needs to be taken regularly (usually two or three times per day). It is most likely to help if you have moderate or severe COPD and have frequent or bad flare-ups.

Treatment of exacerbations

Treatment of a flare-up (exacerbation) of COPD involves adding extra medicines temporarily to your usual treatment. This is usually steroid tablets with or without antibiotics. These medicines are usually taken until your symptoms settle down to what is normal for you.

If you have frequent flare-ups then your doctor may advise on a self-management plan. This is a written plan of action agreed by you and your doctor on what to do as soon as possible after a flare-up starts to develop. For example, you may be given advice on how to increase the dose of your inhalers when needed. You may also be given some steroid tablets and/or antibiotics to have on standby. This will enable you to start these as soon as possible when a flare-up first develops. You will also be told when you need to seek medical attention - for example, if you are concerned that you are not responding to treatment.

Steroid tablets

A short course of steroid tablets called (prednisolone) is sometimes prescribed if you have a bad flare-up of wheeze and breathlessness (often during a chest infection). Steroids help by reducing the extra inflammation in the airways which is caused by infections.

Steroid tablets are usually taken once per day, often for between 5 to 14 days. Depending on the strength of the tablet, you might need to take six or even eight as a single daily dose. If your symptoms improve quickly, your doctor may tell you to stop taking the steroids at the end of the week. If your problems are more severe, the steroid tablets may be tailed off over several days or weeks. Occasionally, some patients take steroid tablets long-term. This is not always advised, as there can be serious side-effects.

Some important side-effects of steroids include:

- 'Thinning' of the bones, due to reduced bone density (osteoporosis).
- Bleeding in the stomach (gastrointestinal bleeds).

A lowering of the immune system (immunosuppression) - making infections more common.

- Weight gain (and a condition called Cushing's syndrome), and a lowering of the body's natural ability to make certain hormones (adrenal suppression).

If you need to have steroid tablets long-term, you will usually be given some medicines to protect your bones and prevent osteoporosis. (See separate leaflet called Osteoporosis for more information.)

Antibiotics

A short course of antibiotics is commonly prescribed if you have a chest infection, or if you have a flare-up of symptoms which may be triggered by a chest infection.

Admission to hospital

If your symptoms are very severe, or if treatments for an exacerbation are not working well enough, you may need to be admitted to hospital. In hospital you can be monitored more closely. Often the same medicines are given to you but at higher doses or in a different form. Tests can be performed, such as either of the following:

- A chest X-ray.
- Blood tests to measure how much oxygen there is in your blood (arterial blood gases).

Chest physiotherapy can be started to help you clear secretions (mucus) from your chest by coughing and suction machines.

If you are very breathless it may be impossible to use your inhaler. Nebulisers are machines that turn the bronchodilator medicines into a fine mist, like an aerosol. You breathe this in with a face mask or a mouthpiece. Nebulisers are no more effective than normal inhalers but they are useful in people who are very tired (fatigued) with their breathing.

You may need oxygen to help you breathe. Sometimes a special machine called bilevel positive airway pressure (BiPAP) or continuous positive airway pressure (CPAP) is used to help you breathe. This is called non-invasive ventilation (NIV). It consists of a close-fitting facemask and drives oxygen into your lungs, forcing the airways open. It can make you feel a bit claustrophobic and it is quite noisy. In very severe cases, you might need more help with breathing, in an intensive care unit (ICU). A tube can be put into your windpipe and connected to a machine that 'breathes' for you (a ventilator). If you have severe underlying COPD (rather than just a severe exacerbation of COPD), this is not always the best option.

About 2-4 patients in 100 admitted to hospital because of their COPD will die due to that illness. Between 1in 10 and 1 in 4 people admitted to ICU with severe COPD die.

End-stage chronic obstructive pulmonary disease

Palliative care

Palliative care means care or treatment to keep a person as comfortable as possible, to reduce the severity of the disease, rather than to cure it. Mostly it is about helping you with your symptoms, to make them easier to bear. Palliative care is not quite the same as terminal (end of life care), when someone is dying and death is expected within a few days.

As COPD progresses, the condition becomes more severe. You might have more frequent exacerbations and/or admissions to hospital. These factors can give a clue as to how advanced the illness is. Palliative care is usually started in COPD when you are on the maximum medication and your condition is continuing to get worse (deteriorate). Sometimes in these situations you might choose to remain at home for any/all treatments, rather than having further hospital admissions, as things get worse.

Your quality of life in the end stages of COPD is very important. Palliative care can be given in a hospice, but is just as likely to be provided by your GP, district nurse or community palliative care team. The idea is that a multidisciplinary team, with different healthcare professionals, can anticipate any problems before they happen. The team can help you with access to medication and any equipment that might be needed.

Palliative care involves not just physical treatments. Psychological and spiritual well-being are important too. The aim is that both you and your family feel supported and that your care is planned.

Home oxygen

This may help *some* people with severe symptoms or end-stage COPD. It does not help in all cases.

Unfortunately, just because you feel breathless with COPD it does not mean that oxygen will help you. Great care has to be taken with oxygen therapy. *Too much* oxygen can actually be *harmful* if you have COPD.

To be considered for oxygen you would need to have very severe COPD, and be referred to a consultant

(respiratory specialist) at a hospital. Your GP cannot just prescribe oxygen to you in this situation. Tests are done to see how bad your COPD is, and how low the oxygen levels in your blood are. This might be done with a pulse oximeter (mentioned earlier) or by taking a sample of blood from an artery in your wrist (blood gases). These tests are needed to decide whether oxygen will help you or not. The monitoring of oxygen levels may take place over a period of several weeks, at rest and with exercises.

If found to help, oxygen needs to be taken for at least 15-20 hours a day to be of benefit. Oxygen can be given with a face mask or through little tubes (nasal cannulae or 'nasal specs') that sit just under your nostrils. Portable oxygen is available in cylinders, but if you need long-term oxygen therapy (LTOT), for long periods of the day, an oxygen concentrator is required. This is a big machine (about two feet square and two and a half feet tall) that plugs into a normal

electrical socket. The concentrator takes oxygen from the air in your room, and concentrates it. This means the oxygen is separated from other gases in air, so you only have pure oxygen to breathe in. A back-up supply of oxygen cylinders is provided if you have a concentrator, in case of an electrical power cut or machine breakdown.

Normally, you will only be considered for oxygen if you do not smoke. There is a serious risk of explosion or fire when using oxygen if you smoke.

Oxygen might be used to treat a flare-up (exacerbation) of COPD *in hospital* but would not be prescribed shortterm for an exacerbation to be used at home. Oxygen might be used in an emergency whilst awaiting transfer to a hospital (for example, by a paramedic).

Other medicines

Medicines such as morphine and codeine may be prescribed to try to reduce your coughing, and to help with breathlessness. Hyoscine is a medication that can be given to try to dry up secretions from your lungs. Anxiety is a common symptom when you are breathless. Morphine can help the feelings of anxiety. In some cases, other anti-anxiety medicines (such as diazepam) can be given. Depression and anxiety are common in patients with COPD, at all stages of the disease. You may already be prescribed medication for this.

