

UNIVERSITY OF BIRMINGHAM

THE ROLE OF THE PHARMACIST IN IMPROVING ADHERENCE TO INHALED MEDICATION AMONG COPD PATIENTS

By

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Abstract

Background: COPD is not a single health problem, but a spectrum of diseases associated with airway obstruction. Adherence to inhaler medication is critical but remains sub-optimal amongst COPD patients. Intervention studies suggest pharmacists could play an important role in improving patients' adherence, but there is a lack of integration of pharmacists within primary care. Despite the potential benefits of community pharmacists in improving adherence/inhaler technique amongst respiratory patients, community pharmacists are an untapped resource. In this thesis, I explore the current practice of UK pharmacists in promoting adherence to inhaler medications for COPD patients, and their views, and those of patients and primary healthcare practitioners on how pharmacists might best be involved in their care pathway.

Aim: To explore the role of the pharmacist in improving adherence to inhaled medication among COPD patients.

Methods: Five studies were conducted to fulfil the aim of this thesis. These involved a) a cross-sectional study to ascertain community pharmacists' knowledge, attitude and current practice and explore views on their role to improve inhaler adherence among COPD patients; b) three qualitative studies exploring COPD patients' perspectives on the role of pharmacists in the management of COPD patients, HCPs' perspectives on the current role of pharmacists and their integration in the management of COPD, and both patients' and HCPs' perspectives on COVID-19 and its impact on healthcare services provided to COPD patients; c) a systematic review of pharmacist role in Shared Decision Making (SDM) for patients with long-term conditions.

Results: This PhD identified a potential willingness from UK pharmacists to help COPD patients by offering high-quality services as most community pharmacists have a solid foundation of knowledge about inhalers. Many HCPs and patients believe pharmacists would benefit from being more involved in their patients' treatment plans. However, patients' and HCPs' perceptions on the role of pharmacists highlighted their limited capacity, the limited collaboration and communication between HCPs and pharmacists as well as HCPs and patients, and regulatory hurdles such as lack of access to medical records.

Conclusion: This PhD highlighted the potential pharmacists' roles in supporting COPD care delivery. However, the results showed some aspects where barriers must be overcome to facilitate this role. Hence, this PhD proposes that future work should concentrate on these aspects to make it more possible to step up the pharmacists' roles and eventually improve adherence to inhaled medication among COPD patients within the UK.

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Publications and Conferences

a) Aljahan, Abdullah M, Jordan, Rachel, Hodgkinson, James, Dickens, Andrew P. Assessing the role of community pharmacist in improving adherence to inhaled medication among COPD patients: protocol for a cross-sectional study. [Poster]. The Primary Care Respiratory Society conference, 2019, 19th – 21st September. Telford, UK.

b) Aljahan, Abdullah M, Jordan, Rachel, Hodgkinson, James, Dickens, Andrew P. Patients' and Health Care Professionals' views about the role of pharmacists in the management of Chronic Obstructive Pulmonary Disease (COPD) patients. [e-Poster presentation]. The Primary Care Respiratory Society virtual conference, 2021, 6th-8th May.

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List of abbreviation

AAI	Adherence Attitude Inventory
AECOPD	Acute Exacerbation Chronic Obstructive Pulmonary Disease
ARMS	Adherence to Refills and Medications Scale
ASRQ	Adherence Self-Report Questionnaire
BBQ	Beliefs and Behaviour Questionnaire
BEMIB	Brief Evaluation of Medication Influences and Beliefs
BLISS	The Birmingham Lung Improvement StudieS
BMQ	Beliefs about Medicines Questionnaire
CAT	COPD Assessment Test
CCGs	Clinical Commissioning Groups
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus disease 2019
CPCS	Community Pharmacies Consultation Services
CRN	Clinical Research Network
DPI	Dry Powder Inhaler
FEV1	Forced Expiratory Volume in One second
FVC	Forced Vital Capacity
FeNO	Fractional Exhaled Nitric Oxide
GCM	Galois/Counter Mode
GDPR	General Data Protection Regulation
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GPs	General practitioners
HCPs	Healthcare professionals
ICS	Inhaled corticosteroids
IMD	Index of Multiple Deprivation
INCA™	The Inhaler Compliance Assessment
KAT	Knowledge of Aerosol Tool
LABA	Long Acting Beta Agonists
LAMA	Long Acting Muscarinic Antagonist
LTC	Long Term Conditions
LTOT	Long-term Oxygen Treatment
MAQ	Medication Adherence Questionnaire
MARS	Medication Adherence Rating Scale
MMAS	Morisky Medication Adherence Scale
mMRC	Modified Medical Research Council
MTM	Medication Therapy Management
MUR	Medicines Use Review
NHS	National Health Services
NICE	National Institute for Health and Care Excellence
NMS	New Medicine Service
OSCE	Objective Structured Clinical Examination
PCN	Primary Care Networks
PCRS	Primary Care Respiratory Society
PDC	Proportion of Days Covered
pMDI	Pressurised Meter Dose Inhaler
PR	Pulmonary Rehabilitation
RCTs	Randomised Controlled Trials
SABA	Short Acting Beta Agonists
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SCR	Summary Care Records
SDM	Shared Decision Making
SGRQ	St George's Respiratory Questionnaire
SMI	Soft Mist Inhaler

SMR	Structured Medication Reviews
STP	Sustainability and Transformation Partnership
TAI	Test of Adherence to Inhalers
TDF	Theoretical Domain Framework
UK	United Kingdom
US	United States
WHO	World Health Organization

Thesis overview

1. Thesis rationale

In my PhD research, each study draws on new research topics given in the preceding chapter. The research began with a real sense that COPD patients were not receiving the optimal possible therapy and care even though an abundance of pharmacological and non-pharmacological approaches were available. Revisiting the literature helps me explore the current evidence concerning COPD management.

Therefore, in this PhD thesis, I will draw attention to five elements, although interconnected, which emerge as challenges and/or knowledge gaps. The first aspect, adherence to inhaler medication is critical, but remains sub-optimal amongst COPD patients. Intervention studies suggest that pharmacists could play an important role in improving patients' adherence. Although several European studies and one Middle Eastern study exists, there is little evidence about the current role of British community pharmacists in practice.

For the second and third aspects, there is a dearth of research exploring patient views about the potential role of the pharmacist in improving inhaler medication adherence. Patients' views and use of pharmacists are likely to vary considerably by country and context; therefore, to optimise the role of the community pharmacist in the United Kingdom a qualitative study among UK COPD patients is needed. Similarly, there is little available scientific literature on the attitudes of healthcare professionals toward the expanded role of pharmacists.

The fourth aspect, the COVID pandemic occurred in the midst of my PhD programme. Patients with chronic diseases such as COPD were particularly affected because they tended to be older, were at higher risk of severe disease because of their condition, and might even have been shielding or caring for other vulnerable people. Studies have suggested that they were affected in terms of loneliness and isolation due to lockdown, inability to exercise and loss of function,

challenge of using mobile and electronic devices for communication, changes in access to healthcare, which included better access to pharmacists than previously. As I was in the process of conducting my planned qualitative interviews with both patients and healthcare professionals, I took the opportunity to explore in more depth the impact of the pandemic on the health and healthcare of COPD patients from the perspective of both patients and professionals, aiming to understand their experiences and identify any aspects which might be useful post-pandemic.

Lastly, while the advantages of shared decision-making are becoming more widely recognised, they are not yet commonly practised in all settings. There is no systematic review focused on the impact of a pharmacist as a part of a multidisciplinary team on Shared Decision Making (SDM) for patients with chronic conditions. This gave me the golden opportunity to identify and summarise the evidence related to the effectiveness of SDM including pharmacists on medication adherence, and views and perceptions of both pharmacists' and patients' regarding SDM.

2. Impacts of COVID-19 on the thesis

It is important to note that COVID-19 had a significant influence on this PhD thesis. I had prepared all work for planned data collection and obtained ethics approvals for the first work package (survey of pharmacists).

Fieldwork/data collection was expected to start in March 2020 with the pharmacists' survey; however, it was interrupted due to COVID-19 restrictions. I received affirmation from the lead coordinators that community pharmacies had come through one of the most stringent operational times in living memory (workload and staff issues), and their ability to respond to external requests for information was severely reduced. Consequently, I delayed the circulation of the survey materials (6 months) for the first work package because I could not guarantee to

obtain a typical response rate and felt it was not acceptable to be contacting pharmacists during this time.

Due to the pressures of the COVID-19 pandemic and Brexit arrangements there were also unavoidable internal delays with ethics and IT issues, Research Governance Team, Research Passport procedures. Further changes in ethics requirements were issued by the UK authorities meaning that a full Integrated Research Application System (IRAS) document was required. The IRAS application was much more complex and took further work and time to develop.

In summary, these issues caused significant delays to my PhD progress. The pandemic probably had close to 12 months impact on my research as this was precisely the time when all my fieldwork was due to occur.

3. Structure of the thesis

Chapter 1

This chapter reviews the international literature on COPD, aetiology, burden, management of COPD, adherence to inhaler treatments, and pharmacists' roles. The overall aim of this research is based on the identification and discussion of many key gaps in the existing literature. This chapter concludes with a statement of the thesis's overarching aim and objectives.

Chapter 2

This chapter describes a cross-sectional study to ascertain UK pharmacists' knowledge, attitudes, skills and practice in supporting COPD patients and obtain views on their role in improving inhaler adherence which may contribute to the optimisation of outcomes for patients, and what further studies are needed.

Chapter 3

This chapter describes a qualitative study to explore COPD patients' views about the enhanced role of pharmacists in the COPD patient care pathway in improving adherence to medications.

After conducting the thematic analysis, the COPD patients' perception of pharmacists' roles is provided.

Chapter 4

This chapter describes a qualitative study to explore Healthcare Professionals' (HCPs) views on the enhanced role of pharmacists in COPD patient care pathways and the integration of pharmacists within the patient care pathway. The potential barriers/enablers to the further integration of pharmacists within the patient care pathway are demonstrated.

Chapter 5

This chapter highlights the findings of qualitative research that interviewed 12 participants, including GPs, nurses, and COPD patients, on the impact of COVID-19 on COPD patients and to explore attitudes to remote consultations as part of health services provided to COPD patients. Also, it generates in-depth information concerning the pandemic and health services provided by the NHS. Subsequent to a thematic analysis, future lessons that could be implemented post-pandemic are also suggested.

Chapter 6

This chapter describes a systematic review to search, assess, and synthesise published studies on Shared Decision Making (SDM) involving both pharmacists and patients with any chronic diseases to guide and promote patient services and eventually improve patient outcomes. The findings demonstrate the effectiveness of SDM and the views of both pharmacists and patients concerning SDM.

Chapter 7

This chapter discusses the results presented in the preceding chapters. The significance of this doctoral research is addressed. This chapter includes a summary of the thesis's findings, as well as its contributions, limits, and strengths.

Chapter 1 : Introduction and literature review

1.1 Definition and description of COPD

Chronic Obstructive Pulmonary Disease (COPD) is currently defined by the Global Initiative for Chronic Obstructive Lung Disease (GOLD) as "*a heterogeneous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction"* (1, 2). Airway obstruction occurs due to an aberrant inflammatory response after lung exposure to hazardous particles. Inflammation may also destroy the alveolar attachments, thus resulting in an irreversible reduction of the expiratory airflow associated with the loss of the lung elastic recoil pressure (1). Patients present with dyspnoea (prolonged shortness of breath) and coughing, with or without significant phlegm production. The advanced stage of COPD is characterised by debilitating physical symptoms associated with severe degrees of psychological distress and loss of functionality (3). Unexpected weight loss is another clinically significant issue for people with severe COPD (4).

1.2 The burden of COPD

Globally, COPD imposes a considerable medical and financial burden on individuals, the healthcare system, and society, not just in the UK but also elsewhere.

Based on GOLD classification, there are 391.9 million COPD patients worldwide (5) and 3.23 million deaths were attributed to COPD in 2019 (6) which makes COPD currently the third leading cause of death in the world (7). In terms of financial cost worldwide, COPD is estimated to have a £1.7 trillion economic effect by 2030, including direct and indirect expenditures to the health system and the economy (8). In the UK, with a prevalence of roughly 2%, or 1.2 million individuals, COPD is the second most prevalent respiratory illness following asthma. COPD causes nearly 30,000 deaths annually which is the UK's fifth leading cause of death (9).

Lung disease costs the English National Health Service (NHS) £11 billion annually (9) where COPD is among the costliest conditions (£1.9 billion each year). By 2030, the combined direct and indirect expenses in England are projected to reach £2.32 billion (10). Moreover, COPD accounts for 1.7% or more than 140,000 hospitalisations annually, 97% of which are emergency cases (9). COPD exacerbations account for a significant portion of the population admitted to hospitals due to acute respiratory conditions (11).

1.3 Risk factors

Smoking rates or vaping exposures, indoor and outdoor air pollution, an ageing population, and hereditary predisposition are all risk factors for chronic obstructive pulmonary disease (COPD), all of which point to an upward trend in COPD prevalence globally in the upcoming years (12). A new risk factor classification suggested by the Lancet commission also includes COPD related to early-life incidents, for example childhood asthma, premature births, infections, and undetermined reasons for COPD (12).

1.4 COPD diagnosis (NICE and GOLD) Guideline and exacerbation

1.4.1 Diagnosis

Individuals with a history of susceptibility to known risk factors (such as smoking) and people who suffer one of the accompanying respiratory symptoms are evaluated for a COPD-diagnosis: dyspnoea, persistent cough, or frequent phlegm production (4). To verify COPD diagnosis, spirometry (lung function test) after administration of a bronchodilator is advised for those who have risk factors and symptoms; a post-bronchodilator FEV_1/FVC less than 0.70 indicates lung function impairment (1). Spirometric FEV_1 readings have also been classified using different cut-off values to reflect disease severity groups in accordance with GOLD (Table 1.1) (1). At the current time, the National Institute of Health and Care Excellence (NICE) uses the modified

Medical Research Council (mMRC) dyspnoea scale or the COPD Assessment Test (CAT) to assess symptom severity in patients with COPD (4).

Table 1.1: Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification COPD severity (Post-bronchodilator)

Severity of airflow obstruction	GOLD staging	Spirometry criteria
Mild	GOLD 1	$FEV_1/FVC < 0.70$ $FEV_1 > 80\%$ predicted
Moderate	GOLD 2	$FEV_1/FVC < 0.70$ $50\% < FEV_1 < 80\%$ predicted
Severe	GOLD 3	$FEV_1/FVC < 0.70$ $30\% < FEV_1 < 50\%$ predicted
Very severe	GOLD 4	$FEV_1/FVC < 0.70$ $FEV_1 < 30\%$ predicted

It is increasingly recognized that the impact of COPD on the lives of patients is not fully described by FEV_1 alone. The evidence shows that dyspnoea (a major symptom of COPD) better measures the severity of the disease and measures its impact level (13, 14). Indeed, the GOLD recommendations stress the need of doing a thorough symptomatic evaluation as well as measuring airflow obstruction (1). To better comprehend, explain, and quantify the effect of COPD on the patient and on guided management using a variety of prognostic indicators, GOLD has established a composite measure (1). It includes the COPD assessment test (CAT score) (CAT is an eight-item survey focusing on how the patient is affected by COPD symptoms), or score for dyspnoea developed by the mMRC (modified Medical Research Council) to assess the risk of exacerbations (defined as the level of airflow obstruction, previous exacerbation, and the existence of comorbidities). See sections 1.4.2 and 1.5.2 for further details.

1.4.2 Exacerbation

Exacerbations are a potential complication for patients with COPD. The definition of a COPD exacerbation is *"an event characterized by increased dyspnea and/or cough and sputum that worsens in < 14 days which may be accompanied by tachypnea and/or tachycardia and is often associated with increased local and systemic inflammation caused by infection, pollution, or other insult to the airways"* (15). Symptoms include aggravation of coughing, changes in sputum colour, sputum output, chest pain, disturbed sleep, and difficulty breathing. (4, 16). In different studies, exacerbations have varying yearly rates, estimated to be between 0.5 and 3.5 per patient each year, and the main causes are respiratory infection, weather conditions and environmental pollutions (17-20). Exacerbations are the most significant determinant of hospitalisations, mortality, morbidity, and therefore, costs (21-23). In addition, the quality of life worsens as the number of exacerbations rises (19).

1.5 COPD management

1.5.1 Non-pharmacological treatment

COPD is an incurable, chronic progressive illness. Nevertheless, the disease can be treated to reduce exacerbations and relieve symptoms. There are two kinds of treatment associated with COPD, non-pharmacological or pharmacological treatments (4). Non-pharmacological treatments involve programmes of smoking cessation, education and self-management support, exercise, and pulmonary rehabilitation, nutritional support, vaccination (against influenza and pneumococcal infection) and oxygen therapy. Smoking cessation is the most important recommendation in managing and changing the progress of COPD (1, 24-26), and can noticeably decelerate the deterioration of lung performance and alleviate symptoms like coughing, wheezing, and difficulty breathing (1).

Patients with COPD should also have an annual flu vaccine and a pneumococcal vaccine to lower their chance of contracting infections that might worsen their condition. Pulmonary rehabilitation (PR) is recommended by NICE for patients having an MRC score of ≥3 or patients who have been released from the hospital after an episode of exacerbations. Physical exercise, education, and behavioural modifications are just a few of the many facets that constitute pulmonary rehabilitation. Patients with COPD may benefit from this approach since it aims to lessen the severity of their symptoms, get them more involved in their everyday lives on both a physical and emotional level, and improve their health-related quality of life (27). A meta-analysis of 9 randomised controlled trials (RCTs) with 432 patients found that PR significantly reduced the risk of hospitalisation due to exacerbations in COPD patients compared to usual care (OR= 0.22, 95% CI 0.08, 0.58), and improved the ability of exercise (measured by six-minute walk test) (mean difference 77.70 meters; 95% CI 12.21, 143.20) (28). Moreover, a meta-analysis of 17 RCTs involving 1649 patients found that PR significantly improved health-related quality of life, as measured by the Chronic Respiratory Disease Questionnaire (dyspnoea mean difference 0.70, 95% CI 0.46, 0.94) (29).

Self-management of COPD is also an integral element in disease management and improvement in patient outcomes. COPD self-management support is "structured but personalised and often multi-component, with goals of motivating, engaging and supporting the patients to positively adapt their health behaviour(s), and develop skills to better manage their disease" (30). Recent evidence from a systematic review of RCTs shows that hospitalisation (OR= 0.60; 95% CI 0.40, 0.89) was substantially reduced and health related quality of life improved (mean difference in St George's Respiratory Questionnaire (SGRQ)) score -3.51; 95% CI -5.37, -1.65) in COPD patients compared to those that received usual care (31). Early symptom detection, action planning (rapid accessibility to therapies amid exacerbation), breathing procedures, physical activity, bronchial hygiene practises, dietary programmes, and managing stress are all examples of self-management health behaviours (32, 33). Long-term oxygen treatment (LTOT) has been

found to enhance survival in patients with severe hypoxemia, but only when given for an extended period of time (more than 15 hours per day in patients with chronic respiratory failure) (34). Research has demonstrated that patient adherence with a treatment plan improves when the patient is involved in designing their therapy plan (35).

1.5.2 Pharmacological treatment

The main pharmacological treatments for COPD patients are inhaled bronchodilators and corticosteroids, either singly or in combination. Regimens can be once or twice daily (or more often during an exacerbation) and may involve several different types of inhalers. Patients with COPD generally suffer from a number of co-existing conditions and must take a wide variety of drugs. Currently, the focus of pharmaceutical therapy for COPD is on symptom management (i.e., lessening symptoms, increasing physical activity, and bettering health condition) or mitigating risk (i.e., halt disease advancement, avert and treat exacerbation and lower mortality).

The selection of a pharmacological agent is based on the level of symptoms, the risk of exacerbation and patient phenotype (1). The GOLD guideline has recently removed the four categories (A, B, C, and D) and suggests classifying patients into three categories (A, B, and E) according to the frequency and severity of their exacerbations. The categorisation and recommended pharmacological treatment are simply demonstrated in Figures 1.1 and 1.2. To note the difference between the previous and current change is that Groups A and B have not altered, however Groups C and D have been combined under Group E to better emphasise the clinical significance of exacerbations. To illustrate pharmacological treatment recommendations, GROUP A is identified as “low symptoms, low risk”. For GROUP A, a bronchodilator should be used. These are muscarinic receptor antagonists and beta 2 agonists, which contain both long- and short-acting preparations. In practice, it could be an inhaled short-acting bronchodilator (SABA) (i.e., salbutamol and/or ipratropium) for recurrent symptoms or

bronchodilator with long-acting action (LAMA) (i.e., formoterol and/or Glycopyrronium) for persistent symptoms. For GROUP B, it is identified as “high symptoms, low risk” and treatment for this category is beta-2 agonist (LABA) or antimuscarinic (LAMA) agent with long-acting actions. The GOLD recommends using a combination of LAMA/LABA as the first-choice therapy. On other hand, GROUP E identified as “low or high symptoms, high risk” and the first choice of therapy is LABA/LAMA combination. Currently, the LABA/ICS (corticosteroid inhaled) co-administration is not recommended for COPD. Triple therapy LABA/LAMA/ICS should be considered for those who have abnormally high levels of eosinophils (over 300 cells per microliter). Moreover, Roflumilast (an inhibitor of oral phosphodiesterase) and long-term macrolide therapy (i.e., Azithromycin) for former smokers should be considered if a response is not obtained.

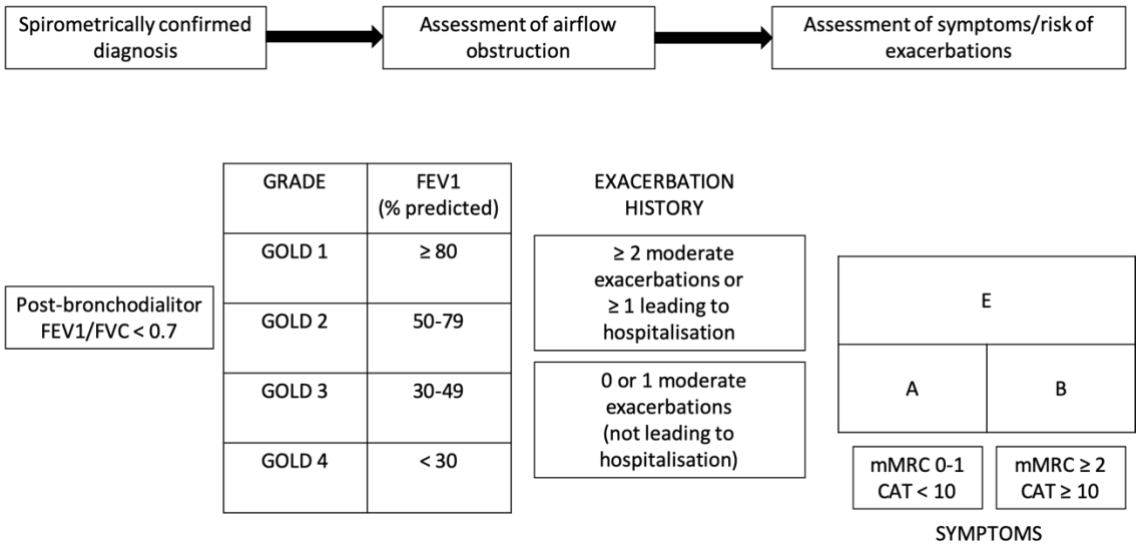


Figure 1.1: ABE assessment tool
Source: GOLD (2023) [(1)]



Figure 1.2: Pharmacological treatment scheme
Source: GOLD 2023 [1]

UK NICE guidance differs from the international GOLD recommendations. A key difference is that the initial treatment, after SABA, is LABA+LAMA, whether it be breathless or often exacerbated. Moreover, rather than breathlessness and exacerbations, NICE chose to group COPD into therapeutic characteristics that have or lack asthma-like features that would show the response of the steroid (Figure 1.3) (4). Lastly, the NICE guidelines recommend that treatment be tailored to the patient's specific needs, with a focus on improving symptoms, reducing exacerbations, and improving quality of life.

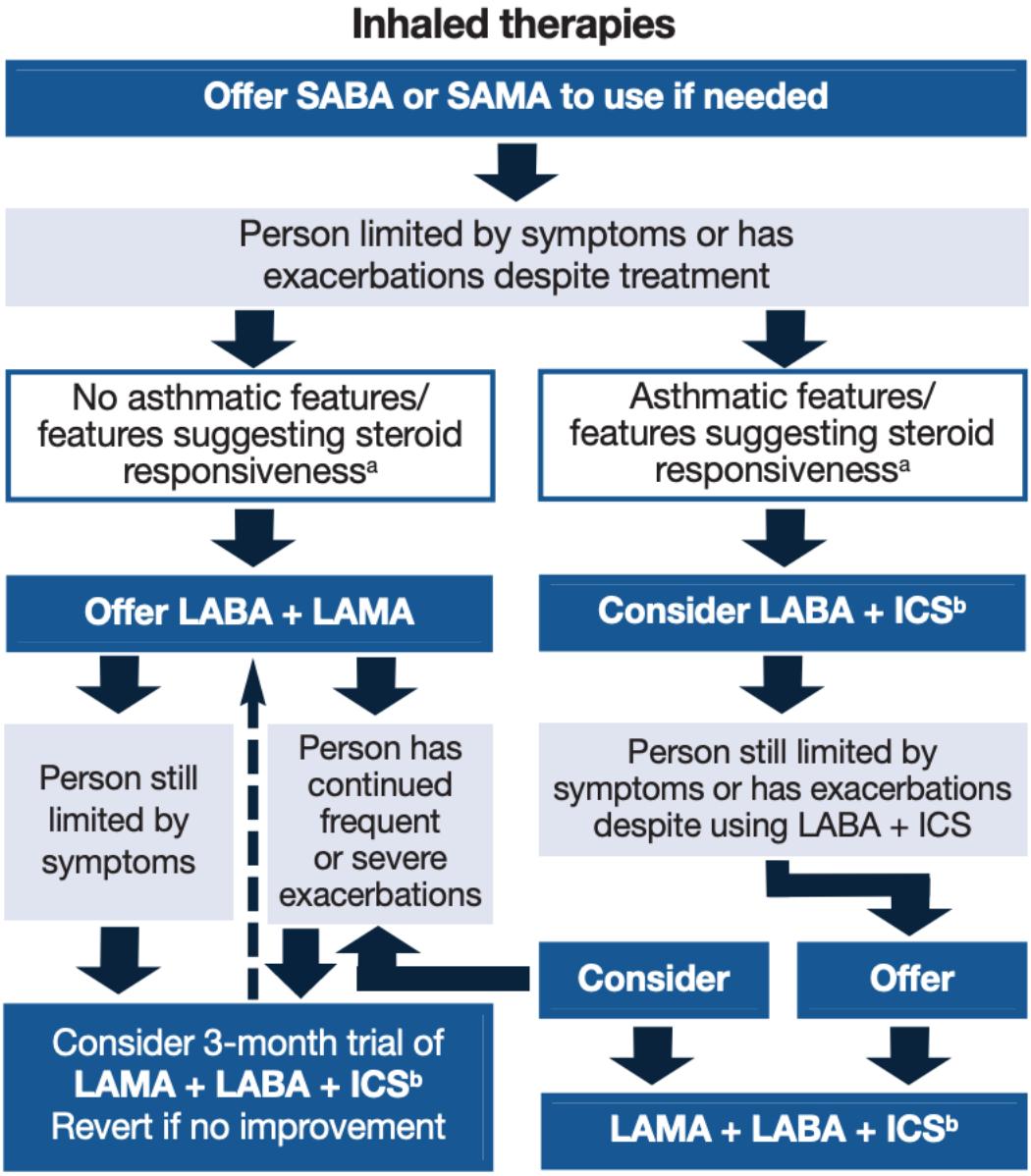


Figure 1.3: NICE inhaled therapies scheme
Source: NICE (2019) [3]

1.5.3 **Different inhaler types**

As mentioned earlier, inhaler medications are the backbone of treatments for COPD (36). In daily respiratory practice, the most frequent inhalers used are pressurised meter dose inhalers (pMDI) and dry powder inhalers (DPI) for the administration of aerosolised therapy. In addition, soft mist inhalers (SMIs) in which, unlike the quick burst of aerosol created by MDIs, the drug released by SMIs flows out progressively and remains in the air for a prolonged time. The pMDIs are prescribed most frequently (37). Patients, however, need proper inhalation

technique such as breathing coordination in order to guarantee effective delivery of treatments (38-41). On other hand, a small, handheld device called a Dry Powder Inhaler (DPI) might be utilised in the shape of dry powder. Dry powder inhalers provide treatment to the lungs as the device is inhaled. DPIs are breath-actuated, and most devices rely on a fast and strong medication inhalation manoeuvre that can sometimes be particularly difficult for patients who have a hard time breathing (41). There has been a recent explosion in the variety of devices in inhaler technologies (42). This abundance of devices, requires different techniques, causes confusion and increases the risk that each device will be misused (43) and lead to reduction of medication adherence.

Many inhalers in the UK market are used for COPD, and currently, there are estimated to be 61 inhalers in the market (Table 1.2). Brand names of inhalers should be included on prescriptions to guarantee patients obtain the suitable inhaler device that best fits their needs and is compatible with the inhaler technique that has been demonstrated. See (Figure 1.4) for some inhaler examples available worldwide (44). General inhaler technique instructions for pMDI, DPI, and SMI devices are listed in the following (Tables 1.3, 1.4, 1.5) (45).

Table 1.2: COPD inhaler devices available in the UK market

	Active ingredient(s)	Number of devices
Bronchodilators	**SABAs**	
	Salbutamol	6 devices
	Terbuataline	1 device
	SAMAs	
	Ipratropuim	1 device
	LABAs	
	Formoterol	4 devices
	Salmeterol	2 devices
	Indacaterol	1 device
	Olodaterol	1 device
	Vilanetrol	Not available as monotherapy
	LAMAs	
	Tiotropium	3 devices
	Aclidinium	1 device
	Umeclidinium	1 device
	Glycopyrronium	1 device
	LABA/LAMAs	
	Anoro (Umeclidinium and Vilanterol)	1 device
	Spiolto (Olodaterol and Tiotropium)	1 device
	Utibro (Indacaterol and Glycopyrronium)	1 device
	Duaklir (Aclidinium and Formoterol)	1 device
Corticosteroids	**ICS**	
	Beclometasone	4 devices
	Beclometasone extra-fine	3 devices
	Ciclesonide	1 device
	Fluticasone propionate	2 devices
	Mometasone furoate	1 device
	Budesonide	4 devices
Bronchodilators/Corticosteroids	**ICS/LABA**	
	Fluticasone propionate/Salmeterol	10 devices
	Budesonide/Formoterol	3 devices
	Fluticasone furoate/Vilanterol	1 device
	Fluticasone propionate/Formoterol	2 devices
	Beclometasone extra-fine/Formoterol	2 devices
	ICS/LABA/LAMA	
	Fluticasone furoate/Umeclidinium /Vilanterol	1 device
	Beclometasone/Glycopyrronium/Formoterol	1 device

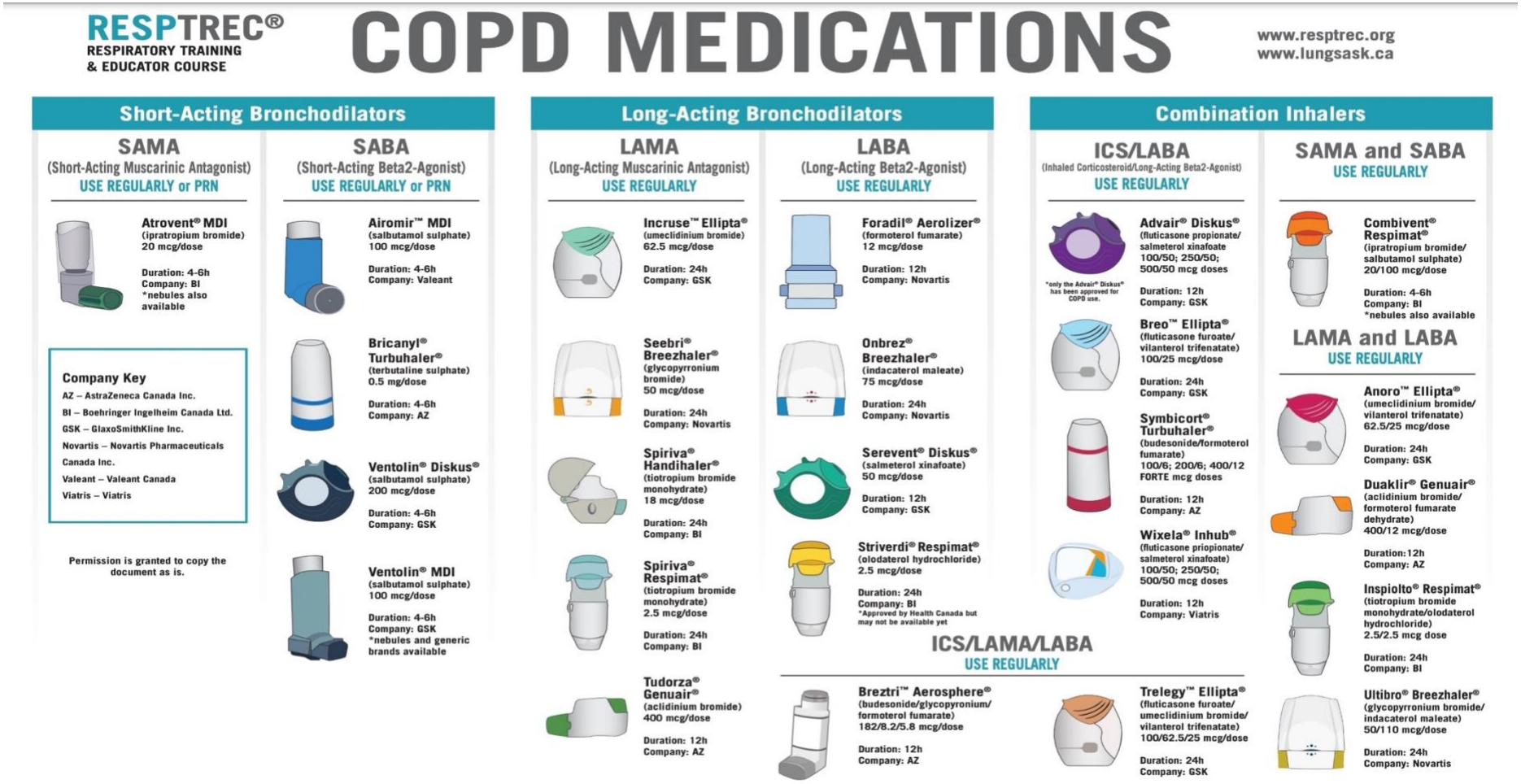


Figure 1.4: Inhaler examples are available worldwide
Source: RESPTREC (2022) [43]

Table 1.3: General instructions to use pMDIs

Steps	Instructions
1	Remember to take the cap off the mouthpiece
2	Be sure there is medication in the canister
3	Shake the MDI vigorously for five seconds before each puff
4	Inhale through the mouth when breathing in the medication, not the nose
5	Keep your tongue under the mouthpiece so that it does not block the opening of the mouthpiece
6	Take a slow, deep breath at the same time you press down on the medication canister
7	Hold your breath for as long as comfortable (5 to 10 seconds) and then exhale

Table 1.4: General instructions to use DPI

Steps	Instructions
1	Remove the cap. For single use devices, load a capsule into the device as directed
2	Breathe out slowly and completely (not into the mouthpiece)
3	Place the mouthpiece between the front teeth and seal the lips around it
4	Breathe in through the mouth quickly and deeply over two to three seconds.
5	Remove the inhaler from the mouth. Hold your breath for as long as possible (4 to 10 seconds)
6	Breathe out slowly

Table 1.5: General instructions to use SMI

Steps	Instructions
1	Hold the inhaler upright with one hand, with the cap closed. Use your other hand to turn the clear base to the right until it clicks
2	Open the cap
3	Breathe out slowly and completely
4	Put the mouthpiece in your mouth, holding the inhaler horizontally (pointing toward the back of your throat)
5	Close your lips around the mouthpiece, making sure not to cover the air vents on the sides
6	Take a slow deep breath in. As you start to inhale, press the button on the side of the inhaler
7	When your lungs are full, hold your breath for 10 seconds to keep the medicine in your lungs
8	Take the inhaler out of your mouth and breathe out slowly
9	Put the cap back on the mouthpiece

1.6 Medication adherence

1.6.1 Definition

According to the World Health Organization, adherence is defined as "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider" (46). Adherence therefore involves the behaviour of the patient with respect to treatment, the treatment prescribing behaviour of the provider, healthcare provider-patient relationship as well as the conditions under which the patient and the provider must act together and individually.

1.6.2 Reasons for non-adherence

Medication adherence is a critically important behaviour for the treatment and maintenance of health. Evidence shows that good medication adherence eventually leads to better control of symptoms, improved quality of life, reduced number of exacerbations, fewer visits for healthcare services and reduced health-care cost (47).

What C. Everett Koop, a former US Surgeon General, said in 1985 is still true today: "Drugs don't work in patients who don't take them". There are three key aspects of adherence, the first is initiation of prescribed therapy, the second is correct implementation of the therapy (including dose, technique and frequency) and the third is persistence (continuing to take the medication appropriately) (21, 48).

Adherence is often suboptimal amongst COPD patients, which is contended to be associated with various reasons including older age, physical/cognitive function (49). When compared to individuals with other chronic conditions, such diabetes, those with COPD and asthma have been demonstrated to have lower rates of adherence: a cross-

sectional study in the Netherlands showed that 68% of diabetic patients adhered to oral medication compared with 48% of asthma/COPD patients who adhered to their inhalers (50). There are many reasons suggested and several points in the pathway where non-adherence might occur. It is crucial to have a good understanding of these obstacles in order to devise interventions that promote adherence.

1.6.3 **Domains of non-adherence**

Inhaled drug adherence has two main elements: “temporal adherence” (the deliberate initiation of medication usage at optimal times and frequencies) and “technique adherence” (successful implementation) (51, 52). Medication non-adherence is associated with two distinct types of behaviour: intentional and unintentional (53-55). Intentional non-adherence is defined as deliberate decrease or discontinuation of treatment during periods when symptoms are minimal (56); this occurs often as a result of a misunderstanding of ailment development and treatment targets (57). However, once patients are unable to adhere to treatment plans for circumstances beyond their authority, such as impediments of language, mental infirmity, or physical inability, this is known as "unintentional non-adherence" (55). Over fifty per cent of COPD patients overuse medicines during respiratory crisis episodes (58). Others may underuse their prescribed medication (49). Moreover, a prospective observation study (LASSYC) evaluated the adherence to inhaled therapies in COPD patients who were in a stable condition in seven Latin American countries using Test of Adherence to Inhalers (10-item TAI) tool. The study found that the adherence rate was not satisfactory as 54.1% of patients were adherent to their inhaler medication (59).

1.6.4 **Predictive factors of inhaled medication non-adherence**

Non-adherence to inhaled medications is affected by a variety of different factors. These include type of inhaler, dosing schedule, individual patient characteristics (60, 61) and ineffective use of the inhaler resulting in inadequate medication delivery (49). To be more specific, 31% employ ineffective inhaler dosing techniques (51). Errors are common in inhaler technique and hinder the adequate administration of drugs (62). For example, in a Spanish study, 43% of COPD patients hospitalised for an exacerbation reported improper inhaler technique as measured using survey and anthropometric measures (63).

An early piece of research looked at self-reported adherence among 78 outpatients at a medical centre in the South-eastern United States. On average, patients in this research were given six drugs, with varying dosages and delivery routes. One-third of patients who underused their inhalers on a regular basis also had poor inhaler technique, and half of patients reported underusing their prescriptions on a regular basis. Although the authors highlighted that patients claimed that they were more prone to utilise rescue medications once they encountered respiratory distress, but neither prescription patterns nor patient demographics were linked with adherence (58).

An observational cross-sectional study of COPD treatment was carried out in the community pharmacy setting in Belgium. The study involved 555 COPD patients in 93 pharmacies. Inhaler technique was evaluated by checking device - specific checklists, while adherence was evaluated for 12 months by retrospective analysis of prescription refill rates. The study reported that the inhaler adherence of primary care COPD patients is suboptimal, 48% of patients had poor medication adherence, with 21% and 3.5% inhaler technique errors for rescue and control medication (64).

A recent cross-sectional observational study assessed inhaler technique in 26 community pharmacies in New Zealand among 103 patients (86 for asthma and 17 for COPD). Prior to the evaluation, researchers were trained on the correct inhaler technique for all devices in the country. A total of 47% of the evaluations carried out reported poor inhaler technique. The study also included a patient survey on past inhaler technique training and evaluation. The majority (76%) of the patients were educated by a doctor, followed by 11% by a nurse, 9% by others (parents, the internet, leaflets), and just 4% by a pharmacist. With regard to technique reassessment, 44% of patients had had their inhaler technique checked with just 1% of them done by a pharmacist (65).

Another issue affecting inhaler medication adherence is psychological profile which is a significant factor for adherence to medication in COPD patients as well. Psychiatric comorbidities are higher among COPD patients than those with other chronic conditions. Up to 40% are clinically depressed and similar numbers also have moderate to severe anxiety (66). Deterioration of health and functional disability are common outcomes of depression and anxiety. Among a nationally representative sample of Medicare users in the United States who filled prescriptions for COPD maintenance medication, a diagnosis of depression, which is common among COPD patients, was related to poorer adherence (67).

1.6.4.1 Health beliefs

Inhaler medications have been demonstrated to minimise COPD exacerbations in individuals with moderate to severe disease (68). Patients often report, however, that they don’t see any clear connection between their medication and its immediate effects on the symptoms. In addition, numerous patients may not believe their disease is severe enough to need long-term therapy to prevent advancement into serious illness (50). Furthermore,

many patients stop their treatment as a result of a decrease in symptoms or a complex treatment regimen. Patients report being worried that if they take the medication regularly over the longer term, their tolerance will develop, believing incorrectly that the medication becomes less efficient (69).

Similarly, a mixed method study (300 COPD outpatients) investigated the association between demographic characteristics, functional and clinical intensity of COPD, and patient perceptions regarding adherence and inhaled treatments. The study showed that smokers and those with better FEV_1 levels were less likely to adhere). The same study also highlighted that the patients' beliefs regarding treatment was the most important predictor of adherence with inhalation therapy, including recognising and relying on the doctor's expertise and being confident in the efficacy of the treatment (70). Similarly, a qualitative semi-structured interview study involving 15 COPD patients indicated that those with poor perception of ICS treatment effectiveness may have worse adherence (71).

1.6.4.2 Poly pharmacy

A simpler inhaled therapy regimen will potentially lead to better adherence. An analysis of retrospective pharmacy claims data indicates that once-daily medications may have a higher rate of patient adherence than their twice-daily counterparts (72). Whilst once-daily therapies may improve adherence in some instances, it would not prove a solution for individuals who purposefully reduce or discontinue treatment (73, 74).

Many studies have indicated that using multiple inhalers at once increases the risk of improper use. If feasible, practitioners should avoid prescribing patients different kinds of devices for the same condition, in order to reduce the patient's overall medication burden and enhance therapeutic outcomes (75-77). Similarly, the inclusion of a once-

daily dose administration has been suggested as a vital approach for enhancing adherence (78). Indeed, it has been observed that once-daily dosing results in considerably greater adherence among COPD patients compared to other dosing frequencies (79).

1.6.4.3 Cognitive issues

An observational study assessed adherence with a LABA/ICS routinely prescribed to patients with COPD after hospital discharge. This was conducted with 244 COPD patients in single centre in Ireland, who received a Salmeterol/Fluticasone inhaler fitted with an Inhaler Compliance Assessment INCA^{TM} device. The study concluded that the aging of the patient combined with the loss of memory and cognitive impairment lowered medication adherence, especially inhaler medication (80). A further observational study of COPD patients following hospital discharge indicated that patient's cognitive status may impact inhaler usage timing and technique, and ability to follow a regular prescribed LABA/ICS combination inhaler. While they may be able to recount detailed information, they are unable to translate them into coherent strategies for physical, behavioural, and cognition. Therefore, inadequate inhaler reminders and forgetting to use the inhaler are two ways in which deficits in executive function and memory could affect patients' ability to stick to their treatment plan (81).

1.6.4.4 Factors related to health care systems and health professionals

There has been a dearth of studies on the impact of the health system and health care teams on adherence to medicines (46). Regulatory initiatives to minimise co-payment or enhance prescription medication availability are examples of measures shown to promote adherence throughout a variety of health diseases (82). Adherence to prescription regimens may be negatively impacted by healthcare providers' inability to effectively

communicate with patients, and shortened patient consultation times (56, 83, 84). The non-adherent patients show that a close therapeutic co-operation (relation between a patient and healthcare professionals) is much less likely to occur during hospitalisation (85). Figure 1.5 shows more details.

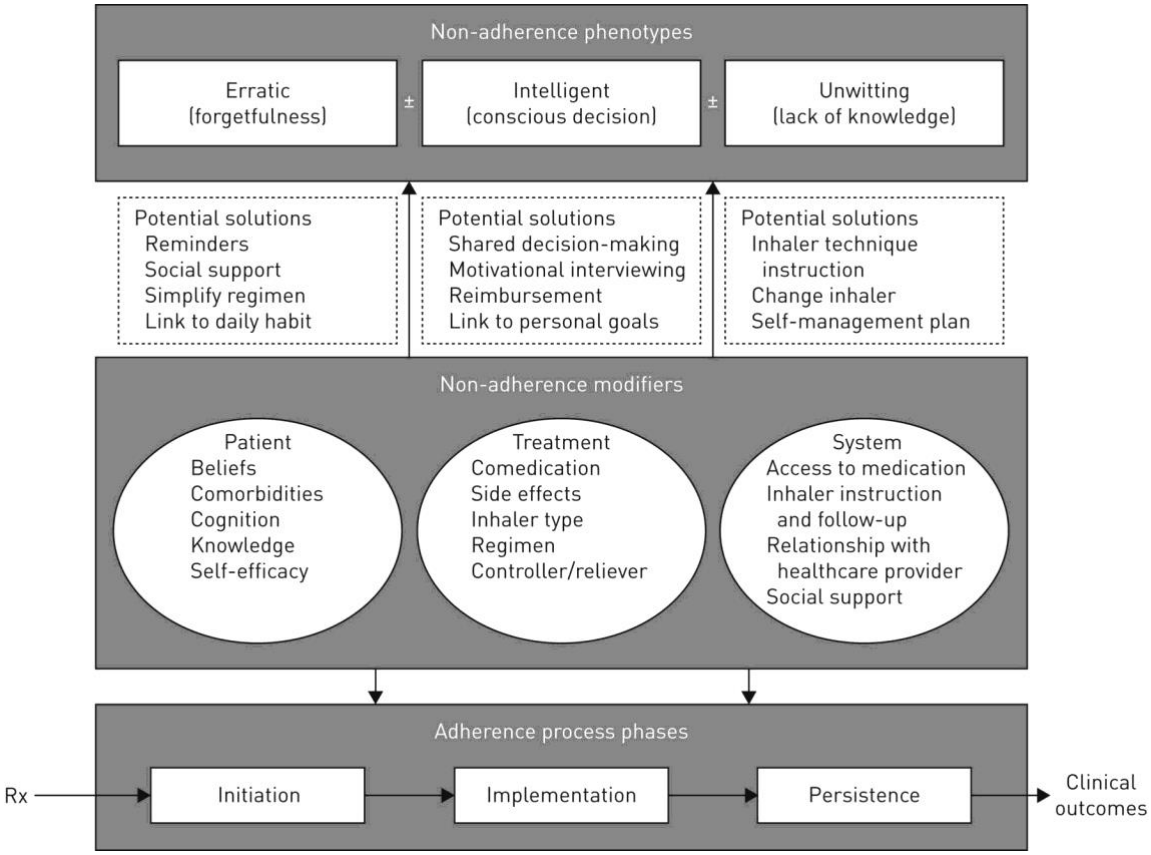


Figure 1.5: Potential intervention targets non-adherence phenotypes, potential modifiers and processes

Adopted from Van Boven et al. (2017) [86]

1.6.5 **Adherence assessment**

Medication adherence should first be accurately assessed in order to improve it. However, one challenge is that investigators and healthcare practitioners do not agree on the best ways to gauge patients' adherence to treatment (87). Currently, inhaled medications adherence may be measured by a number of different methods. There are two types of measurements which include subjective and objective measurements.