Other treatments in chronic obstructive pulmonary disease

Surgery

This is an option in a very small number of cases. Removing a section of lung that has become useless *may* improve symptoms. Sometimes large air-filled sacs (called bullae) develop in the lungs in people with COPD. A single large bulla might be suitable for removal with an operation. This *can* improve symptoms in *some* people.

Lung transplantation is being studied, but is not a realistic option in most cases.

What can I do to help?

Get immunised

Two immunisations are advised.

- A yearly 'flu jab' each autumn protects against possible influenza and
- any chest infection that may develop due to this.

  Immunisation against pneumococcus (a germ that can cause serious chest infections). This is a oneoff injection and not yearly like the 'flu jab'.

Try to do some regular exercise

Studies have shown that people with COPD who exercise regularly tend to improve their breathing, ease symptoms, and have a better quality of life.

Any regular exercise or physical activity is good. However, ideally the activity that you do should make you at least a little out of breath, and be for at least 20-30 minutes, at least four to five times a week. If you are able, a daily brisk walk is a good start if you are not used to exercise. But, if possible, try to increase the level of activity over time.

You may be referred for pulmonary rehabilitation or be under the care of a community respiratory team. You will be given exercises and advice to try to

help you stay as fit as possible. This is important because, effectively, you may become disabled due to your breathlessness.

Try to lose weight if you are overweight

Obesity can make breathlessness worse. If you are overweight or obese it is harder to exercise, and exercise makes you more breathless. It becomes a bit of a vicious cycle. If you are obese the chest wall is made heavy by fat. This means that you have to work much harder to breathe in and take a good breath, to inflate the lungs and expand the chest. A dietician may be able to give you advice on healthy eating and weight loss.

Chronic obstructive pulmonary disease and flying

If you have COPD and plan to fly then you should discuss this with the airline. Some airlines may request a fitness to fly assessment. Although your GP might be able to give *some* advice, they are not well placed to make the final decision. Your consultant (respiratory specialist) may be able to help or alternatively you may need to see a specialist in aviation medicine.

When travelling by air you should keep your medicines, especially your inhalers, in your hand luggage. If you are on LTOT, you will need to inform the airline. It is possible to use your own oxygen in-flight but individual circumstances may differ. Some people with COPD are more likely to need in-flight oxygen. Some people are more at risk of a punctured lung (pneumothorax) at altitude, despite the fact that the aircraft cabin is pressurised.

Regular follow-up

If you have COPD, your GP surgery will probably call you yearly for a check-up or annual review. You can discuss your medication and the GP or nurse might assess your inhaler technique. Regular review allows monitoring of the severity

of your COPD, and gives an opportunity for health promotion such as help with stopping smoking or weight control. Reviews should happen more often:

- If you have frequent flare-ups (exacerbations), or complications.
- If you have very severe COPD.

If you have recently been discharged from hospital.

In summary

- COPD is usually caused by smoking.
- COPD should be considered as a possible diagnosis in anyone aged over 35 years who smokes, or has ever smoked *and* has persistent (chronic) problems. These can be cough with lots of phlegm (sputum), breathlessness or wheeze, and chest infections which come back (are recurrent).
- Symptoms usually become worse if you continue to smoke.
- Symptoms are unlikely to get much worse if you stop smoking.
- Treatment with inhalers often eases symptoms, but no treatment can reverse the damage to the airways.

A flare-up (exacerbation) of symptoms, often during a chest infection, may be helped by increasing the dose of usual treatments. This may be combined with a short course of steroid tablets and/or antibiotics.

Further help & information

British Lung Foundation

73-75 Goswell Road, London, EC1V 7ER

Tel: (Helpline) 03000 030 555 (Admin) 020 7688 5555

Web: www.blf.org.uk

Smokefree - NHS Choices

Web: www.smokefree.nhs.uk

Further reading & references

- Chronic obstructive pulmonary disease; NICE Clinical Guideline (June 2010)
- Chronic obstructive pulmonary disease; NICE CKS, November 2010 (UK access only)
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View this article online at www.patient.co.uk/health/chronic-obstructive-pulmonary-disease-leaflet.

Discuss Chronic Obstructive Pulmonary Disease and find more trusted resources

at www.patient.co.uk.

Appendix 15. Semi-Structured Questionnaire

1. Can I ask what breathing condition it is you have?

2. How long have you had it for?

3. How does it affect your daily living?

4. The pharmacist visited you about a month ago to conduct a review of your breathing- how did you feel about that?

5. Do you feel they helped with your breathing condition? (and if so how?)

6. Do you feel they helped with your medication for any other conditions? (and if so how?)

7. Did they help with anything else while they were visiting you? (and if so what?)

8. How did you find having the review in your house instead of in a surgery?

9. How did you find having a pharmacist carry out the review rather than say a doctor or a nurse?

10. Do you think annual reviews for chronic diseases should be offered to patients that are housebound? *(can elaborate on other chronic conditions explaining that this could include diabetes, blood pressure, etc etc)* (and if so why?)

11. Do you think the review helped you take your medicines more regularly? (and if so how?)

12. Did the review change how you used any of your medications and if so how?

13. Do you have anything else you would like to add?

Appendix 16. CAT Assessment Guide

User Guide

Expert guidance on frequently asked questions

Issue 6: May 2022

[Inside front cover]

Introducing the COPD Assessment Test (CAT)

The COPD Assessment Test (CAT) is a patient-completed instrument that can quantify the impact of COPD on the patient's health. It complements existing

approaches to assessing COPD, such as FEV_1 measurement. It was initially designed, using a rigorous scientific development process, to provide a simple and reliable measure of health status in COPD to aid assessment of patients and promote communication between patients and clinicians.

Validation studies conducted during the development of CAT and in the years since it was launched in 2009 have shown that it has properties very similar to much more complex health status questionnaires such as the St George's Respiratory

Questionnaire (SGRQ)[1]. A recent systematic review[2] confirmed that the CAT provides reliable measurement of health status and is responsive to change with treatment and exacerbations. Since 2013 it has been incorporated as the preferred measure of symptomatic impact of COPD into clinical assessment schemes and is also included in the COPD Foundation guide[17].

Although it was developed in English, nearly one hundred validated translations have been made and local validation studies have been conducted in countries that include China, Arabic-speaking countries, Brazil, Greece, Japan, South Korea, Turkey and Thailand. All have shown that the CAT is reliable in those setting and that both patients and researchers find it easy to use.

Since the launch of CAT, guidance has been provided for health care professionals on how to use and interpret CAT scores in the form of a user manual available through the website (www.CATestonline.org). As it is increasingly used in research this update to the user manual has been expanded

to include information and advice to researchers, based upon our current knowledge of the CAT and its measurement properties.

The information in this guide is accompanied by some frequently asked questions in order to make it accessible and applicable to both practice and research.

We look forward to hearing and reading about your experiences using the CAT in the near future!

Professor Mike Polkey	*Professor Claus Vogelmeier*	*Professor Mark Dransfield*
Independent Chair	*GOLD Science Committee Chair*	*COPD Foundation Consortium Working Group Chair*

On behalf of the CAT Governance Board, May 2022

The COPD Assessment Test (CAT) – the basics

What is the CAT?