Subjective measures include health care practitioner reporting adherence, interviews with patients, self-report and adherence scales (88-92). Patient self-reports are the most common method by which patients evaluate their own behaviour subjectively. Two systematic reviews provide a quick summary of the many self-report adherence measures available (93, 94). Those scales of adherence such as Adherence Attitude Inventory (AAI), Beliefs and Behaviour Questionnaire (BBQ), Beliefs about Medicines Questionnaire (BMQ) and Brief Evaluation of Medication Influences and Beliefs (BEMIB) were based on health belief model (95-98). Moreover, Adherence scales like Morisky Medication Adherence Scale (MMAS), Medication Adherence Rating Scale (MARS), Adherence to Refills and Medications Scale (ARMS) and Adherence Self-Report Questionnaire (ASRQ) have come from the adherence scales that were previously developed. Previous adherence assessments have mostly relied on the 4-item Morisky Medication Adherence Questionnaire (MAQ) (89, 99-104). This can afford feedback in real time and detect specific issues (86). In addition, it may provide an alternate solution or supplementary objective adherence measures. Although the subjective measures are simple and inexpensive, they are susceptible to substantial reporting biases. For many purposive or accidental reasons patients may underreport their level of non-adherence (87), such as response or social desirability biases.

On other hand, adherence may also be objectively measured *via* the use of medication reviews, pharmacy reconciliation, prescription refill patterns (Proportion of Days Covered (PDC), Medication Possession Ratio (MPR)), counter medication assessments, and the In-check dial device (87). Although, these means are useful for predicting healthcare usage and expenditures in the future (105, 106), they are jeopardised due to the notion that medications refills reflect tangible medication taking behaviour while in fact they do not provide evidence on when or how the prescription was consumed.

Furthermore, a straightforward objective measure is to utilise the usual dosage counter monitor that is often affixed to the inhaler. Nonetheless, this approach does not capture valuable data on regular inhaler usage, including but not limited to: time, technique, or inhaler dumping. Consequentially, this approach has a bias toward overestimating adherence (46, 107). Similarly, electronic monitors are employed to track patients' adherence. These trackers log information about when and how often inhalers are used, enabling for analysis of medication regimens (108). However, just opening a drug does not guarantee that it was used afterwards or was taken correctly. As a result, the necessity to have reliable objective measures led to the development of a new device called the Inhaler Compliance Assessment (INCA™). The INCA™ is a portable recorder that can be attached to a Diskus™ inhaler and has a battery, storage capacity, and microprocessor. This gives quantitative information about the inhaler technique, time and duration (52, 109). The acoustic data identify each step of the inhalation process and thereby, spot for inhalation issues such inhaler malfunction, drug spread through exhalation further into the mouth, minimal inhalation rate, dosage dumping, and so forth (109).

1.6.6 **Pharmaceutical service use to enhance adherence**

In the UK, the pharmaceutical services including the Medicines Use Review (MUR) (110), the Prescription Intervention Service and the New Medicine Service (NMS) (111) are intended to aid those living with chronic diseases, so enhancing their treatment safety, increasing their likelihood of adhering to treatment plans, and decreasing unnecessary pharmaceutical use. The MUR service is made up of pharmacist adherence-oriented structured patient reviews of multiple long-term medications (110). On the other hand, the NMS, which has demonstrated significant improvement in adherence, supports patients who have first been prescribed for diseases like COPD, and includes three patient-pharmacist visits every two weeks (111, 112). To note, the 31st of March 2021

marked the end of the MUR services in the UK, while the NMS service is still ongoing. The NMS services were provided for 26.4% of asthma/COPD patients (111).

1.7 Community pharmacies' roles in COPD

The care and treatment of COPD patients are complex, with many challenges, where multiple treatments, both pharmaceutical and non-pharmaceutical, are required. Other challenges include inhaler technique and reviews of asthma/COPD are probably most likely to be undertaken by practice nurses in the UK, who may or may not have either time or qualification to do it properly. Encouraging patients to actively engage in and adhere to a tailored treatment plan, such as therapy maintenance and self-management, is a significant challenge. In most COPD patients, the lack of resources in health care can restrict the time period of contact between the doctor or nurse and the patient (113). Therefore, the effective delivery of COPD management plans could be benefited by an integrated approach that uses other healthcare services, including community pharmacists. Because of their regular patient contact, skills, and knowledge of available treatments, pharmacists have been shown in other countries to have a good contribution to the care and support of patients with COPD (114). The community pharmacy also provides patients with convenient locations, opening times and "open door" opportunities for consultation (114). The COVID pandemic has made it even more difficult to access the GP; therefore, the pharmacist has been an increasingly important contact for patients (116, 117).

The convenience and ease of access provided by a community pharmacy are essential to their function as a supplement to primary care. Community pharmacies in the UK attract 438 million yearly visits from patients seeking health-related services, more than any other kind of medical institution (118). The role of a pharmacist could be important

throughout all phases in the process of medication adherence, setting treatment expectations at the time of initiation, delivering device training to support the implementation of medication, evaluating medication use to determine persistence and detect discontinuation (119), and deciding on the most suitable device, but this is not well utilised by the public. Pharmacists have been acknowledged by the GOLD report (1) as essential partners in reducing patient risk including in optimising therapy delivery (1).

Self-care for COPD patients entails more than only the management of exacerbation; it includes lifestyle modification such as smoking and fumes cessation, physical workouts, diet, and anxiety control. Within the scope of "self-management" strategies, community pharmacists could provide assistance to COPD patients in managing their illness (120) and overcoming the physical and psychosocial implications (121).

Accordingly, if a patient in the UK has COPD and has an exacerbation, their pharmacist may advise them to seek their primary care provider about obtaining a "COPD rescue package", which includes antibiotics and corticosteroids for use at home (4, 122). Furthermore, patients may work with pharmacists to develop an action plan, acquire guidance on recognising the signs of an acute exacerbation and recognising when to utilise rescue medication, and eventually, pharmacists can monitor the use of both maintenance and rescue treatment. As a result, a cost-effective outcome will be achieved (120, 123-125). Several studies have shown that pharmacy-based interventions with self-management support can have benefits to COPD patients, including improvement of quality of life, better adherence to medications and reduced visit rates for doctors and hospitalisation (122, 126, 127).

1.7.1 **Influence of community pharmacy on COPD outcomes**

1.7.1.1 Evidence of the effectiveness of broad pharmacist-led interventions

A systematic review published in 2013 (51) explored strategies to enhance medication adherence among COPD patients. This review reported 7 clinical trials in 8 published articles and concluded that the most effective interventions were brief consultations, comprising inhaler checking with subsequent tracking *via* electronic devices, and self-management and treatment planning supported by pharmacists and primary care teams. This review is limited by a high risk of contamination in three studies, as well as the included studies using heterogeneous measurements of medication adherence, making comparison difficult.

A systematic review of fourteen previous RCT studies around the world found that pharmacist-led consultations including education for COPD patients were associated with a significant reduction in hospital admissions and healthcare costs, and improved medication adherence (128). Davis et al. (129) proposed a pharmacist-led COPD intervention to determine whether expanding the role of the community pharmacist would assist COPD patients overall outcomes. The preliminary findings suggested that pharmacists-led intervention could decrease pulmonary complications related to COPD, reduce the use of healthcare resources and increase the overall quality of life. A general review of the field by Van der Molen et al. (114) in the Netherlands noted that COPD patients perceived that community pharmacists could perform an integral role in (a) prevention; (b) detection; (c) management and support; and (d) review and follow up, and this integral role is not geographically specific but can be implied globally.

1.7.1.2 Evidence of the effectiveness of pharmacist-led interventions specifically targeting inhaler adherence

A meta-analysis of 4 RCTs suggested that pharmacists could take a more proactive role in promoting adherence by making prescription reviews a consistent part of their practice when managing service users with COPD (128). The meta-analysis was part of a wider systematic review regarding medication adherence and education, which recognised and affirmed the sparsity of research on the pharmacists' role in medication adherence amongst COPD patients. Methodological heterogeneity precluded all studies being included in the meta-analysis, and allocation concealment was uncertain in the majority of papers, affecting the likely quality of evidence.

Another systematic review (130) looked across the findings of 10 different types of studies concerning the impact of community pharmacists on the adherence to inhaled medication amongst people with COPD; the authors firstly affirmed that pharmacists could have a highly influential and positive impact on patients' adherence by improving understanding regarding how to correctly use inhalers. However, it provided little guidance regarding how pharmacists could achieve such benefits in practice, with the exception of a single study suggesting pharmacists with more effective communication skills achieved the greatest optimisation of adherence.

Furthermore, the most recent systematic review (131) concerned 22 different community pharmacists interventions and their effect on patient adherence to medications and other health outcomes. In this review, a variety of five chronic conditions were observed, and only 2 of the 22 studies - 1 RCT and 1 cohort study - were related to COPD. Both studies were included in the previous systematic review (130). Although the purpose of this review was to give an overview of all available

studies in this area, it was difficult to determine the common elements leading to improved adherence. The findings suggest that interventions led by community pharmacists helped improve the adherence to treatments and control of diseases for COPD and two of the other chronic conditions.

A large proportion of patients may have poor inhaler medication adherence, and up to 68% may exhibit poor inhaler technique (132); therefore, pharmacists could play a central role in providing education and improving health outcomes and patient quality of life. This argument has received tentative support in the UK, such as in the joint initiative between City & Hackney Clinical Commissioning Group and Barts Health NHS Trust. In this initiative, pharmacists reviewed patients on high doses of inhaled corticosteroid, bronchodilator treatments, with history of prior exacerbations, referral to the Accident and Emergency (A&E) or hospitalisation. This initiative resulted in a greater adherence to therapy, improved quality of life, led to a large number of patients stopping smoking, and improved COPD patients' ability to manage their own condition. Furthermore, fewer medications were required to be prescribed, reducing total costs by an estimated £220,000 per year (133).

In addition, empirical research involving COPD patients has shown that pharmacist-led interventions can optimise patients' inhalation techniques and improve adherence to inhalation treatments (134). There are several intervention studies around the world using various study designs relating to pharmacists led-intervention to improve medication adherence and inhaler technique among COPD patients. Three RCT studies in Belgium (123), Bulgaria (135), and Australia (136) that used structured patient education tailored to patients conducted by pharmacists demonstrated improvement in medication adherence, though this was only statistically significant in the Belgian and Australian studies.

In the Belgian study, a large RCT in COPD patients was conducted to improve inhaler technique and medication adherence. A total of 734 COPD-blinded patients from 170 community pharmacies were followed up at one and three months. Community pharmacists' intervention consisted of providing patients with structured education that was primarily based on the GOLD recommendations and was specifically tailored to meet the needs of each individual patient. The research concluded that adherence to medication was significantly greater in the intervention arm compared with the control arm (mean difference score 8.51; 95% CI 4.63, 12.4; $P < 0.0001$) (123). This research is definitely not without its weaknesses, with potential source of biases including performance bias (pharmacists assess their own learning progress) and selection bias (motivated patients typically acknowledge involvement more frequently).

The Bulgarian RCT assessed whether COPD patients' quality of life, forced expiratory volume in 1 second (FEV_1), and inhaler technique improved after receiving educational intervention. COPD patients (n=30) were involved in the trial; the educational intervention involved COPD as an illness, medication usage, inhaler technique, medication adverse reactions, recognising symptoms during an exacerbation, and quitting smoking compared to usual care. The findings indicated that the FEV_1 rate was the only variable that improved significantly compared to the control group ($p<0.05$ after four months). Additionally, COPD patients in the intervention group had improvements in inhaler technique and quality of life from the beginning to the end of the trial, but these improvements were not statistically significant when compared to those in the control group (135).

The Australian RCT examined the impact of two inhaler technique related educational interventions in community pharmacy among 52 patients suffering from asthma and COPD. In contrast to other studies, the emphasis of this study was exclusively on a single inhaler type which is the pMDI. Participants were randomly assigned to either the Standardised Instruction Group (SIG) with written and oral pMDI guidance or the Extended Instruction Group (EIG) with oral and written instructions as well as a practical illustration involving placebo inhalers. Patients were evaluated at 4, 8, and 16 weeks. The mean of the pMDI technique score for both groups was 5 (SD1). This study reported that SIG, at the last follow-up visit alone, the inhaler technique score increased significantly at 16 weeks (7 ± 1, $P < 0.05$) compared to the baseline. However, For EIG using placebo inhalers, a considerable improvement in pMDI technique mean score was achieved in weeks 4, 8 and 16 (7 ± 1, 7 ± 1, 7 ± 1, 7 ± 1 respectively; $P < 0.05$ for each) (136). In the same study, the inhaler technique deterioration has been highlighted over time. Thereby, the study highlighted the necessity of community pharmacists in assisting patients to maintain and correct inhaler technique over period of time, particularly during medication dispensing.

Moreover, an Australian study used a pharmacists-led intervention and an inhaler-based reminder tags to enhance inhaler technique. The study reported, by the end of 6 months, patients who were received the intervention had significantly greater improvement in their inhaler technique score compared to those in the control group (2.8 ± 1.6 compared to 0.9 ± 1.4, $p < 0.001$) (137).

In the Netherlands, a large prospective cohort study showed that medication adherence in patients with COPD and asthma was shown to be improved with pharmacist-led interventions. The study included 3757 patients in the intervention

arm, and 105,507 patients in the control arm (no structured programme) in a total of 107 pharmacies. This intervention was based on an integrated, structured pharmacy programme focused on: adherence to maintenance therapy, improved inhaler technique and inhaler selection and re-examination of therapy regimen. The intervention entailed three steps for the intervention group pharmacists: (1) web-based patient selection, (2) GPs advice on how to better address identified problems, and (3) pharmacists or GPs informing patients about treatment modifications. The main finding was that patients who were assigned to receive an intervention were shown to have an absolute risk decrease of 0.54 (95% CI 0.21, 0.86) for both corticosteroid and high-dose antibiotic use. Added to that, powder inhaler use decreased by 29% (95% CI 13%, 42%) in patients aged 75 and above because of their poor inspirational flow rate (138).

A randomised controlled trial of pharmacist-delivered education reported significantly increased patient knowledge of COPD and medication adherence, and a reduction in hospital admission rates compared to the control group (126). Such findings have been reproduced by further studies, including one RCT in which longer-term patient adherence to medication improved significantly with a pharmacist-led intervention (6), the authors highlighting that this impact was seen during a two-year follow-up with a medication adherence rate of 80% reported in the intervention, compared with baseline adherence of 49%. In a pragmatic randomised controlled trial (112) in the UK, community pharmacist phone consultations for five long-term chronic conditions led to an almost 10% increase in adherence, compared to standard practice. However, as data was not presented according to the five diseases, it was not possible to assess the magnitude of adherence improvement in each disease area.

There is some evidence that pharmacists can identify patients at high risk of non-adherence and then, using a structured patient-pharmacist consultation based on patient needs, can improve adherence among patients with chronic conditions, including COPD (139). Positive outcomes of a similar consultation method have previously been reported in evaluations with weaker study designs, with patients improving medication adherence (140) and inhaler technique (141).

Overall, the evidence above suggests pharmacists can improve patient inhaler medication adherence through two systematic reviews, five RCTs, a cohort study, three observational studies. Those studies reported that pharmacists-led education could improve inhaler technique and adherence among patients with COPD.

1.7.2 **Pharmacists delivering management, and continued support**

A pre-post study in England has shown that patients with COPD may benefit from COPD services administered by community pharmacists. In the study, 34 pharmacies in four pharmacy chains provided community pharmacist support services for COPD over six months. Before commencing the study, the community pharmacist received a single-day specific training on the delivery of services and a remote learning package compared to usual service. Smoking cessation, training and inhaler technique and inhaler inspection, support and symptom awareness for exacerbation and general lifestyle counselling were all part of the service. Although medication adherence score improved significantly ($P<0.001$), neither smoking reduction nor the quality of life improved significantly (142).

In Germany, a prospective, multicentre study reported that individuals with COPD and asthma who received instruction from a community pharmacist in a single session improved their inhaler technique. Community pharmacies (n= 55) were used to recruit

597 patients suffering from asthma or COPD. Inhalation technique of patients was examined and corrected by pharmacists at baseline and reassessed 4-6 weeks afterwards using 21-item inhalation technique assessment checklists. At baseline, there was at least one inhaler mistake made by 78.9% of participants. The percentage was reduced to 28.3% once the patients returned 4-6 weeks after their training. Hence, pharmacists may improve patients' adherence and quality of life by influencing their inhaler technique after only one encounter (143). Yet, since this is a pre-post study with no control group, only limited conclusions can be drawn.

A Japanese pre-post study of 81 community pharmacies was conducted to determine the impact of a four-year network system. This approach was developed to provide the right and consistent inhaler technique for COPD patients through an educational program. Community pharmacists received training on COPD illness, inhaler technique for several inhaled medication devices, and patient adherence with inhaler medication. They were formally acknowledged as inhaler technique educators after they had completed their training. Improvements in adherence to inhalation therapy were shown to be statistically significant (P= 0.024). Likewise, there was a statistically significant decrease in the incidence of exacerbations after 4 years (P= 0.017). The primary flaw of this research is that, owing to the difficulties of maintaining long-term participant follow-up, the participants were not equivalent at the start of the study and after four years (144).

A small pilot study was conducted in Canada, 21 different community pharmacies participated in the evaluation of 59 patients with COPD and 23 individuals with asthma. All community pharmacists attended a brief ongoing training session related to the management of COPD and asthma before the study. The community

pharmacist's services included smoking cessation advice, health status assessment (medication issues, disease control, and adherence), inhaler technique inspection and correction (when needed), and the provision of an adequate individualised action plan. A total of 59 recommendations were made by pharmacists. Nine were related to inhaled medication device alterations, and seven were reassessments of medication adherence. Moreover, 30 minutes per patient was the estimated time needed to complete this service; therefore, the community pharmacists identified lack of time as a potential service barrier (145).

Overall, the evidence highlighted above suggests that pharmacists can improve patient adherence through two pre-post studies, one prospective study, and one pilot study. Adherence improvement can be achieved by delivering effective pharmaceutical services, continued support, and effective follow-up to COPD patients.

1.7.3 **Views of pharmacists on maintaining treatment adherence**

A qualitative approach was used to probe community pharmacists' views and present practice on inhaler technique and adherence in the treatment of respiratory patients using semi-structured interviews. INCA™ (Inhaler Compliance Assessment) device technology was used. The INCA™ is a novel monitoring tool that provides patients with the advantage of automated and objective evaluation of adherence while they use the item in the comfort of their own homes. Graphs of patient adherence (time/date stamps) and inhalers (showing the most frequent sort of mistake) present objective feedback. The community pharmacists emphasised that they offer assistance to respiratory patients through services provided within the community pharmacy contractual framework. These services primarily include dispensing, re-dispensing,

conducting MUR and NMS, influenza virus vaccination, and aiding in quitting smoking. In addition, patients were supported in terms of inhalation techniques and adherence during the MUR service, which was conducted on an annual basis depending on whether or not the patient agreed to the service. Furthermore, this study identified multiple service barriers, including: time and amount of duty load for pharmacists; inadequate training; absences of rewards/reimbursement; financial obstacles; inadequate resources (staff and placebo inhalers); patients' time; and patients' own attitudes and notions about their own health. A further barrier was the fragmentation of primary care due to poor communication with other healthcare practitioners (146).

In Canada, a mixed-methods study explored the benefits of a community pharmacist for patients who were recently hospitalised for an acute respiratory or cardiovascular incident in maintaining treatment adherence. The qualitative focus group (10 pharmacists) showed that the role of the pharmacist should be to inform people of their disease and therapy, along with monitoring the effectiveness and adherence of their treatment. Moreover, pharmacists have seen a rise in the number of available pharmacists and technicians, as well as the availability of a private space for consultations, which facilitates interventions for patients with medication adherence issues. However, a problem with hospitalised patients was that they often received their medicine at home or had it collected by another person, so neither the patient nor the pharmacist ever actually met in person, which could impact patients' adherence to medications (147).

1.7.4 **Evidence of pharmacists' knowledge and current practice**

There are only a few cross-sectional surveys of pharmacists that explore knowledge and current practice, although none of these were conducted in the UK. Firstly, a large study (148) conducted in Spain included 1722 community pharmacists to assess inhalation therapy knowledge, attitudes, and preferences. The authors used an 11-item questionnaire, including questions on the source of inhalation medication knowledge, familiar and favourite inhalers, knowledge of inhalation techniques and prescriptions, and education of patients. The study highlighted that only 6% of community pharmacists had a sufficient understanding of inhalation treatment and that the package leaflet of devices was a primary source of knowledge. Moreover, one-third of participants acknowledged that inhaled medication technique training was not delivered to patients, plus approximately three-quarters of participants stated that inhaled medication techniques were not checked. Nonetheless, the study illustrated excellent external validity in terms of geographical representation, but the relatively low mean age of participants raises the question of whether this is representative of community pharmacists in Spain.

Secondly, a study in Finland (149) was conducted to assess community pharmacists' knowledge concerning COPD, counselling practices, and perceptions. The authors recruited 263 community pharmacists for this study, of whom 196 were specialised asthma pharmacists. Besides knowledge of COPD guidelines, the study explored medication counselling practices such as instructions for using inhalers and the perception of community pharmacists in terms of their role as health care practitioners, counselling, motivating, and monitoring COPD patients. A large proportion of respondents were not aware of the current COPD guidelines. On the other hand, most community pharmacists agreed that they played a role in providing

counselling to COPD patients, and felt that they were able, as regards disease management, to motivate and follow up (re-checking their medications) COPD patients. However, the low response rate for this study means the results should be interpreted with caution and may have limited wider applicability.

Lastly, a study involving 171 community pharmacists in Iraq developed and validated a Knowledge of Aerosol Tool (KAT) among registered and unregistered pharmacists to assess the pharmaceutical care practice among pharmacists (150). The study suggested that further education and training should be provided to community pharmacists to enhance their knowledge and current practice, which may lead to better outcomes for COPD patients. However, this study has limited generalisability as it was only conducted in two districts of the Iraqi capital, and response rates may have been suboptimal as reminders were not used. Besides, the study defined pharmaceutical-care practise regarding inhaler medication in quite general and broad terms which may not reflect the current care of practice related to inhaler medication.

Thus, the research from Spain, Finland, and Iraq that was previously mentioned demonstrates that in order for community pharmacists to deliver successful patient education and care for COPD patients, they need to possess an in-depth understanding of inhaled therapy.

1.7.5 **Evidence of effectiveness of pharmacists follow-up services**

In regard to follow-up and assessment, the fact that community pharmacists' access to long-term dispensing data equips them to spot patients showing signs of non-adherence and deal with them as necessary. A community pharmacist's fundamental role in comprehensive COPD treatment is the follow-up monitoring that occurs at the same time as the collection of prescriptions. A study in the Netherlands by Van Boven

et al. (119) focused on a programme for Medication Monitoring and Optimisation that involved a "targeted pharmacist programme" to improve long-term treatment adherence for asthma/COPD. The findings demonstrated a significant reduction in the occurrence of exacerbations and a reduction of $400 in overall healthcare expenditures per patient.

Moreover, significant differences in pharmacist consultation approach have been reported in a recent study of 154 respiratory patients (18–65 years of age) investigating the effects on patient treatment satisfaction and adherence to pharmacist counselling and follow-up services. At discharge, the pharmacist provided patients with instructions on how to use an inhaler properly, ensuring that the patients understood the steps and technique by demonstrating and repeating the instructions until the patients were able to use the inhaler correctly. The results showed that medication adherence in the study group rose by 42.9% compared to the control group, and therapy satisfaction rose by 33.5% (151). Given that even a brief medication counselling session with patients might enhance adherence, more extensive, individualised treatments by pharmacists should have positive outcomes.

Self-management plans may offer advantages to some COPD patients, but there is not enough published research on the subject, especially with pharmacists' involvement. An RCT study was conducted to assess the influence of a disease and medication management programme led by a clinical pharmacist on self-management among COPD patients. The programme entailed education on the disease, therapy, breathing methods, and a personalised action plan for exacerbations. The findings revealed at 12 months a notable decline of up to 60% in hospitalisations and emergency department visits, along with enhancements between the group that received the

intervention and the one that received standard care in medication adherence (77.8% *vs* 60.0%) and knowledge about COPD (median score 75.0 *vs* 59.3) (127).

1.7.6 **Patients' views of pharmacist-led consultations**

A survey within Australian community pharmacy services explored the use and views of pharmaceutical services among 602 patients with chronic conditions and their carers, as well as the views of 91 pharmacists (152) in four regions of Australia. The study reported that pharmacies were mainly used for medication counselling, advice about whether a GP appointment was needed, and monitoring/screening services. Patients and carers stated that the most important traits of a pharmacist were patient-centred care and a good understanding of what was important to patients/carers, while other important characteristics included individualised medication counselling, respectful care, and the capacity to access treatments.

A qualitative study (153) conducted in Scotland used semi-structured phone interviews with patients and focus groups with pharmacists to explore patients' and pharmacists' views and experiences of receiving and delivering an enhanced heart failure service. Patients were willing to share their symptoms and medications with community pharmacists in confidence. Moreover, the service aided patients in initiating and developing heart failure medication and self-management strategies. Furthermore, the intervention was viewed positively by patients and pharmacists and suggested a clear role for community pharmacists to support patients to understand and manage their illness and medication, leading to better self-management and medication adherence.

An Australian study (154) explored patient preferences for community pharmacy asthma services among patients with experience of a pharmacy-led specialised asthma

management service. Issues considered included visit frequency, access to community pharmacists, interaction with community pharmacy staff, lung function testing, type and depth of consultation, private space for consultation, and lastly, the cost of service. The majority of patients expressed a preference for pharmacists' friendliness and helpfulness, the pharmacy's private space, and lung function tests when it comes to choosing an asthma service.

A large (N=1089) national survey in Taiwan evaluated the attitudes, need for, and satisfaction of the general public towards community pharmacists and the services they offer (155). The study reported that <50% of those surveyed acknowledged that community pharmacists were able to answer their general concerns about medications. Conversely, nearly a third of participants acknowledged that community pharmacists were the first professionals consulted regarding treatment use and were commonly trusted when it came to medication consultation. The study also reported that approximately 50% of respondents acknowledged a need for medication use consultations. Interestingly, older patients had a more favourable perception, but educated respondents were less favourable.

A further large (N=1104) survey exploring knowledge, attitudes and behaviours regarding self-medication, self-care and public perceptions of the role of pharmacists was conducted in Hong Kong (156). It found that 95% believed patients with chronic illnesses should self-manage their illness, and 68% of participants would consult community pharmacists before using over-the-counter products. However, only 45% agreed that community pharmacists could play a primary role in the self-care of patients with chronic conditions. The study suggested that policymakers should consider forming multidisciplinary community-based partnership programs with

pharmacists and physicians to enhance awareness of pharmacists' roles in self-management and self-care by boosting pharmacists' participation in primary care through patient education, involving pharmacist participation in the campaign to promote well-being and encouraging consultation with pharmacists if patients cannot attend doctor appointments.

1.7.7 Healthcare professionals' views of pharmacist-led consultations

Importantly, studies have demonstrated that an individual's belief in the recommendations of medical professionals is a strong predictor of treatment and intervention adherence (80, 128, 157, 158). Although British pharmacists have not historically been heavily involved in patient counselling, this is gradually changing (159), and there is growing evidence that pharmacists' active participation may enhance patient outcomes (122). Several qualitative studies among doctors in primary care have proposed a pivotal role for pharmacists in therapy management to improve clinical outcomes, decrease unplanned hospitalisations, and cut expenses (160, 161). These studies also noted the importance of educating physicians on the role of pharmacists in forming partnerships with pharmacists.

There are several qualitative studies from the US (160, 161) that indicate primary care practitioners may accept the role of pharmacists in managing chronic conditions, such as COPD, and in the provision of palliative care. These studies suggested that healthcare practitioners' education on Medication Therapy Management (MTM)—a discrete service or group of services that optimise treatment outcomes for particular patients—and the engagement of pharmacists in these services were found to be essential in developing cooperative relationships between physicians and pharmacists.

A recent qualitative study (146) of UK pharmacists aimed to assess community pharmacists' perceptions, experiences, and current practice towards managing respiratory patients concerning inhaler technique and adherence. In addition, this study aimed to highlight community pharmacists' perceptions and need for an objective measure of inhaler technique and adherence, using INCA™ technology as an example (the INCA™ device is intended to record both inhaler technique and adherence objectively). The study (146) identified five major themes, including patient support services and their weaknesses, dysfunctional primary care such as lack of communication among health care practitioners, the need for new technologies to help respiratory patients, the need to encourage the clinical role of community pharmacists, and their professional identity. Furthermore, the NMS services support patients with newly prescribed medicines for long-term conditions. Also, the same study indicated that NMS was beneficial and improved adherence for people with long-term conditions taking new medications, but better integration with primary care was needed.

An ethnographic study of 23 community pharmacies in England (162) explored the implementation of the NMS in pharmacies, including COPD. Interviews with 47 community pharmacists and 11 GPs found that community pharmacists had adopted the NMS pragmatically, and their understanding of the NMS affected their anticipated benefit, whilst GPs endorsed the initiative. Still, pharmacists were unfamiliar with the NMS and its possible benefits, and poor communication was a barrier to NMS implementation. The study suggests better collaboration between community pharmacists and GPs, rigorous piloting, and phased rollout of new systems would improve future implementation (162).

In their study into the barriers to self-management of COPD, Russell et al. (163) found that general practitioners often had a narrow view of patient self-management and might not exhibit the skills or confidence to engage with COPD patients during a consultation. Considering these barriers, alongside the limited consultation time for practitioners, the expanded role of qualified pharmacists could be acceptable. Indeed, many of these health practitioners view patient self-management as lying outside their daily practice and would often refer patients to other experts for psychological or physiological support (164). However, it should be noted that further studies are required both to determine the capability and motivation of pharmacists to play an extended part in facilitating patient management of COPD and to determine additional methods to allow successful implementation in the future (165).

Overall, the evidence highlighted above suggests that HCPs are generally mindful of the advantages of pharmacist-led intervention such as MTM. Pharmacists serve an important role in assisting respiratory patients in their inhaler technique and adherence; however, pharmacists confront obstacles that need to be overcome.

1.8 Community pharmacies' roles during COVID

Pharmaceutical care services throughout the COVID-19 pandemic fell into two classifications: those aimed at preventing and controlling COVID-19 and those aimed at directly treating patients. Community pharmacists are trusted members of the healthcare team by many individuals (166). In the UK, during the main pandemic period, there was a spike in the number of individuals patronising local pharmacies because many people could not meet or reach their clinicians for assistance. Pharmacists saw an increase in patients with more significant medical issues that primary care clinicians traditionally address. Another issue faced by the pharmacies

in the UK related to patients with chronic illnesses who need regular refills on their medicines, as some were worried about their medications, which overloaded pharmacies with their prescription demands. A shortage of several medications in the UK during the early days of the pandemic prompted many individuals to stock up on vital prescription medications (167).

Due to the increased pressure, there was an expansion of hours and personnel at community pharmacies (168), and also a diversification of their role. In the UK, prescriber pharmacists could prescribe mental health medication, including home delivery for those who lived alone if they qualify for an expressly prohibited substance, mental health counselling, and provided prompt COVID-19 testing kits such as the lateral flow test (169).

The COVID-19 pandemic prompted the development of unique innovations such as telepharmacy, which uses digital communication techniques to provide medication consultation remotely. Pharmaceutical services provided by hospital pharmacies in Spain have embraced the remote consultation concept in coordination with general practitioners and neighbourhood apothecaries. As a result, location data prescription delivery and hospital-based medicine dispensation have expanded accessibility and tracing control. Although this concept was promising in Spain, it compromised patient privacy and additional resource consumption (170).

Qualitative research in the UK explored how community pharmacists handled the early stages of the pandemic and adjusted to system stresses. Community pharmacists (n= 23) from 23 different settings (independents, supermarkets, and major chains) were interviewed by phone. This was done by determining which services were most crucial to ensuring the health and well-being of patients. The findings highlighted that

priorities were set to manage the heavy workload. For example, services, including those in the retail sector, were curtailed. In addition, remote consultations were encouraged to facilitate patient interaction while conforming to social distance restrictions and regulations (171).

At China's Huazhong University of Science and Technology, an online pharmacy service was developed using a smartphone app (WeChat App) to provide remote medicine delivery and patient monitoring (169). Since this revolutionary experiment, remote consultation, either by phone or video, has also increased patient follow-up, mainly checking for medication understanding and adherence (172).

In Serbia, ten pharmacists from seven community pharmacies opted to use the telepharmacy service. The study investigated the telepharmacy services throughout the COVID-19 pandemic. Seventy-one people received services, with an average age of 61.31 ± 13.27 years. Chronic illnesses were the most common cause for seeking a pharmacist's advice (74.6%), whereas 7% of patients complained of a chronic ailment deteriorating. Added to that, community pharmacists demonstrated a remarkable degree of resiliency and skill in meeting the requirements of patients (173).

1.9 The role of pharmacists in Shared Decision Making (SDM)

Over the last 20 years, the relationship between patients with long-term conditions and their health care professionals, including doctors, nurses, and pharmacists, has changed. Accepted disease management frameworks include multiple elements such as medication management, monitoring, advising, use, and implementation of specific disease guidance. A recent focus has been on the concept of Shared Decision Making (SDM) in order to provide a well-coordinated course of therapy (159, 174). SDM has often not been well defined. Charles, Gafni (175) have provided a critical description

of SDM, which refers to the relationship between patients and healthcare professionals and integrating the unique features and preferences of the patient into treatment decisions. At the beginning of this millennium, the Institute of Medicine explained the approach was to tailor health care according to patients' expectations and beliefs, to connect patients and providers of healthcare, to interact and to exchange information with them, and to ensure the decision-making process can be made. For patients to be involved in decision-making, patients should obtain information that provides the best evidence for informed decision-making (45). Due to changes in information, conditions and time of the decision, the patients can change their decisions (44, 176).

SDM is a complex, ongoing process that includes a presentation of the clinical options available and their associated benefits, risks and costs, elicitation of the patient's values and preferences, and education. The most common constructs used in SDM are the following: patient values/preferences, patient options, partnership, patient participation, patient education, benefits/risks, deliberation/negotiation, doctor knowledge/recommendations, mutual agreement, process/stages, middle ground, and information exchange (177). The consultation style is distinguished by the lack of command and interruption, avoiding medical terminology and using open-listening dialogue as the basis for SDM. Various modalities have been proposed for the SDM strategy.

A well-accepted model for SDM within the consultation is the 3-talk model, where SDM is implemented in three phases: team talk, option talk, and decision talk (Figure 1.6) (178). The team talk step is when a health professional reminds the patient that choices are available for making the required decisions and that the patient's needs

are relevant in making the decision. Meetings may be held face-to-face or otherwise (i.e., *via* video or telephone call, email, or fax). The option talk step explains and contrasts the different choices for advantages, risks and patient preferences. In the decision talk step, the health service provider steers the patient to develop preferences and make decisions dependent on those preferences. If possible, the patient may be given more time to contemplate the decision (179).

SDM can be particularly pertinent to chronic disease management, which often requires patients to change their lifestyles and reassess their decision-making (180, 181). The potential advantage of SDM relies on patients' and healthcare professionals' willingness and ability to collaborate. This ability could be influenced by factors such as health education, beliefs about chronic diseases and medicines, and the health care system (182). SDM is better when healthcare professionals and patients apply the concept effectively (179, 183). However, SDM may not always be entirely appropriate to all patients or healthcare professionals and thus cannot be applied equally throughout health contexts.

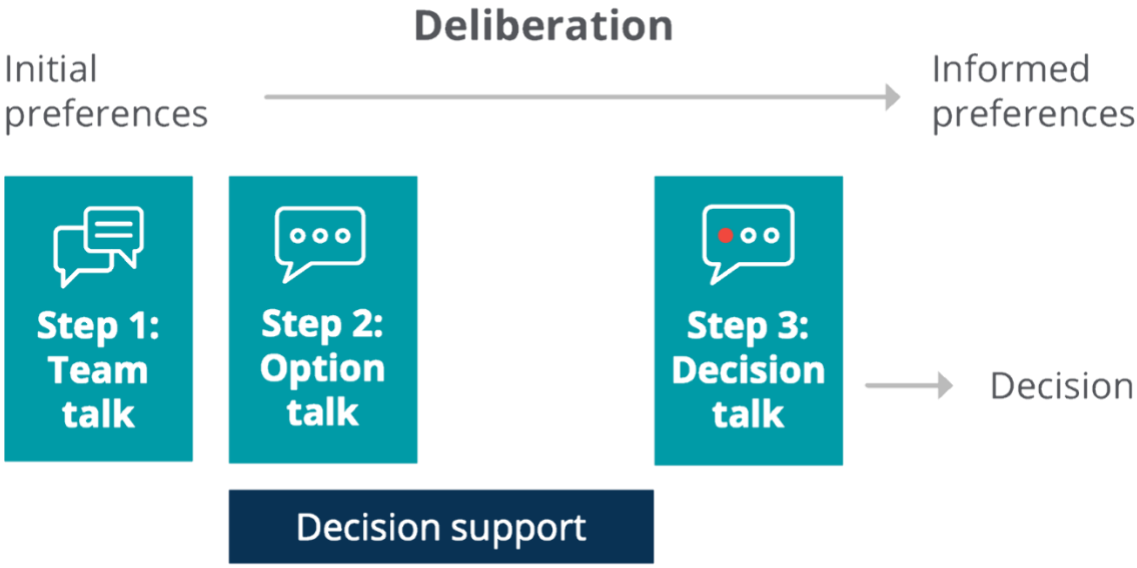


Figure 1.6: Three-talk model of shared decision making

Source: Elwyn et al. (2012) [178]

In this context, integrated practice, for instance, pharmacist-physician shared decision therapy management, includes an assessment of medication use processes, a) prescribing, b) transcribing and documenting, c) dispensing, d) administering, and e) monitoring, to ensure that the prescription drugs are consistent with patient disease status (184). However, this approach has typically been limited to tertiary healthcare settings (185). Practice pharmacists are relatively new members of the primary care team. Many GP practices are starting to employ a pharmacist in addition to working more closely with their community pharmacist in the management of people with chronic diseases. There is a need to evaluate the evidence for this approach.

A Cochrane review conducted in 2014 included 115 RCTs to determine the efficacy of decision aids for patients facing treatment or screening choices, which showed that applying SDM aids for patients led to a 13.34-point increase in the knowledge score in the intervention arm (95% CI 11.17, 15.51) compared to patients receiving standard

care (186). The review revealed positive and valuable impacts on patient engagement (RR 1.51; 95% CI 1.17, 1.96), awareness of risks (RR 1.82; 95% CI 1.52, 2.16), rational understanding of outcomes, HCP-patient communication, and length of consultation time. Another systematic review on how SDM was measured and how these measurements were associated with patients' various outcomes was published in 2015 (187). This review highlighted that SDM was most likely to be associated with positive affective cognitive (in 54%), behavioural (in 37%), and health outcomes (in 25%) (187).

Other reviews (176, 181) have shown a positive effect of SDM and support the suitability of SDM for chronic illness management. NICE recently published a guideline explaining how to make shared decision-making part of everyday care in all healthcare settings (188). The purpose of this guideline was to encourage approaches for healthcare providers and individuals who use services to collaborate in deciding on treatment and care. It provides coaching advice, discussion about the risks, advantages, and implications, utilises decision aids and incorporates SDM into institutional culture and practices.

A study of direct observation of appointments for mental health management has shown that the SDM approach had a beneficial influence on patient satisfaction and adherence to treatments, as well as quality of life (189). Patients who were active in decisions about their own health and care were more likely to consider alternatives thoroughly, understand the value of recommended therapy, and consent to treatment with a positive attitude. In fact, SDM has been shown to enhance long-term outcomes by increasing adherence to the prescribed medication. Additionally, it can result in more efficient healthcare resource allocation (190-192). However, no systematic

review has specifically evaluated the role of pharmacists, as members of interdisciplinary teams, in Shared Decision Making (SDM) for patients with chronic conditions.

1.10 Summary and justification

1.10.1 **Key findings**

1.10.1.1 Gaps in literature

COPD is not a single health problem, but a spectrum of diseases associated with airway obstruction. Adherence to inhaler medication is critical but remains sub-optimal amongst COPD patients. Intervention studies suggest pharmacists could play an important role in improving patients' adherence, but there is a lack of integration of pharmacists within primary care. Despite the potential benefits of community pharmacists in improving adherence/inhaler technique amongst respiratory patients, a few limited studies from Europe and the Middle East suggest that, in general, pharmacist knowledge about inhaled medication and inhaler technique is limited and may hinder the effective implementation of such interventions. There is little evidence-base within British pharmacists concerning the COPD population.

Among the purposes of this thesis, therefore, was to understand the pharmacists' current practice in the UK. The above literature review also indicates a dearth of research exploring patient views about the potential role of the pharmacist in improving inhaler medication adherence and little available scientific literature on the attitudes of healthcare professionals towards this expanded role of pharmacists. Also, the literature suggested that patients' views and use of pharmacists are likely to vary considerably by country and context. Hence, two qualitative studies were planned as part of the thesis to explore UK COPD patients' views about pharmacist-led

consultations to improve understanding of and adherence to inhaler medications, and Healthcare Professionals' (HCPs) views on the potential role of the pharmacist and their integration in the optimisation of medications.

Moreover, the literature review suggests that the advantages of SDM are becoming more widely recognised, but they have yet to be commonly practised in all settings, especially within the primary care context. There is no systematic review focused on the impact of a pharmacist as a part of a multidisciplinary team on SDM. Thereby, among the purposes of this thesis was to systematically appraise the literature to identify and summarise the evidence related to the effectiveness of SDM, including pharmacists, on medication adherence and views and perceptions of both the pharmacists and patients regarding SDM.

1.11 Aim and research questions

In light of the evidence and state of knowledge to date, I will draw attention to five aspects, although interconnected, that emerge as challenges and/or knowledge gaps. The thematic road map in Figure 1.7 illustrates these connections between the chapters.

The following overarching aim for this thesis is:

"To explore the role of the pharmacist in improving adherence to inhaled medication among COPD patients".

To accomplish this thesis's primary goal, the ensuing collection of research questions was formulated:

1. What is the current knowledge and practice of community pharmacists and their perspectives on their role to improve inhaler adherence among COPD patients? (Chapter 2)
2. What are the COPD patients' views about pharmacist-led consultation to improve understanding of and adherence to inhaler medications? (Chapter 3)
3. What are the Healthcare Professionals' (HCPs) views about the potential role of the pharmacist and their integration in the optimisation of medications amongst COPD patients? (Chapter 4)
4. What are the COPD patients' and HCPs' views on COVID-19 and its impacts on the health care service provided to COPD patients? (Chapter 5)
5. What is the evidence related to the effectiveness of SDM including pharmacists on medication adherence, and views and perceptions of both pharmacists' and patients' regarding SDM? (Chapter 6)

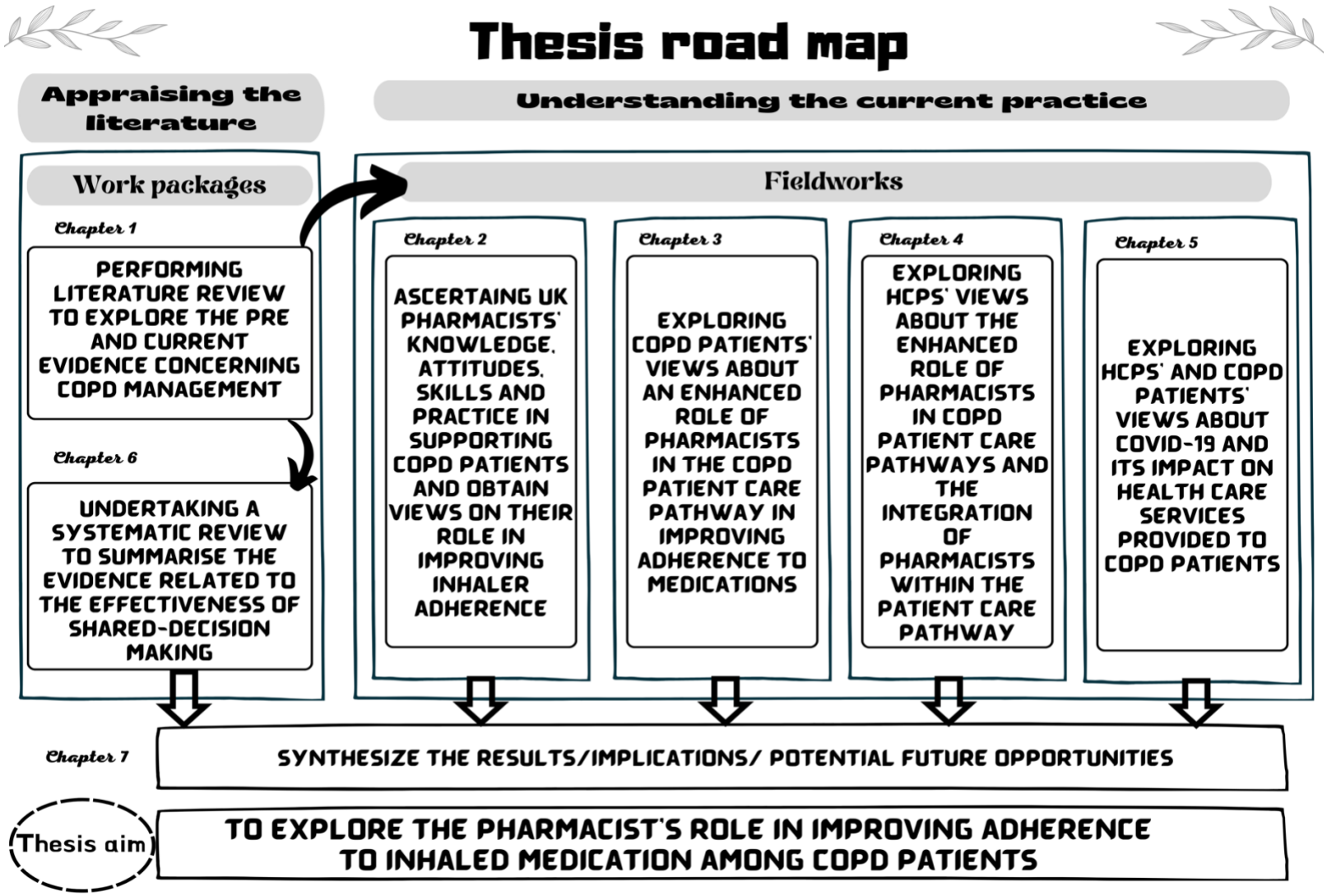


Figure 1.7: Thesis thematic road map

Chapter 2 : Community pharmacists' knowledge, attitude and current practice on their role to improve inhaler adherence among COPD patients: a cross-sectional survey

2.1 Chapter overview

This chapter presents the first work package in this thesis, a cross-sectional study which addresses questions about the knowledge, attitudes, skills, and practice of community pharmacists across the UK. It also explores community pharmacists' views on their role in improving inhaler adherence among COPD patients. The results of this study are presented with a discussion of its significance in light of the prior literature.

2.2 Abstract

Background

Inhaler medication is the most important pharmacological treatment for COPD patients, yet it is recognised that non-adherence is a significant problem, leading to reduced quality of life and increased morbidity, mortality and health care expenditure. Inhaler non-adherence may be related to a range of factors including inhaler type, dosing schedule, patient characteristics and ineffective technique. Inhaler choice and effective training of inhaler technique could be improved by an integrated approach involving community pharmacists.

Aim

To ascertain UK pharmacists' knowledge, attitudes, skills and practice in supporting COPD patients and obtain views on their role in improving inhaler adherence.

Methods

Community pharmacists were identified and recruited *via* various routes including the Primary Care Respiratory Society (PCRS) and professional networks. A questionnaire was available online within the 'Online Surveys' tool (https://www.onlinesurveys.ac.uk) or on paper for distribution at conferences and local community pharmacies. The questionnaire contained three sections: demographics and characteristics of the pharmacist and their pharmacy, pharmacists' knowledge, attitudes, skills and current practices, and views on the role of the community pharmacist. The data were described using simple descriptive statistics using Stata software version 15. Free text answers were imported to NVivo software to extract meaningful information using Braun and Clarke's six steps of thematic analysis.

Results

58 participants completed the questionnaire. Nearly half (N=28, 48.3 %) of the participants were males. Most community pharmacists had adequate knowledge of inhalers, reporting that their primary source of knowledge was their formal university education, or independent prescribing courses (N=49, 84.5 %). Views of pharmacists included that building up trust with COPD patients contributes to patient satisfaction with the services provided by the community pharmacies; accessibility and convenience of pharmacies were positives for the pharmacy industry; and COPD patients were willing to share their views with community pharmacists as they listen more than General Practitioners. Pharmacists reported that COPD patients expressed their appreciation for the counselling offered by community pharmacists on inhalers and other treatments. Few pharmacists (N=13, 22.4 %) reported providing input into the choice of device for COPD patients in their community. However, almost all community pharmacists indicated that they provided training on inhalation technique (N=57, 98.3%), and (N=27, 46.6%) reported checking inhaler technique annually. The main barriers for community pharmacists were: time (N=49, 84.5 %), financial constraints (N=30, 51.7 %), and lack of access to medical records (N=15, 25.9 %). Better communication and integration were required to improve the services provided to COPD patients.

Conclusion

The most essential information about inhalers were well-understood by the majority of UK community pharmacists. There is a potential willingness from UK pharmacists to help COPD patients by offering high-quality services, including appropriate inhaler use instructions and self-management plans. Further research, either quantitative or qualitative, is needed about the integration of pharmacists within the patient care pathway in terms of perceived barriers and enablers to this approach.