The CAT is a validated, short (8-item) and simple patient completed questionnaire, with good discriminant properties, developed for use in routine clinical practice to measure the health status of patients with COPD[1]. Despite the small number of component items, it covers a broad range of effects of COPD on patients' health. Studies have shown that it is responsive to change and to treatment.[2,3,4]

Why has the CAT been developed?

COPD represents a major burden on patients and healthcare systems. Despite the fact that it is projected to become the third leading cause of death by 2030[5], communicating the impact of COPD can be difficult and this can contribute to under-management of COPD in a significant proportion of people who may suffer increased disability and reduced quality of life as a result.

The care of COPD patients can only be optimised if there is a reliable, standardised measure of the overall effect of disease on each patient's health. Unfortunately, commonly used lung function measurements such as FEV_1 percent predicted do not reflect the full impact of COPD.

CAT was developed to address the need for a simple-to-use tool which can measure the effect of COPD on the patient's health and enhance understanding between patients and physicians of the disease's impact, in order to manage patients optimally and reduce the burden of disease as much as possible.

Development and Governance of the COPD Assessment Test (CAT)

How was the CAT developed?

The development of the CAT involved well accepted methodologies used to develop psychometric tools.[1,6] The initial item generation process involved literature reviews, physician interviews and, most importantly, patient input.[6] A structured, rigorous scientific approach was then used in the item reduction process to select the best items and generate the final 8-item questionnaire.[1]

The CAT was initially validated in prospective studies conducted in the USA and Europe[1] and in China[7]. In the years since launch further validation studies have

been conducted around the world which show that the CAT is globally applicable. Since 2009 the CAT has been translated and validated for use in more than 100 languages other than English. Only validated translations of the CAT should be used. You can access a subset (60+) of these translations directly on the CAT website, www.CATestonline.org.

Who developed the CAT?

The CAT was developed by a multidisciplinary group of international experts who have expertise in developing patient reported outcomes tools/questionnaires. The group included pulmonary specialists, primary care physicians, experts in the development of Patient Reported Outcome measures and representatives from patient bodies (appendix 1). Patients with COPD were integral to the development and validation of the tool. The CAT development was commissioned and funded by GlaxoSmithKline (GSK).

How is the CAT governed?

Use and further development of the CAT is overseen by a Governance Board established in 2015. The board has an independent academic chair. GOLD and the COPD Foundation (COPDF) nominate and confirm representatives on the CAT

Governance Board. GOLD is represented by the chair of the Science Committee and

COPDF is represented by a member of the Board or a Consortium Working Group Chair. Other members of the Governance board represent research in industry and academia. The Board also includes a scientific adviser with expertise in the development and use of PROs. GSK continues to own the

copyright for the CAT to ensure its integrity. The COPDF maintains the CAT website and is responsible for the administrative support of the CAT Governance Board in addition to making translations of the CAT available for personal use or clinical practice users. The COPDF cannot grant permission to use the CAT otherwise and those requests should be directed to Mapi Research Trust.

Who are members of the CAT Governance Board?

Current Membership of the CAT Governance Board (May 2022):

Independent Chair:	Professor Michael Polkey, NIHR Respiratory Biomedical Research Unit at the Royal Brompton and Harefield Foundation NHS Trust and Imperial College
GOLD Scientific Committee Chair:	Professor Claus Vogelmeier, Professor of Medicine and Chair Department of Medicine, Pulmonary and Critical Care Medicine, University Medical Center Giessen and Marburg, Philipps-University Marburg, Germany, Member of the German Center for Lung Research (DZL)
COPD Foundation Working Group Consortium Chair:	Professor Mark Dransfield Division of Pulmonary, Allergy and Critical Care Medicine University of Alabama at Birmingham
Academic Research user:	Professor Toru Oga Department of Respiratory Medicine, Kawasaki Medical School, 577 Matsushima, Kurashiki, Okayama 701-0192, Japan

Research users:	Ruth Tal-Singer, President and Chief Executive Officer COPD Foundation, Miami, FL USA Professor Steve Rennard, University of Nebraska Medical Center, 985910, Omaha, NE, USA 68198-5910
Scientific Adviser:	Tom Keeley Director, Patient Centred Outcomes, Value Evidence and Outcomes GSK
Foundation Chair:	Professor Paul Jones, St George's University of London, UK

What does the CAT Governance Board do?

The CAT Governance Board is accountable for the oversight of the CAT in terms of materials, platforms and developments. Key activities will include:

- Maximising the value of the CAT by promoting uptake and usage as widely as possible and ensuring adoption of new terms of use
- Maintaining the integrity of CAT by developing and approving translations available via the website and distributed for research use via Mapi Research Trust
- Expanding the use of the CAT and CAAT in clinical practice and in research

The Governance Board will also contribute to the Regulatory qualification efforts of the

CAT as a drug development tool by the COPD Foundation Chronic Lung Diseases

Biomarker and Clinical Outcomes Assessments Qualification Consortium (CBQC)[17].

How does the Governance Board regulate the use of the CAT?

GSK and the CAT Governance Board have decided that the CAT is free to use in clinical practice within the terms of use there are set out on the CAT website (www.CATestonline.org). Please review these terms to ensure that your proposed use of the CAT is covered. Academic and sponsored research uses require that you complete a request for use with Mapi Research Trust. If your proposed use of the CAT is not covered by the terms of use or our distribution agreement with Mapi, then Mapi will contact GSK with your proposal and GSK will consider the proposal with the CAT Governance Board on a case-by-case basis having regard to the aims set out above.

Why does GSK hold the copyright for CAT?

GSK continues to hold copyright to ensure that translations of the CAT are conducted appropriately and are collected and made available to clinicians and researchers. Translations of the CAT have been approved by the CAT Governance Board and are available from the website for personal use and clinical practice. For other uses contact Mapi Research Trust.

What is the role of the COPD Foundation?

The COPDF provides administrative support to the Governance Board and is the host for the CAT website. In all activities related to the CAT, then COPDF will be guided by the advice and direction given by the CAT Governance Board.

Using the CAT in everyday clinical practice: why, who and when?

Why should I use the CAT?

The CAT is a short, simple questionnaire which is quick and easy for patients to complete. It provides a framework for discussions with your COPD patients and should enable you and them to gain a common understanding and grading of the impact of the condition on their life. It should also help you to identify where COPD has the greatest affect on the patient's health and daily life. As a result you may be better informed when discussing and making management decisions with your patients and be able to ensure that his or her health status is as good as it can be.

Where and how does the CAT fit into the clinical assessment of COPD?

The CAT provides a reliable measure of the impact of COPD on a patient's health status.[1,2] It therefore provides supplementary information to that provided by other aspects of COPD clinical assessment recommended by current management guidelines (i.e. assessment of exacerbation risk and degree of airway obstruction, assessed using spirometry)[8].

The CAT does not replace COPD treatments but can help you monitor their effects, e.g. rehabilitation programmes or recovery from an exacerbation[4,10,11].

For which patients is the CAT suitable?

The CAT is suitable for completion by all patients diagnosed with COPD.

Can the CAT be used in all COPD patients irrespective of disease severity?