2.3 Background

As presented in the literature review (Chapter 1, section 1.7), COPD is one of the most common long-term conditions (LTC) in primary care in the UK and worldwide (46).

Patients are heavily reliant on inhaled pharmacological therapy to alleviate their symptoms and reduce risk of severe exacerbations. Unfortunately, adherence to inhaled medication is often suboptimal amongst COPD patients (51). The community pharmacy has the opportunity to work closely with the primary care team, although this is a new phenomenon and not that common (193). The COVID pandemic has made it even more difficult to access the GP, therefore the pharmacist has been an increasingly important contact for patients (116, 117). The accessibility of community pharmacies is key to their role in supporting primary care services. Several pieces of evidence highlight the positive role of community pharmacists in supporting COPD patients with their inhalers (Chapter 1, section 1.7).

Despite the potential benefits of community pharmacists in improving adherence/inhaler technique amongst respiratory patients, only a few limited studies (148-150, 194) from Europe and the Middle East are available which document pharmacists' knowledge and practice regarding inhaler medications. There is no equivalent evidence for the UK. A qualitative study from London suggested that one main barrier for the community pharmacists in providing COPD support, is a lack of integration with primary care services including inadequacy of communication among health care practitioners, limited technologies to support respiratory patients and limited acceptance of the clinical role of community pharmacists (146). However, further work is needed to explore current practice and services offered by community pharmacists more widely, and to better understand the potential for community pharmacists to have an enhanced role in helping COPD patients improve their adherence to inhaled medications.

2.4 Aims and Objectives

The aim of this study was to ascertain pharmacists' knowledge, attitudes and skills across the UK and obtain views on their role to improve inhaler adherence among COPD patients.

The objectives of this study were to explore among community pharmacists a) current knowledge of COPD treatment guidelines, inhaler medication, and technique, b) attitudes towards the use of technological devices and other possible interventions to help improve inhaler adherence among COPD patients, c) skills and current practices towards COPD patients and inhaler medications, and d) views on the role of the community pharmacist in advising and training on inhaler medications for COPD patients and their role in collaborating with the primary care team.

2.5 Materials and Methods

2.5.1 Study design

A cross-sectional survey disseminated to community pharmacists across the United Kingdom between Sep 2020 and Nov 2021.

2.5.2 Population, recruitment and data collection

The population of this study was community pharmacists in the UK with at least three months of work experience. Regarding the sample size calculation, based on the database provided by the professional organisations and pharmacies, we estimated there were about 9000 community pharmacies registered. A total of 369 or more responses were needed to have a confidence level of 95% that the real value was within ±5% of the surveyed value. To maximise the response rate, we offered an incentive for completing the survey, used reminders to follow-up at two weeks and five weeks, used a variety of

channels to distribute the survey including emails and in-person, and made the survey mobile-friendly by using the Online Survey platform.

Community pharmacists were identified and recruited *via* the Primary Care Respiratory Society (PCRS) and professional networks including Centre for Pharmacy Postgraduate Education, Local Pharmaceutical Committee, and Jhoots chain pharmacies. The primary Care Respiratory Society disseminated the online questionnaire *via* their members' newsletter on one occasion, and the lead coordinator of each professional network disseminated study invitations by email and digital platforms including Twitter, Facebook, or Telegram. Reminders were sent out to all contacts after two weeks and five weeks for the participants who were identified *via* the digital medium (Appendix 2).

A complementary face-to-face approach was accomplished by attending the largest relevant pharmacy conference "the Pharmacy Show" in Oct 2021 as it is the major networking event for more than 2000 pharmacy professionals ranging from the big pharma employees to independent community pharmacists. It covers a wide range of activities including education and networking. Questionnaires with an attached Participant Information Sheet were offered to conference participants using a variety of approaches, including distribution at the registration desks and exhibitor sites. All questionnaires were requested to be returned to the lead researcher and placed in a sealed box at a designated visible space manned by the lead researcher within the conference itself. An additional ten questionnaires were also handed out at community pharmacies (Jhoots) in the central Birmingham area, and returned by hand at the end of the working day, the following day or thereafter. An incentive prize draw to an Apple iPad was provided as a token of appreciation.

2.5.3 **Questionnaire**

The questionnaire content and wording was informed by relevant literature and developed considering the Theoretical Domains Framework (TDF), an important tool for use in behaviour change and implementation research. TDF has been referenced by more than 800 review articles (Web of Knowledge accessed December 2022). Scholars may use TDF, a exhaustive framework, to investigate a wide variety of issues. (i.e., hurdles and enablers) that might drive behaviours. It is a meaningful tool to alter an existing behaviour in which it must first identify the antecedents of that behaviour. The TDF extends beyond other theories by including not only internal factors (such as beliefs and motivations) but also external ones, such as those found in one's social and physical environments. The TDF incorporates 33 behavioural psychological theories in 84 constructs held in 14 domains (Appendix 3). The following domains were considered to address the objectives of this research: knowledge, skill, intention social/professional role, identity beliefs and capability beliefs and consequences, decision process, emotion, social influence, environmental context, and behavioural regulation and were used to construct the questionnaire (Appendix 4) (195).

The questionnaire contained three sections: demographics and characteristics of the pharmacist and their pharmacy, pharmacists' knowledge, attitudes towards the use of technological devices, skills, and practice and their views on the role of the community pharmacist in advising and training on inhaler medications for COPD patients and their role in collaborating with the primary care team. Validated questions were used where available.

The socio-demographic section included: respiratory qualifications of participants, years of work experience, and location, type, and size of the pharmacy they worked at. The second part of the survey consisted of statements based on a 5-point Likert-scale,

categorical and binary questions. This part focused on community pharmacists' knowledge of inhaler medication devices, and its required technique, their skills and current practice related to COPD medication such as disseminating counselling information to patients and details of inhaler technique training, and their attitudes towards education, the use of technological devices, and counselling COPD patients. The final part focused on the pharmacist's role in how to improve medication adherence in COPD patients. This part encompassed the barriers to providing input on the choice of inhaler, approaches to improve inhaler adherence in COPD patients, the views of community pharmacists about the ways to improve communication between community pharmacists and general practitioners and the pharmacists' views on the acceptability of services being offered in a community pharmacy to patients (Appendix 5).

The questionnaire was provided in both an online format using the 'Online Surveys' tool (https://www.onlinesurveys.ac.uk) and face-to-face paper format. Our advisory Group (pharmacy champions, clinical pharmacists, community pharmacists, COPD nurse, COPD expert researchers, and COPD patients) provided important feedback to improve the content and layout of the survey, to improve its validity, in addition to testing compatibility for use on computers, iPads and mobile devices. Piloting also investigated the understandability and appropriateness of the questionnaire by four individuals (three pharmacists with more than ten years of experience, and one health promotion expert).

2.6 Data analysis

The data were analysed using descriptive statistics using Stata software version 15. (132). Categorical variables were reported as frequencies and percentages. There was one continuous variable (age) which was reported as mean and standard deviation as upon visual inspection it was normally distributed. Collapsing the Likert scale responses was done by combining some of the response options to create broader categories. For

example, responses of 4 and 5 could be combined to indicate agreement. For the two free text questions, the data were imported into NVivo software to extract meaningful information using Braun and Clarke's six steps of thematic analysis (see Chapter 3, section 3.6) then the relevant key concepts and word trends were retrieved. After that, the categorisation process was applied to index each response.

2.7 Ethical considerations

The study was approved by the University of Birmingham's Ethical committee (ERN_20-0315) (Appendix 1). Consent was provided on the landing page. All data were anonymised and securely stored following the General Data Protection Regulation (GDPR) rules and policies. The Online Survey tool generated an anonymised ID code for each participant's responses, stored separately from the personal email address form. The questionnaire data were therefore entirely anonymous, with no means of re-identification.

The anonymised data were only accessed by the research team for analysis purposes. The exported data were stored in a password-encrypted personal computer and University of Birmingham cloud storage. A secured standard filing cabinet was used to store hard copies at the University of Birmingham. All submitted personal email addresses were destroyed once the iPad winner was notified.

After completing the study, anonymised data will be stored for ten years (in line with University of Birmingham recommendations), after which electronic files will be deleted, and hard copies will be shredded.

2.8 Results

A total of 544 participants accessed the landing page of the online questionnaire having been recruited *via* digital platforms, including emails and social media. A total of 15

(2.75%) of these completed the questionnaire. An additional 43 (forming 74.1% of respondents) were recruited *via* the large Pharmacy conference. Unfortunately, none of the pharmacists completed the questionnaire *via* direct recruitment at local pharmacies.

2.8.1 **Demographic and characteristics**

Of the 58 individuals that took part, nearly half N=28 (48.3%) were males, and the same percentage 28 (48.3%) were females. Two (3.4%) participants did not disclose their gender (Table 2.1). The majority of the respondents were: Asian or Asian British (N=30, 51.7%); (N=11, 19%) were White and (N=6, 10.3%) were African/Caribbean. The largest group of participants (N=17, 29.3%) were aged 20-29 years, followed by (N=14, 24.1%) between 30-39 years. Over half of the participants (N=30, 51.7%) had a bachelor's degree in pharmacy while (N=25, 43.1%) had a Masters or PhD degree.

The majority of participants N=44 (75.9%) had no specific respiratory qualifications although the remainder reported having a diploma or Master's in respiratory medicine, were COPD or asthma specialist pharmacists, had respiratory disease management, or the Association for Respiratory Technology & Physiology (ARTP) qualifications (the national, professionally recognised qualifications in respiratory function testing and spirometry in the UK) (Table 2.1). Thirty (51.7%) respondents reported ten or more years' pharmacy experience. More respondents were working in larger pharmacies (100-199 prescriptions per day) than in small pharmacies (196). Ten (17.2%) of the respondents reported that their pharmacies were within primary care practice and twelve (20.7%) were adjacent to primary care practices.

When the participants were asked about the type of pharmacy they worked in, 33, (56.9%) indicated that they practised in chain pharmacies whilst 21 (36.2%) practised in independent pharmacies. Furthermore, 36 (62.1%) reported that they worked full-time. In terms of geographical health regions where the community pharmacists were

practising, 14 (24.1%) were from London and 11 (19%) from West Midlands, and 7 (12.1%) responses were received from Yorkshire and the Humber.

Among the community pharmacies represented, the NMS, MUR, vaccination and smoking cessation services were the most widely offered health services for COPD patients. One of the two participants who reported other options indicated that no services were provided, and the other reported that the Objective Structured Clinical Examination (OSCE) was offered to COPD patients. OSCE is a type of assessment used to evaluate pharmacy students' clinical skills. The constructs of OSCE can be applied to patients to enhance their outcomes, including physical examination, patient education, medicines reconciliation, active listening, and dispensing medication. Less than half (N=26, 44.8%) offered training in inhaler technique. To be more specific, more community pharmacists who were working full-time indicated that they trained COPD patients on inhaler technique compared to the community pharmacists who were working part-time (N=17 (65.4%) *vs* N=9 (34.6%)). Another factor was related to the years of experience, where the amount of involvement in inhaler technique training was proportional to the number of years of experience a pharmacist had. For example, community pharmacists with experience equal or more than 15 years reported more inhaler training services for COPD patients (N=5, 57.7%) compared to others.

Table 2.1: Sociodemographic and other characteristics of the participants

Variables	N (%)
Gender	
Male	28 (48.3)
Female	28 (48.3)
Prefer not to say	2 (3.4)
Age	
20-29	17 (29.3)
30-39	14 (24.1)
40-49	11 (19)
50-59	10 (17.2)
60-69	6 (10.3)
Education level	
Diploma	3 (5.2)
Bachelor's degree	30 (51.7)
Master's degree	23 (39.7)
PhD	2 (3.4)
Other	0
***Respiratory Qualification**	
Diploma in Respiratory Medicine	1 (1.7)
Masters in respiratory medicine	1 (1.7)
COPD specialist pharmacists	5 (8.6)
Asthma specialist pharmacists	5 (8.6)
ARTP qualifications	2 (3.4)
Respiratory Disease Management	5 (8.6)
Other	1 (1.7)
None of these	44 (74.1)
Work experience (years)	
<1	3 (5.2)
1-4	14 (24.1)
5-9	11 (19)
10-14	5 (8.6)
≥15	25 (43.1)
Job title	
Assistant pharmacist	5 (8.6)
Pharmacist	44 (75.9)
Senior pharmacist	5 (5.6)
Consultant pharmacist	2 (3.4)
Other	2 (3.4)
Ethnicity	
White	11 (19)
Mixed/Multiple ethnic groups	0 (0)
Asian/Asian British	30 (51.7)
Black/ African/Caribbean/Black British	6 (10.3)
Other ethnic group	4 (6.9)
Prefer not to say	7 (12.1)
Health region of the pharmacy	
London	14 (24.1)
East of England	1 (1.7)
South East	4 (6.9)
South West	6 (10.3)
West Midlands	11 (19)
East Midlands	5 (8.6)
North East	3 (5.2)
North West	0
Yorkshire and the Humber	7 (12.1)
Wales	2 (3.4)
Scotland	2 (3.4)
Northern Ireland	3 (5.2)
Pharmacy type	
Independent	21 (36.2)
Chain	33 (56.9)
Other	4 (6.9)
Size of the pharmacy (prescriptions per day)	
1-50	4 (6.9)
51-99	7 (12.1)
100-199	26 (44.8)
200-299	15 (25.9)
≥300	6 (10.3)
Working pattern	
Full-time	36 (62.1)
Part-time	22 (37.9)
Pharmacy location	
Within primary care practice	10 (17.2)
Adjacent to primary care practice	12 (20.7)
Neither	36 (62.1)
***Professional services provided by the pharmacy**	
Medication use review (MUR)	46 (79.3)
New medicine service (NMS)	52 (89.7)
Vaccination	45 (77.6)
Smoking cessation service	35 (60.3)
Inhaler technique training	26 (44.8)
Pulmonary rehabilitation referral	7 (12.1)
Other	2 (3.4)

*: Participants could answer as many as applied.

2.8.2 Community pharmacist's knowledge about inhaler use

Most respondents (N=49, 84.5%) indicated that the main source of their current knowledge about inhaler use was from formal education, i.e., a university course, but the second most common source of knowledge (N=34, 58.6%) was from reading the device leaflet, followed by attending Continuing Professional Development courses (CPD) (N=27, 46.6%). Despite (N=47, 81%) of respondents stating they were at least moderately aware of different inhaler devices, only (N=7, 12.1%) respondents correctly identified all ten Dry Powder Inhalers. The most frequently recognised DPI were the Accuhaler™ and Turbohaler™. One in five people incorrectly asserted that the Autohaler™ was a DPI (7 individuals with respiratory qualification *vs* 4 individuals with no respiratory qualification), and 17.2% that the Easi-Breathe™ and 17.2% the Respimat™ were DPIs (5 individuals with respiratory qualification *vs* 5 individuals with no respiratory qualification).

Most community pharmacists correctly answered basic essential knowledge questions about inhalers, although some respondents did not recognise the most important steps required for using them. For *pMDIs*, 22 (37.9%) mistakenly reported the second most important step (inhale progressively slowly) instead of the most important step (fire the device during inhalation). Most, however (N=46, 79.3%) of the respondents correctly reported that rapid inspiration was not recommended.

Just under two-thirds (N=37, 63.8%) of respondents distinguished the most important step for the DPI and 34 (58.6%) correctly indicated that it was acceptable if the patient did not feel the DPI powder go down. The majority of respondents (N=47, 81%) showed satisfactory knowledge about the benefits of spacer devices.

More than half (N=34, 58.6%) respondents correctly acknowledged the timing needs to wait before COPD patients taking a second puff, half of the respondents (N= 29, 50%) were knowledgeable about how long the patients should hold their breath after taking a puff.

Only N=24 (41.4%) correctly indicated that the DPI should be cleaned after every use, with a similar proportion N=23 (39.7%) correctly identifying that the spacer should be cleaned every week.

For the steroid inhaler, just over half of the respondents N=32 (55%) correctly reported that their effectiveness was not improved by taking beta-agonist inhalers first. When the respondents were questioned on the most important variable that should be considered when healthcare professionals prescribe an inhaler device, N=37 (63.8%) stated their view that patients' experience with a specific device was the most important variable followed by patients' preferences N=11 (19%), although this was considered much less important (Table 2.2).

Table 2.2: Community pharmacists' knowledge

Item	Participants who have respiratory qualification n=14 N (%)	Participants who don't have respiratory qualification n=44 N (%)
***1. Main source of community pharmacist's current knowledge about inhaler use.**		
Formal education e.g. University course	14 (100)	35 (79.5)
From a specialist website	4 (28.6)	10 (22.7)
From the Right Breathe app	5 (35.7)	7 (15.9)
From attendance at meetings, or workshops organized by pharmaceutical companies or scientific societies	8 (57.1)	19 (43.2)
From reading the inhaler device leaflet	8 (57.1)	26 (59.1)
From personal experience and common sense	11 (78.6)	15 (34.1)
Other	0 (0)	0 (0)
2. Community pharmacists' awareness of different inhaler devices.		
Not at all aware	0 (0)	0 (0)
Slightly aware	1 (7.1)	10 (22.7)
Moderately aware	0 (0)	23 (52.3)
Very aware	8 (57.1)	10 (22.7)
Extremely aware	5 (35.7)	1 (2.3)
***3. Identify the DPI devices from the following list**		
^Accuhaler™	14 (100)	35 (79.5)
Autohaler™	7 (50)	4 (9.1)
^Breezhaler™	12 (85.7)	24 (54.5)
^Handihaler™	12 (85.7)	26 (59.1)
^Nexthaler™	12 (85.7)	24 (54.5)
^Novolizer™	8 (57.1)	6 (13.6)
Respimat™	5 (14.3)	5 (11.4)
^Twithaler™	8 (57.1)	6 (13.6)
pMDI	2 (14.3)	3 (6.8)
Easi-Breathe™	5 (35.7)	5 (11.4)
^Ellipta™	11 (78.6)	31 (70.5)
^Genuair™	12 (85.7)	13 (29.5)
^Easyhaler™	13 (92.9)	22 (50)
^Turbohaler™	12 (85.7)	38 (86.4)
I do not know	0 (0)	2 (4.5)
4. The most important step for correct pressurized metered-dose inhaler (*pMDI*) inhalation.		
Shake the device before inhalation	3 (21.4)	9 (20.5)
Exhale deeply before inhalation	0 (0)	0 (0)
^Fire the device during inhalation	6 (42.9)	11 (25)
Inhale deeply and forcefully	1 (7.1)	5 (11.4)
Inhale slowly and progressively	4 (28.6)	18 (40.9)
I don't know	0 (0)	1 (2.3)
5. The most important step for correct dry powder inhaler (DPI) inhalation.		
To shake the device before inhalation	1 (7.1)	2 (4.5)
To exhale before inhalation	2 (14.3)	1 (2.3)
To fire the device during inhalation	0 (0)	3 (6.8)
^To breathe in deeply and forcefully	10 (71.4)	27 (61.4)
To inhale slowly and progressively	1 (7.1)	9 (20.5)
I do not know	0 (0)	2 (4.5)

6. Basic and crucial knowledge questions related to inhalers.		
a) Patients can stop taking their long-acting inhalers when their COPD symptoms get better.		
Strongly Disagree	9 (64.3)	29 (65.9)
Disagree	3 (21.4)	13 (29.5)
Neither agree nor disagree	2 (14.3)	1 (2.3)
Agree	0 (0)	1 (2.3)
Strongly Agree	0 (0)	0 (0)
b) When using the pressurized metered-dose inhaler (pMDI), a rapid inspiration is recommended?		
True	3 (21.4)	6 (13.6)
^False	11 (78.6)	35 (13.6)
I do not know	0 (0)	3 (6.8)
c) Spacer use results in a significant reduction in the amount of aerosol that is deposited in the mouth and throat.		
^True	12 (85.7)	35 (79.5)
False	0 (0)	4 (9.1)
Depends on the inhaler type	2 (14.3)	3 (6.8)
I do not know	0 (0)	2 (4.5)
d) It is acceptable if the patient does not feel the dry powder inhaler (DPI) powder go down.		
^True	10 (71.4)	24 (54.5)
False	1 (7.1)	5 (11.4)
Depends on the inhaler type	3 (21.4)	8 (18.2)
I do not know	0 (0)	7 (15.9)
e) How long should you tell patients to wait before taking a second puff?		
At least 5 seconds	0 (0)	3 (6.8)
At least 10 seconds	4 (28.6)	16 (36.4)
^At least 20 seconds	10 (71.4)	24 (54.5)
I do not know	0 (0)	1 (2.3)
f) How long should you tell patients to hold their breath after taking a puff?		
At least 4 seconds	1 (7.1)	3 (6.8)
At least 6 seconds	5 (35.7)	16 (36.4)
^At least 8 seconds	8 (57.1)	21 (47.7)
I do not know	0 (0)	4 (9.1)
g) How often should you tell patients to clean their spacer?		
After each use	8 (57.1)	5 (11.4)
Every day	3 (21.4)	16 (36.4)
^Every week	3 (21.4)	20 (45.5)
I do not know	0 (0)	3 (6.8)
h) How often should you tell patients to clean their DPI mouthpiece?		
^After each use	11 (78.6)	13 (29.5)
Every day	0 (0)	17 (38.6)
Every week	3 (21.4)	10 (22.7)
I do not know	0 (0)	4 (9.1)
i) Inhaled steroid effectiveness is improved by taking a β-agonist first.		
True	4 (28.6)	13 (29.5)
^False	10 (71.4)	22 (50)
Depends on the dose	0 (0)	3 (6.8)
I do not know	0 (0)	6 (13.6)
7. The most variable that the health care practitioners should considered when they prescribe an inhaler device.		
Patients' preferences	2 (14.3)	9 (20.5)
Patients' age	1 (7.1)	4 (9.1)
Patients' experience with a specific device	10 (71.4)	27 (61.4)
Patients' educational level	0 (0)	2 (4.5)
Other	2 (14.3)	1 (2.3)

*: Participants could answer as many as applied.
^: Correct choice

2.8.3 **Community pharmacists' current practice/skills**

Just under one third (N=17, 29.3%) reported that the Turbohaler™ was the most commonly prescribed inhaler for COPD patients, followed by the *pMDI* (N=14, 24.1%). 18 respondents (31%) reported that Anoro Ellipta™ was the second most common prescribed inhaler (Figure 2.1, 2.2). Most (N=41, 70.7%) community pharmacists indicated that they did not use (or rarely used) electronic devices to check inhaler technique for COPD patients (Table 2.3). Only 13 (22.4%) reported using *In-Check*™ which accounted for about three-quarters of those using a device.

Few pharmacists (N=13, 22.4%) reported providing input into the choice of device for COPD patients in their community. On the other hand, the majority (N=49, 84.5%) affirmed that they assessed the patient's inhalation technique when dispensing an inhaler device (Table 2.3).

Almost all surveyed community pharmacists indicated that they provided training on the inhalation technique (N=57, 98.3%). Just over half of the surveyed community pharmacists (N=32, 55.2%) reported that only the pharmacists trained the patients on the inhalation technique of the prescribed device. Less than half (N=27, 46.6%) reported checking inhaler technique annually. Only (N=12, 38.7%) of these respondents provided reasons for not regularly checking inhalation technique, including that there were other healthcare providers checking the inhaler techniques, patients rarely attended the pharmacy, and the MUR service was no longer a commissioned service. The main tools used to counsel COPD patients were verbal instructions, N=44 (75.1%) and leaflets N=35 (60.3%) (Table 2.3).

The most common materials provided for patients to take home were inhaler technique brochures (N=33, 56.9%) and COPD self-management leaflets (N=25, 43.1%), followed by verbal instructions alone (N=16, 27.6%). Digital educational materials (digital QR code, digital apps, or YouTube) were the least common (N=14, 24.1 %) (Table 2.3).

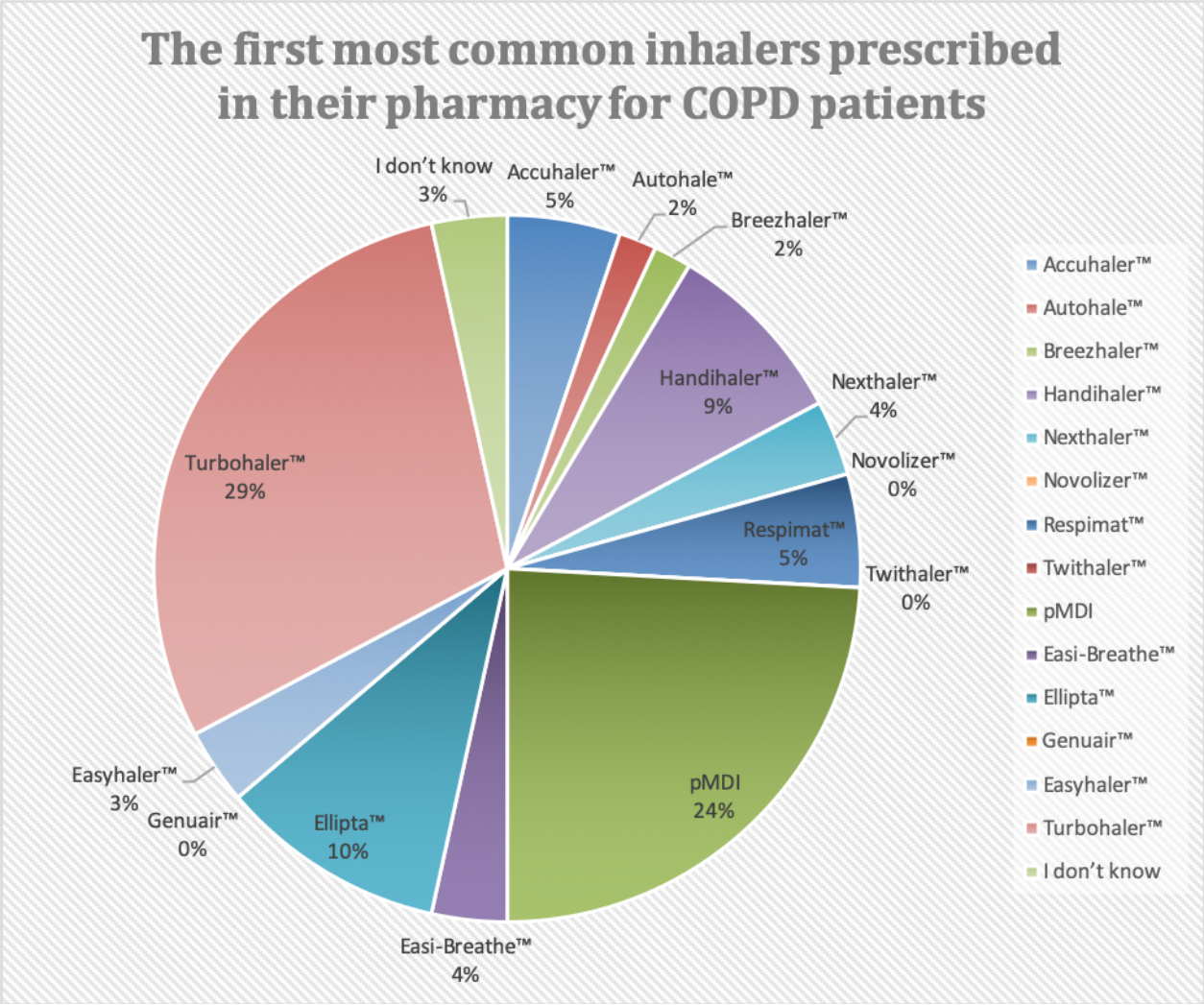


Figure 2.1: The most common inhalers prescribed in their pharmacy for COPD patients

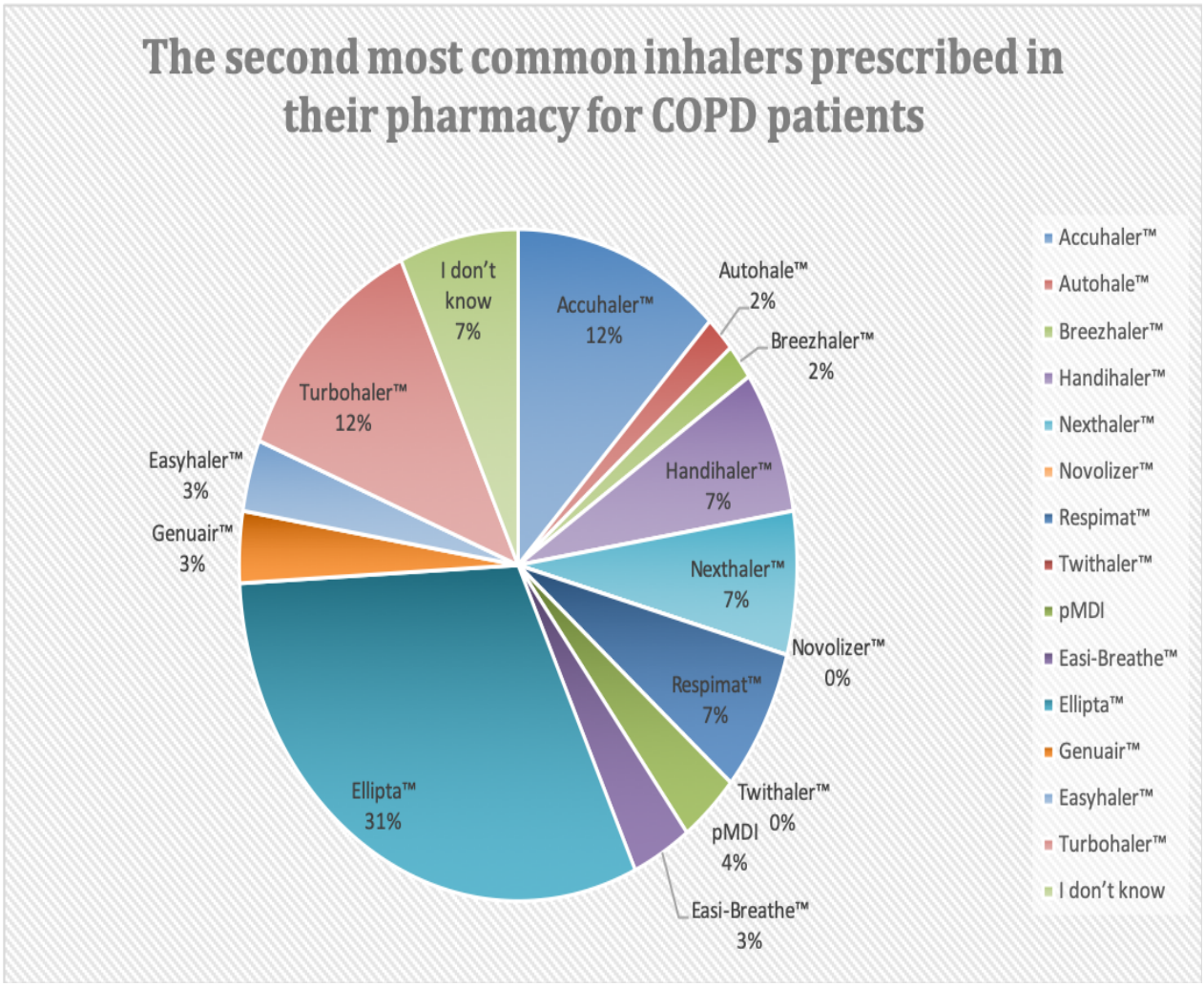


Figure 2.2: The second most common inhalers prescribed in their pharmacy for COPD patient

Table 2.3: The electronic devices use to check inhaler technique, tools use when to conducting services to COPD patients, educational materials that community pharmacist provide to COPD patients to take home, and providing input into the choice of device for COPD

Item	N (%)
***The frequency of use the electronic devices to check inhaler technique for COPD**	
Never	37 (63.8)
Rarely	8 (13.8)
Sometimes	8 (13.8)
often	2 (3.4)
Always	2 (3.4)
*** The electronic devices use to check inhaler (Assume COPD patients)**	
Inhaler Compliance Assessment Device (INCA™)	4 (6.9)
Aerosol Inhalation Monitor (AIM™)	1 (1.7)
In-Check™	13 (22.4)
Mag-Flo™	1 (1.7)
SmartMist™	0
pMDI datalogger™	0
Other	0
No device used	41 (70.7)
At pharmacy, who trains the patients on inhalation technique of the prescribed device	
Only the pharmacists	32 (55.2)
Only assistant pharmacist	3 (5.2)
Either pharmacists or assistant pharmacists, it depends	22 (37.9)
Nobody, patients receive written information	0 (0)
Nobody, patients do not receive written information	0 (0)
Other (i.e. nurse)	1 (1.7)
Annual checking for inhalation technique	
Yes	27 (46.6)
No	31 (53.4)
#Reasons (if No)	
They should already know how to do this	17 (54.8)
It is not necessary	2 (6.5)
Other	12 (38.7)

***The tools use when counselling or conducting services COPD patients.**	
Verbal instructions	44 (75.9)
Leaflets	35 (60.3)
YouTube videos	15 (25.9)
Mobile Apps	7 (12.1)
Guidelines	7 (12.1)
Pictographs (pictures and graphs)	10 (17.2)
Other (to be illustrated by a participant)	3 (5.2)
None	3 (5.2)
*** Educational material provided for patients to take home**	
Inhaler technique brochure	33 (56.9)
COPD self-management leaflet	25 (43.1)
Digital (QR code) COPD overview leaflet	3 (5.2)
Digital App (e.g. my mhealth:myCOPD or RightBreathe)	10 (17.2)
Only verbal instructions	16 (27.6)
Other (YouTube)	1 (1.7)
Not appropriate	3 (5.2)
***Providing input into the choice of device for COPD patients in their community**	
Never	26 (44.8)
Rarely	19 (32.8)
Sometimes	8 (13.8)
Often	3 (5.2)
Always	2 (3.4)
***Assessing the patient's inhalation technique when dispensing an inhaler device**	
Never	4 (6.9)
Rarely	5 (8.6)
Sometimes	29 (50)
Often	8 (13.8)
Always	12 (20.7)

*: Participants could answer as many as applied

2.8.4 **Community pharmacists' attitudes**

All but two community pharmacists agreed or strongly agreed that it was meaningful to provide counselling for COPD patients to improve adherence (Table 2.4).

Similarly, the majority (N=52, 89.6%) agreed/strongly agreed that the pharmacists might be able to support COPD patients to improve the self-management of their disease, and most (N=46, 79.3%) also thought that the pharmacist should have an important role in advising patients on which type of inhalers they should use and in educating patients on how to use their inhalers (N=55, 94.8 %), although slightly fewer (N=48, 82.8 %) agreed that the pharmacist should have an important role in monitoring patients' adherence to inhalers (Table 2.4).

Table 2.4: Community pharmacist attitudes towards the use of technological devices and other possible interventions.

Survey statement	**Number of responses and percentages for each category**				
	Strongly Disagree (N, %)	**Disagree (N, %)**	**Neither disagree nor agree (N, %)**	**Agree (N, %)**	**Strongly disagree (N, %)**
It is meaningful to provide counselling for COPD patients to improve adherence.	0 (0)	1 (1.7)	1 (1.7)	30 (51.7)	26 (44.8)
The Pharmacist may be able to support COPD patients to improve the self-management of their disease.	0 (0)	3 (5.2)	3 (3.5)	30 (51.7)	22 (37.9)
In the treatment pathway for patients with COPD, the pharmacist should have an important role in advising patients on which type of inhalers they should use.	1 (1.7)	0 (0)	11 (19)	32 (55.2)	14 (24.1)
The pharmacist should have an important role in educating patients on how to use their inhalers.	2 (3.4)	0 (0)	1 (1.7)	33 (56.9)	22 (37.9)
The pharmacist should have an important role in monitoring patients' adherence to inhalers.	1 (1.7)	1 (1.7)	8 (13.8)	29 (50)	19 (32.8)

Participants were asked about their main barriers and enablers in supporting patients' use of inhalers. The vast majority of respondents (N=49, 84.5%) indicated that time constraints was the main barrier, followed by financial constraints (N=30, 51.7%), and communication between the pharmacists and other health care professionals (N=27, 46.6%). In addition, some respondents (N=21, 36.2%) identified that lack of training and lack of resources (such as placebo inhalers and technique checking devices) were important barriers. There were other barriers identified by the community pharmacists, including lack of public recognition of the role of community pharmacists (N=17, 29.3%), lack of access to medical records (N=15, 25.9%), and lack of engagement from patients with pharmacists (N=10, 17.2 %) (Table 2.5).

Table 2.5: The main barriers to providing input on the choice of the inhaler.

* Barriers	N (%)
Time constraints	49 (84.5)
Financial constraints	30 (51.7)
Communication between the pharmacist and other health care professionals	27 (46.6)
Lack of training	21 (36.2)
Lack of resources (e.g. placebo inhalers or inhaler technique checking devices)	21 (36.2)
Lack of public recognition of the role of community pharmacists due to patients' perception of the status of the pharmacist in the health professional hierarchy	17 (29.3)
Lack of access to patients' medical records	15 (25.9)
Lack of engagement from patients with pharmacists	10 (17.2)
Lack of knowledge	8 (13.8
Other	1 (1.7)
*** Enablers**	**N (%)**
Simplifying the regimen	40 (69)
Discussing side effects	30 (51.7)
Linking inhaler use to the daily habit	23 (39.7)
Providing reminders	23 (39.7)
Shared decision making	23 (39.7)
Using Smart inhalers	10 (17.2)
Linking inhaler use to personal goals	10 (17.2)
Switching regimen or inhaler	8 (13.8)
Motivational interviewing	7 (12.1)

*: Participants could answer as many as applied.

On the other hand, community pharmacists suggested that the most important enablers (Table 2.5), in their opinion, to improving inhaler adherence in COPD patients would be: simplifying patients' medication regimen (N=40, 69%), discussing side effects (N=30, 51.7%), and providing reminders and SDM (N=23, 39.7%). In contrast, they indicated that the three least important approaches to improving inhaler adherence in COPD patients were motivational interviewing (N=7, 12.1%), switching regimen or inhaler (N=8, 13.8%), using smart inhalers (N=10, 17.2%) and linking inhaler use to personal goals (N=10, 17.2%).

Community pharmacists were asked about their views on what interventions might be helpful to optimise inhaler adherence. The majority (N=56, 96.6%) agreed/strongly

agreed that regularly checking inhaler technique and intervening where necessary would help, 52 (89.7%) agreed that better electronic communication system with primary care would improve inhaler adherence and 50 (86.2%) agreed that additional training for pharmacists would be helpful. The other responses were as follows: 47 (81%) agreed that financial incentives might be important to provide better services for COPD patients, 44 (75.9%) agreed that better access to patient medical records would improve inhaler adherence in COPD patients; 38 (65.1%) agreed that assistant pharmacists would be useful in enhancing adherence among COPD patients and 30 (51.7%) agreed that the point of care meters such as Fractional Exhaled Nitric Oxide (FeNO) had importance but to a lesser extent (Table 2.6).

Table 2.6: Community pharmacists' view related the inhaler medications adherence for COPD patients.

Survey statement	**Number of responses and percentages for each category**				
	Strongly Disagree (N, %)	**Disagree (N, %)**	**Neither disagree nor agree (N, %)**	**Agree (N, %)**	**Strongly disagree (N, %)**
As a pharmacist, regular checking inhaler technique and intervening where necessary would be useful to optimise inhaler adherence in COPD patients.	0 (0)	1 (1.7)	1 (1.7)	36 (62.1)	20 (34.5)
As a pharmacist, better electronic communication system with primary care would improve inhaler adherence among COPD patients.	1 (1.7)	1 (1.7)	4 (6.9)	34 (58.6)	18 (31)
As a pharmacist, additional training to develop the knowledge needed for the new pharmaceutical services is important to provide better services for COPD patients.	1 (1.7)	0 (0)	7 (12.1)	24 (41.4)	26 (44.8)
As a pharmacist, better methods (e.g. Point-of-care meters-FeNO) would help to monitor the use of both maintenance and rescue medications.	9 (15.5)	7 (12.1)	12 (20.7)	21 (36.2)	9 (15.5)
It would be useful for assistant pharmacists to play a role in improving inhaler adherence in COPD patients.	3 (5.2)	0 (0)	17 (29.3)	27 (46.6)	11 (19)
As a pharmacist, financial incentives are important to provide better services for COPD patients.	1 (1.7)	2 (3.4)	8 (13.8)	29 (50)	18 (31)
As a pharmacist, better access to patients' medical records would improve inhaler adherence in COPD patients.	1 (1.7)	1 (1.7)	12 (20.7)	33 (56.9)	11 (19)

2.8.5 **Community pharmacists' perspectives**

2.8.5.1 Pharmacists perceive patients' acceptance of the services

There were positive and negative points captured from the free text responses about how the community pharmacists perceived patients' acceptance of the services offered in the pharmacy. In terms of the positive points, the respondents suggested that continuity of care was crucial to building up trust. Moreover, the respondents expressed beliefs that the community pharmacists listen more than General Practitioners (GPs) and COPD patients would be willing to stay, learn, and discuss the inhalers if they had more time to visit the pharmacy. The respondents highlighted that COPD patients who attended the pharmacies in the community expressed their sense of appreciation regarding the consultation provided by the community pharmacists on inhalers and other medications. They also indicated that COPD patients seek community pharmacists' advice concerning minor illnesses or side effects associated with inhaled medications, mucolytics, or steroids, especially when COPD patients cannot go back to their GP surgeries or when they forget their GP's recommendation.

On the contrary, some respondents highlighted that COPD patients were conscious that community pharmacists did not have enough time or funding to provide most services effectively as most services are rushed. Also, respondents highlighted the view that a small minority of COPD patients believed that pharmacists were underqualified to offer consultation services. Other respondents highlighted that community pharmacists usually played a passive role when dispensing the medication as they often do not provide active consultation unless the COPD patients ask for it. Additionally, the respondents affirmed that COPD patients were generally reluctant to ask about inhaled medications. They perceived that they felt that community pharmacists were replicating the GPs' or even the nurses' job. Lastly, the community pharmacists highlighted that they thought that

COPD patients lacked information on the pharmacist role and services provided to COPD patients (Figure 2.3).

2.8.5.2 Pharmacists perceptions about potential practices to optimise inhaler use among primary care team.

There was a consensus among the respondents that there are many potential feasible ways to collaborate with the primary care team to optimise inhaler use among COPD patients. For example, a) ways to enhance and ease communication; b) multidisciplinary meetings among HCPs; c) integrated care services (Figure 2.3).

2.8.5.2.1 Enhance and ease communication

The community pharmacists acknowledged a fragmented communication between pharmacies in the community and the primary care team. The respondents suggested several ways to mitigate this issue, such as initiating two-way, direct and digital, communication between community pharmacists and the GPs, to save time for both parties and ensure swift feedback. Another example is standardised communication templates to communicate effectively and quickly between primary care teams and community pharmacies. Several participants stressed the importance of unified and constant messages provided to COPD patients regarding their inhaler techniques and use.

2.8.5.2.2 Multidisciplinary meeting among HCPs

The community pharmacists highlighted several suggestions which may lead to improving inhaler use. A clear decision-making process, which involves understanding the community pharmacists', GPs', nurses', and other health care members' roles within the surgeries and in the community to avoid overlapping roles. Furthermore, other important ideas were: regular meetings between disciplinary groups to discuss the current issues that face the community pharmacies and primary care; to provide courses and extra

training for the community pharmacists; to ensure harmonisation of the care services for COPD patients; to strengthen the rapport among HCPs; and to raise awareness of the community pharmacists either within the local network or more widely including Clinical Commissioning Groups (CCGs).

2.8.5.2.3 Integrated care services

Integrated care services are defined as innovative collaborations between entities that fulfil health and care requirements throughout a region, coordinating services and planning to enhance population health and decrease disparities between various groups (197). The community pharmacists identified the importance of this approach and suggested ways to provide better services to COPD patients and eventually help to optimise inhaler utilisation.

The first proposal suggested was expanding the pharmacy networks by nominating pharmacies or electing pharmacies to be aligned with Primary Care Networks (PCNs), then merging or involving community pharmacists with the GP surgeries. In addition, efficiently utilising the resources as many community pharmacists were upset about the insufficient funding and inadequate remuneration designated to community pharmacists and the financial penalties for pharmacies who did not meet targets.

The next suggestion was concerning proactive flagging of new patients and new inhalers by the GPs for the community pharmacists, using the Community Pharmacies Consultation Services (CPCS), an advanced service which enables the general practices to refer patients for a minor illness consultation, to flag the patients needed for inhaler technique checking. The other point is to use Balanced scorecards (BSCs), a tool that can be used in health-system pharmacy to measure the value of the pharmacy in reaching its key performance metrics (drug safety, operations, quality, financing, education, and

research), to access control of symptoms of COPD patients and use the result to provide recommendations.

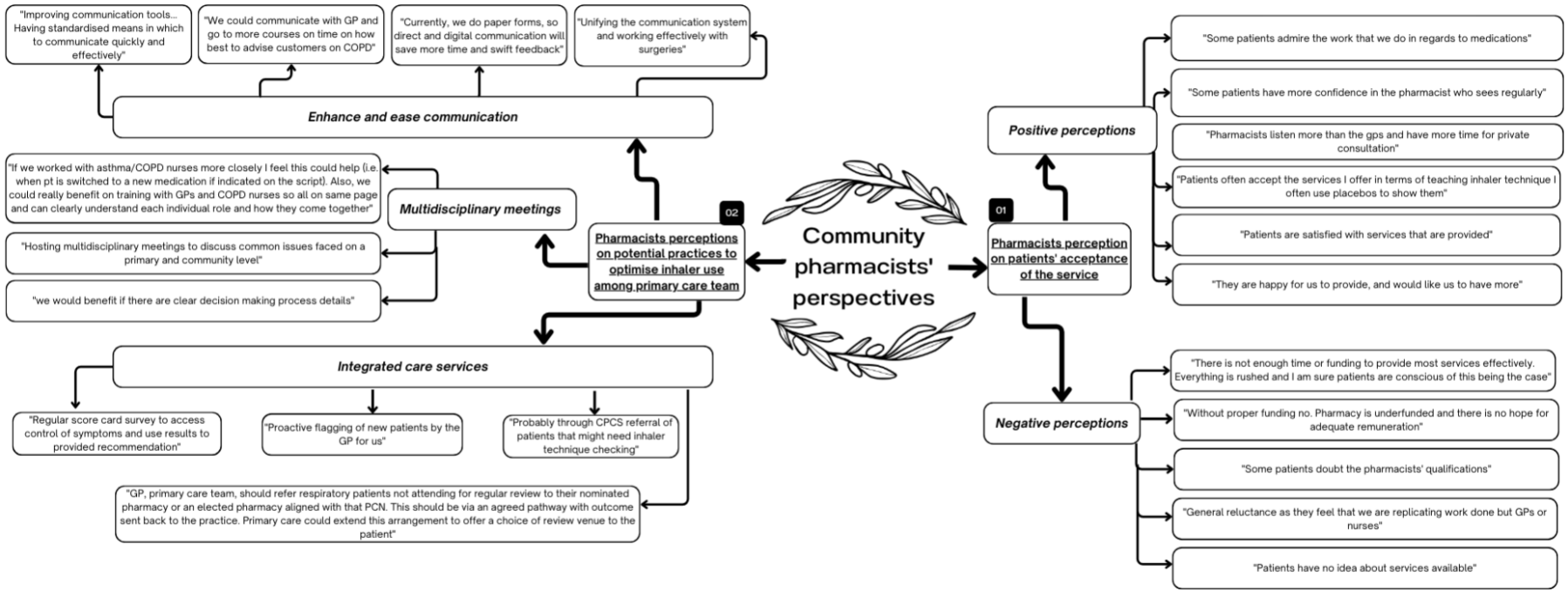


Figure 2.3: Community pharmacists' perceptions themes, subthemes, and quotes

2.9 Discussion

2.9.1 **Key findings**

The present study aimed to ascertain pharmacists' knowledge, attitudes and current practice/skills across the UK and obtains their views on their role to improve inhaler adherence among COPD patients. Although limited in size, there were some useful findings. It was interesting to note that although pharmacists stated their **main education about inhalers was from their university education and inhaler device leaflets, supplementary CPD educational meetings played an important role**.

Although pharmacists showed adequate knowledge about some aspects of their use, there was room for improvement in others, especially those related to **cleaning inhalers and spacers cleaning time**. Interestingly, prior experience with a particular inhaler was viewed as the most important factor when prescribing a device. However, just because it has been used before does not mean it is appropriate for a specific patient (198) and it is noteworthy that **patient preference was typically considered a less important factor**.

Nearly all of the responding community pharmacists stated that **providing counselling services to improve inhaler adherence among COPD patients was worthwhile**, and the **majority assessed patients' technique** when dispensing devices, but most did not use any electronic device for doing so. **Few inputted into choice of device**. The main barriers for this being **time and financial constraints and difficulties in communicating with primary care**. The community pharmacists highlighted several means to optimise patients' inhaler use, including **better electronic communication with primary care, multidisciplinary meetings between HCPs, and integrated care services**.