Yes. The CAT has been developed and validated in COPD patients of all severities. Stable patients of all severities (defined by FEV1) and exacerbating patients were included in the development population [1,3, 6]

Does the CAT replace spirometry?
No. The CAT is not a diagnostic tool. Spirometry is essential for the diagnosis of COPD. The CAT and spirometry are complementary measures which can be used together in the clinical assessment of a patient's COPD to ensure that they are being optimally managed.

Can I use the CAT to diagnose COPD?
No, the CAT cannot be used alone as a diagnostic tool. Although the CAT is a scientifically developed tool for measurement of health status it is not a diagnostic instrument, unlike measures of lung function such as FEV_1, which confirm the diagnosis of COPD and assess the degree of airway obstruction.

Will the CAT help me make management decisions regarding any co-morbidities which my COPD patients may also have?
No. The CAT is a disease-specific tool to measure the impact of COPD on patients. It will not provide an assessment of co-morbid conditions or provide information to help guide any management decisions for co-morbid conditions.

How does the CAT compare with other health status measures used in COPD? The CAT has very similar discriminative properties to the much more complex SGRQ which is often used in clinical trials showing that it will be able to measure the impact of COPD on individual patient's health[1]. However, the CAT is much simpler and quicker to complete. This similarity enables us to describe

what a patient's CAT score may mean and, more importantly, to interpret changes in CAT score.

Practical use of the CAT

When do I give the CAT to my patients to complete?
It is recommended that you ask a COPD patient to complete a CAT questionnaire when they arrive for a check-up appointment for their COPD or immediately before attending. The CAT test can also be completed online via the CAT website and printed out or emailed directly to you and takes only a couple of minutes. Patients could complete it whilst waiting to see you or at home prior to consultation. The completed CAT questionnaire can then provide a framework for your consultation.

Where can I access the CAT questionnaire?
You can access the CAT questionnaire at www.CATestonline.org . The public site provides easy access to a subset of the over 60 translations. These can be completed by patients online or printed/saved to pdf. Health Care Providers wishing to use the CAT for uses such as integration into EMR systems or for purposes of research should contact MAPI Research Trust (see 'Permission to Use' section of the website) and request permission to use.

Will patients require much instruction to complete the CAT?
The content of the CAT questionnaire has been driven by COPD patients. It comprises 8 simple questions that most patients should be able to understand and answer easily. You should not need to assist patients to complete it. In fact it is much better if they complete the CAT independently.

What is the scoring range of the CAT?
The CAT has a scoring range of 0-40.

What do CAT scores mean?
The implication of the CAT scores needs to be considered in relation to an individual's disease severity. Several studies have indicated that the relationship between lung function (FEV1) and health status scores is generally weak[9,12]. As recognised by the GOLD strategic document the lung function, exacerbation frequency and health status are complementary [8] and all together help to define the severity of the disease in a particular patient.

How frequently should the CAT be used in patients?
The CAT Governance Board and the GOLD strategic document recommend that patients routinely complete the CAT questionnaire every 2 to 3 months to detect changes and trends in CAT score[8].

What change in CAT score is meaningful?
A difference or change of 2 or more units over 2 to 3 months in a patient suggests a clinically significant difference or change in health status. Research has been published to define ranges of CAT score severity and to understand the minimal clinically relevant change (often referred to as the Minimum Clinically Important Difference or MCID) in a CAT score from one visit to the next [3,4,11].

Can CAT be used to set a target score?
Since COPD is a progressive disease, a fixed target score for all patients cannot be set. In Practice, a target for improvement in individual patient CAT scores may be set, based on a holistic assessment of the patient. A change of 2 units suggests a meaningful difference.

What if my patient's CAT score gets worse?

Based on the correlation with SGRQ the CAT score would not be expected to decrease by more than 1 unit per year[10]. Worsening scores may indicate that patients are experiencing exacerbations that they have not reported to you. CAT scores may also worsen where a patient has stopped or is not taking their treatment effectively. Check inhaler technique as well as adherence to treatment. Where rapid disease progression is suspected, referral for specialist opinion may be required.

What is the CAAT?

The COPD Asessment Test of CAAT is the CAT but with a very small modification to make it usable by patients with obstructive airways other than COPD. The content has not changed. It's purpose is the same as the CAT – to measure the impact of the patients disease on their health status or health-related quality of life. It has recently undergone very comprehensive tests of its validity and these will be published soon. While it does seem that asthma patients and COPD patients respond slightly different to some items, overall it appears that CAAT scores in asthma mean the same thing as in COPD. This is a very important because it means that one simple questionnaire can be used for a range of conditions.

The COPDF will be adopting and supporting the CAAT and produce more guidance about it over the coming year, but basically it will be used in the same way as the CAT.

In addition, for each scenario, the CAT Development Steering Group proposed some potential management considerations[13]:

CAT score	Impact level	Broad clinical picture of the impact of COPD by CAT score	Possible management considerations
>30 >20	Very high High	Their condition stops them doing everything they want to do and they never have any good days. If they can manage to take a bath or shower, it takes them a long time. They cannot go out of the house for shopping or recreation, or do their housework. Often, they cannot go far from their bed or chair. They feel as if they have become an invalid. COPD stops them doing most things that they want to do. They are breathless walking around the home and when getting washed or dressed. They may be breathless when they talk. Their cough makes them tired and their chest symptoms disturb their sleep on most nights. They feel that exercise is not safe for them and everything they do seems too much effort. They are afraid and panic and do not feel in control of their chest problem.	Patient has significant room for improvement In addition to the guidance for patients with low and medium impact CAT scores consider: • Referral to specialist care (if you are a primary care physician) Also consider: • Additional pharmacological treatments • Referral for pulmonary rehabilitation • Ensuring best approaches to minimising and managing exacerbations
10-20	Medium	COPD is one of the most important problems that they have. They have a few good days a week, but cough up sputum on most days and have one or two exacerbations a year. They are breathless on most days and usually wake up with chest tightness or wheeze. They get breathless on bending over and can only walk up a flight of stairs slowly. They either do their housework slowly or have to stop for rests.	Patient has room for improvement – optimise management In addition to the guidance provided for patients with low impact CAT scores consider: • Reviewing maintenance therapy – is it optimal? • Referral for pulmonary rehabilitation • Ensuring best approaches to minimising and managing exacerbations • Reviewing aggravating factors – is the patient still smoking?
<10	Low	Most days are good, but COPD causes a few problems and stops people doing one or two things that they would like to do. They usually cough several days a week and get breathless when playing sports and games and when carrying heavy loads. They have to slow down or stop when walking up hills or if they hurry when walking on level ground. They get exhausted easily.	• Smoking cessation • Annual influenza vaccination • Reduce exposure to exacerbation risk factors • Therapy as warranted by further clinical assessment.

5		Upper limit of normal in healthy nonsmokers	

What effect does an exacerbation have on CAT scores?

We know from the first CAT validation study that CAT scores in patients with moderatesevere exacerbations are approximately 5 units higher than in those who have stable COPD.[1,3] This finding is supported by subsequent research[14]. Patients responding to treatment for their exacerbation have been shown to reduce their CAT score by 2 units in 14 days, whilst patients who did not respond had no change in score [3]. A systematic review of research studies have also shown that it may take many weeks for patients to recover fully from a single moderate-severe exacerbation and some patients may never recover fully[2]. Therefore another potential application of the CAT may be to assess the degree of recovery following an acute exacerbation by re-assessing the CAT score 2-3 months after the event.