The correlation between the main findings and the TDF behaviour change framework yields significant insight. The main education about inhalers from university education aligns with the **knowledge domain**, highlighting the significance of education in facilitating effective inhaler use. Patients' preferences being a less important factor relates to **beliefs about capabilities**, highlighting the impact of personal beliefs on behaviour. Providing counselling services for COPD patients aligns with **social/professional role and identity**, acknowledging the significance of such services in augmenting patient education. The lack of utilisation of electronic devices relates to **skills**, impeding the ability of community pharmacists to learn and enhance their technical competencies. Time and financial constraints correspond to the **environmental context and resources domain,** hindering the provision of comprehensive care. Better communication with primary care, multidisciplinary meetings between HCPs, and integrated care services align with **social influences**, **Beliefs about Consequences, Memory, Attention and Decision Processes, and Behavioural regulation domains**, highlighting the significance of collaborative efforts. These correlations provide valuable insights for building initiatives aimed at modifying behaviour and possibly enhancing outcomes.

2.9.2 Comparison with existing literature

Even though most community pharmacists had adequate knowledge of inhalers, certain discrepancies were observed in identifying specific DPI devices available in the market. Contrary to ours, a Spanish study (148) that reported that only 6% of community pharmacists had a sufficient understanding of inhalation treatment. Moreover, the Iraqi study (150) contradicts our findings as it reported limited education and training among community pharmacists. This difference in findings between our study and other studies may be due to the nature of the curriculum taught for the pharmacists in these countries.

Moreover, our study found some discrepancies in the cleaning periods to clean either spacers or DPI devices. The pharmacists did not always get the exact frequency correct, but this may not matter because the second option was close enough and probably more practical. Our finding is in line with the Finnish (149) study findings that a large proportion of respondents were not aware of the current COPD guidelines related to inhalers. In addition, our findings also indicate that formal University education, either a curriculum or independent prescribing courses, are the primary source of knowledge among UK community pharmacists. Nevertheless, the main source of knowledge about the inhaler devices was the leaflet included with inhaler devices among the Spanish community pharmacists (148), whilst reading the leaflet devices came as second in ours. Thus, obviously, further education and training should be provided to community pharmacists to enhance their knowledge on the abundance of inhalers licensed for COPD.

Our findings highlighted that the UK community pharmacists identified the second most crucial step for correct use of pMDI (inhale slowly and progressively); although the most crucial step of using pMDI is to fire the device during inhalation. Our findings are consistent with the American study (199) conducted in the 1990s that only 13% of pharmacists initially gave information on the appropriate technique. The appropriate steps for inhaler technique issue raises some concerns as education and training should be periodically maintained to ensure providing the correct inhaler technique in consultations, focusing primarily on pMDI, as currently, there are practice guidelines for using DPIs for its low carbon footprints (200).

The majority of the community pharmacists in this study showed support to COPD patients by providing competent services in the community pharmacy. These services included counselling on which type of inhalers patients with COPD should use, improving the self-management of their disease, and educating patients on how to use the inhalers to optimise inhaler adherence. This finding echoes the study conducted by Hesso

et al., (146) in 2019, which highlighted that community pharmacists play a crucial role in providing objective guidance for patients with respect to inhaler technique and adherence.

Several positive points were projected concerning patients' acceptance of the services offered in the pharmacy. It was found that building up trust between community pharmacists and COPD patients contributes to a belief that they are pleasing patients with the services provided by the community pharmacies. The noticeable point appears to be supported by a qualitative study in Ontario, Canada (201). This may indicate that frequent contact with known pharmacists was not just boosting trust but also generating loyalty among customers.

Furthermore, the accessibility and convenience of pharmacies, whether chain or independent, were and continue to be positives for the pharmacy industry. Our findings align with the NHS recommendation and other primary research about maintaining these virtues which are a top goal for the government, and to continue to preserve access to pharmacies in the community (174, 202).

Moreover, the respondents expressed that COPD patients were willing to share their views with community pharmacists as they actively listened to their customers. Our findings echo qualitative research in the UK (203). Community Pharmacies Consultation Services (CPCS) provides an opportunity to observe patient practice in community pharmacy to achieve the best service possible for COPD patients.

The respondents in this study indicated that COPD patients who visited community pharmacies expressed their appreciation for the counselling offered by community pharmacists on inhalers and other treatments. If they had additional time to visit the pharmacy, several COPD patients were willing to remain, learn, and discuss inhalers. This supports the findings of prior research in which patients valued the services offered by pharmacists in a community pharmacy setting (204, 205).

Moreover, the respondents indicated that COPD patients seek community pharmacists' advice concerning minor illnesses or side effects associated with inhaled medications, mucolytics, or steroids. Our findings reinforce a previous review conducted by van der Molen et al. (206). Although the community pharmacists in the UK tried their best to provide the optimal service, community pharmacists are still well positioned to play an important role in all essential phases of the patient care pathway, from early disease identification through management plan implementation, including pharmaceutical advice, inhaler technique, and treatment adherence.

Conversely, some negative points were observed from our findings. These include the service rush due to the time constraints. Our findings echoed prior research (207-209), that the time barrier could be aggravated due to high operational pressure and intensity, and shortage of staff due to illness or training session events. Further efforts are needed to ensure pharmacists have adequate time to provide more patient-centred services, for instance, increasing experienced workforce to optimise the healthcare services provided to customers.

A further barrier is that the community pharmacists viewed that some COPD patients lacked knowledge about the pharmacist's role and the availability of resources. These results are consistent with a review conducted by Hindi et al. (210); thirty-four primary research (cross-sectional, qualitative, and mixed-method) studies were included in the review and aimed to determine patients and the general public's perspectives on existing community pharmacy services, expanded pharmacist roles, and strategies to increase public awareness of community pharmacy services in the United Kingdom. Accordingly, to obtain more acknowledgement and collaboration of patients with the pharmacists to provide adequate services, it will be critical first to make individuals working in the health care settings more aware of each other's expertise and the community pharmacists' abilities. This awareness should be followed by advocating the community pharmacists'

role to patients for potential contributions to patient-centred care. During the COVID-19 pandemic, it was implicit that community pharmacists could typically be the initial point of contact with the health system for clients who had COVID-19-related health issues or who seek trustworthy information and guidance.

Moving to collaborating approaches with the primary care team to optimise inhaler use among COPD patients, a few methods of communication were suggested as possible solutions. Communication style was a significant consideration whether it is digitally or old fashioned. Predictably, in our results, two ways of communication style were reported, while the same findings were observed in the previous reviews (211, 212). Historically, interactions have typically been confined to mundane things, including checking prescriptions and notifying GPs to possible issues. Hence, routine contact with HCPs especially GPs and their general practices might include disclosure of any discrepancies that have arisen. Communication is a critical component of effective teamwork and multidisciplinary cooperation, according to prior finding (213). In general, such a need to improve pharmacist communication abilities is becoming more urgent, particularly in the context of other patients and HCPs.

The findings from our study are also coherent with a Japanese qualitative study (214). Evidence pointed out that fostering face-to-face contacts, doctors, institutional pharmacists, and community pharmacists may collaborate actively. This resulted in community pharmacists being more aware of their expert position and participating more proactively in the care of patients. In our study, community pharmacists identified some benefits out of the multidisciplinary meetings as the community pharmacists suggested that it may polish the professional relationship and define the expected roles among HCPs including the community pharmacists. Further research is needed on the impact of multidisciplinary meeting sessions at the primary care setting on the COPD patient care.

Lastly, in this study, the respondents were specific about illustrating some elements related to integrated care services as some of the Clinical Commissioning Groups (CCGs) in England UK had already implemented it, such as incorporating community pharmacies operations within the GPs, utilising the resources in efficient manners, and usage of proactive flagging of new patients. Similarly, our study findings matched some previous studies (215, 216) as they concluded that integrated care services could contribute to more time for non-dispensing services, a sufficient workforce, and increased commitment to clinical activities. Since this work was completed, the UK has implemented several changes, including integrated care systems (ICSs), which represent a novel approach to the management and provision of healthcare services in England. Their primary objective is to foster closer collaboration among local NHS institutions, local authorities, and various other stakeholders in order to enhance the planning and delivery of healthcare services (217).

Further relevant modifications have therefore been implemented Practice pharmacists in the UK now provide a crucial function in the healthcare sector by providing thorough medication management services across primary care settings. One of their primary duties is performing structured medication reviews (SMR), including evaluating patients' prescription regimens in terms of appropriateness, identifying possible concerns, and formulating suggestions to enhance treatment results and ensure patient safety (218). Another recent implementation is the Summary Care Records (SCR) service, which facilitates authorised pharmacy personnel in accessing crucial patient data stored in a digital repository including current prescriptions, allergies, and adverse reactions (219).

2.9.3 **Strengths and limitations**

This, as far as we know, is the first comprehensive study concerning the community pharmacist's knowledge, attitudes skills, and views on their role to improve inhaler

adherence among COPD patients across the UK. Using a comprehensive recruitment strategy, we attempted to ensure the questionnaire was delivered to the largest segments of community pharmacists across the UK. However, recruitment was quite problematic. The content and face validity of the survey tool was reviewed by the advisory group during the survey design.

Although we were very clear in the Participant Information Sheet that the respondent's responses about their usual practice should be as in non-pandemic times, we acknowledged that responses may have been affected by the wider circumstances of the COVID-19 pandemic. Unfortunately, data collection was interrupted due to COVID-19 restrictions, plus the ability of pharmacists to respond to external requests for information was severely reduced. Despite offering incentives and contacting potential participants by multiple different avenues, we faced a meagre response rate which may affect the generalisability of the findings. Another limitation of the study is that there are generally some possible drawbacks to the self-reporting survey as cross-sectional studies can be vulnerable to recall bias and social desirability bias. However, an indirect questioning approach was used to mitigate the influence of social desirability bias in the survey. For example, the Third-Person questions technique entails asking the responder an inquiry involving someone other than themselves. Another example was the Item Count questions technique that entails asking the responder to identify different activities from a list they have participated in (220). An interesting point about the relevance of this study is that many of the results and suggestions offered have already been independently implemented in SCR, SMR, and ICSs since the work's completion.

2.10 Conclusion

Inhalers were well-understood by the majority of community pharmacists, but certain areas, including inhaler technique crucial steps, require further improvements. We identified a potential willingness from UK pharmacists to help COPD patients by offering high-quality services, including appropriate inhaler use instructions and self-management plans. Pharmacists believed that continuity of care is vital to building up trust; and because of the accessibility and availability of pharmacies, pharmacists believe that they actively listen to their customers and feel a sense of appreciation regarding the consultation provided to patients on inhalers and other medications. They reported that COPD patients seek community pharmacist's advice concerning minor illnesses or side effects associated with treatments. However, they acknowledge that COPD patients detected the rushed services due to the community pharmacists' time constraints, a passive role when dispensing the medication, and also lacked recognition of the pharmacists' role and the services provided by them. Inhaler use could be optimised among COPD patients with better communication between primary care and pharmacists, multidisciplinary meeting among HCPs, and integrated care services.

The outcomes of this study offer insight into possible approaches to help improve adherence to inhaler medications among COPD patients. Also, it paves the route for further research, either quantitative or qualitative, that is needed about the integration of pharmacists within the patient care pathway in terms of perceived barriers and enablers. For example, time and financial constraints as a barrier, simplifying the regime and discussing the side effect as enablers.

Chapter 3 : COPD patients' perspectives on the role of pharmacists in the management of COPD patients: a qualitative study

3.1 Chapter overview

The qualitative study in this chapter extends the findings of the previous chapter, where pharmacists perceived that patients might have a positive view of their involvement in educating and supporting patients with their inhaler medications. It pertains to the second goal of the thesis: *What are COPD patients' views about pharmacists'-led consultations to improve understanding of adherence to inhaler medications?*

3.2 Abstract

Background

Inhaler medication adherence is often suboptimal amongst COPD patients. Inhaler adherence may be affected by various factors, including ineffective inhaler technique, type of inhaler, and relationship with the healthcare team. The recently introduced enhanced role of the pharmacist could play an important role in improving the care and treatment of patients with COPD.

Aim

To explore COPD patients' views about an enhanced role of pharmacists in the COPD patient care pathway in improving adherence to medications.

Methods

Semi-structured interviews were conducted remotely among COPD patients in the West Midlands, UK. Maximum variation sampling was used to ensure patients with a diverse range of socioeconomic and ethnic backgrounds, age groups, smoking histories, and symptom severity were sampled. Analysis of available interview transcripts was conducted using NVivo 12. Interviews were analysed using an inductive approach based on Braun and Clarke's six steps of thematic analysis.

Results

536 participants were invited to take part in this study (243 by email, 293 by letter). 22 patients with COPD were interviewed: 14 men and 8 women. Median age was 74 years and disease severity (as described according to patients' descriptions and the number and type of inhalers they used) ranged from mild to very severe. The majority of participants were White British. Four main themes were generated from the interviews: 1) Perceptions

of pharmacists' roles; 2) Healthcare professional preference; 3) HCP-Patient relationship; 4) Pharmacists' support.

Conclusion

There was a potential willingness of COPD patients to consult community pharmacists regarding their inhaled medications. Facilitators included: approachability of pharmacists, a high level of professionalism, confidentiality during medication consultations, and pharmacists' support to COPD patients. There were some barriers to overcome, especially those related to effective communication, pharmacists' training or qualification, a lack of prescribing authority, lack of access to patients' medical records, and continuity of care. Moreover, the current study provided a view on the perceptions of COPD patients on SDM and their preferences for which HCPs to consult. Lastly, many patients agreed that an increased role for pharmacists in providing COPD inhaler medication advice would be welcomed.

3.3 Background

Research from across the world reports that pharmacists could play a central role in providing education and improving health outcomes and patient quality of life. Research has shown that trust in the advice given by medical experts is a potent determinant of adherence to treatments and interventions (80, 128, 157, 158).

While some studies have been conducted in other countries, there is a dearth of research in the UK exploring COPD patients' views about the potential role of the pharmacist in improving inhaler medication adherence. The survey among pharmacists in the previous chapter indicated their positivity towards such a role in providing support for COPD patients and their perception that patients might receive this well. This provided the context for further in-depth interviews to gather more information about COPD patients' views. Evidence (221, 222) from the UK suggests that fragmented primary care has a negative impact on COPD patient care. Other international evidence (114, 130) suggests that patients with COPD perceive that community pharmacists might play important key roles in the prevention, management, monitoring, and follow-up of the disease. As patient experiences and healthcare systems are likely to differ by country, it is essential to conduct the proposed research in the UK context. This will improve understanding of patients' perspectives and experiences relevant to an enhanced pharmacy role regarding inhaled medication adherence and support the optimisation of primary care integration.

3.4 Aims and Objectives

The study aimed to explore COPD patients' views about an enhanced role of pharmacists in the COPD patient care pathway in improving adherence to medications.

The objectives of this study were to explore:

1) Patients' current use of pharmacists regarding their inhaler medication.

2) Patients' views about an enhanced pharmacy role to improve adherence to COPD medications.

3.5 Methodology

3.5.1 Study design

This study was conducted among COPD patients in the West Midlands, UK, adopting a qualitative research design. This study used semi-structured interviews with open-ended questions, conducted *via* telephone/ Zoom, which were carried out from April to August in 2021. Thematic analysis was utilised to interpret the data.

3.5.2 Sampling and Inclusion/Exclusion criteria

COPD patients were purposively sampled from those in The Birmingham Lung Improvement StudieS (BLISS) cohort (223) who provided consent to be contacted about future research studies and who were aged 40 years or more. Maximum variation sampling was used to select participants from the BLISS cohort study to include a wide range of key characteristics, such as socioeconomic and ethnic backgrounds, age groups, smoking histories, and severity of their symptoms. The Index of Multiple Deprivation (IMD) is England's official measure of relative deprivation in local communities. IMD rates each local area in England from 1 (the most deprived area) to 32,844 (the least deprived region). According to the English Indices of Deprivation 2019 (224), the IMD integrates data from seven categories to provide a relative measure of total deprivation as follows: deprivation of income, job, education and training, health and disability, crime, living condition, and lastly, barriers to housing. Table 3.1 represents the data (ranks and deciles) of deprivation in England. No specific location has been revealed to ensure

COPD patients' anonymity; the goal is to illustrate the geographical distribution of participants recruited from the practices across the West Midlands, UK. Participants with cognitive impairment or inability to provide informed consent and non-English speakers were excluded.

Table 3.1: The ranks and deciles of deprivation in England

Decile	Decile description	Ranks
1	10% most deprived	1 to 3,284
2	10% to 20%	3,285 to 6,568
3	20% to 30%	6,569 to 9,853
4	30% to 40%	9,854 to 13,137
5	40% to 50%	13,138 to 16,422
6	50% to 60%	16,423 to 19,706
7	60% to 70%	19,707 to 22,990
8	70% to 80%	22,991 to 26,275
9	80% to 90%	26,276 to 29,559
10	10% least deprived	29,560 to 32,844

3.5.3 **Recruitment**

An invitation letter (Appendix 10), Patient Information Sheet (Appendix 11), reply slip (Appendix 12), and consent form (Appendix 13) were sent to all potentially eligible participants in the BLISS Cohort study who consented to future contact, with reminders (Appendix 16) to non-responders after three weeks and six weeks. The BLISS research team sent the study invitations on behalf of the lead researcher, to whom any email and postal replies were forwarded. The lead researcher contacted those expressing interest in the study to answer any questions and arrange an interview date if the person was willing to take part. At the agreed interview time, participants were contacted *via* email or telephone, asked if they had any remaining questions about the study and reminded that participation was voluntary, and that they may withdraw at any time and up to one month (cooling-off period) after the interview. If they were happy to continue, the lead researcher checked if participants agreed to be recorded. When they confirmed, if the

consent was not received prior to the interview, the lead researcher started recording and reading out the consent form to participants, completed the form on their behalf (except the participant signature and date fields), and signed and dated the lead researcher field on the form. The lead researcher sent two copies of the completed consent form and a self-addressed envelope to the participant; one for their records and one to sign, date, and return to the researcher. The interview length was between 45 to 60 minutes, with an average of 34 minutes.

3.5.4 Content of the interview

The interview topic guide was developed using the Theoretical Domains Framework (TDF) (195). For more details see Chapter 2, section 2.5.3 and appendix 14.

The topic guide comprised twelve main question areas. The first part related to questions about the patients' lung condition and inhaler medications. The second part focused on the pharmacist-led consultation.

The interview schedule was designed so that the researcher covered the same topics in each interview with semi-structured open-ended questions. Such questions helped guide the conversation while providing adequate freedom for participants to identify experiences and viewpoints that they considered relevant to the research questions.

Three pilot interviews with COPD patients were conducted with members of our patient advisory group to determine the clarity of the interview question (in terms of language, wording, and relevance). Interview topic guide (Appendix 14) were finalised with input from the pilot interviews and suggestions from the supervisory team.

After each COPD patient interview, a brief 10-item questionnaire Test of Adherence to Inhalers (TAI) (225), was conducted as an additional source of descriptive data so the lead researcher could classify participants as having low, moderate, or high adherence.

The TAI tool (Appendix 15) was analysed separately. The TAI tool involved ten questions, which the COPD patients self-completed on the form. The scoring range for each question is from 1: worst compliance to 5: best compliance, providing a total score of between 10 (minimum) and 50 (maximum). If the score was equal to 50 points, this meant the level of adherence was good; if the score was between 46 to 49 points, this meant the level of adherence was intermediate; if the score was less than or equal to 45 points, this meant the level of adherence was poor. The type or pattern of non-compliance was assessed as follows: items 1 to 5 ascertained 'sporadic' non-compliance (score of 5 to 25), while items 6 to 10 ascertained 'deliberate' non-compliance (score of 5 to 25).

3.5.5 **Data validation**

A set of criteria for judging qualitative research was developed by Lincoln and Guba (226), who suggested that credibility, transferability, dependability, and confirmability should be considered.

3.5.5.1 Credibility

The credibility of research is defined as the degree the results are compatible with reality (226-228). Member checking, peer debriefing, and analyst triangulation were used in this research to ensure the trustworthiness of the findings.

Member checking, also known as responder validation, includes determining the correctness of the information by simply asking individuals for their perceptions on what they previously stated in an interview to determine whether their statements corresponded to what they truly wanted to say. In this study, credibility was tested with the COPD patients throughout the interview by conducting participant validation and confirming answers with follow-up questions instead of performing member checking. At the end of the interview, COPD patients were probed, if they wished, to suggest or make any

changes. In a few situations, COPD patients expanded on an area of the interviews by offering extra details.

Peer debriefing is simply related to receiving input on the phase of this study from independent scholars; peer validation is frequently seen to be somewhat more beneficial than member verification (229). In the present study, peer debriefing was sought by running frequent meetings with the PhD supervisory team to ensure the data analysis was of high quality, offering an assessment of data and mitigating bias. Lastly, analyst triangulation (230) represents the notion that multiple analysts check the same qualitative data to reduce the possibility of bias of an individual analyst. To accomplish this step in the current study, the PhD supervisory team had input while constructing the coding framework book to minimise bias.

3.5.5.2 Transferability

Transferability is primarily defined as the extent to which qualitative research findings may be generalised or transferred to other contexts and studies (226, 231). The results section provided a detailed explanation of COPD patients' demographic data and the investigation's setting to ensure that the findings are transferable.

3.5.5.3 Dependability

Data dependability refers to whether the study's findings are consistent and repeatable by other researchers (232). To achieve that, the methodology is reported in a detailed manner, which allows the study to be reproduced.

3.5.5.4 Confirmability

This aspect focuses on the confidence that the findings are based on the perceptions of the participants. The purpose of this is to guarantee that the analysis of data is based on the individuals' perceptions and thoughts instead of the researcher's interest (231). To

ensure this was done successfully, a data audit was conducted, including the data collection and analysis processes. Confirmability was additionally accomplished by providing insightful remarks (i.e., explaining the coding decisions), as mentioned above, regarding the likelihood of bias or misrepresentation.

3.5.5.5 Reflexivity

Another way of establishing confirmability is through the use of reflexivity, for example, by looking at the researcher's background/ position to consider how those might influence the research process. This qualitative study's confirmability was bolstered by the researcher's use of reflexivity in the data analysis. Reflexivity describes the procedure by which the researcher's perspective, preconceptions, and expectations are recognised; moreover, acknowledging the researcher's involvement in data analysis and interpretation will eventually mould the findings (233, 234). Thus, it is suggested that researchers dealing with qualitative data recognise their own preconceived notions, biases, and encounters.

Regarding how my profession, expertise, and education shaped the research, having a multicultural education (Saudi Arabia, the United States of America, and the United Kingdom) and training in different fields have allowed me to develop interactive skills and the ability to understand pharmacy practice. Working as a senior lecturer in the field of clinical pharmacy, I recognise that my views on addressing pharmacists' challenges to improve medication adherence may be influenced by what I know and have experienced. I have spoken or presented a poster on the constraints pharmacists face in tertiary settings at a number of conferences.

My prior experiences as a pharmacist and medication therapy management specialist have given me insight into the difficulties of tackling non-adherence among patients among the Saudi population and into the challenges facing pharmacists while fulfilling their

roles. As a result, I recognise that I came into this discussion with definite naive assumptions regarding these issues, but among primary and community settings.

To reduce the risk of bias throughout the study, I made an effort to remain objective and non-judgmental throughout participant interviews (235). I made an effort to build rapport with participants by using friendly, sincere welcomes, attentive listening, and a compassionate tone of voice. I had no prior knowledge of any of the other participants. At the beginning of the interviews, I introduced myself as a PhD researcher instead of a pharmacist to create a friendly environment so that the participants could speak without any consideration if they had unfavourable views towards the pharmacy profession. Also, I used probing questions to explain and analyse while keeping my impact to a minimum. I requested that interviewees broaden and provide extra illustrations to obtain more detailed information.

Following each interview, I reflected on the questions I asked and recorded points such as whether or not the interviewee seemed to understand the questions (especially in phone interviews).

I made an effort to put aside my insights and expertise on the pharmacists' roles in the data analysis phase. Although I made every attempt to be objective throughout the interview process, it is conceivable that my own experiences and perspective influenced data collection, evaluation, and presentation in some way despite my best efforts. Therefore, the likelihood of bias was mitigated by making the study process more transparent and by taking into account my past experience, expertise, and perceptions.

3.6 Data analysis

The inductive approach offers a straightforward and organised process for examining qualitative datasets to provide trustworthy and reliable insights. Inductive analysis is often

used with the objective of generating insights and fostering knowledge. The use of a bottom-up strategy enables the identification of intricate and nuanced patterns within the data, which may otherwise go unnoticed when using a deductive approach. Moreover, the use of inductive analysis is often employed in situations when the dataset exhibits a high degree of richness and complexity (such as in this dataset), necessitating a thorough exploration of its intricacies. Data analysis started during the early stages of data collection. It used the Braun and Clarke (236) six-step approach which is a useful framework for undertaking this sort of research—undertaking this approach before the following interview enabled immediate engagement in the dataset and the identification and incorporation of any new themes for the following interviews. These steps are: a) data familiarisation; b) initial code generation; c) theme searching; d) theme reviewing; e) theme definition; f) writing-up. Relevant observations, including body language and emotions, were recorded in field notes and subsequently typed up. The lead researcher transcribed all interviews verbatim. The data were imported into the qualitative analysis package NVivo software (237) for coding and thematic analysis. This software programme aids in the organisation of qualitative data. Once all the transcripts were uploaded into the software, the programme allowed for rapid quote-coding manoeuvres when patterns emerged, enabling in-depth analysis.

Step 1: Data familiarisation.

In this step, the interview data were transcribed line by line, highlighting the notions made by COPD patients concerning the current use of pharmacists and their potentially enhanced roles in improving inhaler adherence. Then the transcripts were read and re-read, as it is the initial stage of any qualitative research. This is very useful to actively engage with data before starting the coding process.

Step 2: Initial codes generation

In this stage, the lead researcher coded the information and attributes of the data systematically throughout the whole dataset and then assembled coding data pertinent to each code. The preliminary coding was done using NVivo software, utilising phrases, keywords, or sentences to characterise, condense, and interpret the data. The coding helped to reduce a large amount of data into fragments of meaningful information.

Step 3: Themes searching

In this step, codes were collapsed into preliminary themes and sub-themes. Themes were first captured in the sequence in which they emerged in the transcripts. Data themes were projected by creating links and commonalities among sub-themes, which were then consolidated using mind map software (MindNode) on a computer to facilitate and ascertain the uniformity or variance of different COPD patients' thoughts.

Step 4: Themes reviewing

During this step, the preliminary themes established in step 3 were read, examined, revised, and expanded to ensure the preliminary themes were really present within the overall data. Furthermore, the lead researcher held a meeting with the supervisory team (who independently assessed the transcripts for codes and themes) to establish the potential themes that emerged from the dataset. By consolidating and polishing themes, a mind map of themes was developed, in which some subthemes are intergraded, divided, or transformed as a result of deeper engagement.

Step 5: Themes definition

In this step, the analysis continued to fine-tune the details of each theme, developing distinct definitions and titles for each theme. Major themes were not chosen on the basis

of their recurrences; attention was also devoted to the fruitfulness of the information and finding the best match with respect to the research question (section 3) whilst still returning to the study's objectives. After the supervisory team audit, a hundred per cent consensus was attained.

Step 6: Writing-up

In this final step, a narrative description was created with direct quotations to back these interpretations and answer the research questions (section 3.4), followed by preparing an academic summary of the key findings.

In Table 3.2, an example shows what was done based on the previous steps mentioned above and accordingly, how the codes, basic and major themes and features were formed.

Table 3.2: Examples of the development of themes

Analysis steps	Code/Theme	Participants	Example
1, 2	Code	COPD	Service provision
1, 2	Code	COPD	Professionalism
1, 2	Code	COPD	Lack of prescribing authority
1, 2	Code	COPD	Limited access of patients' medical record
2, 3	Basic theme	COPD	Positive perceptions
2, 3	Basic theme	COPD	Negative perceptions
4, 5	Major theme	COPD	Perceptions of pharmacists' roles

3.7 Ethical and regulatory considerations

Before the start of the study, a favourable opinion (REC reference: 21/SC/0047) (Appendix 6, and 7) was obtained from an NHS REC for the study protocol, informed consent forms and other relevant documents (Appendix 8, and 9).

The study was conducted in accordance with relevant regulations of the University of Birmingham's Code of Practice for Research. The PhD supervisory team reviewed the

study, and the University of Birmingham provided sponsorship for the study following peer review. The study was covered by the Sponsor's Public Liability Policy and/or Clinical Trials policy.

In terms of participants' confidentiality, the data were only accessible by the research team. The BLISS study's confidentiality statement was signed prior to dealing with any personal data. Several training modules were attended, for example, the University of Birmingham data protection/data security/GDPR. Interviews were recorded on an encrypted device/Zoom and transcribed afterwards. Transcripts were anonymised through the use of an ID code instead of participants' names (238). Only the lead researcher had access to the study key document, linking ID codes to participants' contact details. Any direct quotes used in any research output did not include any personal information such as the participant's name, the names of others, or any identifiable information. The study complied with the Data Protection Act, which requires data to be anonymised.

Participants were informed about the option to withdraw from the study at any time up to one month after the interview date. They received this information in the Participant Information Sheet, received prior to the interview date, and again on the day of the interview, they were informed of the option to withdraw. In case of withdrawal, all written and electronic data were shredded/securely deleted and not used for any analysis. However, if the participants withdraw after one month, it was not possible to exclude the data from the analysis.

Regarding data access and storage, direct access was granted to authorised representatives from the sponsor or host institution to monitor and audit the study to ensure compliance with regulations. Three forms of information were collected: audio recordings, electronic communication (emails), and consent forms (paper records).

Interviews were conducted *via* telephone and recorded on an encrypted device or *via* Zoom's AES 256-bit GCM end-to-end encryption platform *via* the University of Birmingham account. This platform was only accessible using the lead researcher's University of Birmingham credentials. All interview recordings and transcripts were stored on the University of Birmingham secure server as well as password-protected University cloud storage. Verbatim transcripts and digital recordings were stored in separate password-protected files. Transcripts and recordings were indexed solely with the study ID number so that participants were not identifiable. Secure University servers hosted electronic communications with participants, and digital contact information about the participants was stored in a separate password-protected file on a password-protected cloud of the University of Birmingham server. Two drawers of a secured standard filing cabinet were used for hard copies at the University of Birmingham.

After study completion, data will be stored for ten years (in line with the University of Birmingham Code of Practice for Research), after which electronic files will be deleted, and hard copies will be shredded at the end of the required period. The interviews did not pose a risk for participants. Participants were involved in a single interview either online or *via* telephone, based on their own preference, so the burden posed by this study was minimal. Moreover, there was no risk to the lead researcher because interviews were conducted remotely.

3.8 Results

536 participants were invited to take part in this study (243 by email, 293 by letter), see (Table 3.3) for more details. 22 patients with COPD were interviewed. Demographic details for each patient (Table 3.4) and a map depicting the distribution of primary practices where the patients were recruited across the West Midlands area are provided below (Figure 3.1).

Table 3.3: Response Rate and Participation from Letters and emails

Emails	**Total emails sent**	**N=243**
	Failed to be delivered	N=48
	Agree to take part in the study	N=6
	Decline to take part in the study	N=2
	No response	N=187
Letters	**Total letters sent by post**	**N=293**
	Agree to take part in the study	N=16
	Decline to take part in the study	N=74
	No response	N=203
Total numbers of participants who have agreed to take part in the study from both emails and letters	N=22	

3.8.1 **Participants demographics**

The study cohort consisted of fourteen men and eight women. The median age was 74 years old, and disease severity was described according to patients' descriptions, and the number and type of inhalers they used. Disease severity ranged from mild to very severe. The vast majority of the participants were White British. A distribution map (Figure 3.1) demonstrated that practice locations covered an area of 455.2 km^2.

From the TAI tool, half of the participants (N= 11) indicated good adherence. On the other hand, more than a quarter of participants (N= 6) signified that they had both patterns of non-adherence (deliberate and sporadic). The following figures illustrate the full details of the participants regarding the level of adherence and the pattern of non-adherence (Figures 3.2 and 3.3).

Table 3.4: Sociodemographic and other characteristics of the participants

Participants ID and mode of Interview	Gender	Age (years)	Ethnicity	Education	Length of diagnosis (years)	Physical activity	Severity of disease	Level of adherence	Type of non-compliance (sporadic or deliberate)	Index of Multiple Deprivation Decile
P1 Online	M	71	White British-English	High school	12	Moderate	Moderate	Intermediate	D	4
P2 Online	F	71	White British-English	University	16	Good	Moderate	Good	Not applicable	3
P3 Telephone	M	77	White British-Welsh	University	4	Limited	Mild	Good	Not applicable	5
P4 Telephone	M	75	White-German	Diploma	>30	Limited	Severe	Intermediate	D	4
P5 Telephone	M	74	White British-English	None	24	Limited	Severe	Poor	S + D	4
P6 Online	F	71	White British-English	PhD	19	Limited	Severe	Good	Not applicable	5
P7 Telephone	F	70	White British-English	None	10	Limited	Severe	Poor	S + D	3
P8 Telephone	M	72	White British-English	None	12	Limited	Severe	Intermediate	S + D	3
P9 Telephone	M	74	White British-English	High school	10	Moderate	Moderate	Poor	S + D	9

Participants ID and mode of Interview	Gender	Age (years)	Ethnicity	Education	Length of diagnosis (years)	Physical activity	Severity of disease	Level of adherence	Type of non-compliance (sporadic or deliberate)	Index of Multiple Deprivation Decile
P10 Telephone	M	76	White British-English	High school	18	Limited	Very severe	Good	Not applicable	2
P11 Telephone	F	71	White British-English	Diploma	10	Limited	Severe	Good	Not applicable	2
P12 Telephone	M	85	White British-English	None	10	Good	Moderate	Good	Not applicable	6
P13 Telephone	M	78	White British-English	University	20	Good	Moderate	Good	Not applicable	4
P14 Telephone	F	62	White British-English	High school	9	Limited	Mild	Intermediate	S	3
P15 Telephone	M	81	White British-English	None	5	Limited	Severe	Good	Not applicable	5
P16 Telephone	F	90	White British-English	High school	12	Limited	Severe	Intermediate	S	9
P17 Telephone	M	72	White British-English	HNC	20	Limited	Very severe	Good	Not applicable	4
P18 Telephone	M	84	White British-English	High school	>30	Limited	Severe	Good	Not applicable	5
P19 Telephone	M	67	White British-English	None	20	Limited	Severe	Poor	S + D	2

Participants ID and mode of Interview	Gender	Age (years)	Ethnicity	Education	Length of diagnosis (years)	Physical activity	Severity of disease	Level of adherence	Type of non-compliance (sporadic or deliberate)	Index of Multiple Deprivation Decile
P20 Telephone	F	75	White British-English	High school	7	Limited	Severe	Intermediate	S	1
P21 Telephone	F	76	White-Irish	None	14	Limited	Severe	Good	Not applicable	2
P22 Telephone	M	83	White British-English	Diploma	5	Moderate	Moderate	Intermediate	S + D	6

Table key: M: Male F: Female S: Sporadic D: Deliberate S + D: Sporadic and Deliberate HNC: Higher National Certificate
Index of Multiple Deprivation Decile (IMD): (1:most deprived, 10: least deprived)

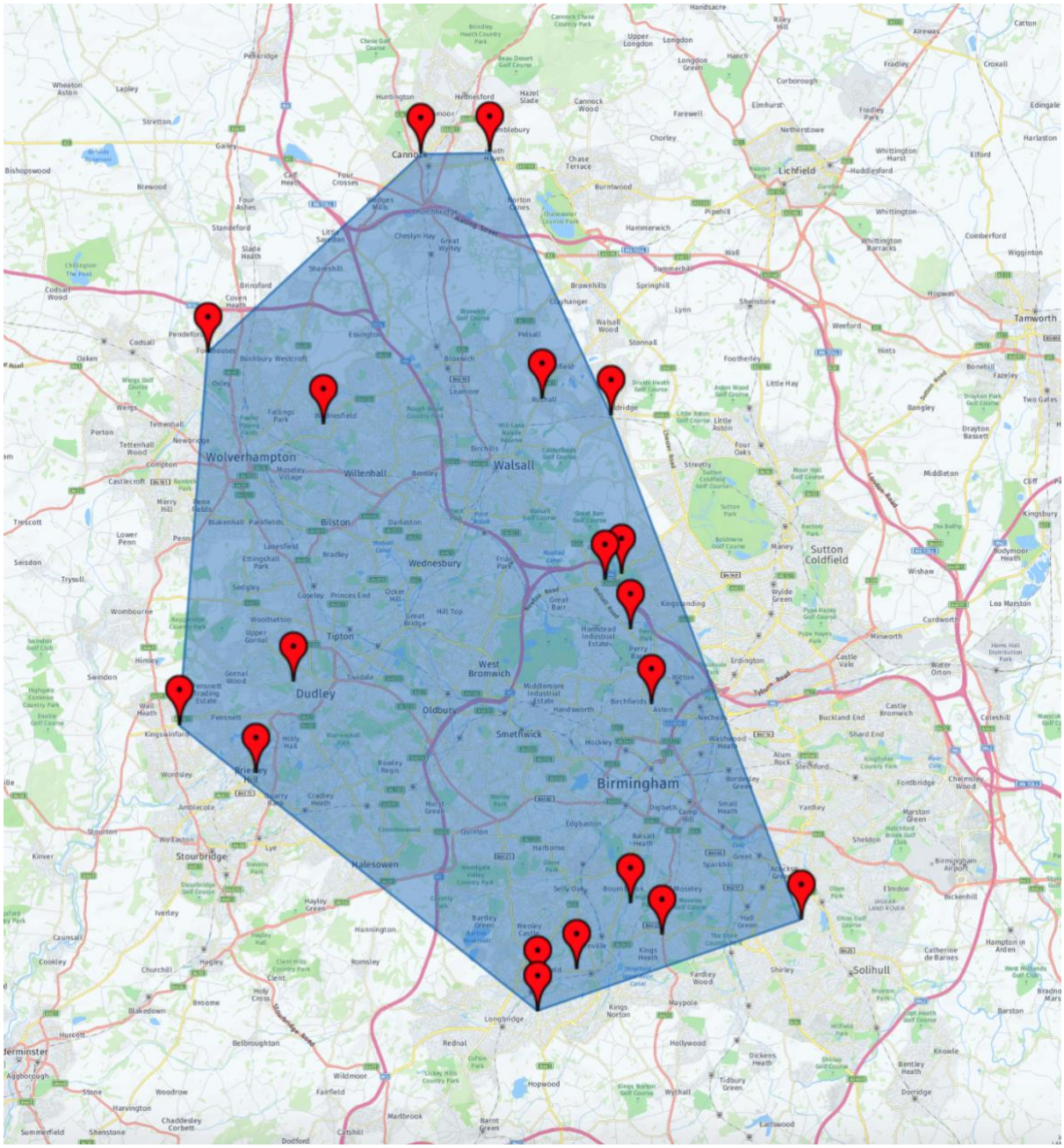


Figure 3.1: Distribution map of primary practices

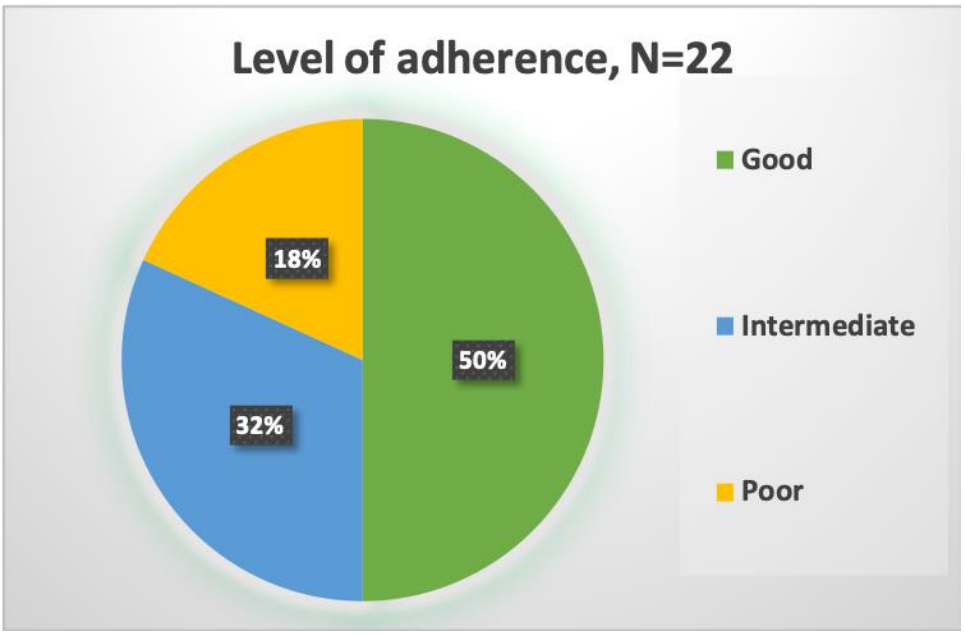


Figure 3.2: The level of adherence of COPD patients developed using the TAI tool

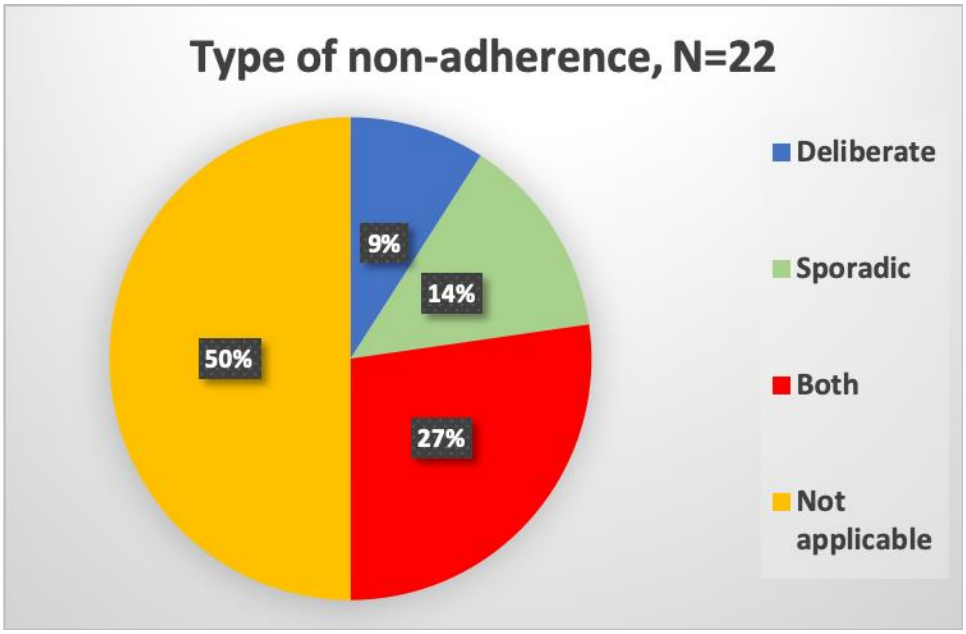


Figure 3.3: The pattern of non-adherence of COPD patients developed using the TAI tool

Table 3.5: Major themes and subthemes

Major themes	Sub-themes	Code units
Perceptions of pharmacists' roles	Positive perceptions	i. Service provision ii. Consultation time iii. Convenience to reach the pharmacists iv. Professionalism v. Consultation privacy
	Negative perceptions	Perception of pharmacists as having limited role: i. Qualification doubts ii. Lack of prescribing authority iii. Limited access to patients' record iv. Busyness of pharmacists v. Unprofessionalism
Healthcare professional (HCP) preference		i. GPs experience ii. Nurse skills
HCP-Patient relationship	Trust	i. Continuity of care ii. Shared Decision-Making
Patient Support	Patients inhaler knowledge and monitoring	i. Inhaler education

Four major themes were identified from the interviews: 1) Perceptions of pharmacists' roles; 2) Healthcare professionals' preference; 3) HCP-Patient relationship; 4) Pharmacists' support. To classify COPD patients during the results, they were specified with a tag; the following profiles were generated: (ID code – Gender – Age – Severity of COPD). The above table illustrates the complete picture related to the major themes, subthemes, and code units that emerged from the patient interviews (Table 3.5).

3.8.2 **Perceptions of pharmacists' role**

Given that pharmacists' roles are quite wide, it was hardly unexpected that COPD patients thought of this role both positively and negatively. These two subthemes were captured as the following: positive perceptions and negative perceptions.

Service provision including delivery of medications

When inquiring of COPD patients about the service provided to them by the pharmacists, many patients expressed their satisfaction with the services.

> *"It's fine by me because a while ago, I normally use to get my medication myself, but now* (During the pandemic) *I have it delivered. So, they have a delivery service and you can phone up the site today and would come tomorrow. So that's good"* (P7, F, 70, Severe COPD)
>
> *"I think the service they offer is very good and I have no complaints. It is very efficient"* (P17, M, 76, Very severe COPD*)*
>
> *"Very good, actually I haven't got a problem with it* (service provision including pharmacist's advice). *I'm talking about minor ailments"* (P1, M, 71, Moderate COPD)
>
> *"It's excellent, I ordered my prescription on the Internet…, So me and also my wife prescriptions, they are delivered to us at the door which is helpful to us in the bad weather where I live. I need to go up a steep hill or come down a steep hill, neither of which I particularly want to do when it's covered in snow and ice"* (P3, M, 77, Mild COPD)
>
> *"First class a hundred percent first class, all the staffs are very helpful as well"* (P5, M, 74, Severe COPD)
>
> *"The one that I use, no problem, they deliver my medication very quick"* (P9, M, 74, Moderate COPD)
>
> *"I think it's a fabulous service idea because I mean, the range of people that they have to look after with all the different medicines and everything else, they have to keep track of what available to me. They're very good at the jobs"* (P10, M, 76, Very severe COPD)
>
> *"Excellent, I have no I've got no complaints. If I phone for a prescription today, I would probably get it on Friday or Monday, so I was given plenty of time…, And they deliver them at the moment…, I've no complaints, fortunately"* (P12, M, 84, Moderate COPD*)*

> *"Excellent, I'm due for a repeat prescription at the moment and I know it will be ready and waiting for me when I go over to take it later today or first thing tomorrow. You know, it's almost, always been done"* (P13, M, 72, Moderate COPD)

> *"In general, it's okay. I'll go in there, get medications and I'm gone. Actually, it's hello, thank you and bye"* (P14. F, 62, Mild COPD)

> *"I will rate this* (pharmacist) *service with top mark every time"* (P18, M, 84, Severe COPD)

Following that, some patients mentioned the precise way in which they collected medication from their pharmacists. They meticulously described how their pharmacy texted and notified them when the treatments were ready to collect or delivered to the patient's house.

> *"I think its good service…, They text you and say that your medications are due, and they put it for you and you could go in and pick it up. But I didn't want that, I'm not that good on these phones, technically. So, what I do about it, I take the prescription from the doctor and then go to the pharmacist. And then my husband or daughter picks it up for me, or it could be delivered because they have said it to me before. But I suppose if I haven't got my husband or daughter I would be happy to be delivered, but at the minute I don't"* (P21, F, 76, Severe COPD)

> *"At the moment, what's happened over the last couple of years, they've now taken to send the prescriptions regularly to the pharmacist. And I know that the pharmacy then will notify me by text once a month to say my prescriptions are ready. And that's it, I collected them at morning in relation to a text that I had yesterday"* (P22, M, 83, Moderate COPD)

Even though there were some pitfalls concerning some medication availability, especially with small community pharmacy, some patients still understood this issue and rated the service as fair.

> *"I do have a few problems getting medication on time from the pharmacy, that's for sure. Nine times out of ten, they haven't always got every medication. However, it's* (Service) *quite good; they're doing the best they can. Don't forget, this place is a little chemist near my doctor with only one room. So, they are doing the best they can"* (P20, F, 75, Severe COPD)

Consultation time

A number of the COPD patients commented that some pharmacists devoted time to discuss medication and related side effects, provide instructions on how to use the inhalers correctly, and flag up contraindicated medications prescribed by the authorised HCPs.

> *"Our local chemists, where I get the medication. We have talked on the side about consultation time which wasn't a problem; but it's probably a better way of doing that actually. I've always said when I had the consultation about reviewing the medication. I've got to be fair, I will say they do know if the medication mixing together cause a problem"* (P1, M, 71, Moderate COPD)

> *"I have done that consultation with a pharmacist when I went to pick up my prescription, the pharmacist approached me and asked me if I would have a chat regarding the medication that I am using; I was using it; And if I was getting on with it"* (P17, M, 76, Very severe COPD*)*

> *"One time when I had my medication reviewed, the pharmacist was pretty thorough"* (P11, F, 71, Severe COPD)

Convenience to reach the pharmacists

There was general consensus that pharmacists are the healthcare providers who are the most available and accessible among other healthcare providers.

> *"There's one right inside the GP surgery. There's also other pharmacies in Morrisons which is more or less the same area"* (P7, F, 70, Severe COPD)

> *"It* (pharmacy) *is quite near my house. Um, five minutes-walk"* (P6, F, 71, Severe COPD)

> *"Oh gosh, we got so many pharmacies near to us. In fact, within about half a mile, there is probably four no five within half a mile"* (P3, M, 77, Mild COPD)

> *"Well, funny enough, you know, I usually choose the pharmacist. Umm one of the reasons which is right opposite the practice* (name masked)*"* (P4, M, 75, Severe COPD)

> *"I go to the appointment at the pharmacy to speak with a pharmacist. Sometimes you are so lucky because it is an easy access to pharmacy"* (P14. F, 62, Mild COPD)

"The one I use it (pharmacy)*, it's not the closest, but it's the best one it's about 1.2 miles away from home. It moved away 400 yards from where they were before. Very reliable and I trust them a lot"* (P5, M, 74, Severe COPD)

Pharmacists seemed less desirable options as the first choice of healthcare providers, though opinions varied. For a few patients, pharmacists were their first choice to seek health care due to their easy access and availability most of the time compared to other health care providers.

"At the moment (during COVID), *I suppose the first one* (HCPs choice) *is the pharmacist, give or take I say yes or no, they can help"* (P22, M, 83, Moderate COPD)

"You just pop in and maybe they are not busy, so you can ask them about anything and you just open up if you would like" (P14. F, 62, Mild COPD)

"If the pharmacists wasn't so busy, I'd probably go there first (for advice) *because it's easier to access"* (P1, M, 71, Moderate COPD)

Pharmacists' professionalism

Aside from the pharmacists' accessibility, COPD patients underlined how crucial it was to feel helped and welcomed by the pharmacists. Also, patients stated that pharmacists assisted them by providing care, which improved their ailment management whilst allowing them to attain their therapy targets.

"Yeah, they (pharmacists) *are confident with their knowledge to provide me with optimal management plan for my medicine"* (P19, M, 67, Severe COPD)

"*Um the pharmacist used to, sort of like, give me an interview every 12 months, they do that just to make sure everything's alright… I rather use them* (pharmacists) *very proficient"* (P17, M, 76, Very severe COPD)

"I have no complaints. All the pharmacists I've dealt with have been very good indeed" (P13, M, 72, Moderate COPD)

"They are respectful and they're easy to talk to" (P7, F, 70, Severe COPD)

"I find all the pharmacist I've dealt with them being professional and very helpful, most of them like, you know, I can't really say I've come across a problem with any pharmacist" (P1, M, 71, Moderate COPD)

"I've always found them very friendly and helpful" (P3, M, 77, Mild COPD)

"The pharmacist is a professional or a professional person anyway, there's nothing you can say about it as regards the courtesy of the professionalism, you know, it is great" (P12, M, 84, Moderate COPD)

Consultation privacy

It was evident that COPD patients appreciated the existence of a private room in pharmacies, which enhances confidentiality and privacy.

"Well in our local chemists, where I get the medication; I do usually use the private room and don't discuss it in front of people, which is good, really, because you could probably know some of the local people. I've got to be fair, I've always said when I had the consultation about reviewing my medication, they always took me in the room and shut the door, so it's just like it is completely confidential" (P1, M, 71, Moderate COPD)

"Well at pharmacies, (they) *do have a room. And like I said, if you wanted to talk privately to them, you would go into the room and talk to them and try to sort out your issues or your problems. Yeah, they would do that"* (P7, F, 70, Severe COPD)

"I wouldn't be happy discussing my condition in public and the other thing is they usually quite busy, so I'm happy to go into one of the rooms and discuss it" (P2, F, 71, Moderate COPD)

"The one (pharmacy) *I use, they have got that room. And you can just point to the room and you can go…, I think in that respect, they affectively given you a consultation probably for fifteen minutes something like that"* (P4, M, 75, Severe COPD)

"It'd be good if you weren't overheard by the other customers in the shop. I've not been in the one at my local pharmacy, but it looks rather some of your knees touching with the pharmacist…, It looks quite small" (P6, F, 71, Severe COPD)

"I would assume it (private room) *would improve the confidentiality, yes"* (P7, F, 70, Severe COPD)

"If you are worried about anything on this issue (medications), *they* (pharmacists) *will get you in a little room for a private interview"* (P8, M, 72, Severe COPD*)*

"It's interesting to see a little room on the left, and if you want a consultation with the pharmacists, they take you into there…, Of course, that's everything, it is private between the two of you" (P10, M, 76, Very severe COPD)

"Certainly, I wouldn't want to discuss it in front of other people anyway. So, we would have to be in a in an enclosed room to improve the confidentiality" (P12, M, 84, Moderate COPD)

"The pharmacy I use, we've got two rooms…, The only time I've used it is when doing a medication review and there is complete privacy" (P13, M, 72, Moderate COPD)

"It's taking confidence, nobody else is listening. I know they do right thing downward…, Now I feel much happier" (P14. F, 62, Mild COPD)

Perception of pharmacists as having limited role

Qualification doubts

Other patients directly discussed that they did not know if the pharmacists could provide them with trusted advice because they were unsure about pharmacists' qualifications.

"As a patient, I don't know how well qualified the pharmacist is to give that information to me? It can't be as qualified as a GP, I don't think. But then again, you know I could be proved wrong of course" (P22, M, 83, Moderate COPD)

"No, the pharmacist is not qualified as doctor. I don't suppose all pharmacists are the same" (P20, F, 75, Severe COPD)

Furthermore, one severe COPD patient with limited physical activity and poor adherence was not optimistic about pharmacists' ability to enhance inhaler treatment

"They (pharmacists) *haven't diagnosed me or anything. All they do is see what's on the prescription…, they don't say anything"* (P7, F, 70, Severe COPD)

Lack of prescribing authority

Several COPD patients perceived that the lack of authority to prescribe medication, including inhalers, was a potential reason not to utilise the pharmacist's service in full.

"The pharmacies won't do anything because they have got no authority from the doctor…, There's no point in going see the pharmacist" (P20, F, 75, Severe COPD)

"The pharmacist couldn't prescribe medication that you needed to be on! So, I think it's best that you go and see your doctor" (P14. F, 62, Mild COPD)

"It's unlikely that the pharmacist could alter my medication, if it was necessary, whereas the doctor could do" (P13, M, 72, Moderate COPD)

"A pharmacist cannot give me a prescription. Only my doctor can give me a prescription. And if it's a prescribed drug, you can't buy it out of the counter in the chemist" (P5, M, 74, Severe COPD)

"I know that pharmacists can't change the prescription, so there will be no points to have any inputs from them" (P6, F, 71, Severe COPD)

"Occasionally I need a rescue pack of antibiotics and steroids. The fact if you go to a pharmacy, they usually send you a GP" (P11, F, 71, Severe COPD)

Several patients perceived that pharmacists did not really have a role in the medication prescriptions process.

"I've never really wanted to talk about anything with my pharmacist, so I'm reluctant to go to see the pharmacists, the only thing I have to do with them is handing me the prescription" (P9, M, 74, Moderate COPD)

"I just go to the pharmacy… There's no need for me to talk to the pharmacist, I suppose, because they just give me the medications. Again, I just go there to pick up the prescription and come out" (P7, F, 70, Severe COPD)

"If a need a prescription I phone the doctor, give the information that (he/she) *required, then he/she contacts the pharmacy…, I pick the prescription and go back home"* (P19, M, 67, Severe COPD

"As I said you get in the chemist for your prescription and you walk out so you are not staying that long. And let's face it, it is not the actual pharmacist you see, they are the girls who working there, they are dealing with you" (P16, F, 90, Severe COPD)

<u>Limited access to patients' record</u>

Numerous interviewees discussed how pharmacists might not have full and written access to patients' medical records.

"I don't think the pharmacist again, you could say I'm wrong. I don't think the pharmacy has access to that information" (P22, M, 83, Moderate COPD)

"Well, he (the GP) *got the records and what's going on and he can look at what's happening or what's going on with me. As with the pharmacies, I would assume they would have some kind of record as to what I'm taking, other than that, they don't"* (P7, F, 70, Severe COPD)

"The GP has got the background information… in writing so it's recorded. Where the pharmacist, It's just a normally a chat over a desk. What the background information they've got? They've got your own list of medication, but they haven't got the background, causes, considerations and conclusions of why that medication was given" (P4, M, 75, Severe COPD)

"Obviously, the doctor would have been a more in-depth knowledge of the other difficulties or illnesses that I were suffering from. If the pharmacists had access to your notes, it would be reasonably enough yeah" (P6, F, 71, Severe COPD)

Busyness of pharmacists

However, some COPD patients emphasised that pharmacists were not available due to their busy workload.

"They (pharmacists*) are busy, how can a pharmacist do that* (inhaler consultations) *if people come in and out in the chemist"* (P20, F, 75, Severe COPD)

"The pharmacists are always so busy, it takes me two hours to get through two of them on the telephone. That just to get a repeat prescription! It is bad at the moment (during pandemic) *in our pharmacy, I'll be honest, they don't seem approachable"* (P14. F, 62, Mild COPD)

Unprofessionalism

Although pharmacists try their best to serve the patients, several COPD patients doubted the pharmacy personnel's professionalism based on their experience with local pharmacists.

"(Huge laughing), we had a girl, we used to call her sales preventative officer, and the person who runs the pharmacy who is not normally the chemist. In other words, there's a lady she's very motive, but I think a little bit too close of being rude… she has got poor attitude, so I said we should call them sales preventive officers." (P4, M, 75, Severe COPD)

"I can go in our pharmacy; the door was opened, and I could be standing there for 10 minutes and nobody's seen me. And yet they won't look at you because then once they've looked at you, they've got to assist you or ask what you want. So, I find it very disconcerting" (P14. F, 62, Mild COPD)

3.8.3 **Healthcare professionals (HCPs) preference**

A few patients with severe COPD expressed more faith in their GP.

"Mostly I've got more faith in my GP and especially if he has the other experts at the same time. It comes straight from the horse's mouth, I got a lot of confidence in doctors" (P15, M, 81, Severe COPD)

"The personal side, doctors are doctors and pharmacists are pharmacists. So, I've always had a pure habit going to my doctor first, we all have to" (P5, M, 74, Severe COPD)

"I definitely would say my GP. So, I just go to my GP that's it. I occasionally need a rescue pack of antibiotics and steroids. I always need to have in hand in case my condition would deteriorate. Plus, the fact if you go to pharmacy, they usually send you to a GP. So, I just go to my GP, make the journey short" (P11, F, 71, Severe COPD)

In contrast, a severe COPD patient who had a poor adherence level (sporadic and deliberate non-adherence) expressed displeasure with some GPs regarding the GPs' behaviours and body language.

"The doctors know, they don't think about the patients. They think about one thing and one thing only themselves…, These doctors, we've gotten now I don't know who are they? I've never seen them, I don't even describe them and I don't know their (***) given names. These new-fangled doctors what they put down in the surgery is the cause…, they are sitting behind a desk twiddling their thumbs on a computer" (P19, M, 67, Severe COPD)

<u>GPs understanding</u>

Several COPD patients indicated a unified opinion of preferring to see doctor either for emergency or regular visits. Patients described why they chose GPs based on their medical experience and knowledge of their health conditions.

"I think the doctor probably, if I've got the choice surely I choose a doctor that would know more of this (COPD)*..., If it is urgent thing I just book in to see a doctor and you don't know who seeing until you get there"* (P16, F, 90, Severe COPD)

"I think first stop for me would be my surgery, I mean the GP. I feel I can get the right people there." (P15, M, 81, Severe COPD)

"I would have thought the doctor would have been the best person because I would have thought they would do more about it [talking about lung health and treatment] *than the pharmacist"* (P16, F, 90, Severe COPD)

One severe COPD patient with an intermediate level of inhaler adherence and limited physical activity provided a rather prejudiced opinion:

"I choose my doctor…, The pharmacists, they are only young girls, they don't know my complaints" (P20, F, 75, Severe COPD)

Nurse skills

On the other hand, several COPD patients indicated that they would choose general practice or specialist nurses as the first option, though not in emergencies, as the nurses can provide the care they need, have capability to engage and listen more to patients.

I've always spoken to my GP who actually is in touch with a COPD specialist (Nurse in the practice)*"* (P15, M, 81, Severe COPD)

"I would try and contact the practice nurse. She knows more about me and about the condition than what the doctors do, I mean the GP. The nurse did sort of specialise a little bit in lung conditions, but she was the one that gave me the Eklira Genuair ™. You know, I just I haven't seen a GP for years, not about my COPD anyway" (P17, M, 76, Very severe COPD)

"Well, with a nurse, you go in and talk to them about anything and they listen. And if you see a doctor, they don't listen, you have to keep repeating what you're going to say" (P19, M, 67, Severe COPD

"I would choose to phone up the bronchiectasis nurse at the hospital…, to try and get in touch with him. I wouldn't ask anybody else" (P6, F, 71, Severe COPD)

"The nurse, the last time that she spoke to me about my inhaler, she did change it for me because and put me on another one which she said it was going to be easier for me to use" (P14. F, 62, Mild COPD)

"So, among the three of them, I would think the specialist practice nurse is by far the best" (P17, M, 76, Very severe COPD)

3.8.4 **HCP-Patient relationship**

Continuity of care

Notably, the interpersonal contact involving patients and their HCPs by seeing them on a regular basis was thought to be an important aspect of the health context in general in terms of HCPs identity.

"The pharmacists are not doctors. They change all the time, they are not being there on regular basis, they change" (P20, F, 75, Severe COPD)

"I think the continuity of seeing the practice nurse helps because she knows you. She knows what you're about? What you're doing?" (P17, M, 76, Very severe COPD)

"Well, I know the pharmacist first name, we get on quite well together… Very reliable and trustable…, He is as good as a doctor" (P5, M, 74, Severe COPD)

"Well, I had a good relationship with the pharmacist at a local pharmacy who retired. He'd been there for many years and everybody knew him and trusted him whatever. Then, there are a series of locums…, I don't know, but I wouldn't speak to them about anything" (P6, F, 71, Severe COPD)

"They are, they're very easy to talk to, the ones who are there at the moments because they do change" (P7, F, 70, Severe COPD)

"I'd like to think that we all like friends than customers… We are all calling by first names, because I've known them for a such long, long time" (P15, M, 81, Severe COPD)

Shared Decision-Making

Despite several COPD patients discussing how HCPs provide them with the medications, many also presented the view that healthcare practitioners did not involve them in the treatment decision-making process.

"I haven't had the choice for inhaler. They (HCPs) *just gave me and you put me on these things"* (P16, F, 90, Severe COPD)

"Let's say there are not really choices because as a layperson, I don't know the medications that are on the market. You have to go with what your professionals prescribing you" (P17, M, 76, Very severe COPD)

"I had been given no choice as just they said use this inhaler, use this one. Then new sort of inhaler comes out, they said use this inhaler, try this one. They don't tell what it is or what kind of inhaler it is like something else. They just hook you in" (P19, M, 67, Severe COPD)

"Well, I don't have a choice really. They (HCPs) *choose it, they choose what the best is for me"* (P21, F, 76, Severe COPD)

"No, it wasn't a discussion we had. It was a strong recommendation that I use it and I relied on their (HCPs) *superior knowledge and experience"* (P13, M, 72, Moderate COPD)

"It (inhaler) *was just prescribed right. There was no discussion because it was always like an emergency to me"* (P2, F, 71, Moderate COPD)

"Well, no discussion. He (the GP) *said that the Salbutamol one wasn't working, and he prescribed this* (Spiriva ™) *and the effect was magical"* (P3, M, 77, Mild COPD)

"Not really. She (nurse) *just recommended this blue one to help relieve the symptoms of COPD"* (P9, M, 74, Moderate COPD)

"I can't 100% remember or think that they tried to do so. They prescribed me the Ventolin™ first 100 grams or milligrams, and then as the years progressed, they hooked me on Seretide™ and upgraded that to 250 mg or grams, I don't know. And then subsequently, after that, as my condition has worsened, they put me on Braltus™. So that's three inhalers that I have consistently been using" (P11, F, 71, Severe COPD)

3.8.5 **Pharmacists' support**

Inhaler knowledge and technique

Though not as frequently mentioned as the aforementioned themes, it was apparent that COPD patients with good levels of adherence perceived the utilisation of pharmacist instructions on inhaler technique to benefit them, and that kind of support built up confidence in the pharmacist's abilities.

"It certainly helped me work this (how to take inhaler correctly) *thing out and I was quite confident in his* (pharmacist) *abilities"* (P2, F, 71, Moderate COPD)

"The pharmacist went through my application with me of the medications and how and when to use, especially the reliever medication, which was good because I don't think I was taking it properly. So that was a good experience" (P11, F, 71, Severe COPD)

Some COPD patients described the pharmacists' attention and interest in medications and their condition, as well as reassuring the patients.

"When I went to pick up my prescription, the pharmacist approached me and asked me if I would have a chat regarding the medication that I am using and how I am getting on with it… we discussed the technique of using inhalers also use them properly and any fears that I would have regarding my condition if I needed further support" (P11, F, 71, Severe COPD)

"I'm always kept up to date with what drugs are available, if I got any problems, they (pharmacists) *interact as well with me, not my doctor. The last time I discussed anything was about the Symbicort… but just every time you pick your prescription, just before you leave the counter, they* (pharmacists) *might double check that Symbicort…. All* (inhalers*) are designed for certain flow rate of drugs into the lungs….Sometimes I've found by modifying my mouth position on the inhaler* (valve position), *I making the mouth-piece into the mouth smaller to increase the speed of the drug into my lungs and sometimes it goes farther into my lungs…, It is like playing a trumpet and I can actually suck it through"* (P4, M, 75, Severe COPD)

"I have been in hospital with pneumonia and I'm feeling as weak as a kitten, the doctor prescribed me something (Fencamfamine), *the pharmacist* (name masked) *said to me, if I were you, I'd take one the first week, two for the next three weeks and then leave it for seven, and then go back to one because they're very addictive…"* (P5, M, 74, Severe COPD)

3.9 Discussion

3.9.1 Summary of key findings

The current study aims to explore COPD patients' views about the enhanced role of pharmacists in the COPD patient care pathway. For this study, we interviewed COPD patients in the UK. The findings revealed **four major themes: perceptions of pharmacists' roles, healthcare professionals (HCPs) preference, HCP-Patient relationships, and pharmacists' support.**

3.9.2 Findings in relation to literature

Pharmacists' roles

Patient satisfaction is a significant and routinely recognised indication of healthcare quality, and it helps determine the worth of such services (239). In our findings, most COPD patients highlighted an appreciation towards the service provided by pharmacists, for example, the perception of enough time to discuss an inquiry, approachability, and professionalism. However, patients with COPD placed emphasis on the delivery of medication services, which were much appreciated. This may raise a concern about whether the patients would be able to consult pharmacists in an efficient way due to time constraints or if it was not the pharmacists themselves delivering the medication. Our findings related to patient satisfaction are consistent with a survey conducted in the USA in 2021, which concluded that patients were generally happy with the services offered by their pharmacists (240). However, our findings contradicted an Ethiopian study conducted in 2017 where client satisfaction with the pharmacy service was found to be poor (241). This difference is related to cultural influences, where Ethiopian participant expectations are greater among those who earn more money (~15.50 pounds) each month, which leads to low satisfaction.

Some concerns related to the availability of medication in the pharmacy were expressed by one COPD patient in this study. Since inhalers are vital for individuals with COPD for both maintenance and urgent treatment, there seems to be a significant supply shortage throughout the UK due to the COVID-19 crisis. This increased demand has generated periodic shortfalls in several inhalers, including but not limited to Fostair (167, 242, 243). Whenever a particular manufacturer is producing pharmaceuticals for multiple nations, it is hard to forecast and accommodate production problems on both a national and international level. The lower availability of inhalers or any medications that the patient relies on is worrying and may contribute to medication non-adherence, poor disease management, and poor health outcomes. So, future research is needed to investigate the relationships between inhaler availability and the frequency of exacerbations and hospital admissions (pre- and post-COVID-19).

Patients viewed that pharmacists provided more consultation time to discuss medications and side effects. In line with this, two qualitative studies in the UK which aimed to comprehend the perspectives of the public on pharmaceutical services highlighted that participants provided positive opinions regarding pharmacy services, with modest acknowledgement of responsibilities in the treatment of minor diseases and advice provision (244), and considerable gratitude from patients for the consulting time provided by the community pharmacists (245).

A further major finding is related to the views of COPD patients in which they recognised the importance of the proximity of pharmacists. In fact, in the UK, there are community pharmacies in close proximity (20-minute walking) to 89% of people's homes (246); the reason why the community pharmacy seems to be very accessible is due to the recommendation made by the NHS to preserve the right to access to a community pharmacy within a very short period of time to allow better health services and reduce health inequalities. Our finding is supported by a Canadian trial (247) which evaluated

the influence of patient engagement on community-level healthcare improvement priorities. The Canadian study highlighted that patients cherished community healthcare accessibility. Another qualitative study in the UK conducted to examine the public's relative preferences for community pharmacy qualities highlighted that patients desired approachability in pharmaceutical services (248).

In the UK, 90% of community pharmacies now have a private consultation room (249). Most patients appreciated the high professionalism of pharmacists. In particular, patients discussed the importance of private consultations and how confidentiality was preserved. In addition, patients valued the pharmacists' respect and empathy. These findings are paralleled with the randomised control trial findings conducted by Boivin et al. (247) in Canada to evaluate the influence of patient engagement on community-level healthcare improvement priorities. The Canadian study concluded that chronic patients (including COPD patients) valued primary care respect and empathy.

On the other hand, some negative perceptions were identified among COPD patients concerning the pharmacist's role. Our study found a negative perception of some COPD patients regarding the training and qualifications of pharmacists. Similar perceptions among community pharmacists were discussed in the previous chapter (Chapter 2, section 2.8.5.1). Previous studies have shown that pharmacists lack confidence in their clinical examination and decision-making abilities (250, 251). Fear, apprehension, and aversion to risk have already been highlighted as impediments to practise change among pharmacists (252). Making a diagnosis requires the skills to handle ambiguity, and it may be claimed that pharmacists should be taught this competence in the future (253). Moreover, in June 2020, 24% of PCNs had yet to apply for NHS England funding to recruit a pharmacist (254) due to a lack of adequately skilled pharmacists for the positions (255). Pharmacy students in the United Kingdom may soon benefit from new criteria for pre-licensing study and training that were recently approved (256).

Another negative perception among COPD patients is related to the lack of both authority to prescribe and access to complete medical records. This supports the findings of prior research in Canada (257) and America (258) that reported that community pharmacists undertaking patient care are fettered by a lack of access to patient health information. This has significant implications for the enhanced pharmacy role to improve adherence to COPD medications. It is recommended that the UK government allow pharmacists to extend the privileges given to them to access medical records in a more comprehensive way than what is currently possible, which is only access to the medical summary. More recently, access to additional patient data has indeed been made possible by SCR for licenced pharmacy personnel (see Chapter 2, section 2.9.2).

HCPs preference

A number of negative points were identified among COPD patients related to HCP preferences. A major negative perception among COPD patients is related to the low faith in pharmacists compared to GPs. This finding is supported by a qualitative study conducted in the UK to explore people's faith in the enhanced services offered by community pharmacists compared to those offered by GPs, which reported that individuals had more faith in physicians than in community pharmacists and participants perceived pharmacists as solely engaged in the distribution of medications, with limited recognition of the pharmacist's broader role (259). To overcome this issue, pharmacist-patient contacts may be improved by raising the quality and frequency of interactions and securing GPs promotion and approval for expanded pharmacy services.

Furthermore, COPD patients in this study preferred choosing GPs and nurses rather than pharmacists due to the understanding of GP and the acquired skills of nurses. This finding is in line with numerous studies that have shown the medical knowledge and training of a HCP have a significant impact on patients' decision-making (260-262). In terms of

knowledge and training, doctors were considered greater than pharmacists (263, 264), and pharmacy advice was seen as less trustworthy by patients because of the perceived authority of physicians (265).

The overwhelming evidence is about positivity from COPD patients to their GPs in this study. It is revealing that COPD patients in our data showed different opinions regarding which HCPs to choose. A really interesting point is that their preference about GPs is related in part to the GPs access to other professionals, for instance, a practice nurse. In general, having access to a wider pool of professionals' knowledge made them feel comfortable, which gave them assurance in their preferences. The present study is concordant with a qualitative study conducted by Officer et al. (266) in New Zealand, in which they concluded that the roles of various health practitioners should be encouraged so that patients may make informed care providing choices. Future research is needed to understand the integration of pharmacy services into primary care as a way of maximising current healthcare facilities.

Even though GPs are actively involved with patients, the GPs lack of consultation time, difficulty gaining access in the first place, and focusing on computers during consultations, may well be experienced as problematic by patients. In the present study, some undesirable behaviours by either junior or trained doctors were mentioned. For instance, limited communication with COPD patients will likely have an accordion effect that generally decreases the throughput of the system in which it occurs, where communication is critical for high-quality care, especially in chronic diseases (267). A review by Booker et al. (268) demonstrated that a better bond with patients necessitates a people-oriented attitude whereby good communication leads to better adherence, satisfaction and eventually superior clinical outcomes. Also, a pinnacle paper by Asher et al. (269) in 1955 concluded that as GP, giving patients the idea that you could spare sixty minutes and still make them satisfied in five minutes is a priceless aptitude and far more

helpful than investing thirty minutes with them in which each minute with them feels like they are intruding on yours or their time.

HCP-Patient relationships

A number of noteworthy points were identified among COPD patients related to HCP relationships. The COPD patients in this study emphasised the importance of the continuity of care. This finding is supported by a recent systematic review of 13 Canadian and American studies (9 retrospective observational studies, 3 cross-sectional studies, and 1 prospective cohort study), which aimed to investigate the existing circumstance of continuity of care between pharmacists and patients, and showed that continuity of care has the potential to enhance adherence to medication, minimise irrational drug usage, and reduce the expenditure of additional expensive services. However, the same review highlighted that continuity of care in pharmacy is still scarce and only addressed in a minimal scale (270). There is also a need to address this issue in terms of staff turnover or rotation though locum GPs have access to full medical records, this is not possible in the case of pharmacists.

Another negative major finding was identified related to SDM. Our findings conveyed that SDM is not adequately offered by HCPs. This may raise a concern considering the benefits of SDM related to COPD knowledge, adherence, and perceived health status (271). Our findings are supported by prior research that clearly shows that many overloaded primary care professionals continue to eschew SDM rather than utilise existing SDM approaches (272-274). Despite intense initiatives, SDM techniques are infrequently used in regular primary care (275). SDM models, as they now exist, have serious problems. The problems include non-time-related challenges to SDM implementation and include patients, clinicians, and organisational and system-related

factors (276). Future research needs to be undertaken to explore multidisciplinary professionals' perceptions on encompassing COPD patients in the process of SDM.

Pharmacist's support

A few points were identified among COPD patients related to pharmacist support to COPD patients. Those who have good adherence attributed their high level of inhaler knowledge and technique to the high level of support and monitoring from their pharmacists. This finding is supported by several studies that pharmacists may play a crucial role across all processes of medication adherence and highlight the effectiveness of pharmacists in the treatment pathway (123, 129, 138, 144, 146, 149, 277, 278). Notably, we found several COPD patients who highlighted evidence of effective pharmacist medication counselling. Moreover, pharmacists may narrate and adjust the advice they provide to the abilities and needs of the patient.

3.9.3 **Strengths and limitations**

To the best of our knowledge, this is the first study concerning the views of COPD patients about the enhanced role of pharmacists in the COPD patient care pathway in the UK. This study provides a novel insight and a better understanding of the advantages of using pharmacy services or concerns that may arise when patients with COPD seek medical services, including from pharmacies.

We sought a sample size sufficient to recruit a wide range of patients' characteristics, including age group, gender, symptoms severity, and socioeconomic background, so that the results can be generalised to patients in primary care in the West Midlands and other similar areas. However, some drawbacks in our sample were observed; the ethnic diversity of the sample was not as broad as intended, with a number of ethnicities (especially those of Black or British ethnicity) omitted. This was because no people from

these ethnic groups applied to participate in the study. Also, this study did not recruit participants whose language is not English. Future research should seek to recruit a more ethnically diverse sample.

Another limitation of this study is that the patients with COPD who participated in this study did not reflect the entire population of the UK as it is only confined to a specific geographic area. The original study interviews only conveyed COPD participants' views at one time. Longitudinal research looking at their lives over several years as the disease advanced might have yielded more information. Due to the study's time limits, this was not feasible.

Furthermore, the study interviews were held either by telephone or online video. There were a few glitches, from delayed transmission through the internet to total loss and the need to re-establish connectivity. Problems with the internet connection meant that voice quality was subpar, leading to confusion and repeated questions and responses. Consequently, there was a possibility of losing some of the nuances of the participants' language when they talked about their disease experiences. Moreover, even were this not the case, the use of reflexivity to be conscious of the researcher's own preconceptions and the ways in which such preconceptions affect the study's findings were minimal. Another limitation of this study involved the analysis flexibility when constructing themes based on study data, and this flexibility can contribute to irregularity and a lack of cohesion. However, when analysing the data, these issues were considered and mitigated based on experts' recommendations in the field of qualitative research.

3.10 Conclusion

This study aimed to explore COPD patients' views on the enhanced role of pharmacists in the COPD patient care pathway. No prior research emphasises pharmacists' enhanced role in improving adherence to COPD medications and patients' current use of pharmacists regarding their inhaler medication. Important information has been presented regarding patient perceptions of pharmacists' roles, and the potential willingness of COPD patients to consult community pharmacists regarding their inhaled medications. In addition, it shed light on some possible barriers and facilitators to this novel role concerning pharmacists. Facilitators included pharmaceutical services approachability, a high level of professionalism, confidentiality during medications consultations, and pharmacists' support to COPD patients. There were some barriers to overcome, especially those related to effective communication, pharmacists' training or qualification, a lack of prescribing authority, access to patients medical records, and continuity of care. Moreover, the current study provided a view on the perceptions of COPD patients on SDM and their preferences for which HCPs to consult. Lastly, many patients agreed that an increased role for pharmacists in providing COPD inhaler medication advice would be welcomed.

Chapter 4 : Healthcare professionals' perspectives on the current role of pharmacists and their integration in the management of COPD: a qualitative study

4.1 Chapter overview

This chapter explores HCPs' perceptions of the enhanced pharmacists' roles in COPD patient care pathways, and the integration of pharmacists within the pathway and the role of primary HCPs in optimising patients' inhaler adherence. The present study fulfilled the thesis's third goal— *What are the Healthcare Professionals' (HCPs) views about the potential role of the pharmacist and their integration in the optimisation of medications amongst COPD patients?*

Note that since this study was conducted, there have been some changes in practice including change from CCG to integrated care systems (ICSs) so that some of the findings will be superseded. Through the Health and Care Act 2022, integrated care systems (ICSs) were formally established, and CCGs were abolished. See details about the ICSs in Chapter 2, section 2.9.2.

Abstract

Background

COPD is a long-term condition that imposes a substantial burden on society. There is limited time in GP practice to educate and monitor patients' use of inhalers. The recently introduced enhanced role of the pharmacist could be valuable in educating and encouraging appropriate inhaler use. Although these studies have shown that community pharmacists can provide support to COPD patients' ongoing care, there is little available scientific literature on the attitudes of healthcare professionals toward the expanded role of pharmacists.

Aim

To explore HCPs' views about the enhanced role of pharmacists in COPD patient care pathways and the integration of pharmacists within the patient care pathway.

Methods

Semi-structured interviews were conducted remotely among HCPs in the West Midlands, UK. Maximum variation sampling was used to ensure HCPs with a diverse range of age groups, gender, patient list size (number of patients registered as patients with an individual HCP), hours worked per week (full time/ part-time), years of experience, rural/urban areas, and the Index of Multiple Deprivation (IMD) were sampled. Analysis of available interview transcripts was conducted using NVivo 12. Interviews were analysed using inductive approach based on Braun and Clarke's six steps of thematic analysis.

Results

Twelve healthcare professionals (eight GPs and four practice nurses) were interviewed. The healthcare professionals' age ranged from 30-70 years old, the majority were women (N=8), and 42% of interviewees had ten or more years of practice experience. Four main themes emerged from the data: 1) Healthcare professional perceptions towards inhaler technique, inhaler training, and adherence 2) Communication among HCPs 3) Attitude towards pharmacists' integration 4) Expectation of pharmacists role within integrated approach.

Conclusion

Healthcare professionals agreed that an increased role for pharmacists integrated within the patient treatment pathway would be welcomed. Several barriers were identified, especially related to effective communication and pharmacists' access to medical records, limited resources, general practice culture, and external health system factors such as alternative initiatives of the CCG and PCN regarding medication prescription (e.g., cost-saving initiatives). The systematic adoption of integration will require financing and support from important contributors other than pharmacists, such as GPs and nurses. Further evidence of the healthcare advantages of incorporating pharmacists into general practice settings is required, including quantifying the effectiveness of pharmacists' efforts to improve COPD patients' health outcomes, such as inhaler adherence.

4.2 Background

Several qualitative research studies have proposed a pivotal role for pharmacists in therapy management, to improve clinical outcomes, decrease unplanned hospitalisations, and reduce costs (160, 161). These studies also noted the importance of educating physicians on the role of pharmacists in forming partnerships.

Although these studies have shown that community pharmacists can provide support to COPD patients' ongoing care, there is little available scientific literature on the attitudes of other HCPs towards the expanded role of pharmacists (Chapter 1, section 1.7). This is important as the pharmacist's role must integrate into the current health system to impact patient care.

According to many studies, pharmacists play a crucial role in COPD care, helping ensure that patients fully comprehend and use their medication regimens. Although studies investigating healthcare providers' perspectives on the pharmacist's possible involvement in enhancing inhaler medication adherence have been undertaken in other countries, such studies are lacking in the UK. Some evidence indicates that patients with COPD get suboptimal treatment because primary care is so dispersed. Since healthcare systems and patient experiences may vary from nation to nation, it is vital to undertake the suggested study in the UK.

In the UK, pharmacists may act in association with primary care either at the level of the PCN or at the level of individual practices, or independently in the community. PCN pharmacists and in-house and community pharmacists are all integral to providing primary care services, but their roles differ in scope, focus, and level of autonomy. PCN pharmacists have a more extensive range of responsibilities, operating across multiple practices within a network to provide services such as medication reviews, clinical advice, and support for the optimisation and safety of medicines (279). In contrast, practice

pharmacists have a narrower focus, operating within a single practice to conduct structured medication reviews, manage repeat prescriptions, and aid patients in adhering to their medication (279). Community pharmacists play a crucial role in delivering a broad services, including the dispensing of prescription, provision of guidance on over-the-counter medications, facilitation of health promotion and public health initiatives, and provision of assistance to patients in effectively managing their health problems (279).

4.3 Aims and Objectives

This study aims to explore UK primary care HCPs views about the enhanced role of pharmacists in COPD patient care pathways and the integration of pharmacists within the patient care pathway.

Objectives

To explore:

a) The role of primary HCPs in optimising patients' inhaler adherence.
b) The views of HCPs about an enhanced pharmacy role to improve adherence to COPD medications.
c) The potential barriers/enablers to the further integration of pharmacists within the patient care pathway.

4.4 Methodology

4.4.1 Study design

This study was conducted among HCPs in the West Midlands, UK, implementing a qualitative research design. This study used semi-structured interviews with open-ended questions conducted *via* telephone/ Zoom, which were carried out from April to August 2021.

4.4.2 Sampling and Inclusion/Exclusion criteria

To include a range of primary HCPs (GPs/nurses/in-house pharmacists) in the research study, we purposively sampled HCPs by age group, gender, patient list size (number of patients registered as patients with an individual HCP), hours worked per week (full time/part-time), years of experience, rural/urban areas, and the Index of Multiple Deprivation (IMD) (see details about the IMD in Chapter 3, section 3.5.2). Administrative staff, HCPs outside the West Midlands area, and non-English speakers were excluded.

4.4.3 Recruitment

HCPs were recruited *via* an advert in the Clinical Research Network (CRN) newsletter (Participate), the Primary Care Respiratory Society (PCRS) newsletter, the Local Pharmacy Committee in West Midlands covering Birmingham and Solihull, the Local Medical Committee for Birmingham, Birmingham and Solihull CCG, Birmingham and Solihull STP, Black Country and West Birmingham STP, Coventry STP, social media, and from GP practices who participated in the BLISS study (223). HCPs were recruited through two separate activities. Firstly, the invitation letter (Appendix 17), Participants Information Sheet (Appendix 18), reply slip (Appendix 12), and consent form (Appendix 19) were sent to the GP practices that took part in the BLISS cohort, with reminders (Appendix 21) to non-responders after 3 and 6 weeks. The BLISS research team sent the study invitations on behalf of the lead researcher, to whom any email and postal replies were forwarded. The lead researcher contacted those interested in the study to answer any questions and arranged an interview date.

Secondly, a brief advert (Appendix 22) about the study was disseminated *via* the CRN newsletter (Participate), the PCRS newsletter (Fortnightly), the Local Pharmacy Committee in the West Midlands covering Birmingham and Solihull, Local Medical Committee for Birmingham, Birmingham and Solihull CCG, Birmingham and Solihull

STP, The Black Country and West Birmingham STP, Coventry STP, and social media. The advert briefly described the study and provided an email address for anyone interested in finding out more. Those individuals were then sent the invitation letter, Participants Information Sheet, reply slip and consent form *via* email. Again, the lead researcher contacted those expressing interest in the study to answer any questions and arranged an interview date.

At the agreed interview time, participants were contacted *via* email or telephone and asked if they had any remaining questions about the study. They were reminded that participation was voluntary and that they may withdraw at any time and up to one month (cooling-off period) after the interview. If they were happy to continue, the lead researcher checked if participants agreed to be recorded. The interview length was 21 to 59 minutes, with an average of 39 minutes.

4.4.4 **Content of the interview**

The interview topic guide was developed using the TDF. See Chapter 2, section 2.5.3 and appendix 20 for more details.

The topic guide comprised eighteen main question areas—the first part included questions about the role of primary HCPs in optimising patients' inhaler adherence. The second part focused on healthcare professionals' views about the proposed enhanced role of pharmacists.

The interview schedule was designed so that the researcher covered the same topics in each interview with semi-structured open-ended questions. Such questions helped guide the conversation while providing adequate freedom for participants to identify experiences and viewpoints that they considered relevant to the research questions.

Two pilot interviews with HCPs (COPD nurse and clinical pharmacist) were conducted to determine the clarity of the interview question (in terms of language, wording, and relevance). Neither pilot interviews were included in data analysis. Interview topic guide (Appendix 20) were finalised with input from the pilot interviews and suggestions from the supervisory team.

4.5 Data analysis

The inductive approach offers a straightforward and organised process for examining qualitative datasets that aims to provide trustworthy and reliable insights. Data analysis started during the early stages of data collection. It used the Braun and Clarke (236) six-step approach — undertaking this approach before the following interview enabled immediate engagement in the dataset and the identification and incorporation of new themes for the following interviews. The six steps are: a) data familiarisation, b) initial code generation, c) theme searching, d) theme reviewing, e) theme definition, and f) writing-ups. The lead researcher transcribed all interviews verbatim. The data were imported into the qualitative analysis package NVivo software (237) for coding and thematic analysis. Once all the transcripts were uploaded into the software, the programme allowed for rapid quote coding manoeuvres when patterns emerged, enabling in-depth analysis (Chapter 3, section 3.6).

4.6 Ethical and regulatory considerations

Before the start of the study, a favourable opinion (REC reference: 21/SC/0047) (Appendix 6, and 7) was obtained from an NHS REC for the study protocol, informed consent forms and, other relevant documents (Appendix 9) (Chapter 3, section 3.7).

4.7 Results

4.7.1 Participants demographics

Sixty-three general practices from the BLISS cohort (223) were invited to participate in this study. We cannot determine the number of practices who may have seen the advert invitation. Thirteen HCPs agreed to take part in this qualitative research. One pharmacist was excluded as a result of the practice location which was out of research jurisdiction as stated in the study protocol, leaving twelve HCPs (eight GPs and four practice nurses). The HCPs' ages ranged from 30-70 years old, the majority were women (N= 8), and 42% of interviewees had ten or more years of practice experience (Table 4.1). Interviews were gathered from geographically diversified areas in terms of level of deprivation of area practice is situated in (approximately area covered 391.1 km^2).

4.7.2 Themes

Four main themes emerged from the data (Table 4.2): 1) Healthcare professional perception towards inhaler technique, inhaler training, and adherence 2) Communication among HCPs 3) Attitude towards pharmacists' integration 4) Suggestions for pharmacists' roles within integrated approach. To classify HCPs during the results, they are specified with a tag; the following profiles were generated: (ID code – Gender – years of experience) to prevent the possibility of a confidentiality infringement.

Table 4.1: Sociodemographic and other characteristics of the participants

Participants ID and mode of Interview	Gender	Age (years)	Ethnicity	Education	Length of work experience (years)	Index of Multiple Deprivation Decile (IMD) of workplace/GP practice
GP1 Online	M	40-50	British Asian-Pakistani	University	12	6
GP2 Online	F	30-40	White British-English	University	3	4
GP3 Online	M	30-40	White European	University	2	4
GP4 Online	M	40-50	British Asian-Indian	University	16	6
GP5 Online	F	40-50	British Asian-Indian	Master	4	1
GP6 Online	F	30-40	White British-English	University + PG	5	4
GP7 Online	F	40-50	Pakistani	University	5	9
GP8 Online	M	30-40	British Asian-Indian	University + Diploma	2	1
N9 Online	F	50-60	White British-English	University	30	1
N10 Online	F	60-70	White British-English	Master	40	8
N11 Online	F	70-80	White British-English	PhD	4	5
N12 Online	F	50-60	White British-English	University + RQ	10	6

Table key: M: Male F: Female RQ: Respiratory Qualification

Index of Multiple Deprivation Decile (IMD): (1: most deprived, 10: least deprived)

Table 4.2: Major themes and subthemes

Theme	Subthemes
Healthcare professional perception towards inhaler technique, inhaler training, and adherence	Current practice related to inhalers training
	Patients' adherence
Communication among HCPs	Positive views on communication with pharmacists
	Negative views on communication with pharmacists
	Varity of communication systems
Attitude towards pharmacists' integration	Enablers
	Barriers
Suggestions for pharmacists' roles within integrated approach	

4.7.3 Healthcare professional perception towards inhaler technique, inhaler training, and patients' adherence

A few HCPs (two GPs and one nurse) expressed a lack of knowledge among medical practitioners about the correct usage of inhalers, or about how to train patients in better inhaler technique.

> *"There's an expectation from us that they already have good inhaler technique or know how to use the medication"* (GP1, M, 12 yrs.)

> *"Literally you can search in the EMIS for the COPD patients who are on inhalers and people with the percentage pick up rates below 40%. We don't do that, but perhaps we should. The trouble is, there's no time to do any of the good stuff that would be really useful. We don't specifically target, measure or search for compliance…. Healthcare professionals don't know how to use an inhaler properly*" (N9, F, 30 yrs.)

> *"I have no formal training in inhaler technique"* (GP6, F, 5 yrs.)

<u>Current practice related to inhalers training</u>

There was the prevailing opinion among most GPs and nurses that the nurse does most of the work related to COPD reviews, discussing the inhaler options, and patient training for inhaler technique. In some cases, nurses may amend the inhalers for certain patients.

"*No, I don't* (train patients). *So I tend to just give them the diagnosis to start off with and discuss a bit about their inhalers. But then I'm pretty much booked. And the following day for a COPD initial review with the practice nurse"* (GP2, F, 3 yrs.)

"So we are quite lucky at our practice. We've got, um, two COPD nurses. They tend to do a lot of the routine reviews with the patients in the practice. They might amend their inhaler medication… the nurses tend to do the routine work... and definitely do technique" (GP3, M, 2 yrs.)

"It's quite an involved process. So at my surgery, there's myself and one of the practice nurses and she does hold, um, some extra respiratory qualifications. She's spirometry trained and has her diploma in spirometry and all that sort of stuff. So the key thing that she helps us decide what is the patient's ability of handling and using the inhaler" (GP4, M, 16 yrs.)

"I'm part of that respiratory group. So I, I, um, regularly attend updates to keep up to date with what inhalers are available and what are recommended. We regularly conduct long term condition reviews. So COPD falls into the umbrella of long term conditions… Um, so yes, we do annual reviews for the majority of COPD patients. We do twice yearly reviews for the very severe COPD patients" (N12, F, 10 yrs.)

"I can decide it without the help of anybody, but I do work along with very closely with us COPD nurse… It would be this (training COPD patients)*, major role of COPD nurses here. Because often I tend to see them during exacerbations, and that is not the time usually to change inhalers really. Then following that, they would often have the annual COPD reviews with the nurse. I think the nurses are in a better position to change and discuss"* (GP5, F, 4 yrs.)

"I do ad-hoc when I see them, but it's actually a practice nurse that does the COPD/asthma reviews, so then they check the inhaler technique and obviously it's been difficult in COVID because a lot of it had to be done over a video consultation. If I see them for an exacerbation of COPD, then I will go through inhaler technique really briefly" (GP6, F, 5 yrs.)

Interesting evidence of positive attitudes to the existing involvement of pharmacists was highlighted by a relatively young GP when he referred the patients to pharmacists to support them with their inhaler use as part of their management plan using the NMS.

> "*I tend to say when they* (patients) *collect the inhaler from the pharmacist. If you haven't used an inhaler for the first time, ask the pharmacist to show you how to use the inhaler"* (GP2, F, 3 yrs.)

Adherence

When asking healthcare providers about the COPD patients' level of adherence to their treatment, HCPs had a variety of perspectives on the subject. Several HCPs indicated their cohort of COPD patients had poor adherence or were doubtful about their adherence to the single or combination inhalers.

> *"I don't think the adherence is very good. The adherence or the technique of the inhaler is not good… It is a significant issue in COPD management"* (GP5, F, 4 yrs.)

> *"So they told me that they always take it. But I really doubt it (LAUGHING)"* (GP6, F, 5 yrs.)

> *"It is horrendous. Yeah, the compliance will be low for everything, including COPD inhalers. …the patients aren't using it regularly, either they don't need to use it or whatever else like they're just too busy"* (GP7, F, 5 yrs.)

> *"I think they* (COPD patients) *adhere to their SABA* (Short-Acting Beta Agonist) *well obviously when they're breathlessness, unsure about the LAMAs* (Long-Acting Muscarinic Antagonist) *and the combination inhalers"* (GP2, F, 3 yrs.)

Nevertheless, HCPs expressed that COPD patients had good adherence compared to asthmatic patients. In addition, the patients with more prominent/severe symptoms tended to adhere to their medication more.

> *"I actually think that they're* (COPD patients) *probably better with their inhalers than the asthmatics are. Um, a lot of COPD patients, obviously breathlessness is their most debilitating symptom"* (GP3, M, 2 yrs.)

> *"COPD patients by far adhere to their medication better than asthma patients. Because what I find from experience is that COPD patients generally are much more symptomatic and struggle with their breathing"* (N12, F, 10 yrs.)

> *"I think the patients with more advanced COPD, the better the adherence. The more severe the disease gets, the more desperate patients are. So then the more they start to listen to what we're telling them"* (GP4, M, 16 yrs.)

> *"They* (COPD patients) *are not very good at dealing to medication. If they've got symptoms, then they will be adhering to the symptoms* (medication) *and if they're feeling fine then they're probably wouldn't be doing so, I probably say about 50%"* (GP1, M, 12 yrs.)

4.7.4 **Communication among HCPs**

A couple of GPs working in the more deprived areas perceived that the communication within multidisciplinary teams inside the general practice was good, including the in-house pharmacists, though there remains room for improvement.

> *"I think already we are good at communicating in our practice with each other, with nurses and pharmacists and GP pharmacists to nurse either directly in person at meetings or through our communication system on our consulting software, but probably could be strengthened by a more integrated approach"* (GP8, M, 2 yrs.)

> *"We all use the same computer system in-house just in the next room. So they'll* (in-house pharmacists) *just come and chat with us if there's a problem"* (GP6, F, 5 yrs.)

One GP with more experience indirectly referenced that the communication was good and highlighted the preference for face-to-face communication with the community pharmacist with an emphasis on Proforma form (document utilised by both GPs and community pharmacists to streamline the exchange of patient information) to reinforce communication.

> *"The pharmacist* (in community) *was communicating with me individually face to face, but also was giving a document that had been filled out on top of that. In my experience, when we did this before, there was a Proforma that they were filling out as well, which we would counter sign. Um, I think those are all useful things to be done. So a GP is aware of the changes that are being made to patients, medications, or the fact that they've been reviewed"* (GP4, M, 16 yrs.)

HCPs' perceived communication with community pharmacists is enhanced if the pharmacy is adjacent to the general practice.

> *"So the way it normally works, though, Lloyd's pharmacy is next to us, joined to our practice, if they ever have any concerns or questions about medication or repeat medication or weird doses or something, they either come straight in and show us and say, will you just ask the doctor to double-check. That could be the pharmacy technicians or one of the staff there"* (GP7, F, 5 yrs.)

> *"There is a community pharmacy attached to us. Not part of our practice, but it is attached. So occasionally we will have phone calls, queries, but it's not common. It tends to be uncommon. And then again, on a similar level, occasionally we will have a phone call from a community pharmacist. If they have a query, something's not clear. And they will usually come via reception to see the GP"* (GP8, M, 2 yrs.)