Will I be able assess response to therapy with the CAT?

We know that the CAT has good repeatability[1,2], which is similar to that for the FEV_1 and, based upon our current knowledge, we believe that the relative size of its response to therapy will also be similar to that of the FEV_1. In a study of patients undergoing rehabilitation, CAT scores decreased by 3 units over 42 days in patients reporting an improvement in their COPD. In patients who reported worsening of COPD over the same period CAT scores increased by 2 units[3]. In assessing whether an *individual patient* has had a worthwhile response to a specific therapy, a thorough individual assessment taking a number of factors into account – including change in CAT score - will be required. However, the CAT *will* provide a measure of the individual patient's health that will be very useful in initial assessment and for following medium to long-term trends. It should also provide a prognostic measure of future health resource use in

individual patients. The design of the CAT may also allow clinicians to readily identify areas of a patient's health that are more severely impaired than others, such as mood, daytime physical function or sleep.

Can I just use a few of the questions included in the CAT?
No. The CAT should be used in its entirety. The CAT was validated as an 8-item questionnaire and the questions should not be split up or used independently of each other which will reduce the integrity and measurement properties of the questionnaire. However, responses to the individual items can be used to provide you with an indication of the areas of the patient's health that are more affected than others. For example, one patient may have higher scores for cough and sputum, whereas another may have highest scores for the items about activity or sleep.

Is the CAT free to use?
The CAT is available and free to use globally (no charges will be associated with its use) for personal use, clinical practice, academic and non-profit projects. For sponsored or for-profit research a licensing fee will be assessed.

Do I need permission to use the CAT?
The CAT can be used in clinical practice without permission, as long as you respect the integrity of the test. To use the CAT in research you will need to request Permission to Use through MAPI Research Trust. All copyright information must be maintained as they appear on the bottom of the CAT questionnaire.

Is the CAT available in different languages?

Yes. The CAT is available in more than 100 different languages, though only a subset of 60+ are available on the www.CATestonline.org website. Only approved translations of the CAT questionnaire should be used to ensure the validity and measurement properties of the questionnaire are maintained. For further details on validated translations please visit MAPI Research Trust or www.CATestonline.org. Requests for development of new translations should be sent through MAPI. It is not a requirement that new translations be developed via Mapi.

Systematic Use of the CAT

Can I include the CAT routinely in health records in Clinical Practice?

Yes. The CAT was developed to help health care professionals monitor the health status of their patients with COPD so recording CAT scores in the patients medical record assists this process and is encouraged.

Can I include the CAT in my Hospital Electronic Medical Record System?

The systematic inclusion of CAT in an electronic medical record by a hospital or other health organisation is possible. If the CAT is to be completed by the patient then request Permission to Use through MAPI Research Trust. Mapi will review screenshots to ensure they adhere to GSK and Governance Board guidelines. The role of GSK, the CAT steering committee and the CAT Governance Board must be acknolwledged. If any change to the CAT layout is made guidance should be sought via MAPI who will revert to GSK and the CAT Governance Board for guidance.

Using the CAT in Research

During the development of the CAT it became apparent that the measurement properties and responsiveness of the instrument were very similar to those of the more complex and longer SGRQ[1]. This relationship has been demonstrated further in a number of studies[2]. A formal mapping exercise was carried out which described the relationship and constructed a 'ladder' of COPD disease impact at different cut-off points of CAT score (Table 1: Jones, Tabberer, Chen 2011).

Furthermore, following extensive translation and linguistic validation the measurement properties and responsiveness of the CAT have been evaluated in many different countries and found to be similar[2].

The primary focus of the CAT Governance Board is to maximise the use and value of the CAT for patients, health care professionals and researchers. The information in the next sections of this guide will help you to use the CAT productively in research.

How do I get permission to use the CAT?

We have partnered with MAPI Research Trust for the management of requests for use and distribution of the CAT. The Permission to Use tab on the website includes a short summary of information on how to submit a request as well as a link to the MAPI Research Trust website.

How do I obtain translations for my study?

You can obtain multiple translations and supporting certificates from Mapi Research Trust.

What happens if the language I need is not available?

If the language you require is not available you will be able to develop an appropriate translation with guidance from Mapi Research Trust.

How can I get a new translation made?

The CAT is used as a Patient Reported Outcome measure (PRO). It is therefore important that new translations are linguistically validated to the highest standards. Internationally recognised processes for translation[18] are required for all new translations which are commissioned. New translations should be developed under the guidance of Mapi Research Trust.

Why do I have to use approved translations?

To maintain the global use of the CAT in research it is extremely important that only one translation is used for each language in a country. It is for this reason that GSK maintains the copyright of the CAT, provides advice on translations in progress and the Mapi Research Trust manages the distribution of translations.

Can the CAT be used on electronic data collection devices?

The CAT has been tested and used on a number of electronic data collection devices (electronic Clinical Outcomes Assessment or eCOA).

Migration of the CAT to a new eCOA device should be conducted and evaluated using international guidelines[15, 16]. Further details are provided in the next section of this user guide.

Use of the CAT on electronic data collection platforms

As indicated above, the CAT has been tested and used on a number of electronic data collection devices (eCOA).

Can you tell me more about eCOA's?

There are two main categories of eCOA administration platforms: voice/auditory devices (primarily telephone-based and commonly referred to as interactive voice response (IVR) and screen text devices (such as desktops, laptops and tablets) which provide the respondent with a computerized version of the PRO items and responses in a visual text format. CAT has been migrated to a number of screen text devices.

Does migrating a PRO to an eCOA make a difference?

Generally, existing evidence suggests that as long as only minor modifications were made to a PRO measure during the migration process the psychometric properties of the original measure will still hold for the eCOA version. Measurement equivalence of the two measures will still need to be demonstrated but the level of evidence required may be less than if more substantial changes are required.

What if I want to develop and use a new ePRO adapted from the CAT?

Migration of the CAT to a new eCOA platform or device needs to be supported by evidence to demonstrate the comparability, or measurement equivalence, of the ePRO to the paper-based CAT. Important considerations with regard to the level of evidence needed include a) the extent of modification required to administer the PRO on the eCOA device and b) how best to effectively test the measurement equivalence of the two modes of administration. Published reports

and guidance are available which provide support and general frameworks for this development[15].

Are there specific requirements for migrating CAT to a new eCOA platform?

When migrating CAT to a new screen based platform the horizontal format of the questions must be maintained, i.e.; the anchor statements should be located at each end of the response scale (not above or below the scale). Additional line breaks may be incorporated into each anchor statement. On e-diary devices it is acceptable to show one question per screen with the instructions on one or more introductory screens. For devices with larger screens multiple questions may be shown, In the ideal case the whole questionnaire should be presented to the patient however international requirements on text size and usability may prevent this.

Any incorporation of CAT into a 'bring your own device' data collection method should take into account the screen sizes likely to be used in any study[16].

Further information on the requirements for eCOA migration and formatting can be obtained from Mapi Reseach Trust.

Modes of administration

What mode of administration was the CAT developed for?