Although HCPs made conscious efforts to communicate with pharmacists either in-house or in the community, there was still limited communication and coordination among them, especially with those who work in the community.

> *"Not as much input, to be honest, from my side, that is minimal, if any, I've never really had a discussion with the community pharmacist about inhalers, to be honest"* (GP8, M, 2 yrs.)

> *"We have regular clinical meeting and the pharmacists aren't part of that clinical meeting, it would need to be improved"* (N12, F, 10 yrs.)

> *"We have community teams out there that see patients and we don't know about it. We don't know what their treatment plan is going to be. So that would be my biggest concern"* (GP6, F, 5 yrs.)

> *"I think we need some input from them* (pharmacists) *in terms of what they have communicated and discuss with the patient"* (GP1, M, 12 yrs.)

> *"I think communication's a massive problem. Um, if the truth be told for a whole variety of reasons, um, they're busy, we are busy... So answering one query a day from a pharmacist would probably be enough, if I'm doing 3, 4, 5, 6, it could really be a big impact on my day"* (GP3, M, 2 yrs.)

> *"I don't think the pharmacist email us. They don't have access* (direct access). *It's easy for them to write the Proforma… They* (pharmacists) *need to speak to us if they're making any changes or recommendations in a formal manner"* (GP7, F, 5 yrs.)

> *"There will be emails that come from community pharmacies with non-urgent queries that go to our reception and then will be forwarded to the relevant person to do it"* (GP8, M, 2 yrs.)

> *"It is about communication not always about money, because we've got people out there already"* (N9, F, 30 yrs.)

Some GPs expressed their frustration over pharmacy waiting times on the telephone. In addition, community pharmacists had to wait in line to reach the general practice staff.

> *"Um, if they wanna ring us, they've gotta sit in ages to get through a switchboard. So it puts them off doing it. Um, they can send an email, but the response might not be quick enough for them… The pharmacists and their phone lines are jammed, that can be quite frustrating"* (GP3, M, 2 yrs.)

> *"They* (pharmacists) *have to call the GP surgery wait in line, you know, just like other patients or staff to speak to us"* (GP1, M, 12 yrs.)

> *"They* (pharmacists) *need to speak to us if they're making any changes or recommendations in a formal manner"* (GP7, F, 5 yrs.)

Furthermore, limited coordination between the GPs and pharmacists in the community was particularly perceived by two GPs who worked in the most deprived areas. Some HCPs also emphasised the benefits of continuity in working relationships for effective execution of the therapy management plan.

"I think having someone in-house in person is much better than perhaps having someone who is just working remotely, I think that can perhaps limit communication still" (GP8, M, 2 yrs.)

"I work across two different practices… I have had a pharmacist there for a long time. When I sent him a task about a patient, I clearly give indication of what I would expect him to do and then he would feedback. But on the other hand , the other practice where the pharmacist keep changing because they are new and they don't find it easy, they are switch over, it becomes very difficult. I don't get a good feedback of what's happening so that I will relatively involve the pharmacist less because I feel it's just delaying the management plan rather than sorting it out" (GP5, F, 4 yrs.)

Other HCPs said that the variety of communication systems could be a limiting factor affecting communication between pharmacists and other disciplinary teams in general practice.

"It's unfortunate that we use different systems I think we need to ease the communication between the professionals" (GP1, M, 12 yrs.)

"I know that's often been a problem with integrating the other teams, where I work they used a completely different piece of software" (N10, F, 40 yrs.)

"I think that's just a problem that the NHS faces. There are different providers of clinical systems and sometimes getting those things to talk to each other can be quite difficult. But that's issue, um, which needs to be fixed" (GP4, M, 16 yrs.)

"I have seen Proformas not often, it looks to me like its maybe from a large pharmacy chain. So I think maybe I've seen one or two from Boots where you can see that they're using their own Proforma ticking a box to say this is the query. But we don't have a universal Proforma that I have seen use" (GP8, M, 2 yrs.)

"I don't think there's a way the pharmacist could send in anything to us independently using AccuRx, but yeah, that if there's any if there's any digital way of them communicating, that'd be great. It'd be fine… They have a proper Proforma that they fill out details and then that comes to the duty doctor of the day and they can have a look" (GP7, F, 5 yrs.)

"Before I joined, there was communication through paper. And I felt there was no there is no trail. We don't know what was happening and I didn't follow that method… Pharmacies are made aware that will be tasks setting for them, to have a look and they would write back to me. So that, again, it has taken a few months to develop the system" (GP5, F, 4 yrs.)

4.7.5 **Attitude towards pharmacists' integration**

Several HCPs said that they would prefer to see pharmacists integrated into the primary care services, which would eventually help the patient.

> *"I'm happy for pharmacists to come on board… Very pro towards pharmacists being incorporated into primary care and being able to do fulfil role. They are ideal position because they are a public facing role or community facing role. We probably underestimate how much knowledge they have in regards to being able to deliver such a service… This would be a natural progression of their role"* (GP1, M, 12 yrs.)

> *"I'm very supportive of bringing pharmacists in. I think that, um, they're an underused resource"* (GP3, M, 2 yrs.)

> *"I think to a very high degree* (positive impact of integrated services). *So I know from working with our own pharmacists that they do excellent with the knowledge of inhalers, inhalers techniques, and efficacy. You know, what's recommended in guidance, cost effectiveness. So I have a lot of confidence in our pharmacist being able to do that"* (GP8, M, 2 yrs.)

> *"Absolutely fantastic. Yeah, I'd really like that* (integrated services). *We have some pharmacist here at the moment and they do an excellent job of going through the medications with the patient"* (GP6, F, 5 yrs.)

> *"I would describe it* (integrated services) *as it has a very good impact. I think the COPD patients are pretty much neglected to deal with exacerbations, hospital admissions, and sadly sometimes with very severe, severe COPD who are going to oxygen pathways. I think the more care can be put into, it is better. Sometimes we send them to the chemist and to the pharmacist and they would advise on how to rinse after using the inhaler, how to identify thrush those kind of things…. I would say that the pharmacies/ pharmacists would play a very good role"* (GP5, F, 4 yrs.)

> *"They can be there to assist an inhaler technique, discuss about sort of pulmonary rehabilitation and smoking cessation and so. I think it's a very good idea"* (GP2, F, 3 yrs.)

Several enablers were identified by HCPs regarding the integration of pharmacists within the patient care pathway (Figure 4.1). Pharmacists' knowledge concerning COPD therapy was identified as an enabler for the integration approach.

> *"A pharmacist definitely have the knowledge and definitely can show the patients how to use these inhalers most effectively than what I could"* (GP2, F, 3 yrs.)

"They've (pharmacists) *already got background knowledge in treating minor respiratory illnesses. Certainly they've got good, better knowledge often of the drugs than maybe a GP would"* (GP3, M, 2 yrs.)

"I think they've (pharmacists) *got the appropriate skill to advise on their inhaled medication. Definitely, that's what they're trained for. They're keeping up to date with all new inhalers; there's seems to be zillions of them at the moment"* (N12, F, 10 yrs.)

"I worked with groups of pharmacists and I found them quite a different audience from traditional practice nurses in that they have a lot more drug knowledge" (N10, F, 40 yrs.)

Patient trust in pharmacists is another enabler as the GPs said that pharmacists fulfil their roles well by providing pharmaceutical care to patients.

'They (COPD patients) *might always not tell us what the full truth is. Whereas they might even be more honest with the pharmacist… maybe it gives them the opportunity to feel they can speak a bit more candidly. So I certainly think that could help. I say, it's just an extra source of support for them, and their families to get it* (care) *right"* (GP3, M, 2 yrs.)

"My feeling is that patients do have that trust with the pharmacist, especially those who have go repetitively there to pick up their repeat prescriptions on a monthly basis they do" (GP1, M, 12 yrs.)

"I see the trust, the clinical expertise, and their advice to patients, and the patients trust them… They could do all the inhaler technique, monitoring the compliance pick up rate, check effectiveness and make sure it's actually working for the patient" (GP7, F, 5 yrs.)

A further advantage identified related to the ability of pharmacists to share the workload when the integration approach is implemented.

"I think it would help because it would share the load. Actually saving the GP appointment due to the accessible pharmacist in the all the local areas and local supermarkets" (N9, F, 30 yrs.)

"They (in-house pharmacists) *help with the practice workload"* (N10, F, 40 yrs.)

"I think it would just take more of the workload off the practice nurses rather than GP's so the pharmacist could sort of step in" (GP2, F, 3 yrs.)

> *"For me of course it* (integration approach) *saves me time. It's good for the patient from a GP contractual point of view, it ticks a lot of boxes that need to be done from the quality and outcomes framework perspective. I think they're very well placed. Actually, I mean, I'm a hundred percent in favour of it"* (GP4, M, 16 yrs.)

Several HCPs said that they advise or should advise patients better about how they can receive health services from pharmacists.

> *"We need to increase awareness amongst patients that pharmacists are offering the service so that could be as amongst as GPs when they are prescribing inhalers, informing them that the pharmacist can look after this COPD care as well"* (GP1, M, 12 yrs.)

> *"Whole practice approach is needed so that everybody knows what the pharmacist is there to do"* (N10, F, 40 yrs.)

> *"Because of COVID, we're not doing as many face to face. So I've been telling them* (Patients) *to speak to the pharmacists when I initiate their inhalers for the first time"* (GP2, F, 3 yrs.)

> *"The patients benefit because they get to talk to somebody who is endorsed by the practice, or is part of the practice. They get to speak to somebody who can give them time to specifically talk to them about their COPD as part of that"* (GP4, M, 16 yrs.)

Conversely, many barriers emerged from the HCPs' views (Figure 4.1). Limited resources were the foremost concern. The HCPs stated that financial payment, time, workforce availability, and readiness were barriers to pharmacists' integration within patient care pathways.

> *"The question arises, has a community pharmacist got time to do it to counsel? Are they going to get paid or recompensed for spending their time away from doing their normal job; 10 minutes, 15 minutes counselling on inhaler technique?"* (GP7, F, 5 yrs.)

> *"I suppose there are two things probably comes down to money and time… Again, money is an issue in terms of the training who will pay for that training*?*... Some pharmacists might find it a challenge to deal with COPD patients… And there's a lot of like anxiety, so again, for a pharmacist who's not used to dealing with*

patients, they might feel overwhelmed at times with some of them" (GP3, M, 2 yrs.)

"I suppose the main barrier to this (integration approach) *is money, to be honest, who is going to pay to have a highly qualified individual offering this service to patients… and I suppose then another barrier would be the actual availability of the pharmacists themselves"* (GP4, M, 16 yrs.)

"I think time is probably like the limiting factor on everything…Probably the financial impacts, somebody would have to pay" (GP6, F, 5 yrs.)

A couple of HCPs perceived the need for appropriate training and support for pharmacists in which pharmacists can improve their skills and capabilities.

"I think probably needs a conversation to make sure that if they're (pharmacists) *taking on the role that they feel supported, trained, able to do it"* (GP8, M, 2 yrs.)

"Well, I know pharmacists are not comfortable bending the algorithms and jumping here and there (altering the inhalers that not listed in local guidelines)*"* (GP7, F, 5 yrs.)

Extending from the limited resource barrier, one GP raised some concerns about the integrated approach and suggested the need to quantify the benefits of community pharmacists-led consultation concerning inhaler technique within an integrated approach, as several pharmacists, such as in-house and PCN pharmacists, are already offering such services.

"Can somebody prove that that 10 minutes intervention actually works to increase compliance in that patient if the evidence isn't there?" (GP7, F, 5 yrs.)

Numerous HCPs remarked on pharmacists' lack of complete access to patient medical records, especially those working in community pharmacies, due to either confidentiality concerns or a lack of infrastructure resources. This relates to the communication aspects stated above. One-third of HCPs highlighted some positivity towards opening medical records access to pharmacists as they are healthcare professionals.

"They (pharmacists) *don't have access to their* (patients) *medical records. They wouldn't really know which inhaler to start the patient on the day. So they can't you can't really initiate an inhaler without knowing the cases… They won't be able to step up or step down medication because they need access to the medical records… I think pharmacists in the community definitely need access to the medical records and the pharmacist needs to have their completed part; pulmonary rehabilitation* (referral program) *and smoking cessation"* (GP2, F, 3 yrs.)

"In-house pharmacists have access to full medical records in the same way that all clinical staff working in the practice do. Community based pharmacist, they do have access to a record, but it's certainly not as comprehensive as what we hold. (GP8, M, 2 yrs.)

"Um, I think it would be quite difficult for a community pharmacy. I just don't think the infrastructure is good enough to allow a community pharmacist, to be able to see the whole patient record. Um, I think that for something like this, it would be a, as things stand, it would be better done from within the GP practice itself" (GP4, M, 16 yrs.)

"I think that that's a definitely a big problem in the NHS. I mean, it would be wonderful if they could, if the pharmacist (in the community) *could log into the same record that I see and they could see my notes, you know, that would be really good. But obviously confidentiality is always a big issue. The more people that have got access to a patient's record, the more chance there is of a breach"* (GP3, M, 2 yrs.)

"I know a doctor who gets really, really anxious about that. Every time in a meeting, they start getting really animated about other people having access to the records, I don't think is a big deal. They are health care professionals, there's a good reason to have access" (GP7, F, 5 yrs.)

"Definitely, I can't see any reason to be hesitant. I have no hesitation in providing them (pharmacists) *records. Nowadays, it's been shared with all kind of clinicians. I think I can't see any issues with that"* (GP5, F, 4 yrs.)

Another barrier was identified by one GP who is working in the most deprived area concerning the cultural differences among general practice, hospital, and community settings.

"In my experience, pharmacists don't know how it (general practice) really works or the challenges, and what/ how the general practice operates, unless they have been working in general practice. It's pretty much of a shock to them of how we operate, it is quite different. One of the differences with hospital pharmacists is they will see the patient once so they believe they can just be as direct as they want. And while in these primary care, they're not somebody who will just see once, they (patients) will come back to you again and again. So anyone has to be very careful about what they promised" (GP5, F, 4 yrs.)

Patients' beliefs towards the enhanced services provided by the pharmacist, especially those of older patients, were also highlighted as a potential limiting factor in accepting the enhanced services provided by the pharmacist.

> *"They might initially be resistant to going to a pharmacist, especially some of the older patients that they like what they like"* (GP6, F, 5 yrs.)

> *"Practice based pharmacies, patients expect a phone call from them about their medication so they quite willingly will discuss their health condition. With the community based pharmacist, I think that will be a barrier"* (GP2, F, 3 yrs.)

Among healthcare professionals, there was some opposition to pharmacists' integration as a threat to professional role boundaries.

> *"I wonder whether there may be some practices, some doctors who will feel that. They don't see why a pharmacist should be doing this. They might feel a bit defensive about it"* (GP4, M, 16 yrs.)

> *"The priorities are slightly different and pharmacies are businesses. So if pharmacists were changing for that kind of purely financial reason, it caused more headaches than benefits"* (GP7, F, 5 yrs.)

> *"Pharmacists would prove valuable, but in terms of inhaler therapy, I don't know if I'm being a bit possessive of my patients. So I don't feel that there's a need to involve the pharmacists… And I think it would remove some of the responsibility from the nurse and the way you maintain your skills and your knowledge is by practice. I'm not wholeheartedly agreeable to that this way forward"* (N12, F, 10 yrs.)

> *"If they're not confident to suggest a change to medication and then they're asking for your guidance, then perhaps again it means that they're not getting as much value out of the role"* (GP8, M, 2 yrs.)

> *"I think, you know, there's always going to be a bit of fear amongst GPs, that the taking over our job, and what are we going to be left to do at the practic*e" (GP1, M, 12 yrs.)

Some barriers were also identified by the GPs concerning the budgetary concerns of the policymakers or the health service leadership.

> *"I don't know what the reason is why there's such a slow response or a slow uptake of pharmacists being involved in primary care.* (GP1, M, 12 yrs.)

> *"They* (pharmacists) *do medication reviews, but not specific to COPD and its normally led by the CCG. They decide what area the pharmacist are going to work on…But it's mostly about switching it* (inhaler) *for the sake of cost saving rather than for the patient's own benefit"* (GP6, F, 5 yrs.)

> *"As for the CCG pharmacist, everyone's got different priorities, so it's nothing bad against them, but CCG pharmacist cut the bill, the budget for the medication, so they've got their own priorities….We get the big headache when Mrs. X rings up and said I hate this inhaler and now we have to talk to change the inhaler back, one inhaler goes in the bin. …Also, the PCN* (Primary Care Networks)*, they're throwing stuff at us all the time"* (GP7, F, 5 yrs.)

One GP perceived an additional layer of bureaucracy in large pharmacy chains, which could negatively impact the services provided to the patients and their perception of the pharmacist's integration into patients' treatment pathway.

> *"It might depend on the pharmacy and the pharmacist. So I know one area that I work in, and everyone loves, the pharmacist is amazing, it is independent pharmacy so that they won't have their own kind of bureaucracy from high up. They just do the best for the patient. And then the other ones, the Boots and Lloyds of the world. Maybe there's less positivity"* (GP7, F, 5 yrs.)

A GP working in an area with high deprivation identified that continuity of care was an essential feature in building up trust between pharmacists and either patients or HCPs. Furthermore, another GP highlighted that patients trust the pharmacist they see frequently. However, a lack of continuity of care among pharmacists was perceived as a barrier as it minimised the communication process (e.g., feedback), which led to simply postponing the therapy management plan instead of optimising it.

> *"They* (patients) *do share it* (in general discussion about medications and other thing). *That's the beauty of general practice. I said yes with the pharmacist also, if they see the same pharmacist, not if there's high turnover, they don't…. I work across two different practices… I have had a pharmacist there for a long time. When I sent him a task about a patient, I clearly give indication of what I would expect him to do and then he would feedback. But on the other hand, the other practice where the pharmacist keep changing because they are new and they don't find it easy, they are switch over, it becomes very difficult. I don't get a good feedback of what's happening so that I will relatively involve the pharmacist less because I feel it's just delaying the management plan rather than sorting it out"* (GP5, F, 4 yrs.)

> *"My feeling is that patients do have that trust with the pharmacist, especially those who have go repetitively you know there to pick up their repeat prescriptions on a monthly basis they do"* (GP1, M, 12 yrs.)

In addition, an experienced nurse perceived deprivation as a barrier that impacts the integration of pharmacists into patients' treatment pathways.

> *"I think this may differ depending on what area of the West Midlands you work in, and in terms of social deprivation. Obviously it depends on the demographics of the patients"* (N12, F, 10 yrs.)

4.7.6 **Suggestions for pharmacists' roles within integrated approach**

This final theme represented the roles and tasks that pharmacists could potentially do within a more integrated approach. Participants indicated various functions for pharmacists that might vary according to the requirements of each practice. Several HCPs suggested that pharmacists should provide pharmaceutical services by keeping communication channels open, coordinating with other professions efficiently, utilising the traffic light triage (colour-coding approach to help healthcare practitioners make a rapid assessment and initiate treatment based on the extent of patient need) to support COPD patients, and prescribing and deprescribing medications cost-effectively, in addition to the enhanced pharmacists' role related to educating and training COPD patients about using inhalers correctly and dealing with minor ailments. Moreover, pharmacists could be engaged to make some changes on a practice level.

> *"Pharmacist* (in-house and PCN) *will do medication reviews, re-authorise medications high risk drug monitoring, dealing with urgent prescriptions and queries, and is also working on changing some of the processes and policies on prescribing practice level in terms of medication, request medication issues, working with our prescriptions team receptionist, deprescribing high risks drugs. Also working in terms of how we deliver things on the universal offer, making sure fulfilling our duties based on that"* (GP8, M, 2 yrs.)

> *"The patients would have regular reviews, the medications would be optimised, and actually would be taught how to use their inhalers. So from a personal point of view, we should see fewer exacerbations, fewer symptomatic patients coming in crisis… and obviously would increase patient satisfaction"* (GP6, F, 5 yrs.)

"I think when you're changing the role, you need to be clear about all definitions and all need to be agreed. And all need to be happy with what the role is… They (all type of pharmacists) *wouldn't be involved in diagnosis or long term chronic review, but they would be involved in medicines reconciliation"* (N10, F, 40 yrs.)

"So if they (all type of pharmacists) *see the patient that same day, within a day or two, they should have sent us some message to us and updated us what the plan is. They just need to have regular clear communication and timely manner… The pharmacist could do red, amber, green in the initial assessment and then maybe the red ones will automatically get a review four months down the line. But then again, the green ones every year"* (GP7, F, 5 yrs.)

"Making sure that we're prescribing the right medication or the most cost effective medication" (GP1, M, 12 yrs.)

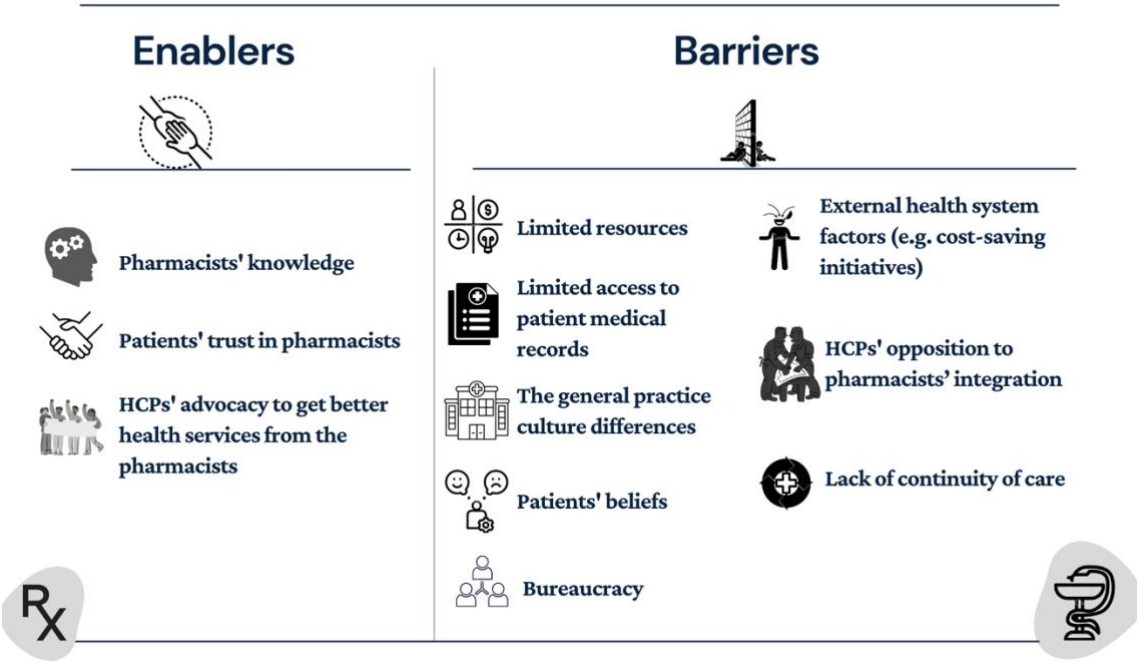


Figure 4.1: Enablers and barriers of pharmacists' integration to patients' treatment pathways

4.8 Discussion

4.8.1 Summary of the key findings

The current research aims to explore HCPs' views about the enhanced role and integration of pharmacists in COPD patient care pathways. The results showed **four main themes: healthcare professional perception towards inhaler technique, inhaler training and adherence; communication between HCPs; attitude towards pharmacists' integration;** and **suggestions for pharmacists' roles within an integrated approach**.

4.8.2 Finding in relation to existing literature

Inhaler knowledge/ training HCPs

Inhaler technique knowledge and training

Our study highlighted that some HCPs had no training in inhaler technique or how to use the inhaler properly. Similarly, a previous study showed that nearly 75% of HCPs (113/150) reported being engaged in the instruction of inhaler technique; but of those, only approximately 9% were able to perform all standard steps of inhaler technique correctly (280). The right demonstration of the inhaler technique may be learned in a single training session, according to previous findings on inhaler technique education for HCPs (137, 281, 282). Nevertheless, even after just up to three months, there was evidence that the skill was wholly or partially forgotten (281, 282).

Communication

Limited coordination and communication

In our study, HCPs pointed to the utilisation of both in-person meetings and written communications such as Proformas as ways of communicating information. Furthermore, the adjacency of pharmacy to general practices or integration of pharmacists within the primary care team was perceived as contributing to enhancing communication. In our

study, HCPs said there is still limited communication and coordination between GPs and pharmacists. Collaboration amongst health personnel has been characterised as a shared method of communication to address the patient's health and disease demands while preserving every personnel's distinctive characteristics and capabilities (283). High-quality, most secure, and most efficient patient treatment relies heavily on open lines of communication between HCPs (284). It is critical to provide pharmacists and other health personnel with enough training in effective communication, but also, the proper infrastructure to do it.

Waiting time frustration

Our findings indicated some frustration for HCPs, due to time spent either waiting for someone or having a conversation with an individual other than the prescriber. Our finding is consistent with qualitative research conducted in Germany to explore structured inter-professional communication that promotes teamwork between HCPs and community pharmacists. The German study highlighted that reaching the prescriber is a major challenge, and it infringes on time needed to provide the services for the users (285).

Welcoming pharmacist integration

Pharmacists' knowledge

In our study, HCPs said that pharmacists hold the expertise and skills to offer COPD inhaler therapy. Our result is in line with a previous cross-sectional study conducted in the UK, which aimed to explore primary care doctors' experiences, perspectives, and attitudes regarding pharmacists. The cross-sectional study reported that 83% of primary care doctors (n= 162) said that their pharmacist always or very frequently has the necessary clinical abilities (knowledge and skills) to deliver high-quality, safe treatments (286).

Reduce the workload

In our findings, there was a perception from the GPs and nurses that both in-house and community pharmacists may alleviate the workload pressure. A fair amount of research corroborates the positive effects pharmacists may have when they are employed in general practices (287-289). A qualitative study in the UK showed that pharmacy professionals are ready and prepared to take on more responsibilities in primary care settings, which might significantly reduce the burden on general practitioners (290).

Enablers & Barriers

Limited resources (Time; Workforce availability; Payment)

Three resources can be distilled from our data, including time, financial payment, and staff, which could contribute to barriers of most concern to pharmacists' integration into patients' care pathways. At the same time, integration is not a solution to resource constraints. Integrating two distinct operations could result in cost savings; however, incorporating new services into an established system needs sufficient financing. Regarding pharmacists' availability, PCNs are set to get more funding to significantly increase pharmacists' employment from 6,000 to as many as 7,500 by 2024 (291). There has also been considerable growth, with a 7x increase, in full-time healthcare practitioners in England (from a mean of 0.04 per practice in 2015 to a mean of 0.28 in 2019) (292).

Furthermore, this study identified a lack of financial remuneration as a barrier to pharmacist integration. This finding is echoed in prior qualitative research that reported that HCPs, including GPs and nurses, expressed their inability to offer the suggested service in the absence of some reimbursement for their time (293), and this could be extended to pharmacists. This is further supported by other qualitative research that highlighted that severe budget restrictions created an environment where plans were

difficult to carry through because of rapid dynamic changes in the healthcare settings (294). Time constraints were also mentioned in the interviews. This is similar to prior research that revealed a general practice was unable to take on more tasks due to ever-increasing time demands and the fact that many employees are already overburdened (293).

Patients' beliefs

A few points were identified among the GPs concerning what they perceived as patients' beliefs towards pharmacist integration into their treatment. This issue is a barrier, but pharmacists, either in general practice or in a community, should combat this negative trend as they must strive to develop a loyalty-based connection to increase their positioning and competence (295). Comprehensive patients' perceptions towards pharmacists were discussed in the previous chapter (Chapter 3, section 3.8.2); the general practitioners' opinions about the patients' views are similar to the actual patients' views, as the previous chapter explained that some patients were concerned about whether pharmacists could provide them with trusted advice because they were unsure about pharmacists' qualifications, and pharmacists did not really have a role in the medication prescription process.

Access to the medical records

As expected, lack of medical access to patient's medical records is a significant barrier to pharmacists' integration, especially for pharmacists working in community settings. This issue is yet to be resolved; since 2015, when the Royal Pharmaceutical Society first made the request, they have been lobbying for pharmacists to have full read/write access (296). Recently, the Department of Health and Social Care 2022 declared that each integrated care system should put up a 'shared care record' by 2024 (297). Nevertheless, it is

important to note that some areas are still putting the finishing touches on their Shared Care Records platform, including the West Midlands region.

GP culture differences

Cultural differences were highlighted as a challenge to pharmacists' integration into patients' treatment pathways. Our results are consistent with a recent Delphi study which aimed to provide a consensual view on the educational requirements of pharmacists planning to operate in the general practice environment. The Delphi study highlighted the importance of training for new pharmacists working in a general practice context (298).

External inputs (organisational factors)

Findings from this study shed light on an issue related to inputs from policymakers, such as CCGs, as they play a crucial part in strengthening primary care quality besides their commissioning role. In this study, some GPs were concerned about the conflict in pharmacist roles resulting from CCG requirements, which could affect patients' satisfaction or adherence to inhaler therapy. This is consistent with the report by Holder et al. (299), which suggested that possible conflicts of interest, frayed relations with other GPs and NHS England, and cutbacks in operating expense allocations might impair the gains afforded by the transition to the co-commissioning primary healthcare system.

GP opposition

In our findings, some GPs may resist the new role of pharmacists within the integrated services, or at least some GPs state that some of their colleagues might hold that view. Similar to our results, a recent qualitative study conducted with pharmacists working in community settings in Ireland explored the pharmacists' views on pharmacists' integration into the primary care setting. The pharmacists recalled GPs' past resistance to the idea of community pharmacists delivering jab shots. The qualitative research

underlined that financial reimbursement, rather than expanded responsibilities, could have been at the root of GP resistance. Nevertheless, besides the financial reimbursement, pharmacists in the same study perceived that habitual resistance among senior doctors was another concern (300).

Suggestions for pharmacists' roles

The present study considers expectations of pharmacists' roles within an integrated approach, for example, continuing education and training of COPD patients on the correct use of inhalers, medicines reconciliation, prescribing and deprescribing high alert medications, and administrative positions. Our findings are supported by a recent cross-sectional investigation of the roles of in-house pharmacists and how they integrate into the healthcare system. It reported that among the many clinical tasks performed by pharmacists in England, medicine use reviews and medication reconciliation remained standards (301). Further efforts are needed to promote the pharmacists' capabilities and skills among HCPs to maximise the benefits generated from the integration approach and optimised services provided to patients.

4.8.3 **Strengths and limitations**

To the best of our knowledge, this is the first qualitative study on the perception of HCPs in the UK concerning the enhanced role of pharmacists in the COPD patient care pathway and integration of pharmacists within the patient care pathway. It sheds light on the perspectives and experiences relevant to an enhanced pharmacy role in COPD management and illuminates the enablers and barriers to supporting the integration of pharmacists within the COPD patient care pathway.

We aimed for a reasonable sample size that would allow us to incorporate a broad diversity of HCPs' characteristics, including age group and gender, ethnicity, qualification, length of experience, and deprivation level of area, so that the findings

could be generalised throughout primary care in the United Kingdom. We achieved a good balance among participants in terms of gender, ethnicity, age, length of experience, and deprivation levels of areas HCPs served. Although this research intended to include in-house and community pharmacists, there were no pharmacists in the West Midlands area who opted to participate in this research. Pharmacists' perceptions were missed, and would have added a further dimension to this research. Future research should consider including pharmacists to seek their perspectives.

Since HCPs are already working full-time, scheduling an in-person interview might be difficult. Interviews conducted remotely make this issue more manageable. It is considerably simpler for candidates to take 60 minutes out of their workday to participate in a remote interview. Although most interviews ran smoothly, one interview faced some technical issues related to the internet connection, which led to inadequate sound quality that caused misunderstandings and the needless repeating of questions and responses. Moreover, due to the distance between the researcher and HCPs, it is significantly more challenging to establish rapport throughout a remote interview. However, the researcher has attended training to overcome this issue and thus was able to engage with participants and build rapport successfully.

Another potential limitation related to the study design was freedom in the interpretation of the data, which might have led to inconsistencies and a lack of cohesiveness. However, these problems have been mitigated with vigilant monitoring by ensuring the credibility, transferability, dependability, confirmability, and reflexivity of study procedures and findings (Chapter 3, section 3.5.5). In addition, the outcomes may be influenced by social desirability bias. To minimise these impacts, the researcher phrased the questions in the most impartial manner possible. Although we clearly asked questions to HCPs related to the roles of each pharmacist, there were responses from HCPs about pharmacists, some

of which mentioned roles in a mixed way and did not differentiate among the roles of community, in-house, and CCG pharmacists.

A further drawback of this research is that the findings and recommendations presented herein have been limited due to insufficient knowledge regarding post-study recent modifications in SCR, SMR, and ICSs. Moreover, it is essential to acknowledge that the superficial reporting of NMS in our research does not lessen their overarching significance. The inclusion of some findings about NMS in our study was primarily motivated by our intention to expand upon the existing literature, rather than duplicating the investigation of healthcare professionals' perspectives on NMS.

4.9 Conclusion

This study aimed to explore HCPs' views on the enhanced role of pharmacists in the COPD patient care pathway and the integration of pharmacists within the patient care pathway. This study's results could be beneficial to HCPs working in general practice and the community, including pharmacists and policymakers, as it sheds light on healthcare providers' efforts in facilitating inhaler use and the process of pharmacists' integration. It is noteworthy that many HCPs agreed that an increased role for pharmacists' integration within patients' treatments pathways would be welcomed. There were several barriers to overcome, especially related to effective communication and pharmacists' access to medical records and limited resources, general practices culture, and health system external inputs such as CCG and PCN additional roles. In this light, the systematic adoption of integration will require financing and support from important contributors other than pharmacists. Further evidence of the healthcare advantages of incorporating pharmacists into general practice settings is required, including quantifying pharmacists' efforts to improve COPD patients' health outcomes, such as inhaler adherence.

Chapter 5 : COVID-19 and its impact on healthcare services provided to COPD patients: a qualitative study with COPD patients and health care professionals

5.1 Chapter overview

This chapter details a study that explored COPD patients' and HCPs' perceptions about COVID-19 and its impact on healthcare services provided to COPD patients. The COVID-19 pandemic hit in the middle of conducting my PhD. This work package fulfilled the thesis's fourth goal— *What are the COPD patients' and HCPs' views on COVID-19 and its impacts on health care service provided to COPD patients?*

5.2 Abstract

Background

COVID-19 has had a significant impact on the health and well-being and the provision of primary healthcare services for patients with chronic diseases such as COPD because they tend to be older. A few companies provided NHS remote consultations tools designed to aid practices. E-consultation and telephone triage strategies were deployed, with the vast majority of triaged consultations taking place over the phone or through video calls. There is little information about whether virtual or remote consultations are effective or acceptable to COPD patients.

Aim

To explore COPD patients' and HCPs' views on the impact of COVID-19 on COPD patients including advantages and disadvantages of remote consultations.

Methods

Semi-structured interviews with open-ended questions were conducted *via* telephone/Zoom among COPD patients and HCPs in the West Midlands, UK. COPD patients were recruited from the BLISS cohort. HCPs were approached *via* an advert distributed through GP practices that were part of the BLISS cohort and brief adverts were disseminated to several professional organisations throughout the West Midlands area. Interviews were analysed using Braun and Clarke's six steps of thematic analysis.

Results

12 interviews were conducted, eight COPD patients were interviewed (five men, three women), mean age 78.5, severity of disease ranging from moderate to very severe. The four HCPs' age ranged from 30-50 years old, and 75% of interviewees had four or more

years of practice experience. Three major themes emerged: a) coping and life adjustment, b) the accessibility of the NHS services, and c) health inequalities and e-health literacy.

Conclusion

COPD patients and HCPs agreed that increased pressure on health services led to a deterioration in the management of COPD. Considerable hurdles included those linked to access to health facilities, COPD patients' beliefs towards remote consultations, the impact of lifestyle alteration on restoration of patients' physical fitness capacity, and digital skills and difficulty of communication with an older cohort of patients, especially in deprived areas, for telemedicine services. Future lessons could be implemented post-pandemic, including rethinking how HCPs are trained to conduct remote consultations, emphasising building rapport and aspects related to therapy, and flexibility around patients' access to healthcare to ensure patients' continuity of care.

5.3 Background

The COVID pandemic started in the midst of my PhD programme. COVID-19 was designated a pandemic by the World Health Organization (WHO) on March 11, 2020 (302). By the end of August 2022, over 606 million individuals worldwide had contracted the SARS-CoV-2 virus (COVID- 19), leading to about 6.49 million deaths (303). Fever, cough, trouble breathing, lethargy, and headaches are the most typical signs of infection with COVID-19 (289). Most people who are symptomatic had just minor symptoms, although some people had more serious life-threatening sequelae such as pneumonia or acute respiratory distress syndrome (ARDS) (304).

A sizable population was at increased risk for greater serious illness (hospitalisation required), mortality or prolonged COVID-19. Indeed, this is especially evident for those who suffer from comorbidities (305). In the UK, electronic records analysis (486,149 individuals with confirmed COVID-19) from primary care showed that patients who reported symptoms for longer than 12 weeks were more likely to have pre-existing conditions like COPD and mental health diseases (306).

Moreover, in COPD patients delays in the elimination of respiratory viruses were also evident, suggesting that both their adaptive and innate immune mechanisms are compromised. It is possible that these characteristics combine to make it easier for SARS-CoV-2 to spread throughout the lungs of COPD patients, which might hasten the onset of severe COVID-19 (307). Nevertheless, research has shown that only 2% of patients with COVID-19 infection admitted to Chinese hospitals had COPD as an underlying condition (308, 309).

Numerous public health strategies, including washing hands, mask use, and social distancing, were implemented to reduce the COVID-19 infection, in which these measures were associated with reducing the spread of COVID-19 (310). Lawless et al.

explored hospital admission for acute exacerbation chronic obstructive pulmonary disease (AECOPD) between the end of March 2020 to the end of December 2020 in comparison with the previous year in the North-East of England. The findings showed that significantly fewer patients were admitted to hospitals with AECOPD over the COVID-19 period, but neither their fatality nor the severity of their exacerbation rate rose (311).

Patients with chronic diseases such as COPD were particularly affected because they tended to be older, were at higher risk of severe disease because of their condition (312), and might even have been shielding or caring for other vulnerable people (313). A review has shown that they were affected in terms of loneliness and isolation due to lockdown, inability to exercise and loss of function, the challenge of using mobile and electronic devices for communication, and changes in access to healthcare (314).

All HCPs, including pharmacists, played an important role during the pandemic by interacting directly with communities and maintaining care for chronically ill patients (315, 316). Historically, people have turned to community pharmacies for their medicine, which should be readily accessible (295). Furthermore, pharmacists may give trustworthy information for coronavirus prevention, detection, treatment, and management (301, 317). Besides COVID-19-specific roles, pharmacists' responsibilities are framed as the following: affording the public with information and education on pharmaceutical items and equipment (such as medicines and masks, while also ensuring proper storage and supply), counselling and referring patients, and lastly, promoting disease prevention (301). Further community pharmacies' roles are described in the literature review chapter (Chapter 1, section 1.8).

To lessen the likelihood of spreading COVID-19 among patients and HCPs in the UK, the NHS began offering remote consultations. A few companies provided NHS remote

consultation tools designed to aid practises such as AccuRx, EMIS, TPP, and Vision. In the first quarter of 2020, technological firms introduced remote consultation solutions at little or no charge (318), as proper management of COPD patients is critical. E-consultation and telephone triage strategies were deployed (319), with the vast majority of triaged consultations taking place over the phone or through video calls (320). A virtual consultation methodology has yet to be shown to be successful or popular (321, 322).

As I was in the process of conducting my planned qualitative interviews with both patients and HCPs, I took the opportunity to explore the impact of the pandemic on the health and healthcare of COPD patients from the perspective of both patients and professionals, seeking to understand their experiences and identifying any aspects that might be useful post-pandemic. This qualitative study aimed to fill a gap in the scientific literature on COPD patients' and HCPs' views on the impact of COVID-19 on COPD patients and to explore attitudes to remote consultations as part of health services provided to COPD patients.

5.4 Methods

This chapter describes an additional qualitative study conducted among COPD patients and HCPs in the West Midlands, UK from April to August 2021, using the patients and HCPs recruited for the studies described in Chapters 3 and 4. This study used semi-structured interviews with open-ended questions conducted *via* telephone/ Zoom (an account provided by the University of Birmingham). Thematic analysis was utilised to interpret the data and emphasise COPD patients' and HCPs' perspectives and experiences, as described in the previous chapters (Chapters 3 and 4; sections 3.6 and 4.6). The topic guide for the third and fourth chapters were amended after the study had commenced, and this included adding some new questions related to the impact of the COVID-19 pandemic on their mental and physical health and their views and experiences

of the accessibility of healthcare services and use of remote consultations when managing COPD patients (Appendix 23). The last twelve interviews included these questions.

5.5 Results

5.5.1 Sociodemographic Characteristics

Twelve interviews were conducted. Eight COPD patients were interviewed (five men, and three women), mean age 78.5, severity of disease ranging from moderate to very severe. The four HCPs' age ranged from 30-50 years old, and three interviewees had four or more years of practice experience (Table 5.1).

Table 5.1: Sociodemographic and other characteristic of the participants

	Patients (N=8)	HCPs (N=4)
Gender		
Men	5 (62.5 %)	2 (0 %)
Women	3 (37.5 %)	2 (0 %)
Not declared	0 (0 %)	0 (0 %)
Average age (yrs.)		20-30 0 (0%)
Mean (SD)	78.5 (7.4)	31-40 2 (50 %)
		41-50 2 (50 %)
		51-60 0 (0 %)
		61-70 (0 %)
Ethnicity		
White British	7 (87.5 %)	1 (25 %)
White Irish	1 (12.5 %)	0 (0 %)
British Indian	0 (0 %)	2 (50 %)
Other	0 (0 %)	1 (25 %)
Education		
Elementary	0 (0 %)	-
Middle school	0 (0 %)	-
High school	3 (37.5 %)	-
Diploma	2 (25 %)	-
Bachelor	0 (0 %)	3 (75 %)
Master	0 (0 %)	1 (0 %)
PhD	0 (0 %)	0 (0 %)
None	3 (37.5 %)	-
Index of Multiple Deprivation Decile *		
1	1 (12.5 %)	2 (50 %)
2	2 (25 %)	0 (0 %)
3	0 (0 %)	0 (0 %)
4	1 (12.5 %)	1 (25 %)
5	2 (25 %)	0 (0 %)
6	1 (12.5 %)	0 (0 %)
7	0 (0 %)	0 (0 %)
8	0 (0 %)	0 (0 %)

	Patients (N=8)	HCPs (N=4)
9	1 (12.5 %)	1 (25 %)
Length of diagnosis (yrs.)		
1-4	0 (0 %)	-
5-10	3 (37.5 %)	-
11-14	2 (25 %)	-
15-19	0 (0 %)	-
>=20	3 (37.5)	-
COPD severity		
Mild	0 (0 %)	-
Moderate	1 (12.5 %)	-
Severe	6 (75 %)	-
Very severe	1 (12.5 %)	-
Specialisation		
General practitioners	-	4 (100 %)
Nurse	-	0 (0 %)
Pharmacists	-	0 (0 %)
Length of work experience (yrs.)		
1	-	0 (0 %)
2	-	1 (25 %)
3	-	0 (0 %)
4	-	1 (25 %)
5	-	2 (50 %)

* Index of Multiple Deprivation Decile (IMD): (1: most deprived, 10: least deprived)

We identified three major themes within the data including a) coping and life adjustment, b) the accessibility of the NHS services, and c) health inequalities and e-health literacy. Each major theme has multiple subthemes derived from the major theme. See Table 5.2 for more details.

Table 5.2: Major themes and subthemes

Theme	Subthemes
Coping and life adjustment	Changes to lifestyle
	Impact of isolation, shielding, and masking
	Self-management (carer dependency)
The accessibility of the NHS services	Limited access to health facility (HCP appointments, follow up)
	Frustrations on the services provided by NHS
	COPD patients' beliefs
Health inequalities and e-health literacy	Patients' digital disadvantage
	Inhaler technique

5.5.2 **Coping and life adjustment**

Changes to lifestyle

The COPD patients stated that lifestyle restriction was inevitable when the government imposed it.

> "*The problem at the moment, we've not been seeing anybody because of the COVID…My daughter and myself, we've been both in very strict isolation. So I don't really get out too much, I mean at all at the moment. I hope it will change one day, but not sure when?*" (P15, M, 81, Severe COPD)

> *"We've had just to adapt to this* (government regulation)" (P16, F, 90, Severe COPD)

> *"Well, I was in Scotland for the best part of a year with my partner, and we obviously couldn't go anywhere. We were in isolation then, but that is only because it was forced upon us by the government"* (P22, M, 83, Moderate COPD)

Physical activity

A couple of patients talked about physical activity before and amid the pandemic, especially the difficulty in regaining physical fitness after restrictions were lifted.

> *"No I am not able to walk now, and since we've had this pandemic, I am not going out at all. It made my walking worse"* (P16, F, 90, Severe COPD)

> *"In a warm climate, I exercise. When I'm abroad, I can walk up to 10000 steps a day because I do walk in the morning a bit, in the afternoon a bit. Also, I walk at*

night. Obviously, that has gone so far with nowhere opening doors like a large shopping centre; it will be closed, which I could use during the winter because obviously, they're warm and dry… My fitness dropped alarmingly in the winter because I've not been able to get out and walk on a regular basis because either it is too windy, too wet, or just too cold… I know what I'm doing. I know what I've got to take, and how often, and I've got to take it. It's just the exercise probably backwards, and once you lose it, like everything, it's very difficult to get that back" (P17, M, 76, Very severe COPD)

Impact of isolation, shielding, and masking

Aside from physical impacts, the pandemic of COVID-19 possibly led to increased mental ill-health among COPD patients as a result of advised preventative practices such as social isolation and quarantine.

"Well, I shall continue to wear a mask if I go out, but I did not go out" (P16, F, 90, Severe COPD)

"I still like what I do with driving. But, unfortunately, I ain't going nowhere with a pandemic. I used to pop out me and my wife and run out somewhere. But of course, now I can't do that" (P18, M, 84, Severe COPD)

"Well, I haven't been out at all. I don't mix with other people. In the last two years I have not been able to go out. So I miss all the local areas like Dudley and others" (P19, M, 67, Severe COPD)

"Well, I haven't gone out in a while. We've been on lockdown; the only time I went out was to have my injection twice. Over the Christmas, we never went anywhere when the lockdown came before Christmas" (P21, F, 76, Severe COPD)

"I'm shielding, I don't mix with other people" (P20, F, 75, Severe COPD)

Self-management (carer dependency)

A COPD patient with serious health conditions perceived that taking care of a family member during the pandemic was challenging.

"It is affecting me with the COVID quite a bit. Plus my daughter's a very sick person so as to care for her as well… In the past couple of months, I've had a problem with my spine, problem with my hip, and also I've had pneumonia. They've discovered it (pneumonia) *three times, so I had pneumonia. So I'm hopefully getting over it now"* (P15, M, 81, Severe COPD)

Some COPD patients were aware that caregivers such as family members and close friends and neighbours had to help them more than usual.

> *"Because of COVID my daughter has been picking up my prescriptions, and my next-door neighbour's been picking up my prescriptions, and sometimes the pharmacy itself* (name masked) *Pharmacy will deliver them to my house"* (P15, M, 81, Severe COPD)

> *"My daughter picks me up and takes me to my hairdresser. And she did my shopping for me, or I'll go with her to do shopping. I haven't been out on my own since February of last year"* (P16, F, 90, Severe COPD)

> *"My daughter gets my medication and my husband as well. I have two good daughters. But the old one is ill at the moment, she got cancer. So I don't ask her to do anything"* (P21, F, 76, Severe COPD)

5.5.3 **The accessibility of NHS services**

<u>Limited access to health facility (HCP appointments, follow up)</u>

Access to the NHS services is obviously a top concern for COPD patients. Patients reported the difficulty of seeing the medical staff at the surgery.

> *"Well, you can't see a doctor. Yes, I have not seen my doctor for oh almost 2 years… And to get to speak, you have to explain everything to the receptionist before, and then you have to wait for a phone call from the doctor. Unless that is absolutely urgent that I need an appointment. And that's only when I have my infection and I need an antibiotic… I can go to the pharmacist, which is where I live, where I have to go first. At the moment, I can manage to get to the pharmacy."* (P16, F, 90, Severe COPD)

> *"I haven't seen anybody. No one has contacted me, so I haven't thought of that. Sorry. They did ring me up and said, could I go for COVID jabs? But that's the only contact that I had from them. I used to get there annually, I haven't seen the nurse for a year and a half"* (P17, M, 84, Severe COPD)

> *"You can't get to see a doctor; you can't see anybody because of this pandemic"* (P19, M, 67, Severe COPD)

> *"It's very difficult to get into seeing a medical staff; a doctor is very difficult"* (P20, F, 75, Severe COPD)

> *"I haven't had any (UNCLEAR WORD) at the surgery because they can't, can they? It looks like hell. I haven't been down to the surgery for two years to have a test to see what the number is. But if it is really bad, I will phone them up"* (P21, F, 76, Severe COPD)

"I've been having tests occasionally at the surgery, not in the last two years, touch wood, I haven't had COVID at all" (P22, M, 83, Moderate COPD)

The HCPs raised other concerns related to COPD patients' diagnosis, annual reviews, and inhaled medication technique and consultation during the pandemic.