The CAT was developed for patient self-complete mode of administration.

Can the CAT be administered via clinician/investigator interview?

The CAT was developed for self-complete mode of administration and has not been tested for interviewer administration. As such we cannot confirm that the CAT will behave the same way as it would in self-complete mode of administration. If it is absolutely necessary to undertake interview administration (e.g., due to profound vision impairment), then the interviewer must endeavour to read the instructions, items, and responses in a neutral tone, adding emphasis only where indicated via the text. The patient's selected response should be repeated to him/her to confirm.

Can the CAT be administered via caregiver interview?

The CAT was developed for self-complete mode of administration and has not been tested for interviewer administration. We do not permit caregiver interview using the CAT.

Other materials for Researchers

Other materials are available on the website to assist your research

Within the website we have provided links to the publications describing the development of the CAT. You may wish to refer to these key references in your protocol, analysis plan and subsequent publication.

When using the CAT in a Regulatory submission in the US, please refer to A Drug

Master File containing compiled data on CAT has been submitted by the COPD

Foundation to the FDA and can be referenced by interested companies by contacting

CATmailbox@copdfoundation.org

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19. [Back cover]

www.CATestonline.org

The COPD Assessment Test was developed by a multi-disciplinary group of international experts in COPD supported by GSK. GSK and COPD Foundation activities with respect to the COPD Assessment Test are overseen by a

governance

board that includes independent external experts, one of whom chairs the board.

Appendix 17. Repeat Medications Patient X

Salbutamol MDI 100mcg- 2 puffs when required

Tiotropium 18mcg capsules and inhaler- 1 capsule to be inhaled daily

Levothyroxine 25mcg- 1 daily

Levothyroxine 100mcg- 1 daily

Dermol 500- use as soap substitute

Paracetamol 500mg- 1-2 tablets up to four times daily

Clobetasone cream- use sparingly two to three times weekly

Freestyle libre 2- use as directed

Novorapid 100 units 3ml cartridges- use as directed

Levemir 100 units 3ml cartridges- use as directed

Freestyle Optium test strips- use as directed

Ketostix- use as directed

Glucagon hypokit – use as directed

Glucose oral gel 40%- use as directed

BD Microfine needles screw on 4mm/28 gauge- use as directed

Carbocisteine 375mg capsules- two twice daily

Fostair 200/6 MDI inhaler- 2 puffs twice daily

Uniphyllin 200mg MR tablets- one twice daily

Freestyle lancets- use as directed

Ramipril 2.5mg capsules- 1 in the morning

Ramipril 5mg capsules- 1 at night

Bumetanide 1mg tablets-2 morning and 1 at lunchtime

Atorvastatin 40mg tablets- 1 at night

Glyceryl trinitrate spray 400mcg- use as directed

Bisoprolol 2.5mg tablets- 1 daily

Aspirin 75mg tablets- 1 daily

Ravlo patches- apply one patch for12 hours then remove for 12 hour plaster free period

Cetirizine 10mg tablets- 1 tablet daily

Xailin night ointment- use in eyes at night

Blink intensive tears- use for dry eyes as directed

Appendix 18. A list of all the interventions and the rationale for their change

Action Taken	Rationale
restart Clenil inhaler	patient breathless on slightest exertion
salmeterol inhaler stopped	LABA alone not recommended if there is airway reversibility
Seretide Evohaler changed to Fostair Nexthaler 100/6-2bd	struggles with MDI & overusing Seretide
Lyrinel MR tablets stopped	no benefit
paracetamol dosage reduced	due to low weight
Zerobase cream stopped	no longer used
Ventolin Accuhaler switched to MDI	does not have inspiration to use DPI
salbutamol MDI stopped and switched to Easyhaler	could not use MDI. Poor technique
Carbocisteine capsules reduced to bd	reduced to maintenance dose as feels helping
Symbicort 200/6 inhaler stopped	poor technique, poor compliance
Seretide 500 Accuhaler stopped	finds doesn't have enough inspiratory flow to use
tiotropium inhaler stopped	non-compliant
Carbocisteine capsules stopped	not coughing much nor bring up much phlegm would like to reduce number of meds needs to take
Seretide 500 inhaler stopped	trial of switch from Accuhaler to Evohaler device as losing inspiratory flow and possibly not getting full benefit from Seretide Accuhaler
referred to practice nurse to refer to pulmonary rehab/community respiratory team in the new year	not appropriate to alter inhalers at present (very recent bereavement)
Clenil inhaler stopped	started Fostair inhaler
switched Seretide Accuhaler to Fostair 100/6 MDI 2 puffs bd	non-compliant with Seretide Accuhaler as cannot use
sore on foot- referred to district nurse	Sore on foot
Carbocisteine changed from liquid to capsule	liquid keeps running out whereas capsule can go in plus Pak (dosette box)
Seretide 250 Accuhaler changed to Fostair inhaler	unlicensed dose of Seretide and can use salbutamol mdi. Simplifies
Seretide 500 Accuhaler changed to Fostair inhaler	to improve inhaler technique and streamline inhaler devices
salbutamol mdi switched to Easyhaler	unable to use mdi properly
stop Seretide 500 Accuhaler and start Symbicort 400/12 DPI	non concordance with Seretide as patient believes causes low back pain
Atorvastain 40mg reduced to 20mg	cannot swallow the larger tablets and has been putting in the bin
inhaler technique demonstrated	slight room for improvement
Calcichew d3 forte changed to Adcal dissolve	patient not taking as doesn't like- causes nausea
Seretide 125 Evohaler stopped	switched to Fostair inhaler
Spiriva Respimat directions updated	should state 2 puffs OD not apply daily
Symbicort 200/6 DPI stopped	symptomatic despite exceeding the max dose
salmeterol inhaler stopped	using as a reliever
Seretide 500 Accuhaler stopped	not using would prefer MDI device

Action Taken	Rationale
started fostair 100/6 inhaler 2 puffs bd via aerochamber	to prevent exacerbations
Seretide 250 Evohaler stopped	unlicensed dose
Fostair inhaler added to serial prescription	not getting as didn't realise has to order monthly unlike the rest of her meds which are on a serial prescription
start Eklira inhaler 1 puff bd	patient has current symptoms. Unable to use tiotropium Handihaler device
Seretide inhaler changed to Fostair MDI	still symptomatic
stop Symbicort DPI and start Relvar inhaler 92mcg/22mcg 1 puff od	struggling with inhaler technique and current dose unlicenced for COPD
Blood glucose test strips and lancets removed from repeat	no longer on insulin
Symbicort inhaler stopped	FEV>50% and no exacerbations in last year so doesn't need steroid
Seretide inhaler stopped	?not COPD, not breathless- start Clenil inhaler
restart salbutamol inhaler	patient breathless on slightest exertion
Carbocisteine dose reduced	reduced to maintenance dose- patient finds beneficial
salbutamol MDI changed to Easyhaler	struggles with mdi device
cefalexin UTI prophylaxis	not working- stop
codeine 30mg started	back pain not controlled by paracetamol alone
sodium chloride nebs stopped	no longer used
aero chamber given	to aide inspiration
salmeterol MDI stopped	cannot use
stop Adcal d3	forgets to take, stop until DEXA results
Fostair 100/6 inhaler started	can use with a spacer to improve co-ordination
Fostair 100/6 inhaler started	can use with aero chamber
Symbicort inhaler stopped	non-compliant
Seretide 250 Evohaler started	has used before- mdi technique excellent. Stay with current dose as asthmatic
Fostair 100/6 inhaler started	audible wheeze and SOB- patient could benefit from increase in ICS dose and re-introduction of LABA
spacer added	to aid inhaler technique
Symbicort inhaler stopped	doesn't feel like she is getting anything out of it
aero chamber given	to improve lung deposition
start formoterol Easyhaler	current symptoms suggest better control required
reduce carbocisteine to maintenance dose	patient only taking twice daily but finding beneficial
thiamine 100mg tds reduced to 50mg tds	smaller size as has been putting in the bin
furosemide 80mg/40mg alternate days changed to 40mg od	only taking 40mg od and only needs 40mg od for ankle swelling
Fostair 100/6 inhaler started	more cost effective than Seretide inhaler
Ventolin MDI switched	changed to generic salbutamol for cost effectiveness
Seretide 500 Accuhaler started	Symptom control
tiotropium stopped	cannot open device
Action Taken	**Rationale**

Fostair 100/6 2 puffs bd started	7 exacerbations in last year. To try ICS to see if reduces number of exacerbations
aspirin for primary prevention stopped	stopped unclear why started
Fostair inhaler 2 puffs bd	full dose LAMA to see if patient benefits from better bronchodilation
liaised with community pharmacist to ensure Seretide inhaler ordered with monthly tablets and concurrent inhalers	under ordering
lansoprazole dose reduced from 30mg to 15mg daily	avoid high dose PPI where possible and treat symptoms with lowest effective dose
inhaler technique demonstrated	inhaler technique poor
salbutamol directions updated	so correct directions on label
Areo chamber	add in to improve technique
Bricanyl turbo inhaler changed to salbutamol MDI	cannot manage Turbohaler device
nil	refuses inhalers despite explanation that would help
salbutamol Easyhaler started	use as a reliever when sob
start Clenil 100mcg MDI	? Asthma instead of Seretide inhaler
start tiotropium inhaler	has had exacerbation in last year
Symbicort inhaler started	has asthma as well
reduce Carbocisteine dose	to maintenance
Qvar inhaler stopped	breathing very good, no FEV1
folic acid stopped	folate level within range
formoterol 12mcg DPI started	step up COPD treatment- to be used alongside LAMA and nebuliser
Symbicort inhaler switched to Fostair inhaler	does not have inspiration flow to manage DPI
formoterol Easyhaler started	different device may improve technique and compliance
Alendronic acid stopped	at risk of side effects as in bed all the time. Stop and refer for DEXA
aspirin 75mg stopped	on for hypertension- poor concordance
Carbocisteine capsules dose reduction	not been taking. Encouraged to take 2bd
atorvastatin dose reduced from 80mg to 40g	risk of rhabdomyopathy
Tiotropium inhaler compliance	encouraged as patient thought was to stop using it
tadalafil stopped	no longer takes- sildenafil on repeat
tiotropium switch to Eklira inhaler	cannot open capsules to put in Handihaler so not using
Fostair MDI started	can use with aero chamber- potentially better deposition
acute prescription for GTN spray	current spray out of date
switch aspirin to clopidogrel	as has h/o occipital infarct + small vessel ischaemia
cancelled lancets from repeat	stopped as no longer monitors blood glucose levels
Action Taken	**Rationale**

chemist asked to deliver inhalers and nebules with dosette	has not been getting so not been taking as doesn't like to be a bother to query why inhalers and nebules not being delivered
Adcal d3	stopped due to poor compliance
repeat prescriptions aligned	to aid compliance and script ordering
counselled on GTN spray	using 1-2 sprays daily which is normal for her- explained when and how often to use and when to call for an ambulance
Aero chamber issued	for use with mdi
Anoro Elipta inhaler started	provide symptomatic benefit
community respiratory team leaflet left	doesn't want pulmonary rehab as doesn't leave house
folic acid stopped	no longer needed
simvastatin, aspirin, valsartan and atenolol removed from repeat as not ordered since 2012	DN to go out to check bloods and bp and can take from there
salbutamol Accuhaler changed to mdi with aero chamber	symptomatic benefit
issued GTN spray	has angina but no spray inhouse for prn use
referred to GP	patient has low mood and needs bloods checked
formoterol Easyhaler started	replace Symbicort for symptomatic control
Aveeno cream	stopped is not ACBS
DN to check BP	BP raised
salbutamol MDI started	patient would benefit from taking before exercise
add simvastatin 40mg at night	Diabetic should be on secondary prevention
Salamol inhaler removed from repeat	patient has stockpile at home
Accrete commenced	cannot tolerate Adcal or Calfovit
request bloods	check for digoxin toxicity, check folate and ferritin as patient complains of dizziness, shakes, blurred vision and TATT. No postural deficit recorded and denied falls
bisoprolol dose reduced	BP lower than previous readings
salbutamol Easyhaler started	different device may improve technique and compliance
refer to DNs for flu vaccine	will miss flu vaccine if not given at home
Aero chamber provided	to improve inhaler technique
renewed aero chamber	current one old and dirty
bisoprolol 5mg reduced to 2.5mg	postural deficit
discussion re flu vaccine	importance to have- checked on DN list
thiamine stopped	no longer drinking
constipated & on MST	add lactulose
not taking atorvastatin 40mg as causing myalgia	reduce atorvastatin dosage to 10mg at night
paracetamol dose reduced	weight <50kg
tiotropium discontinued	not taking despite ordering every month
accrete d3 started	would prefer swallowable preparation
Laxido stopped	patient not using
Salbutamol inhaler started	to have reliever medication for immediate symptomatic relief
Action Taken	**Rationale**

smoking cessation undertaken	patient thinking about giving up
new tiotropium inhaler issued as lost old one	to improve compliance and patient symptoms
Epilim chrono removed from repeat	patient stopped taking in 2013 and has not had any seizures in past year
refused dietetic input	
encourage concordance with Adcal and Alendronic acid	not ordered since 2014
omeprazole stopped	lansoprazole started as on clopidogrel and potential drug interaction
referred to respiratory service re pulmonary rehab/community respiratory service	patient would like to participate (but not up to leaving house hence why community respiratory service referral)
Calcichew d3 changed to accrete	fit in dosette to aide compliance
Tiotropium combo pack on repeat	changed to refill pack to reduce wastage and for cost effectiveness
Varenicline	Commenced to aide smoking cessation
calcium/vitamin D prep changed to vitamin D prep only	dislikes taking. Diet reasonable. Willing to try one small vitamin D tablet once daily
reinforced compliance with Tiotropium	not using every day
explained what Simvastatin for	to improve adherence
explained what Seretide inhaler was for	patient didn't think she was on a 'preventor'
Carbocisteine 375mg dose reduced to maintenance	reduced to maintenance dose
counselled re rinsing mouth after nasal spray	feels nasal spray causing sore throat but is helping
Fluoxetine 40mg dose reduced to 20mg	mood reported as good
Ferrous reduced to maintenance dose	last ferrous level in range
recheck folate level	to see if folic acid if still needed
Seretide 500 inhaler switched to Fostair inhaler	could not use Seretide
Omeprazole dispersible 20mg tabs stopped	poor compliance as supplied out with dosette
Aero chamber added	improve technique
Aero chamber issued	patient used to use spacer but had stopped as spacer was old and needed replacing. To improve inhaler technique
Fultium d3 started	at risk of osteoporosis
co-dydramol dose reduced from 30/500 to 10/500	only taking occasionally and worried re falls risk
Lisinopril withheld	continue to withhold
phone number of smoking service	expressed desire to stop
DN for bloods and hba1c	patient has diabetic symptoms
Dihydrocodeine	dosage changed on repeat to reflect actual dose being taken
Senna dose increased	to avoid constipation with addition of codeine
Glyceryl Trinitrate spray removed from repeats	has not used one in ages- knows to keep an in date one
reinforced use spacer	forgetting to use and will help sore mouth
advised not to take Calcichew at same time as Alendronic acid	better absorption of Alendronic acid
Tamsulosin stopped	postural deficit- redundant therapy?
Action Taken	**Rationale**