"Massively. So we haven't done spirometry for kind of a year and a half or maybe a year and a quarter, a long time that we just stopped doing it…We've not been able to have official diagnosis with spirometry for a lot of COPD patients" (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

"Oh, hugely, I mean, from obviously the diagnosis, we haven't been able to do spirometry for chronic disease reviews. Now they have to change to being just remotely done. So, yeah, it had a massive impact" (H13, M, 30-40 yrs., GP, 2 yrs. of experience)

"You can't see the patient so often, you know before they bring their inhalers and discuss inhalers with them. We put all the COPD checks on hold. We're not diagnosing people with COPD as frequently as we were before because we don't have access to the tests. We treat people blindly over the phone. You know, it's really poor at the moment. We're doing our best, but it's not great at the moment" (H11, F, 30-40 yrs., GP, 5 yrs. of experience)

"Significantly, a lot of COPD reviews haven't happened during the pandemic last year. This means less face to face consultations and also with COPD patients at increased risk of severe COVID so they are hesitant to come to GP surgery as well? And also, if they have exacerbation, it's difficult to see at that stage of the initial consultation to have COVID or not so I think it's affected a lot. (H10, F, 40-50 yrs., GP, 4 yrs. of experience)

<u>Frustrations about the services provided by NHS</u>

Several patients raised a point related to their frustration with the services provided by the NHS, notably their reluctance to seek health care during the pandemic due to the lack of easy availability of doctors.

"I just don't phone the doctors. I try to avoid bothering them with anything wrong" (P18, M, 84, Severe COPD)

"When COVID was on, she wasn't in the clinic in the doctor's surgery. There's no appointment, we can't come in, so that was it; we couldn't get in our doctor. So we had to go and see the doctor at the hospital" (P21, F, 76, Severe COPD)

"Badly, I normally have or used to have breathing tests once every year at the surgery, you know, blowing something up into something to see what the pressure

was inside. And I haven't had one now, for must be now two years or more" (P22, M, 83, Moderate COPD)

COPD patients' beliefs

Some patients clearly stated that they avoided contacting the surgery due to their concerns about bothering doctors unnecessarily.

"I got to avoid going unless it's really necessary because I think they're wasting their time and mine" (P18, M, 84, Severe COPD)

"Well, I've been ill at a time, and I just haven't bothered asking to see a doctor because I know I can't see one" (P20, F, 75, Severe COPD)

Although the NHS services were viewed as busy during the pandemic, one COPD patient living in the most deprived area stated that they understood the current situation and she had no objection to waiting longer for treatment.

"I know that the National Health is in distress, so I don't push the doctor and I don't push the pharmacist; I will wait, I understand the problem that we deal with the national health at the moment" (P20, F, 75, Severe COPD)

5.5.4 **Health inequalities and e-health literacy**

Patients' digital disadvantage

Notably, many patients explained that using remote consultation technology—a video or phone consultation with HCPs to discuss their health—was difficult for them, and they did not like it compared to the traditional method, which is a face-to-face consultation.

"Well, I don't use a computer, it has to be by phone" (P16, F, 90, Severe COPD)

"To be honest with you. Um, I don't have Zoom anyway. I prefer to see them, or by phone, I don't know. I don't see the point of that" (P17, M, 76, Very severe COPD)

"No idea about it (remote consultation)" (P18, M, 84, Severe COPD)

"*I'm not very familiar with the video call. I can assure you, I'm not that good with technology*" (P20, F, 75, Severe COPD)

> *"Well I don't really need that. If there is something really seriously wrong with me, I don't like the doctor to come on the telephone and tell me"* (P21, F, 76, Severe COPD)

> *"Well, there is no need to know a little more about it, but yes, I probably would think about it. I mean, I've not thought of anything like that before. I'm prepared to listen and see what it is, but I don't know"* (P22, M, 83, Moderate COPD)

> *"I don't think it* (remote consultation) *would be detrimental, but I don't think it would particularly offer that much either. For me personally, probably no help at all"* (P17, M, 76, Very severe COPD)

> *"Well, I haven't spoken to the doctor on the phone and I'd rather see the doctor face to face, and I haven't been able to do that. No, I don't want to get involved. That's not right, you must see a doctor face to face. ...If that's the only way you can see the doctor, and speak to the doctors, so be it, hopefully"* (P20, F, 75, Severe COPD)

> *"Yes, it* (remote consultation) *can be easy to go over the phone, some things you can, but not everything can be. I like to see the doctor face to face to see what particularly he says"* (P21, F, 76, Severe COPD)

In contrast, several COPD patients said they welcomed the idea of using remote consultation for health safety purposes during the pandemic.

> *"Well, yes, that would be nice. You know, it* (remote consultation) *would be safe at the moment* (during the pandemic)" (P18, M, 84, Severe COPD)

> *"To be quite honest, I sort of, I suppose I welcomed it* (remote consultation) *because it helped, and that's the only reason I see. As far as I know, I've not felt any detriment. I just happen to think the process of not seeing any patients face to face is wrong. But that's my opinion at the moment"* (P22, M, 83, Moderate COPD)

> *"It* (remote consultation) *doesn't bother me. If someone phone me asking, I will inform anyway. But infections being around in this country for many years, for the last 200 years. I don't really bother about the infection because new infections come out every *** day"* (P19, M, 67, Severe COPD)

HCPs raised some concerns for some patients regarding using remote consultations, especially those related to communication difficulties, diagnosis, and assessment of severity of respiratory illness.

> *"I don't know if you've ever tried consulting with an elderly person on the phone, but it's really hard like, communication difficulties, hearing difficulties"* (H11, F, 30-40 yrs., GP, 5 yrs. of experience)

> *"I'm not very good at talking. I'm much more expressive on my hands, my face. You know, you miss all of them sort of over the phone"* (H11, F, 30-40 yrs., GP, 5 yrs. of experience)

> *"I'd have to guess I think initially was a lot on the phone, not even seeing them, telling them on the phone, it sounds like COPD, try an inhaler, see how you get on for a month"* (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

> *"... There are those areas where because the face to face contact has been limited, it has been much more challenging to manage certain conditions, certain problems. We do have many patients who I think find it difficult in a remote consultation to describe how the COPD is? I think there's lots of different factors, they would say a lot of the time it is worse. Quantifying that, using a scale they find it difficult, whether that would be better addressed in the face to face. Possibly, they would find it easier to talk in face to face consultation…We have to be a bit more cautious with purely using remote consultations especially for any exacerbation of a respiratory illness, because it can be very difficult to be safe in a remote consultation for respiratory illness. Sometimes you need to have some objective markers of assessment"* H13, M, 30-40 yrs., GP, 2 yrs. of experience)

A GP who operated in a very deprived area highlighted the inequalities in access or ability to use the internet.

> *"We have sent out like loads of COPD template patients, some of COPD patients would not have replied because these patients who are not very good with computers, don't have Internet access. I work in a very deprived area. So the patient education is not very high"* (H10, F, 40-50 yrs., GP, 4 yrs. of experience)

HCPs positively perceived remote consultation as the main method during the pandemic. Some methods were used more frequently than pre-pandemic, such as telephone triage and the AccuRx template.

> *"Now, we or the nurse, the asthma COPD nurse, sends out a link. The patient fills out the CAT score for that COPD and asthma version as well, whose name slipped my mind, the questionnaires as they send it back to us and depending on what they write, we will reply back with AccuRx text message saying, carry on, everything's perfect. You seem to be doing really well based on the scores. if there's anything worrying, the nurse will ring them, speak to them on the phone and potentially just ask them, you're really bad with your score"* (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

> *"A lot of any information you can get beforehand through AccuRx. There are some templates already loaded up and if you send it to them, they are computer savvy; they will reply and get recorded to the patient notes. So you have a fair idea on the COPD control through that to decide because they give a CAT score whether they need to review them quickly or can it wait for a few more weeks, I think"* (H10, F, 40-50 yrs., GP, 4 yrs. of experience)

> *"Our reviews for COPD are done by the nurses. So we've got a respiratory nurse who calls patients on a recall basis every year before, used to be face to face. Now it's primarily on the phone"* (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

> *"I think there are some issues regarding consultations that are safely and effectively dealt with in remote consultations, which are more convenient for both doctor and patient, so it has been positive in some areas… In my experience, for the stable ones, I think remote consulting has been fine because generally they* (COPD patients) *perhaps have already engaged with a lot of the things we try and do for the COPD like pulmonary rehab, stopping smoking cessation, and have good knowledge of COPD, maybe they are able to clearly express how things are with the symptoms… Certainly on a personal level and on a practice level, we are not denying anyone who wishes to have a face to face appointment if they want it, even if perhaps the clinician feels it's not needed"* H13, M, 30-40 yrs., GP, 2 yrs. of experience)

Interestingly, a HCP practising in the least deprived area discussed stretching time beyond usual during remote consultations.

> *"Everyone wants to see the GP in the flesh. Um. There's no real reason why we need to see them face to face. That's the honest truth. Now it's on my head to diagnose it and tell the patient to put all the pieces together. I don't need to see them face to face. I know they want to see me face to face, but I don't think it hampers the information. I can spend a bit more time compared to rushing through 10 minutes like it used to be; I can spend 15 minutes on the phone"* (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

<u>Inhaler technique</u>

Some HCPs stated concerns related to demonstration of the inhaler technique in remote consultations.

> *"I think because it's done remotely. I'm not sure how much we go into the detail about using their inhaler? The computer system EMIS the one we use. It's meant to be quite accurate because he has a percentage of how often they picked up the medication. It is sometimes a nightmare because it says 100% and 90 % or will say 70%, but there'll be a reason for them to explain that slight variation…But if it is really low 20, 30% pickup rates, then our nurse would ask them, are you using your inhaler? Because it doesn't look like it? But we don't actively search out that*

or do searches looking for low pick up rates" (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

"Obviously, it's been difficult in COVID because a lot of it had to be done over a video consultation. So you got an idea of how well they're using the inhalers, but, it's still a bit of guesswork because you cannot; the patient is not there in front of you. So I do like if I see them for an exacerbation of COPD, then I will go through inhaler technique really briefly. But I have no formal training in inhaler technique either. So, I mean, it's probably guesswork from my side as well" (H11, F, 30-40 yrs., GP, 5 yrs. of experience)

"I don't think it's a substitute. I think of face to face inhaler demonstration technique has a bigger impact. The only thing I can think of which I was asking my nurse also is to find out a video of inhaler techniques and then if we could upload them through AccuRx which we could send them to patients" (H10, F, 40-50 yrs., GP, 4 yrs. of experience)

"I think we have had to move away to less in a face to face training and more perhaps signposting to videos, online videos to demonstrate and inhaler technique again. I think we've become a bit better in as a result of remote consulting. We're still using a telephone triage module as the first point of contact, which I think is good. I think that's helpful" H13, M, 30-40 yrs., GP, 2 yrs. of experience)

"I didn't get the patient in and for some reason, I'll send them a link to the website. We've got it on our own. I'll put it on our website, the link to the respiratory inhaler technique, videos, all of them. So I just send them the link quite often… Inhaler technique might be an issue if they're 97 years old, or 98 years old, and they haven't got a smartphone and haven't got a link to the websites and the videos. It's more of an issue. They should be shown really how to use the inhaler" (H12, M, 45-50 yrs., GP, 5 yrs. of experience)

Notably, a HCP practising in the most deprived area discussed directing people more often to websites explaining how to use their inhalers correctly.

"I have been doing a lot more is signposting patients to online resources about inhaler techniques. So I mean, mainly, to be honest, I've been using the Asthma UK website where they have a lot of seeing, a lot of the videos about inhalers, inhaler techniques, different inhalers, spacers, and either sending a link in a text message for the patient to look at it" (H13, M, 30-40 yrs., GP, 2 yrs. of experience)

5.6 Discussion

5.6.1 Summary of the key findings

The current study aimed to explore COPD patients' and HCPs' views on the impact of COVID-19 on COPD patients and to explore effective remote consultation and its potential enablers and barriers. The findings highlighted **three major themes: 1- coping and life adjustment; 2- the accessibility of NHS services; 3- health inequalities and e-health literacy**.

5.6.2 Finding in relation to existing literature

Lifestyle changes

In the present study, the circumstances of COVID-19 impacted patients' daily lifestyle, as the pandemic posed a greater risk to patients with COPD (323). During the UK government coronavirus lockdowns, COPD patients in this study attempted to minimise the potential threat of COVID-19 by staying at home and avoiding contact, but this had psychological impacts. This is in line with a recent review (314) of 24 papers from 11 different countries (USA, Canada, Australia, South Korea, China, Hong Kong, Sweden, Taiwan, Senegal, Sierra Leone, and Liberia), which aimed to appraise the psychological effects of confinement due to the pandemic, and concluded that the absence of regular daily activities and a reduction in social interaction often resulted in dissatisfaction and a feeling of loneliness from the world. Furthermore, in our study, COPD patients stated that the regulations imposed by the government impacted their physical fitness, and it was difficult for them to regain their fitness capacity as they were obliged to remain at home. In addition, the closure of public indoor facilities added another dimension to this issue, as many COPD patients chose to exercise indoors in the warmer air. Similarly, other research found that physical exercise dropped during COVID-19 lockdown (324, 325), and according to a multicentre study, over the course of a year, COPD patients

experienced a decreasing trend in physical capacity by 18 % in daily steps (325). While the long-term repercussions of these changed exercise patterns are yet unknown, the difficulties of delivering appropriate pulmonary rehabilitation in the midst of COVID-19 or post-COVID is a serious worry (326).

Carer dependency was observed in our findings, where COPD patients acknowledged that family members, close friends, and neighbours needed to assist them more than previously. This finding is in line with an observational study conducted in the UK to evaluate alterations in self-reported health and behaviour, which reported a growing reliance on someone else to perform daily tasks such as shopping. The same UK study reported that 6.9% of those surveyed managed their own needs, 23.1% said shopping was conducted by a member of their household, while 70% said it was handled by an individual who did not reside in their house or was brought to their door (313).

Patient difficulty in seeing medical staff and HCPs: suspension of lung function tests and reviews.

COPD patients also acknowledged the difficulty accessing NHS services and HCPs, especially when seeking doctors' support. Our finding is reinforced by other studies, which reported that accessibility to chronic care decreased owing to the repositioning of medical professionals as a "call of duty" for critical COVID-19 patients (327). Moreover, healthcare access significantly decreased for chronic diseases such as COPD, hypertension, and diabetes (328). HCPs in our study reported multiple concerns related to lung function tests and limited reviews. Lung function specialists examine patients with respiratory problems on a regular basis. However, during the pandemic, patients are required to take off their face masks during the examination and cough when doing the manoeuvres, which increases the risk of viral transmission to healthcare staff, the testing environment, and equipment. As a result, there was a substantial lack of access to

pulmonary function testing services (329). Also affected has been the annual review check. NHS England and NHS Improvement have suggested that GPs could pause or suspend certain regular tasks to spare them time to cope with COVID-19. Officials addressed a letter to GPs and commissioners outlining a list of tasks that GPs should suspend or delay, including performing health checks on patients aged 75 and above and standard medical reviews "if in their view that is not the proper priority" as stated in the letter (330).

Digital literacy and health inequalities

Our findings highlighted enablers and barriers to remote consultation. The remote consultation enablers include reduced exposure to pathogens and pollution (safety during the pandemic) and patients partially welcoming of remote consultation. On the contrary, several barriers were identified in our study, including the difficulty of computer and technology use, patients' age, the difficulty of communication, the lack of non-verbal signs of HCPs, and limited internet access, with some barriers mentioned exacerbated by deprivation. Many COPD patients favour face-to-face consultation with their HCPs. Similarly, previous research identified an overwhelming preference for in-person consultations continued to exist (331, 332), and comparable results to ours in terms of the preferences of patients and their experiences with remote consultations (333, 334).

A key result of our study is that some patients have trouble interacting over the telephone. According to the Patient Information Forum, 1.7 million individuals in the UK struggle to adequately describe their illnesses or experiences over the phone, and 9 million individuals find it challenging to utilise digital technologies on their own (335, 336). Prior research reported similar findings to ours, that older persons, particularly those with limited health literacy, hearing or vision impairment, or cognitive impairments, are more inclined to encounter obstacles related to health inequities (336, 337). Deprivation is a

significant barrier to providing remote consultation. Individuals with lower educational attainment and who reside in regions of significant deprivation are less cognizant of and not inclined to utilise remote healthcare services (336).

Our findings identified important information related to providing inhaler technique training using remote consultation either by telephone or video consultation and by referring people to online videos and inhaler information specific websites to demonstrate inhaler technique remotely, and uploading inhaler technique materials *via* AccuRx (an integrated platform that links HCPs with patients) for dissemination to patients. Overall, video consultation seemed to be the preferred approach by HCPs to providing inhaler technique training. Similarly, prior research found that video consulting is preferable to phone consultations and provides a time-saving option once incorporated into an information technology system (338) such as AccuRx.

Some HCPs indicated concerns about whether all patients could benefit from the remote consultation approach. Previous research has also highlighted questions regarding remote consultation's influence on certain patients' ability to get care (339). The second point concerned some HCPs' limited training to provide accurate inhaler techniques, as HCPs have a crucial role in maintaining proper inhaler techniques among their COPD patients. Similar findings to ours were reported in previous research; HCPs infrequently acquire rigorous inhaler technique training (340), which may be more problematic to provide in remote consultations.

5.6.3 **Strengths and limitations**

As far as we are aware, this is the first qualitative study concerning the views of both GPs and COPD patients on the impact of COVID-19 on COPD patients and to explore advantages and disadvantages of using remote consultations. For the purpose of

generalising our findings to patients in primary care in the West Midlands and other comparable places, we obtained a broad variety of patient characteristics, including age group, gender, symptom intensity, and socioeconomic background. Moreover, a drawback in our sample was witnessed; the small size and diversity of HCPs in the sample were not as broad as envisioned. This was due to the fact that no one from other HCP groups agreed to take part in the study.

It was not feasible to conduct face-to-face interviews as planned because of the danger of contracting or transmitting COVID-19. Through warm, heartfelt, genuine greetings, active listening, and a caring speech tone, interviews with patients helped them to feel relaxed and open up about difficult topics. Some COPD patients shared confidential information about their diseases and other issues regarding their family members. Furthermore, since most COPD patients had respiratory issues, the online interview had an advantage over the face-to-face interview. Thus, it is reasonable to suppose that a face-to-face encounter may affect their stamina and respiration, leading to a higher risk of failing to complete the interview.

5.6.4 **Practice and research implications**

According to the recently released NHS Long Term Plan, technological advancements in primary health care will see a significant increase in the usage of remote consultations (341). Some patients may embrace these changes based on the outcomes of this research. However, discretion should indeed be exerted prior to broadening the adoption of remote consultation without recognising the potential barriers to successful implementation, such as deprivation and the decline of some patients' satisfaction toward the service. Further research is needed to thoroughly investigate the potential advantages and disadvantages of remote consultation, particularly video consultation, within the primary care context on a larger scale and evaluate the cost-effectiveness of this approach.

5.7 Conclusion

This study aimed to explore COPD patients' and HCPs' views on the impact of COVID-19 on COPD patients and to explore remote consultation and its potential enablers and barriers. COPD patients and HCPs agreed that increased pressure on the health services led to a deterioration in providing COPD diagnosis and inhaler technique consultations. Considerable hurdles to overcome included access to health facilities, COPD patients' beliefs towards remote consultations, the impact of lifestyle alteration on restoration of patients' physical fitness capacity, and digital skills and difficulty of communication with an older cohort of patients, predominantly in deprived areas, for telemedicine services. Furthermore, the importance of frequent HCP training to provide accurate inhaler techniques was highlighted to equip HCPs with the knowledge and abilities required to enhance care delivery. Lastly, there is no clear right or wrong way to conduct a remote consultation; rather, there are benefits and drawbacks that can arise based on the specifics of the situation. Future lessons could be implemented post-pandemic, including rethinking how HCPs are trained to conduct remote consultations, emphasising building rapport and aspects related to therapy, and providing flexibility in patient access to healthcare to ensure patients' continuity of care.

Chapter 6 : Pharmacist impact on Shared Decision Making (SDM) for patients with long-term condition: a systematic review

6.1 Chapter overview

This chapter provides a comprehensive appraisal of the existing literature on the effectiveness of SDM involving pharmacists on medication adherence and the perceptions of both pharmacists and patients regarding SDM. It expands on the points regarding SDM raised in the cross-sectional and qualitative chapters, which identified that one of the most important enablers perceived by community pharmacists and COPD patients is SDM, which could improve inhaler adherence among COPD patients. This review fulfils the thesis's final goal— *What is the evidence related to the effectiveness of SDM, including pharmacists on medication adherence, and views and perceptions of both pharmacists and patients regarding SDM?*

6.2 Abstract

Background

SDM is a complex, ongoing process that is defined as a presentation of the clinical options available and their associated benefits, risks and costs, elicitation of the patient's values and preferences, and education. SDM may not always be entirely appropriate to all patients or HCPs and thus cannot be applied equally throughout health contexts. Pharmacists are relatively new members of the primary care team as many GP practices are starting to employ a pharmacist or work more closely with their community pharmacist in the management of people with chronic diseases. There is a need to evaluate the evidence for this approach.

Aims

This study aims to evaluate the effectiveness of pharmacist-led SDM on medication adherence and clinical outcomes (research question 1), and to explore the pharmacists' and patients' views and perspectives regarding SDM (research question 2).

Design

A mixed-methods systematic review was conducted (PROSPERO ID: CRD42023395168).

Methods

Seven electronic bibliographic databases were systematically searched. Two researchers independently analysed the data and evaluated each study's methodology.

Results

A total of 13 papers from six different nations were involved in this review. Six studies with a total of 2422 participants for research question one and eight studies with a total of 2497 participants were involved for research question two. Pharmacist-led SDM had positive impacts on patient adherence, satisfaction, and other clinical outcomes, including weight loss, HbA1c, hospital admission, and length of stay at the hospital. However, there was no effect on the severity of depression or quality of life. On the other hand, barriers and enablers of SDM perceived by pharmacists and patients were summarised into themes: the knowledge/awareness of patients or pharmacists, communication among HCPs and patients-pharmacists, time constraints, patient-centeredness *vs* paternalism, physical space issues, regulatory hurdles, and integration of care.

Conclusions

A variety of HCPs have been involved in SDM with patients, but there has been a scarcity of information concerning the pharmacist as part of a multidisciplinary team with regards to SDM. There are positive findings related to SDM on patients' adherence, satisfaction, and other clinical outcomes. SDM challenges and enablers from the perspectives of patients and pharmacists were identified. Future research is needed focusing on the accessibility of professional resources and communication infrastructure that promote SDM and exploring barriers and facilitators of SDM within multidisciplinary teams.

6.3 Background

A recent focus has been on the concept of SDM (159) (174). SDM has often not been well defined. Charles, Gafni (175) have provided a critical description of SDM, which refers to the relationship between patients and HCPs and integrating the characteristics and preferences of the patient into treatment decisions. SDM is a complex, ongoing process that is defined as a presentation of the clinical options available and their associated benefits, risks and costs, elicitation of the patient's values and preferences, and education. Several research investigations have investigated the effect of SDM and its advantages, facilitators and barriers in relation to chronic diseases (Chapter 1 section 1.9).

Practice pharmacists are relatively new members of the primary care team as many GP practices are starting to employ a pharmacist in addition to working more closely with their community pharmacist in the management of people with chronic diseases. There is a need to evaluate the evidence for this approach.

While the benefits of SDM are increasingly being acknowledged (342), this approach is still not always used (342). A pharmacist's role in the interdisciplinary team shared decision-making has not been the subject of a systematic study. Therefore, one goal of this thesis was to review the existing literature in order to locate and synthesise data supporting the efficacy of SDM involving the pharmacist, assessing its effectiveness on medication adherence and clinical outcomes and evaluating the pharmacists' and patients' views and perspectives regarding SDM. The research question was focussed on the management of any chronic diseases due to the insufficiency of studies on COPD or other respiratory conditions.

6.4 Aim and objectives

The aim of this study was to conduct a systematic search, assessment, and synthesis of published studies on SDM involving both pharmacists and patients with any chronic diseases to guide and promote patient services and improve their outcomes. The following two research questions were addressed:

1. Is SDM involving pharmacists effective for improving medication adherence and clinical outcomes amongst patients with chronic diseases?
2. What are the views/perceptions of pharmacists and patients regarding SDM and barriers and facilitators to SDM?

6.5 Methods

A systematic review of mixed study methodologies (MMSR). The MMSR combines qualitative, quantitative, and mixed methodology research to provide a rich, systematic view of diverse health strategies and practices (343). As part of the convergent segregated approach, quantitative and qualitative data were separately synthesised before being merged to provide evidence of both types.

6.5.1 **Search methods for identification of studies**

6.5.1.1 Electronic searches

The Database of Abstracts and Reviews (DARE) was searched to identify any previously published systematic reviews before commencing the search for original studies. Systematic searches were then performed in seven electronic bibliographic databases (PUBMED/MEDLINE, COCHRANE, Embase, CINHAL, PsychINFO, Web of Science, CDR/DARE databases), and the Joanna Briggs Institute (JBI) database. Searches were performed from inception until April 2022. The search phrases “shared decision”, “sharing decision or informed decision”, and “informed choice or decision aid”

and their plural versions, together with the commonly utilized abbreviation SDM, were used to search the title, abstract, and keywords. MEDLINE was the initial database searched, having MeSH terms included in conjunction with text words (see search strategy Appendix 24). Each database's search phrases were derived from the MEDLINE technique and altered accordingly. There was no language restriction applied.

Two further sources were searched to identify any ongoing studies:

1- (http://eppi.ioe.ac.uk/cms).

2- (http://www.joannabriggs.edu.au/pubs/systematic_reviews).

6.5.2 **Inclusion /exclusion**

6.5.2.1 Type of studies

Each article was subject to the following inclusion criteria (see Table 6.1). For the first objective, studies were included if they assessed the effectiveness of SDM involving pharmacists for improving medication adherence or clinical outcomes amongst patients with chronic diseases. Experimental design studies such as randomised controlled trials (RCTs) and quasi-controlled trials (QCTs), were included, as were observational studies. For the second objective, surveys and qualitative studies that highlighted the perceptions of pharmacists or patients regarding SDM were included. Non-research studies (e.g., editorials, letters) and conference abstracts were excluded. In addition, unpublished (grey) literature, dissertations, conceptual papers and review articles were excluded.

6.5.2.2 Types of participants

Studies including adult patients with any chronic conditions were sought for both objectives, with the addition of studies involving pharmacists' views for objective 2.

6.5.2.3 Type of intervention

For objective 1, research on the effectiveness of SDM including all forms of contact involving pharmacists were included. Studies which involved any of the following constructs of SDM were included: patient values/ preferences and options, partnership, patient participation, patient education, doctor knowledge/ recommendations, benefits/ risks, and information exchange.

For objective 2, studies that explored the views of pharmacists or patients regarding SDM were included. Studies focused purely on the implementation of SDM were excluded.

6.5.2.4 Type of outcome measures

Objective 1: medication adherence (measured with any tool), any clinical outcomes such as quality of life, health outcomes, healthcare utilisation, or satisfaction. Additional outcome measures were recorded.

Objective 2: preferences or willingness to participate, specific to pharmacists'/patients' perceptions and experiences of SDM, barriers and facilitators for shared decision-making.

6.5.3 **Data collection and inclusion**

Electronic search results were imported through the EndNote reference manager software, duplicates discarded where appropriate, and the remaining references exported to the Covidence Systematic Review software for screening and data extraction. Two authors reviewed all studies from the search strategy independently (AA and MA). Any disagreements were resolved through consensus with ongoing disagreements resolved through discussion with the third author (RJ). An eligibility form based on inclusion criteria was used to examine the titles and abstracts independently, with exclusions documented for each one. Also, both reviewers (AA and MA) reviewed possibly relevant

full-text articles separately. Disagreements were settled *via* discussion. The third author (RJ) resolved disagreements regarding the inclusion of two full-text articles. JBI (344) served as a model for developing this mixed methods systematic review (MMSR) to give a comprehensive body of evidence.

6.5.4 **Quality appraisal**

Two independent reviewers evaluated the included studies independently for methodological rigour. After an independent review, the principal reviewer compiled the findings. Any disagreements were resolved through consensus with ongoing disagreements resolved through discussion with the third author (RJ).

Five appraisal tools (available online) were used to assess the risk of bias in the full-text articles. For randomised and quasi-randomised controlled trials, the domain-based evaluation suggested by The Cochrane Handbook for, the Risk of Bias 2 (RoB 2) tool was used (345). The Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool was used as suggested by Cochrane to evaluate cohort and pre-post studies. The Appraisal tool for Cross-Sectional Studies (AXIS) (346) was used to evaluate cross-sectional studies (347, 348). The Critical Appraisals Skills Programme (CASP) (349) tool was used to evaluate qualitative studies. The Mixed Methods Appraisal Tool (350) (MMAT) was used to evaluate mixed method studies.

For each tool, there were several questions to be answered to assess the quality of each study. In the Rob 2 tool, there are five domains in which bias is evaluated with responses of “low risk of bias," "some concerns," or "high risk of bias". The domains are: 1) bias arising from the randomisation process; 2) bias due to deviations from intended interventions; 3) bias due to missing outcome data; 4) bias in measurement of the outcome, 5) bias in selection of the reported result. In ROBINS-I, there are seven major domains: 1) bias due to confounding; 2) bias in selection of participants into the study; 3)

bias in classification of interventions; 4) bias due to deviations from intended interventions; 5) bias due to missing data; 6) bias in measurement of outcomes; 7) bias in selection of the reported result. The possible answers to address the risk bias in the ROBINS-I tool are: yes, probably yes, probably no, no, and no information. Following that, the overall judgment of bias responses are: low, moderate, serious, critical, or no information.

The AXIS appraisal tool has twenty questions to record a “yes”, “no”, or “don’t know” answer for each question, with room for short comments as well. The Critical Appraisal Skills Programme (CASP) tool for qualitative studies has ten items to be answered as “yes”, “no”, or “can’t tell” to systematically evaluate the risk of bias. The MMAT tool has multiple steps to assess a study, at first, two screening questions to determine if a valid research purpose has been established and if the proposed research design is adequate to meet this need. Then, quantitative and qualitative aspects of studies are evaluated independently and also as mixed-method studies. A total of 15 questions address the quality of mixed-method studies.

6.5.5 **Data extraction and management**

To minimise bias, data were extracted, collected and reported by two reviewers (AA and MA). All disagreements were resolved with third and fourth authors (RJ and JH). The categories on the extraction grid included elements based on the PICO mnemonic (PICO = population, intervention, comparison, outcome). The data extraction form (Appendix 25) was pretested and reviewed and piloted on two articles by the two reviewers.

6.5.6 **Data synthesis**

The lead researcher was responsible for data compilation at first, however the results were reviewed often with the rest of the research members. A narrative synthesis was used to

evaluate the articles that were selected for inclusion in the systematic review. Data were summarised using a process identical to that employed in prior literature reviews (351, 352), and based on the specified topics of method/research design; study aims; sample population; outcome measure; and findings. For objective 1, the results were given in a narrative style, with the use of tables and figures, where statistical pooling was not feasible because the studies were too heterogeneous.

For objective 2, the quantitative part was addressed like for objective 1. However, the qualitative analytical procedures and synthesis were carried out in two stages: (a) research organised into logical categories based on design, methods, and coding using NVivo software; (b) cross-study data synthesis using an adaptation of the stepwise thematic analysis built by Lucas et al. (353), according to the following (1) two reviewers independently reviewed data collected under each study's questions; (2) codes generated by each researcher; compared and a compiled list of themes produced by each research question; (3) themes emerging under each question grouped along common dimensions; and (4) results of the thematic analysis discussed with the research team at the consensus meeting. The number of articles supplying data on each theme was listed in the summary tables (354).

Table 6.1: Inclusion/ exclusion criteria for objective 1, and 2.

Inclusion / Exclusion criteria				
	Include	**Exclude**	**Include**	**Exclude**
	Objective 1		**Objective 2**	
Population	Adult patients with any chronic conditions	Pediatric patients with any chronic conditions	Adult patients with any chronic conditions. Also pharmacist's views	Pediatric patients with any chronic conditions
Intervention	SDM involving pharmacists for improving medication adherence and/or clinical outcomes amongst patients with chronic diseases Studies which measure satisfaction	Not clearly reporting about the SDM or any collaboration SDM delivered by student/internee Studies focused on the implementation of SDM	All studies (quantitatively and qualitatively) that focus on preferences or pharmacists'/patients' willingness to participate in SDM, barriers and facilitators for shared decision-making	Not clearly reporting about the SDM or any collaboration SDM delivered by student/internee Studies focused on the implementation of SDM
Comparator	No SDM or usual care	n/a	No SDM or usual care	n/a
Outcomes	Medication adherence or use of adherence enhancement services (e.g. MUR, NMS), or patients' quality of life, or clinical outcomes (weight loss, cholesterol levels, glucose levels, emergency visit, hospital admission and length of stays) or satisfaction	Study assesses financial outcomes only	Preferences or willingness relating to SDM or barriers or facilitators	
Setting	Any setting involving pharmacists e.g. Community or retail pharmacy, General practice (in-house pharmacy) Primary care Secondary care Family practice	Colleges/universities Tertiary care	Any setting involving pharmacists/HCPs/patients e.g. Community or retail pharmacy, General practice (in-house pharmacy) Primary care Secondary care Family practice Postal survey of the public	Colleges/universities Tertiary care
Study types	Randomized controlled trials studies (RCTs) Quasi-controlled trials (QCTs) Observational studies Prospective cohort Mixed method studies Pilot trial	Qualitative studies Editorials & letters to editor Review articles Conference abstracts Unpublished (grey literature) Dissertation Conceptual papers	Non-randomized intervention studies Observational studies Prospective cohort Qualitative studies Mixed method studies Pilot trial	Editorials & letters to editor Review articles Conference abstracts Unpublished (grey literature) Dissertation Conceptual papers
Year of publication	No date restriction	n/a	No date restriction	n/a
Language	No language restriction	n/a	No language restriction	n/a

HCPs: Health Care Professionals, SDM: Shared Decision Making, RCTs: Randomised Controlled Studies

6.5.7 Judgment of the Strength of the Evidence

The quantitative data were evaluated using the criteria specified in the GRADE guidelines: risk of bias (study limitations), inconsistency, indirectness, imprecision, and publication bias. An overall rating of high, moderate, low, or very low was assigned based on the results of the specified criteria.

Following the advice of the Cochrane Qualitative and Implementation Methods Group (355), the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) system was implemented to summarise our assurance in synthesised qualitative results (e.g., themes were generated). The CERQual is divided into four fundamental parts: the studies' methodological weaknesses, the review's overall consistency, the quality of the data used to draw conclusions, and the studies' applicability to the research topic. Overall confidence was assigned a score of high, moderate, low, or very low based on the results of the four fundamental parts.

6.6 Results

6.6.1 Selection of articles and study characteristics

A total of 5741 citations were initially identified (Figure 6.1). After the removal of duplicates, abstracts and titles of 5503 articles were screened and 25 full-text articles were assessed for eligibility. 5478 were excluded; the major reasons for exclusion were related to the absence of SDM, absence of pharmacist-led SDM, or either pharmacists' or patients' views were not reported. An additional 12 articles were excluded on full-text review, leaving 13 papers finally included (Table 6.2). 4 qualitative studies (356-359), 6 quantitative studies (2 RCTs (parallel and cluster) (360, 361), one cohort study (362), one pilot study (363), one cross-sectional study (364), one feasibility study (365)), and three mixed method studies (366-368). No relevant systematic reviews were found.

Each of the 13 selected papers was published in English. The included studies involved participants from six different nations. The majority were from the USA (n= 4 studies) (361, 362, 365, 368), followed by the UK (n= 3) (357, 366, 367), Canada (n= 2) (358, 359), Australia (n= 2) (356, 363), Saudi Arabia (n= 1) (360), and Taiwan (n= 1) (364). Diabetes was the focus of the vast majority of the studies (n= 5) (358, 359, 361, 362, 368); four studies focused on mental health diseases (356, 357, 360, 365), and one on cardiovascular diseases (363). Three studies involved multiple diseases, including mental health, diabetes, cardiovascular, respiratory, and GI diseases (364, 366, 367). All of the articles were written in English even though no language restriction was applied.

In detail, **for research question one**, six studies with a total of 2422 participants were involved. Four quantitative studies (2 RCTs (360, 361), 1 cohort (362), and 1 pilot (363)) included 785 participants (sample size ranged from 69 to 351), while two mixed method studies (367, 368) included 1637 participants (sample size ranged from 275 to 1362). Three studies were from the USA (361, 362, 368); one from the UK (367); one from Saudi Arabia (360); and one from Australia (363). Three studies focused on diabetes (361, 362, 368); one study involved mental health (360); one study involved multiple diseases (367), including mental health, diabetes, cardiovascular, respiratory, and GI diseases; and one study focused on atrial fibrillation (363). Two studies were carried out in hospital settings (360, 363). Two studies were carried out in clinics (361, 362). One study was carried out in primary care settings (367). One study was carried out at a non-profit health service corporation (368).

For research question two, eight studies with a total of 2497 participants were involved. Two quantitative studies (survey (364) and feasibility (365)) included 424 participants (sample size ranged from 24 to 400); four qualitative studies (356-359) included 96 individuals (sample size ranged from 16 to 33). Two mixed method studies (366, 368) included 1977 participants (sample size ranged from 615 to 1362). Two studies from USA

(365, 368), two studies were from the UK (357, 366), two studies from Canada (358, 359), one study from Australia (356), and one study from Taiwan (364). Three studies focused on diabetes (358, 359, 368); three studies involved mental health (356, 357, 365); and two studies involved multiple diseases (364, 366), including mental health, diabetes, cardiovascular, respiratory, and GI diseases. Two studies were carried out in hospital settings (364, 366). Two studies were carried out in community pharmacies (358, 359). One study was carried out in clinic settings (365). One study was carried out in primary care settings (357). One study was carried out at a non-profit health service corporation (368), and one study was conducted in varied settings (356), including primary care, hospital, and community pharmacy.

Participants

For both research questions, the majority of participants were women with mild to severe illnesses, with the exception of two studies that did not clearly describe the gender distribution of the participants (357, 368).

SDM interventions

SDM was offered in a number of different forms including:

- A pharmacist intervention based on SDM using SDM competency framework-designed specifically for patients with depression (360).
- A face-to-face SDM visit with a pharmacist who used a decision aid to describe prediabetes and 4 possible options for diabetes prevention (361).
- Diabetes Self-Management Education and Support class followed by interdisciplinary Speed Dating session (362).

- One to one education session with a clinical pharmacist during patients' admission to promote SDM (363).

- A 2-step process that integrated brief negotiated interviewing and SDM using the telephone consultation (367, 368).

SDM interventions were measured against different "control" interventions (e.g., usual pharmacist care, usual care, no intervention, guideline, and pre-post of an intervention arm).

Studies' outcomes included: adherence, satisfaction, severity of depression, uptake of Diabetes Prevention Program, metformin or both, weight change, HbA1c, LDL, emergency visits, hospital admissions, lengths of hospital stay, pharmacist/patient involvement, appropriateness of anticoagulation therapy, Drug Therapy Problems (DTPs) during the consultation, acceptability and feasibility of SDM, medication effectiveness, safety, perceived barriers and facilitators for SDM.

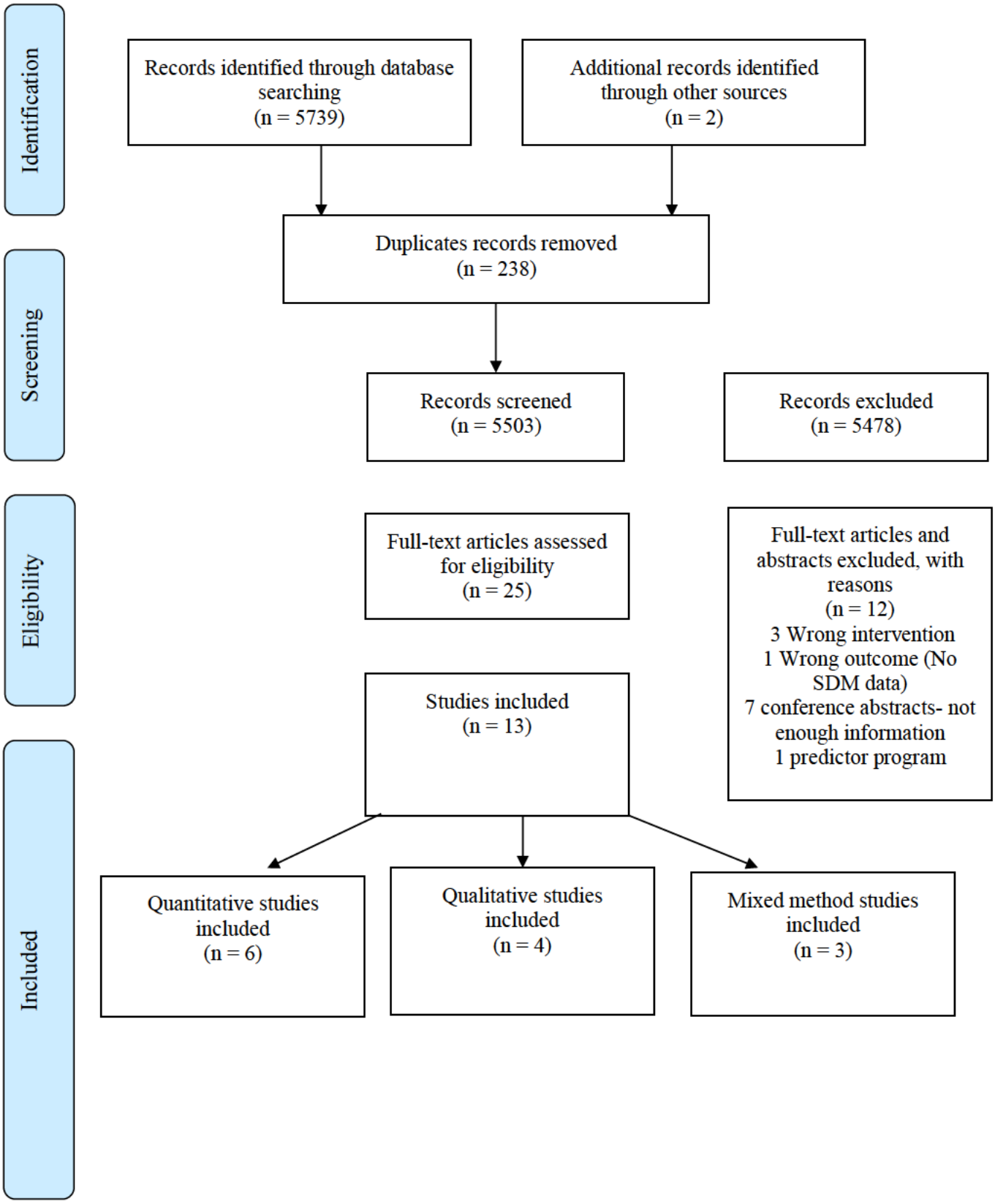


Figure 6.1: Flowchart of studies across this review

Table 6.2: Brief characteristics of all studies included in the systematic review

Study (in hierarchy of evidence)	Aims	Design and data collection period	Setting and location	Participants (sample size)	Disease	Provider	Intervention	Comparator	Outcome
Aljumah et al. 2015 [360] (Research question 1)	Assess whether pharmacist interventions based on shared decision-making improved adherence and patient-related outcomes	RCT 6 months (3 and 6 months follow-up)	Hospital, Saudi Arabia	Newly diagnosed Major depressive disorder N= 239 DSM-IV; 1994 criteria	Mental health	Pharmacists	Pharmacy services plus pharmacist intervention based on shared decision making using SDM competency framework- designed specifically for depressed patients Included tool to enhancing patients' involvement in decision making by assessing beliefs/ knowledge about antidepressants	Usual pharmacist care	Adherence (MMAS) Medication beliefs (BMQ) Treatment satisfaction (TSQM) Quality of life (EQ-5D) Severity of depression (MADRS)
Moin et al. 2019 [361] (Research question 1)	To assess the effectiveness of a SDM intervention for patients with prediabetes. PRIDE trial	Cluster RCT 4 months Secondary outcome at 12 months follow-up	20 primary care clinics USA	Overweight/obese adults with prediabetes N= 351	Prediabetes	Pharmacists	A face-to-face SDM visit with a pharmacist who used a decision aid (DA) to describe prediabetes and 4 possible options for diabetes prevention: DPP, DPP ± metformin, metformin only, or usual care.	Usual care	Uptake of Diabetes Prevention program, metformin or both Weight change
Whitley et al. 2020 [362] (Research question 1)	To determine if a novel interdisciplinary "speed-dating" clinic augments Diabetes Self-Management Education and Support (DSMES)	Cohort 12 months	Family medicine clinic USA	Adult patients with diabetes N= 69 Referred by their primary care providers to attend a seven-hour, ADA-accredited DSMES class	Diabetes	Physician, pharmacist, nurse/dietitian, case manager, and psychologist.	7h self-management class (DSMES) + 3h interdisciplinary Speed Dating session for SDM (n=40) Patients progressed through five stations hosted by different healthcare professionals	7h DSMES class (n=29)	A1C LDL Pre-post in intervention arm only: Emergency visit Hospital admissions Lengths of hospital stay

Study (in hierarchy of evidence)	Aims	Design and data collection period	Setting and location	Participants (sample size)	Disease	Provider	Intervention	Comparator	Outcome
Khalil et al. 2020 [363] (Research question 1)	Evaluate the impact of pharmacist-led shared decision making on patients' satisfaction and appropriateness of their anticoagulation therapy in newly diagnosed atrial fibrillation patients.	Pilot intervention with historical controls 5 months observation 7 months intervention	Hospital Australia	Adult diagnosed and admitted AF patients N= 126 Phase 1 observation n= 61 Phase 2 intervention n= 65	Atrial fibrillation	Pharmacists	The intervention phase involved a one to one education session with a clinical pharmacist during patients' admission to promote SDM.	First phase 'observational' phase, usual care process of one session of patient-pharmacist interaction. Based on the observations, specific written brochures detailing anticoagulation options were created and a hospital-wide policy written	Pharmacist involvement Satisfaction Appropriateness of anticoagulation therapy
Chung et al. 2019 [364] (Research question 2)	To apply the knowledge-attitude-behaviour (KAB) model to probe health care professionals' perceptions of SDM	Survey 2 months (Nov 2018 – Jan 2019)	Hospitals, Taiwan	Varied HCPs (n=400): Physicians, pharmacists (n=15), nurses, and other healthcare professionals	Multiple diseases	HCPs	n/a	n/a	Attitudes to SDM Perceived barriers to SDM

Study (in hierarchy of evidence)	Aims	Design and data collection period	Setting and location	Participants (sample size)	Disease	Provider	Intervention	Comparator	Outcome
Schafer et al. 2016 [365] (Research question 2)	To evaluate the preliminary efficacy, feasibility, and acceptability of a template-based intervention to facilitate shared decision making (SDM) in medication therapy management (MTM) consultations.	Feasibility study April to August 2014	Internal medicine primary care clinic at a hospital USA	Patients aged ≥18 yrs. with mental health disorders identified from appointment schedules of primary care provider N= 20 patients and 4 pharmacists	Mental health diseases	Pharmacists	Patients completed 1h consultation with pharmacists trained in SDM, guided by electronic template	n/a	Drug Therapy Problems (DTPs) during consultation Compliance Acceptability Appropriate indication Medication effectiveness Safety
Chong et al. 2013 [356] (Research question 2)	Explored healthcare providers' perceptions of barriers and facilitators to both shared decision-making and interprofessional collaboration in mental healthcare	Qualitative; semi-structured interview n/a	Hospitals, GP practices, hospital pharmacy departments and community pharmacies. Australia	Varied Healthcare providers: Medical practitioners (psychiatrists, general practitioners), pharmacists, nurses, occupational therapists, psychologists and social workers N=31	Mental health	Healthcare providers	n/a	n/a	Perceived barriers & facilitators for SDM Perceived barriers & facilitators for interprofessional collaboration

Study (in hierarchy of evidence)	Aims	Design and data collection period	Setting and location	Participants (sample size)	Disease	Provider	Intervention	Comparator	Outcome
Harris et al. 2017 [357] (Research question 2)	To compare and synthesise mental health stakeholder views on antipsychotic prescribing in one NHS Trust, to understand potential reasons for the difficult enactment of shared decision-making in practice	Qualitative; semi- structured and focus group interview 6 months (April-Oct 2015)	Mental Health and Social Care Trust UK	Service users, carers, consultant psychiatrists, community psychiatric nurse (CPNs), and one pharmacist. N= 33	Mental health	n/a	n/a	n/a	To compare and contrast how different stakeholders (nurses, carers and service users) view the current antipsychotic prescribing processes, value different elements of SDM, and require different levels of support and preparation for SDM to work in practice
Rosenberg-Yunger et al. 2018 [358] (Research question 2)	Describe community pharmacists' perceptions of SDM within the context of delivering Ontario's MedsCheck for Diabetes (MCD) programme and providing general diabetes management, and potential challenges of implementing SDM within the community pharmacy setting	Qualitative telephone semi-structured interview	Rural and urban setting Canada	Community pharmacists through e-mailing approximately 9000 members of the Ontario Pharmacists Association N= 16	Diabetes	Pharmacists	n/a	n/a	Community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management.