Salbutamol inhaler and aero chamber	added as reliever
discussed concordance	as poor
monitor weight loss	patient reports weight loss
Aero chamber	added to help inhaler technique
Omeprazole capsules 20mg started	to be added to dosette
Gliclazide dosage changed from bd to once daily	aide concordance as family not in in the afternoon to prompt
referred to doctor as tachycardic	doctor not overtly worried as patient is anxious- to recheck at next visit
advised about over ordering leg bags	aid compliance and reduce wastage
stop peppermint capsules	patient doesn't like and doesn't think help
referred to dietician	low weight
reinforce rinse mouth out after Seretide inhaler	good oral hygiene and prevent oral thrush
Ferrous sulphate 200mg added to repeat	borderline anaemic added to dosette to aid compliance
referred to community respiratory team	due to low oxygen saturations
Co-codamol 30/500 stopped	already on MST- both not usually used together
Laxido	encouraged compliance as prob with bowels
Prochlorperazine 3mg buccal tabs stopped	poor compliance as out with tray
Simvastatin directions updated	changed to morning as not taking at night
smoking cessation advice given as heavy smoker	
stop Solifenacin	trial to see if symptoms resolved falls risk
referred to DEXA	was due a follow up in 2010
Duaklir Genuair inhaler started	replace tiotropium inhaler
Alendronic acid counselling	advised how to take properly as was taking with all other medicines
Prochlorperazine 5mg started	to add to dosette box
Aspirin 75mg once daily started	History of angina
Aqueous cream stopped	non formulary
compliance with correct procedure to take risedronate weekly encouraged	ensure getting maximum benefit from medication
Referred to hearing clinic	has hearing aid but doesn't feel benefit
Alendronic acid stopped	compliance poor- referred for DEXA and consideration of IV/SC therapy.
compliance importance discussed with daughter and patient	improve compliance as poor
Prescribing support technician visited next day to show inhaler technique with new inhalers	to ensure correct inhaler technique

Appendix 19. List of pharmacist inventions during visit two

Intervention	Rationale
add in aero chamber	improve inhaler technique
recommended quinine	leg pain
spare aero chambers issued	only has one and spares would help daughter
LAMA & LABA in separate inhalers at present. Switched to Duaklir Genuair	patients feeling benefit of switching to DPIs- managing well. Switch to 1 inhaler to simplify regimen for patient and aid compliance
declined aero chamber	
was rushing MDI inhalation- went over technique with aerochamber	improve technique to benefit more from inhaled therapy
switched back to Seretide Accuhaler from Evohaler	prefers Accuhaler device
Seretide Evohaler switched to Fostair MDI	to see if longevity of formoterol and quicker onset of action help breathing at all
check on list for flu vaccination	to prevent flu infection
reinforced inhaler technique and importance of regular use of Spiriva and Fostair inhalers	improve drug delivery and symptomatic benefit to patient
mdi technique re-enforced	improve technique to gain more benefit from using
another pulmonary rehab leaflet sent and encouraged to attend	patient thinking about attending but had lost leaflet
switched back to Seretide Accuhaler from Fostair MDI	felt Fostair inhaler made her cough
clopidogrel stopped	patient felt like getting side effects
issued new Handihaler device	needed new one
reinforced mdi technique (i.e., Breath out before inhaler and shake MDI before each puff)	improve drug delivery to the lungs
Eklira Genuair inhaler 322mcg/dose- 1 puff bd started	now got to grips with switch to Fostair and aero chamber from Seretide Accuhaler therefore try to introduce lama for better symptomatic control
remined when to use different inhalers	improve compliance
reinforced mdi technique	to improve delivery to lungs
switched back to Symbicort from Seretide Accuhaler	felt Seretide made her dizzy and not helping her breathlessness. Stated she has an allergy to lots of medicines
Aero chamber without mask issue	does not like version with mask
Fostair inhaler stop	patient developed sore mouth/throat (blisters) after using
another Ensure nutrition script issued as had ran out	just started but only given one prescription as acute
repeated mdi technique	improve delivery into lungs
switched back to Seretide Accuhaler from Fostair MDI	doesn't find Fostair as effective not confident in new inhaler
stop salmeterol MDI	now on Fostair MDI- not to take both
reminder to rinse mouth out after using Clenil MDI	reduce risk of sore mouth

Intervention	Rationale
handwritten script for tiotropium	To get patient started on medication as surgery prescription has not appeared in last 4 weeks
advised to get spare aero chamber and spare salbutamol MDI	worried about running out of salbutamol (can't tell when inhaler is nearly empty). Knows to wash aero chamber regularly (having spare with encourage this)
encouraged to attend pulmonary rehabilitation in new year	increase probability of attending pulmonary rehabilitation
repeated mdi technique	was using two puffs together as part of one inhalation. Increase amount of drug reaching lungs
aero chamber use and care explained	maximise benefit
reminder to take tiotropium in addition to formoterol	encourage compliance
Aspirin 75mg OD restarted	patient doesn't wish to take clopidogrel
managing MDIs at the moment but admits strength in hands not great	wants to stick with current devices but knows to contact surgery when/if she feels she can no longer manage
sodium bicarbonate er drops 5% issued for wax	has ear wax and affecting hearing. Patient.co.uk info sheet given as well
re-enforce inhaler technique	improve benefit to patient
Seretide 250 MDI 2 puffs bd restarted	not licensed for COPD but patient wanting an MDI and has had Seretide before with no sore mouth
referred to domiciliary podiatry	problems with toe nails
salbutamol mdi also switched back to Accuhaler	more confident with this device
handwritten prescription for aero chambers	aide inhaler technique
mention nebuliser to respiratory department in hospital when goes	struggling with breathing
reminded to rinse moth after using Fostair MDI	prevent sore mouth/oral thrush
importance of daily use of tiotropium inhaler	improve bronchodilation
Symbicort MDI stopped	patient feels making his gums bleed
aero chamber	getting on well- have issued a spare
repeated mdi technique	improve delivery into lungs
aero chamber issued	increase inhaler technique