Study (in hierarchy of evidence)	Aims	Design and data collection period	Setting and location	Participants (sample size)	Disease	Provider	Intervention	Comparator	Outcome
Verweel et al. 2017 [359] (Research question 2)	To explore pharmacists' perspectives on decision aids, their place in a community pharmacy setting	Qualitative telephone semi-structured interview January 1, 2016, and March 30, 2016	Rural and urban setting Canada	Pharmacists through e-mailing approximately 9000 members of the Ontario Pharmacists Association N= 16	Diabetes	Pharmacists	n/a	n/a	Pharmacists' understanding of decision aids, pharmacists' perceptions of the DMC decision aid
Kayyali et al. 2018 [366] (Research question 2)	Investigate hospital patients' receipt and involvement in medication counselling, patients' HCP preference for receiving medication information at the transition of care, and awareness of community pharmacy services such as the MUR. Explore perceptions and experiences of patients with LTCs about the quality of care received in primary care and their awareness of the MUR service provided in the community pharmacy sector, focusing on COPD patients.	Mixed method study Surveys (Dec 2013-June 2015) and semi structured interview (Jan-Mar 2016)	2 hospitals, UK	Long-term conditions patients. Survey 1, N= 357 Survey 2, N= 240 Interview, N= 18	Patients with long-term conditions: (Diabetes, COPD/ Asthma, cardiac condition, Rheumatoid arthritis and osteoarthritis, epilepsy, chronic renal disease, and inflammatory bowel disease	n/a	n/a	n/a	SDM experience and medication counselling at discharge Patients' perception on quality of care Patients' views on SDM

Study (in hierarchy of evidence)	Aims	Design and data collection period	Setting and location	Participants (sample size)	Disease	Provider	Intervention	Comparator	Outcome
Lauffenburger et al. 2019 [368] (Research questions 1 and 2)	Evaluate the impact of a telephone-based patient-centred intervention on glycosylated haemoglobin (HbA1c) control for individuals with poorly-controlled diabetes ENGAGE-DM	Two-arm pragmatic RCT within an explanatory sequential mixed-methods design 3 months and 12 months follow-up	Non-profit, health service corporation USA	Type 2 diabetic adult patients with poorly-controlled type 2 diabetes. N=1362 (Baseline N=1400, ineligible patients N=38)	Diabetes	Pharmacists	A 2-step process that integrated brief negotiated interviewing and shared decision-making to choose one of four strategies for improving diabetes control with tailored interventions using telephone consultation	Usual care	HbA1C Medication adherence Patients' involvement in SDM
Weiss et al. 2015 [367] (Research question 1)	1) To explore whether specific components of shared decision making were present in consultations involving nurse prescribers (NPs), pharmacist prescribers (PPs) and general practitioners (GPs). 2) To relate these to self-reported patient outcomes including satisfaction, adherence and patient perceptions of practitioner empathy.	Audio-recordings from the consultations and survey October 2009 to September 2011	Primary care UK	Varied HCPs; consultations were audio-recorded with 20 GPs, 19 NPs and 12 PPs N= 51 prescribers N= 532 consultations Total included consultations N = 275	Multiple diseases; Acute conditions: Chest Throat UTI Acute pain: (injury) Skin conditions Chronic conditions: Cardiovascular Diabetes Asthma Depression	Nurse prescribers (NPs), pharmacist prescribers (PPs) and general practitioners (GPs)	SDM in consultation	No SDM	% patients offered treatment options Patients' satisfaction levels Treatment decision characteristic related to adherence, satisfaction, and provider empathy Relationship of time describing treatment options to satisfaction and adherence

6.6.2 **Study appraisal**

For research question 1, one study (361) was classified as having a low risk of bias, while three had some concerns (360, 367, 368), and two had a high risk of bias (362,363). Interpreting the results of these studies should be considered with caution. For research question 2, six studies were classified as having a low risk of bias (356-359, 364, 366) while one (368) had some concerns and another (365) had a high risk of bias.

6.6.2.1 Quantitative studies

Two out of the six included quantitative studies had a low risk of bias (361, 364), but the remaining four (360, 362, 363, 365) were classified as having a moderate to high risk of bias. The parallel RCT by Aljumah et al. (360) did not satisfactorily blind the individuals delivering the interventions or provide information about allocation concealment. In the same parallel RCT, patients were excluded from the analysis if they did not respond to the treatment, although it was around just under 10% in each arm. Thus, the parallel RCT showed some concerns overall in terms of the risk of bias. In the cluster RCT by Moin et al. (361), the randomisation and allocation process were not well described however the remaining domains suggested a low risk of bias overall (Figure 6.2 and 6.3).

A cohort study by Whitley et al. (362) showed a high risk of bias overall because the intervention was only provided to participants who chose to attend the speed dating SDM component (i.e., not randomised), mainly because they had better access to transport, and there was no adjustment for any of the differences in baseline characteristics observed e.g., HbA1c (thus creating selection bias) (Figure 6.4).

The pilot study conducted by Khalil et al. (363) showed a high potential for bias as the paper suffered from a) the fact that the outcome could have been influenced by varying knowledge/skills of the different pharmacists delivering the intervention, b) more importantly,

the use of historical controls without adjustment for potential confounding factors, c) the exclusion of patients from the analysis who were lost to follow-up, and d) potential for bias in pharmacists' patient selection. Moreover, the outcome measures reported in this pilot study were confusing and could have been clearer (Figure 6.4).

The feasibility study by Schafer et al. (365) showed a high risk of bias, while certain concerns were detected related to confounding and selection bias. On top of that, bias in measurement of the outcomes was identified as the study reported on views around effectiveness, acceptability, satisfaction, and compliance with non-validated scales (dichotomous answers only). The study only reported 20 individuals who completed the intervention; the study's sample size was not adequately justified and failed to disclose potential sources of bias, such as financing or conflicts of interest, and reasons for non-response (Figure 6.4).

One cross-sectional paper by Chung (364) was classified as having a low risk of bias. The study scored ≥ 80% in the 20 questions in the AXIS tool, indicating a satisfactory low level of bias was achieved. The study accurately explained its aim, methodology, population studied, data collection, and statistical techniques. However, the study failed to disclose potential sources of bias, such as financing or conflicts of interest and reasons for non-response (Table 6.3).

6.6.2.2 Qualitative studies

All of the qualitative studies (356-359) fulfilled all of the criteria for good quality evaluation and had a defined objective and an adequate research methodology. The results were properly reported and discussed, and the studies were deemed important for their contribution to the evidence on pharmacists'/patients' perceptions regarding SDM (Table 6.4).

6.6.2.3 Mixed methods studies

The three mixed-methods papers (366-368) in the systematic review reflect some of the most recent investigations. One study (366) out of the three studies with quantitative descriptive components demonstrated a low risk of bias with limited concerns regarding the sample as it did not reflect the balance among targeted population. Another mixed method study (367) with quantitative descriptive components did not consider how the study's setting would affect the results, or whether or not the researcher had any influence over the results. Moreover, the same mixed methods study (367) provided limited information concerning how findings were derived from the data, and how consistency in the interpretation of qualitative data was maintained. In addition, in the quantitative components, the study (367) showed a high risk of nonresponse bias. One study (368) had an RCT component, which was well designed with imputation for missing outcomes and adjustment for baseline imbalances, but less than a third of intervention patients accomplished a preliminary SDM telephone consultation. Lastly, one out of the three studies (368), was not clear about any divergences and discrepancies between quantitative and qualitative findings. The quality assessment of these mixed-method studies was presented in (Table 6.5).

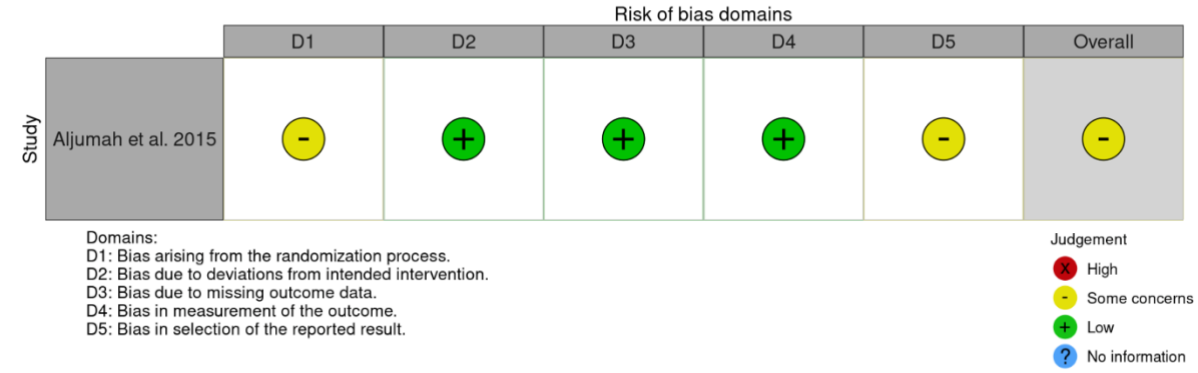


Figure 6.2: RoB-2 for the randomised controlled trials (RCTs)

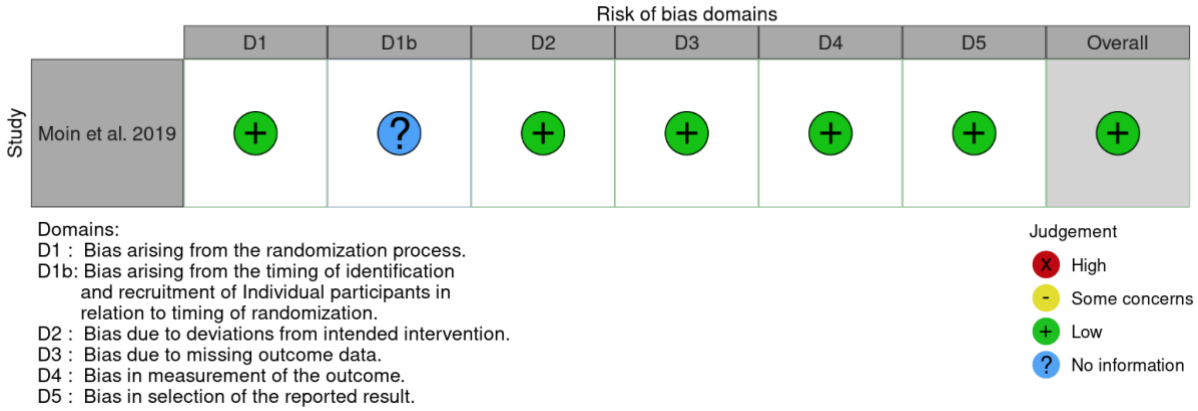


Figure 6.3: RoB-2 for the cluster randomised controlled trials (RCTs)

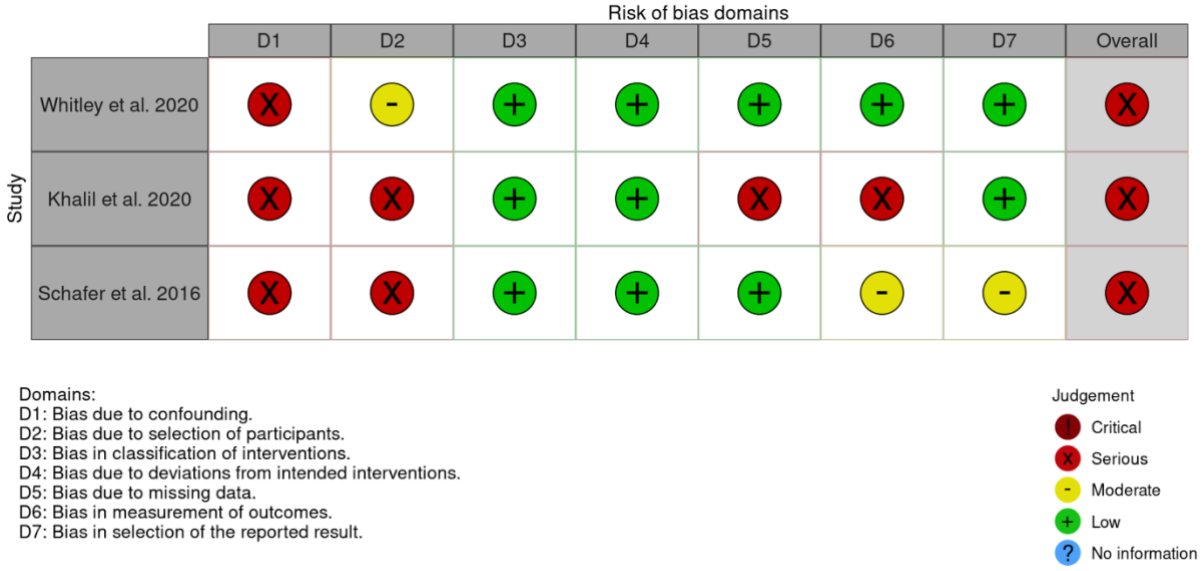


Figure 6.4: Non-Randomized Studies of Interventions (ROBINS-I) for non-randomized studies

Table 6.3: AXIS for the cross-sectional studies

Questions	Study
	Chung et al. 2019
Clear aims?	Yes
Appropriate study design?	Yes
Justified sample size?	No
Population defined?	Yes
Sample representative?	Yes
Unbiased selection process?	Can't tell
Measures undertaken to address and categorise non-responders?	Can't tell
Variables measured appropriate to the aims of the study?	Yes
Appropriate measurement tools?	Yes
Clear statistical significance criteria?	Yes
Repeatable methods?	Yes
Basic data adequately described?	Yes
Non-response bias?	No concerns
Information about non-responders described?	Can't tell
Results internally consistent?	Yes
All results described?	Yes
Conclusions justified by results?	Yes
Limitations discussed?	Yes
Funding sources/ conflicts affecting interpretation?	Can't tell
Ethical approval and consent obtained?	Yes
AXIS score	85%

Judgment

Yes
No
Can't tell

Table 6.4: Critical Appraisals Skills Programme (CASP) for the qualitative studies

Questions	**Studies**			
	Chong et al. 2013	*Harris et al. 2017*	*Rosenberg-Yunger et al. 2018*	*Verweel et al. 2017*
Clear statement of the aims?	Yes	Yes	Yes	Yes
Appropriate qualitative methodology?	Yes	Yes	Yes	Yes
Research design appropriate?	Yes	Yes	Yes	Yes
Recruitment strategy appropriate?	Yes	Yes	Yes	Yes
Data collected sufficiently addresses the research issue?	Yes	Yes	Yes	Yes
Relationship between researcher and participants considered?	Yes	Can't tell	Yes	Yes
Ethical issues considered?	Yes	Yes	Yes	Yes
Risk factor and outcome variables measured appropriate?	Yes	Yes	Yes	Yes
Data analysis sufficiently rigorous?	Yes	Yes	Yes	Yes
Clear statement of findings?	Yes	Yes	Yes	Yes
Overall score	Valuable (10/10)	Valuable (9/10)	Valuable (10/10)	Valuable (10/10)

Judgment

Yes
No
Can't tell

Table 6.5: Bias assessment with the Mixed Methods Appraisal Tool

Types of mixed method components	Methodological quality criteria	Studies		
		Lauffenburger et al. 2019	Kayyali et al. 2018	Weiss et al. 2015
Screening questions	Clear research questions?	Yes	Yes	Yes
	Collected data allow to address research questions?	Yes	Yes	Yes
Qualitative	Qualitative approach appropriate?	Yes	Yes	Yes
	Qualitative data collection methods appropriate?	Yes	Yes	Yes
	Findings adequately derived from the data?	Yes	Yes	Can't tell
	Interpretation of results sufficiently substantiated by data?	Yes	Yes	Can't tell
	Coherence between qualitative data sources collection analysis and interpretation?	Yes	Yes	Can't tell
Quantitative-RCT	Randomization appropriately performed?	Yes		
	Groups comparable at baseline?	No		
	Complete outcome data?	No		
	Outcome assessors blinded to the intervention provided?	Yes		
	Participants adhere to the assigned intervention?	Yes		
Quantitative-descriptive	Relevant sampling strategy?		Yes	Yes
	Sample representative of the target population?		Yes	Yes
	Measurements appropriate?		Yes	Yes
	Low risk of nonresponse bias?		Yes	No
	Statistical analysis appropriate?		Yes	Yes
Mixed methods	Adequate rationale for using a mixed methods?	Yes	Yes	Yes
	Different components of the study effectively integrated?	Yes	Yes	Yes
	Outputs of the integration of qualitative and quantitative components adequately interpreted?	Yes	Yes	Yes
	Divergences and inconsistencies between quantitative and qualitative results adequately addressed?	Can't tell	Yes (no divergence)	Yes (no divergence)
	Components of the study adhere to the quality criteria of each tradition of the methods involved?	No	Yes	Yes

6.6.3 **Study findings**

Objective 1

6.6.3.1 Adherence

There were only 4 studies which addressed medication adherence. Three of these were shown to improve patients' adherence (Table 6.6). In a parallel RCT, Aljumah et al. (360) (N= 239) compared the direct patient care given by a pharmacist intervention based on SDM to patients with major depressive disorder to the standard pharmacy services and found that adherence to medicines, measured by MMAS, was significantly higher when pharmacists engaged with the patients using the SDM competency framework (369), at 5.79 (SD 1.89) compared to the control group (5.04 (SD 1.98), p 0.004) at 3 months. At six months of follow-up, mean MMAS scores were 5.99 (S.D. 1.88) and 4.94 (S.D. 1.94), p <0.0001 respectively. A mixed methods study with a range of different patients conducted by Wiess et al. (367) explored whether specific components of SDM were present in consultations involving nurse prescribers (NPs), pharmacist prescribers (PPs) and GPs and related these to self-reported patient outcomes including adherence using MARS. Patients were more inclined to comply with treatment regimens when therapists spent more time presenting available therapy or alternatives (Spearman's $\rho = -0.3$, P= 0.05). Furthermore, Moin et al. (361) found in the PRIDE trial of lifestyle change and/or metformin amongst (N= 351) overweight/obese adults with prediabetes that uptake of Diabetes Prevention Program and/or metformin were significantly higher among patients additionally receiving SDM than those receiving usual care (n= 1028) at 12-month follow-up (38% *vs* 2%, p < .001) (IG *vs* CG %). However, one RCT with sequential mixed method by Lauffenburger et al. (368) of pharmacists SDM telephone consultation among poorly controlled diabetic patients found no evidence of a substantial difference in medication adherence between those that were allocated to an intervention based on SDM compared with the control group (no SDM) (adherence mean difference -0.16 (95% CI -3.41, 3.08)), although

with an on-treatment analysis among 196 similar patients in each arm, the mean difference was +4.4, (95% CI: -1.4, 10.30). To note, in Lauffenburger et al.'s (368) study, less than one-third of participants took up the SDM consultation which was reflected in the lack of effectiveness in the intention-to-treat (ITT) analysis.

Overall, the results of the parallel trial (360) and mixed method study (367) should be interpreted with caution due to concerns related to the risk of bias. The results of the cluster trial (361) were more reliable due to the low risk of bias.

Table 6.6: Findings related to adherence

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Aljumah et al. (2015)	Saudi Arabia	Assess whether pharmacist interventions based on shared decision making improved adherence and patient-related outcomes	Quantitative: Parallel RCT	Adherence (MMAS) Treatment	3 months (mean IG vs CG): **Adherence** 5.79 (1.89) vs (5.04 (1.98), P = 0.004 6 months (mean IG vs CG): **Adherence** 5.99 (1.88) vs 4.94 (1.9), P = <0.0001	Descriptive and comparative statistics ANCOVA analysis Mixed ANOVA T-test
Weiss et al. (2015)	UK	1) To explore whether specific components of shared decision making were present in consultations involving nurse prescribers (NPs), pharmacist prescribers (PPs) and general practitioners (GPs). 2) To relate these to self-reported patient outcomes including satisfaction, adherence and patient	Mixed method: Audio-recordings from the consultations and survey	Treatment decision characteristic related to adherence	**Adherence (Spearman's ρ)** (Spearman's ρ = − 0.3, P = 0.05).	Descriptive statistics Kruskal-Wallis test Multiple regression

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
		perceptions of practitioner empathy.				
Lauffenburger et al. (2019)	USA	Evaluate the impact of a telephone-based patient-cantered intervention on glycosylated haemoglobin (HbA1c) control for individuals with poorly-controlled diabetes	Mixed method: RCT, Audio recorded consultation	Medication adherence	12 months (Mean SD (IG vs CG) **Adherence:** **ITT adherence mean difference between groups (adj.)** **81.9 (30.1) vs 81.9 (31.0)** **On treatment analysis:** **84.6 (27.5) vs 80.2 (31.8)**	Descriptive and comparative statistics Grounded theory analysis Logistic regression
Moin et al. (2019)	USA	To assess the effectiveness of a SDM intervention for patients with prediabetes	Quantitative: Cluster RCT	Uptake of Diabetes Prevention Program (DPP)	**Uptake of Diabetes Prevention Program (IG vs CG %)** (38% vs 2%, $p < .001$)	Descriptive and comparative statistics Generalised linear mixed effect models Sensitivity analysis for missing weight data

IG: intervention group, CG: control group, ITT: intention-to-treat, MMAS: Morisky Medication Adherence Scale

6.6.3.2 Clinical outcomes

6.6.3.2.1 Severity of depression

The Aljumah et al. RCT (360) found that pharmacists using the SDM competency framework had no impact on the severity of depression, measured by MADRS, compared to the control group either at the end of 3 and 6 months follow-up (21.07 (12.21) *vs* 21.01 (12.63), p = 0.971) and (20.65 (11.97) *vs* 20.86 (12.54), p = 0.897) respectively.

6.6.3.2.2 Weight loss

Moin et al. (361) found in the PRIDE trial of lifestyle change and/or metformin amongst (N=351) overweight/obese adults with prediabetes that weight reduction was more considerable among patients additionally receiving SDM than those receiving usual care (N= 1028) at 12-month follow-up (-5.3 *vs* -0.2 lbs., p = 0.001) (Table 6.7). However, since this study was done in a single health system with integrated pharmacists, the results may not apply to different healthcare settings. Note that the results might be explained by the fact that those in the SDM arm had better uptake to the treatment and services provided.

6.6.3.2.3 HbA1c/ LDL/ emergency visit/ hospital admission/ length of stays

In a cohort study of (N= 69) adult patients with diabetes (362), many clinical outcomes such as HbA1c, LDL, emergency visits, hospital admission, and length of stay were reported (Table 6.7). In this innovative approach, 40 of the 69 (58%) patients attended an interdisciplinary clinic using a "speed-dating" style in which they moved through five stations hosted by various healthcare specialties in 30-minute intervals. SDM was used to identify suggestions that were acceptable to all parties. The doctors' major emphasis was about evaluating preventive and maintained care. Specialised nurses deliberated with patients about their eating and exercise habits in relation to their self-reported glycaemia levels. The pharmacists assessed the suitability of all therapy (prescribed or non-prescribed), and insulin administration technique.

Ultimately, healthcare providers prioritised treatment based on what was most important to each individual patient but still giving emergency situations the first priority. Every "speed-dating" session concluded with health care providers each documenting their own notes in the electronic medical records and sending their own suggestions to the patients' primary care providers. The study found that attending both Speed Dating clinic and the Diabetes Self-Management Education and Support (DSMES) class compared to the baseline significantly reduced mean HbA1c (%) by -1.2% (8.5%, S.D. ± 2.3 *vs* 9.7%, S.D. ± 2.4, P = 0.003) and LDL levels (mg/dl) by -24.7 (83.2 ±27.3 *vs* 107.9 ± 36.5, P = 0.003).

In addition, following the speed-dating clinic, patients experienced lower emergency unit visits than prior to the intervention (baseline mean 1.10, S.D. ± 1.55 *vs* intervention mean 0.93, S.D. ± 1.29, p = 0.366), hospitalisations (baseline mean 0.55, S.D. ± 0.99 *vs* intervention mean 0.28, S.D. ± 0.60, P = 0.036), and reduced hospital stays (baseline mean 8.11, S.D. ± 5.80 *vs* intervention mean 4.11, S.D. ± 3.33, P = 0.030).

In a mixed method study conducted by Lauffenburger et al. (368), the study reported that integrated concise negotiated interviews and SDM had no impact on diabetes management among patients who were managed by a pharmacist using SDM approach compared to usual care (HbA1c mean difference 0.06 (95% CI -0.20, 0.32)), although with an on-treatment analysis among 196 similar patients in each arm, the mean difference was -0.48, 95% CI: -0.91, -0.05). There were several reasons including less than one-third took up the SDM consultations, patients found lifestyle the most difficult to change (diet/exercise) and 25% were not ready to change their regimen or management. This was reflected in the lack of effectiveness in the ITT analysis, but improvement in HbA1c in as-treated analyses (Table 6.7). Overall, the results of the cohort study (362) and mixed method study (368) should be interpreted with caution due to concerns related to the risk of bias.

6.6.3.2.4 HRQOL

Only one trial by Aljumah et al. (360) examined SDM and health-related quality of life (Table 6.8), and found that SDM had no effect. There was no discernible difference in health-related quality of life (measured by the EuroQol-5D) after six months of follow-up between normal pharmacy services and SDM-based pharmacist treatments (mean intervention *vs* mean control) 0.68 (0.40) *vs* 0.66 (0.38), P = 0.356.

Table 6.7: Findings related to clinical outcomes

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Aljumah et al. (2015)	Saudi Arabia	Assess whether pharmacist interventions based on shared decision making improved adherence and patient-related outcomes	Quantitative: Parallel RCT	Severity of depression (MADRS)	3 months (mean IG vs CG): 21.07 (12.21) vs 21.01 (12.63), P = 0.971 6 months (mean IG vs CG): 20.65 (11.97) vs 20.86 (12.54), P = 0.897	Descriptive and comparative statistics ANCOVA analysis Mixed ANOVA T-test
Lauffenburger et al. (2019)	USA	Evaluate the impact of a telephone-based patient-cantered intervention on glycosylated haemoglobin (HbA1c) control for individuals with poorly-controlled diabetes	Mixed method: RCT, Audio recorded consultation	HbA1C	12 months Mean SD (IG vs CG) **ITT HbA1C mean difference between groups** -0.75 (1.96) vs -0.79 (2.01) **On treatment analysis:** -0.96 (1.69) vs-0.48 (1.73) **% reaching HbA1c<8.0%** 34.8% vs 38% **On treatment analysis** **46.1% vs 34.7%**	Descriptive and comparative statistics Grounded theory analysis Logistic regression
Moin et al. (2019)	USA	To assess the effectiveness of a SDM intervention for patients with prediabetes	Quantitative: cRCT	Weight change	**Adj. Weight change (lbs.)** at 12 months. (− 5.3 vs. − 0.2, p < .001)	Descriptive and comparative statistics Generalised linear mixed effect models Sensitivity analysis for missing weight data

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Whitley 2020	USA	To determine if a novel interdisciplinary "speed-dating" clinic augments Diabetes Self-Management Education and Support (DSMES)	Quantitative: Cohort	HbA1C LDL Emergency hospital visit Hospital admissions Lengths of hospital stay	**HbA1C** (mean %) Baseline 9.7%, SD ± 2.4 Speed Date + DSMES 8.5%, SD ± 2.3 p = 0.003 **LDL** (mg/dl) Baseline 107.9 ± 36.5 Speed Date + DSMES 83.2 ±27.3 p = 0.003 **ER visit** (mean SD) Before 1.10, SD ± 1.55 Speed Date + DSMES 0.93, SD ± 1.29 p = 0.366 **Hospitalisation** (mean SD) Before 0.55, SD ± 0.99 Speed Date + DSMES 0.28, SD ± 0.60 p = 0.036 **Length of stay** (mean SD) Before 8.11, SD ± 5.80 Speed Date + DSMES 4.11, SD ± 3.33 p = 0.030	Descriptive and comparative statistics T-test Wilcoxon rank sum test Fisher test

IG: intervention group, CG: control group, ITT: intention-to-treat, HbA1c: Haemoglobin A1C, LDL: Low-density lipoprotein, DSMES: Self-Management Education and Support, ER: Emergency room

Table 6.8: Findings related to quality of life

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Aljumah et al. (2015)	Saudi Arabia	Assess whether pharmacist interventions based on shared decision making improved adherence and patient-related outcomes	Quantitative: RCT	Quality of life (EQ-5D)	3 months (mean IG vs CG): **Quality of life** 0.66 (0.39) vs 0.65 (0.38), P = 0.939 (no sig.) 6 months (mean IG vs CG): **Quality of life** 0.68 (0.40) vs 0.66 (0.38), P = 0.722 (no sig.)	Descriptive and comparative statistics ANCOVA analysis Mixed ANOVA T-test

IG: intervention group, CG: control group

6.6.3.3 Patient satisfaction

A SDM approach was shown to improve patient satisfaction in all three studies which measured it (Table 6.9). According to an RCT by Aljumah et al. (360), SDM-based pharmacy services showed considerably better patient satisfaction levels towards treatment than traditional pharmacy services. The mean Treatment Satisfaction Questionnaire for medication (TSQM) scores for intervention and control (3 months) were 86.6 (SD 11.08) and 82.82 (SD 13.40), p = 0.021 after three months of therapy. After six months, there was still a statistically significant effect on treatment satisfaction (intervention and control mean TSQM scores were 88.71 (S.D. 10.77) and 82.89 (S.D. 13.40), p = <0.0001). This was also confirmed by the pilot study conducted in Australia by Khalil et al. (363) (N= 126), among newly diagnosed atrial fibrillation patients. The study found a positive association between SDM and patient satisfaction where patient satisfaction was much greater (68% *vs* 25%, P = 0.001), when the pharmacist handled shared decision-making compared with usual care. In terms of overall patient satisfaction, Weiss et al. (367) explored whether specific components of SDM were present in consultations involving NPs, PPs and GPs and related these to self-reported patient outcomes including satisfaction which reported that the median satisfaction ratings were 4 out of 5, in the presence of SDM during the prescribing decision process.

The results of the parallel trial (360) and mixed method study (367) raised some concerns regarding the risk of bias, and the pilot study (363) had a high risk of bias, so the findings should be interpreted with caution.

Table 6.9: Patients' satisfaction

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Aljumah et al. (2015)	Saudi Arabia	Assess whether pharmacist interventions based on shared decision making improved adherence and patient-related outcomes	Quantitative: RCT	Treatment satisfaction Questionnaire for medication (TSQM)	3 months (mean IG vs CG): **Treatment satisfaction** 86.68 (11.08) vs 82.82 (13.40), P = 0.021 6 months (mean IG vs CG): **Treatment Satisfaction** 88.71 (10.77) vs 82.89 (13.40), P = <0.0001	Descriptive and comparative statistics ANCOVA analysis Mixed ANOVA T-test
Khalil et al. (2020)	Australia	Evaluate the impact of pharmacist-led shared decision making on patients' satisfaction and appropriateness of their anticoagulation therapy in newly diagnosed atrial fibrillation patients	Quantitative: pilot	Satisfaction (among those with pharmacist input)	**Satisfaction** (%) (25% (controls) vs 68% (post-intervention), P < 0.001)	Pre- and post-test comparison, descriptive statistics Chi-squared test

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Weiss et al. (2015)	UK	1) To explore whether specific components of shared decision making were present in consultations involving nurse prescribers (NPs), pharmacist prescribers (PPs) and general practitioners (GPs). 2) To relate these to self-reported patient outcomes including satisfaction, adherence and patient perceptions of practitioner empathy.	Mixed method: Audio-recordings from the consultations and survey	Offering treatment options to patients Treatment decision characteristic related to satisfaction Patients' views about treatment option	**PPs Compared to NPs and GPs:** **PPs more inclined to inquire about patients choices %** (PPs= 25%, GPs= 19%, and NPs= 13%) **PPs provided patients with therapy alternative %** (PPs= 32%, GPs= 20%, and NPs= 16%) **PPs provided the patient a prefer course of therapy %** (PPs= 31%, GPs= 26%, and NPs= 19%) **Satisfaction with pharmacist** Mean SD 4.04 (0.62) Median 4/5	Descriptive statistics Kruskal-Wallis test Multiple regression

IG: intervention group, CG: control group, NPs: nurse prescribers, PPs: pharmacist prescribers, GPs: general practitioners

Objective 2

6.6.3.4 Barriers and enablers of SDM

6.6.3.4.1 Knowledge/awareness

Seven papers highlighted awareness of SDM and knowledge of how to practise it as key issue. Chung et al. (364) in a quantitative study assessed the willingness of medical professionals, including pharmacists, to practice SDM and the obstacles that stand in their way. The study found that lack of knowledge and decision aids tools were significant barriers to providing SDM consultation. Besides that, the study reported that the challenge of creating or developing decision support tools was a hurdle to offering SDM for patients. Four qualitative papers (356-359) focused on the pharmacists' perceptions and identified a lack of knowledge related to the SDM approach as a barrier. Verweel et al. (359) found that many pharmacists observed that the tool used for SDM consultation might be restricted by the pharmacists' knowledge. A related paper based on the same interviews by Rosenberg-Yunger et al. (358) found that pharmacists often lacked a comprehensive understanding of SDM or experience managing diabetic patients in their clinics. Harris et al. (357) explored the importance of SDM in various aspects and the support and preparation pharmacists and other HCPs feel are necessary for SDM to be effective in practice. The paper highlighted that psychologists and pharmacists strive to engage patients, caregivers, and family members as much as possible in prescription choices. However, HCPs believe that patients' lack of understanding and their ability to stop taking medicine present issues. A qualitative study by Chong et al. (356) reported that although lack of cognitive ability and social stigma among mental health patients hindered mental health care use, one way to encourage SDM amongst patients and their families was by getting them more involved in the SDM process, including teaching them about mental illness and treatment choices.

Two mixed method studies (366, 368) highlighted patients' perceptions on SDM including the pharmacist provision of education support and awareness of pharmacy services. One paper by Lauffenburger et al. (368) reported that the clinical pharmacists could provide any necessary counselling but may not have provided sufficient educational support for some patients. On the other hand, Kayyali et al. (366) interviewed 18 respiratory patients with COPD in two hospitals. The paper indicated that patients had limited awareness of the community pharmacy's MUR service, which hinders the SDM in general. Also, the study highlighted that patients were willing to participate in SDM process (Table 6.10).

The findings from four qualitative studies (356–359), one cross-sectional study (364), and one mixed-method study (366) were reliable due to a low risk of bias. At the same time, the findings of one mixed method (368) with some concerns regarding bias and one feasibility study (365) with a high risk of bias should be interpreted cautiously.

6.6.3.4.2 Communication/ collaboration

Five studies were highlighted in this theme. There were two subthemes involved in the synthesis of these findings including communication across different health sectors and pharmacist-patient communication/collaboration. Chong et al's. (356) study identified that pharmacists highlighted the importance of both communication/collaboration among HCPs, and pharmacist-patient communication. The study explored the perspectives of mental healthcare practitioners about the obstacles and enablers of SDM and interdisciplinary cooperation. The findings found that open communication and competence in consultation and listening using good communication skills are essential to facilitate SDM. However, SDM barriers related to communication/collaboration among HCPs were highlighted, such as the lack of effective methods for conveying information among HCPs and the level of quality of clinical notes shared among the HCPs during or after patients discharge. Another barrier was

the inadequate or lack of integration of health services to SDM consultations. A further paper by Rosenberg-Yunger et al. (358) in 2018, illustrated community pharmacists' perceptions about SDM in diabetes care. This study highlighted that pharmacists emphasise the value of an open line of communication in relation to pharmacists' roles in dissemination of the most reliable evidence to inform patients about their disease.

A qualitative paper by Harris et al. (357) highlighted the perceptions of service users and HCPs including pharmacists regarding communication/ collaboration in mental health care. The paper spotlighted service users' views and reported that the majority of users did not have a sense of involvement in medication discussions. However, the pharmacist's view was also highlighted in the paper and suggested collaboration with patients and providing treatment information were crucial to ensure successful SDM.

From the patients' perceptions, the inability to effectively utilise SDM was hampered by a lack of clear communication amongst healthcare practitioners. Kayyali et al. (366) reported a dearth of communication between HCPs in secondary and primary care, particularly community pharmacists, severely impacting extended consultations like SDM. Furthermore, Lauffenburger et al. (368) shed light on the patients-pharmacists communication as they found that it is possible that the patients were not completely involved in the dialogue (limited engagement in conversation) as part of SDM, which would make the consultation less effective (Table 6.11).

The findings from three qualitative studies (356-357) and one mixed method study (366) were reliable due to a low risk of bias. While the findings of one mixed method (368) had some concerns therefore should be interpreted with caution.

6.6.3.4.3 Time

Five papers highlighted time constraints for SDM: two quantitative studies, one qualitative study, and one mixed method study. Chung et al. (364) assessed the willingness of medical professionals, including pharmacists, to practice SDM and the obstacles that stand in their way. The study found that lack of time was a significant barrier to providing the SDM consultation. Similar results were also found by Schafer et al. (365) which aimed to determine whether or not SDM could be acceptable and useful during a Medication Therapy Management consultation. The study highlighted from the pharmacists' and patients' perceptions that pharmacists' limited time was a barrier to providing SDM consultations. Furthermore, from the perspective of pharmacists, two qualitative papers by Chong et al. (356) and Rosenberg-Yunger et al. (358) also reported that time constraints during the SDM process were an obstacle to delivering health services. Moreover, from the patients' views, Lauffenburger et al. (368) in a mixed method study demonstrated that time was a barrier to offer SDM effectively (Table 6.12).

The findings were trustworthy regarding two qualitative studies (356, 358) and a cross-sectional study (364) due to a low risk of bias. However, the results of one mixed method (368) and one feasibility study (365) were inconclusive due to issues related to the risk of bias.

6.6.3.4.4 Patient-centeredness

Rosenberg-Yunger et al. (358) highlighted pharmacists' representation in the patient-centeredness "circle of care" as an enabler to SDM, while the absence of pharmacists' representation in patient-centeredness was a barrier. Also, pharmacists have stressed the need to provide individualised therapeutic care to boost patient adherence. However, Harris et al's. (357) qualitative study among mental health patients found that some patients believed that their personal experience with the disease was given minimal consideration. Kayyali et al.

(366) indicated that COPD patients had no input in the decision of the selection of their medication (Table 6.13).

The findings from two qualitative studies (357, 358) and one mixed method study (366) were reliable due to a low risk of bias.

6.6.3.4.5 Medical authority/ paternalism

A qualitative paper highlighted the views of service users and HCPs, including pharmacists, regarding paternalism in mental health care. Harris et al's. study (357) spotlighted the pharmacist's view and described the patients' focus on the lack of autonomy and cooperation with professionals in the antipsychotic prescription process, which may have been impacted by the perceived patient-professional power imbalance in this area. For the most part, service users believed that their personal experience of disease was undervalued in favour of focusing on the HCP, who was seen as the highest power and in charge of making final decisions (Table 6.14). Overall, the results of the qualitative study (357) could be reliable due to the low risk of bias.

6.6.3.4.6 Stigma

Chong et al. (356) discussed HCP' conceptions of the reputation surrounding psychiatric care, in which some mental health professionals, including pharmacists, perceived stigma prevented them from working effectively with those in different medical disciplines (Table 6.15). The results of the qualitative study (356) were trustworthy due to the low risk of bias.

6.6.3.4.7 Physical environment

Two qualitative papers highlighted the concern over physical spaces while offering SDM services. Chong et al. (356) indicated that the availability of designated spaces to offer SDM was recognised as an enabling factor, especially in community pharmacies. Furthermore, Rosenberg-Yunger et al. (358) highlighted the pharmacists' perception of limited private space while interacting with patients, which was identified as an impediment to providing SDM

(Table 6.16). The results of the qualitative studies (356, 358) were trustworthy due to the low risk of bias.

6.6.3.4.8 Regulatory hurdles

Only one qualitative study by Harris et al. (357) represents this theme. From the pharmacists' views, the study highlighted the intricacies of SDM, but the existing regulations and guidelines have yet to recognise SDM in pragmatic practice which may hurdle the benefits of SDM related to mental health services (Table 6.17). The qualitative study (357) had a low risk of bias.

Table 6.10: Findings related to knowledge/awareness

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Chung et al. (2019)	Taiwan	To apply the knowledge-attitude-behaviour (KAB) model to probe health care professionals' perceptions of SDM	Quantitative: Cross-sectional	Healthcare professionals perceptions on SDM	**KAP score for pharmacists (mean)** Knowledge (3.08), Attitude (3.85), Behaviour (3.7) **Challenges of performing SDM (%)** Lack of knowledge (38.25%). Difficulty of developing patient decision aids (PDAs) (37.75%) Lack of PDAs (36.75%) **Attitudes to performing SDM (%)** SDM may deliver the best health care for patients (81.62%). SDM can preserve and enhance individual clinical expertise (77.38%). SDM can meet patient and social expectations (48.40%).	Descriptive statistics Linear regression
Verweel et al. (2017)	Canada	To explore pharmacists' perspectives on decision aids, their place in a community pharmacy setting and the implementing of a decision aid, such as Diabetes Medication Choice (DMC).	Qualitative telephone semi-structured interviews	Pharmacists' understanding of decision aids, pharmacists' perceptions of the Diabetes Medication Choice (DMC) decision aid	**Barrier (s)** Pharmacists limited awareness/ understanding of diabetes decision aid used in SDM No prior knowledge with diabetes decision aid **Enabler (s)** Streamlined evidence based information and chances for patients education about therapy choices	Thematic analysis

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Rosenberg-Yunger (2018)	Canada	Describe community pharmacists' perceptions of SDM within the context of delivering Ontario's MedsCheck for Diabetes (MCD) programme and providing general diabetes management	Qualitative telephone semi-structured interview	Community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management, and barriers and facilitators to implementing SDM	**Pharmacists awareness** Pharmacists lacked a comprehensive understanding of SDM **Education** Pharmacists emphasised the value of dissemination of recent evidence based information to patients to optimise their health **Barrier (s)** Lack of up-to-date, comprehensive patient information **Enabler (s)** Education tools Specific certification (CDE designation)	Thematic analysis
Harris et al. (2017)	UK	To compare and synthesise mental health stakeholder views on antipsychotic prescribing in one NHS Trust, to understand potential reasons for the difficult enactment of shared decision-making in practice	Qualitative; semi-structured and focus group interview	Understand potential reasons for the difficult enactment of shared decision-making in practice	Discrepancy in views of professionals carers and users on what involvement in SDM should entail. Importance of SDM valued by all stakeholders, though valued discrete aspects differently **Barrier (s)** Users' cognitive skills & literacy **Enabler (s)** Development of evidence-based tools to support SDM	Framework analysis (both deductive and inductive approaches)

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Chong et al. (2013)	Australia	Explored healthcare providers' perceptions of barriers and facilitators to both shared decision-making and interprofessional collaboration in mental healthcare	Qualitative; semi-structured interview	Healthcare professionals' views on SDM and collaboration among multidisciplinary team	**Factors associated with mental health consumers** **Barrier (s)** Cognitive capacity Social stigma **Enabler (s)** Users attitude and behaviour Knowledge and understanding of disease Support network/ family involvement Patient education	Thematic analysis
Lauffenburger et al. (2019)	USA	Evaluate the impact of a telephone-based patient-cantered intervention on glycosylated haemoglobin (HbA1c) control for individuals with poorly-controlled diabetes	Mixed method: RCT, Audio recorded consultation	Barriers of SDM	Limited patient support related to knowledge	Descriptive and comparative statistics Logistic regression Grounded theory analysis

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Kayyali et al. (2018)	UK	1) Investigate hospital patients' receipt and involvement in medication counselling, patients' HCP preference for receiving medication information at the transition of care, and awareness of community pharmacy services such as the MUR. 2) Explore perceptions and experiences of patients with LTCs about the quality of care received in primary care and their awareness of the MUR service provided in the community pharmacy sector, focusing on COPD patients.	Mixed method Surveys and semi structured interview	SDM experience and medication counselling at discharge Patients perception on quality of care Patients views on SDM	**Survey** **62.2%** of patients desired participation in SDM **83%** and **93%** of patients not aware of MUR and NMS respectively **88.8%** of patients attentive in getting medicine use review	Descriptive statistics No robust statistical analysis, only Excel Thematic analysis (inductive/deductive)

Table 6.11: Findings related to communication/collaboration

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Chong et al. (2013)	Australia	Explored healthcare providers' perceptions of barriers and facilitators to both shared decision-making and interprofessional collaboration in mental healthcare	Qualitative; semi-structured interview	Healthcare professionals' views on SDM and collaboration among multidisciplinary team	**Factors associated with mental health consumers** Support network/ family involvement **Factors associated with healthcare providers** **Enabler (s)** Healthcare professionals' attitude and collaboration Good communication/ interpersonal skills **Factors associated with healthcare service delivery** **Enabler (s)** Interprofessional team approach Integration of care to ensure continuity of care **Barrier (s)** Lack of integration of care	Thematic analysis
Rosenberg-Yunger (2018)	Canada	Describe community pharmacists' perceptions of SDM within the context of delivering Ontario's MedsCheck for Diabetes (MCD) programme and providing general diabetes management	Qualitative telephone semi-structured interview	Community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management, and barriers and facilitators to implementing SDM	**Communication** Pharmacists emphasised the value of open line of communication to inform their patients	Thematic analysis

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Kayyali et al. (2018)	UK	1) Investigate hospital patients' receipt and involvement in medication counselling, patients' HCP preference for receiving medication information at the transition of care, and awareness of community pharmacy services such as the MUR. 2) Explore perceptions and experiences of patients with LTCs about the quality of care received in primary care and their awareness of the MUR service provided in the community pharmacy sector, focusing on COPD patients.	Mixed method Surveys and semi structured interview	SDM experience and medication counselling at discharge Patients perception on quality of care Patients views on SDM	**Barrier (s)** Lack of communication among the HCPs in different sectors.	Descriptive statistics No robust statistical analysis, only Excel Thematic analysis (inductive/deductive)

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Lauffenburger et al. (2019)	USA	Evaluate the impact of a telephone-based patient-cantered intervention on glycosylated haemoglobin (HbA1c) control for individuals with poorly-controlled diabetes	Mixed method: RCT, Audio recorded consultation	Barriers of SDM	Limited involvement in SDM, due to limited engagement in the conversation	Descriptive and comparative statistics Logistic regression Grounded theory analysis
Harris et al. (2017)	UK	To compare and synthesise mental health stakeholder views on antipsychotic prescribing in one NHS Trust, to understand potential reasons for the difficult enactment of shared decision-making in practice	Qualitative; semi-structured and focus group interview	Understand potential reasons for the difficult enactment of shared decision-making in practice	Most users did not feel involved in medication discussions **Barrier (s)** No current way for professionals to document disagreement	Framework analysis (both deductive and inductive approaches)

Table 6.12: Findings related to time

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Chung et al. (2019)	Taiwan	To apply the knowledge-attitude-behaviour (KAB) model to probe health care professionals' perceptions of SDM	Quantitative: Cross-sectional	Healthcare professionals perceptions on SDM	**Challenges of performing SDM (%)** Lack of time (57.50%)	Descriptive statistics Linear regression
Schafer et al. (2016)	USA	To evaluate the preliminary efficacy, feasibility, and acceptability of a template-based intervention to facilitate shared decision making (SDM) in medication therapy management (MTM) consultations.	Quantitative: Feasibility	Drug Therapy Problems (DTP) Efficacy, feasibility, and acceptability of SDM	**Pharmacists feedback on SDM:** Many pharmacists have reservations about SDM due to the lack of utility and timeframe it would demand.	Descriptive statistics No robust statistical analysis only Excel
Chong et al. (2013)	Australia	Explored healthcare providers' perceptions of barriers and facilitators to both shared decision-making and interprofessional	Qualitative: semi-structured interview	Healthcare professionals' views on SDM and collaboration among multidisciplinary team	**Factors associated with healthcare service delivery** **Barrier (s)** Time constraint	Thematic analysis

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
		collaboration in mental healthcare				
Rosenberg-Yunger (2018)	Canada	Describe community pharmacists' perceptions of SDM within the context of delivering Ontario's MedsCheck for Diabetes (MCD) programme and providing general diabetes management	Qualitative: telephone semi-structured interview	Community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management, and barriers and facilitators to implementing SDM	**Barrier (s)** Lack of time	Thematic analysis
Lauffenburger et al. (2019)	USA	Evaluate the impact of a telephone-based patient-cantered intervention on glycosylated haemoglobin (HbA1c) control for individuals with poorly-controlled diabetes	Mixed method: RCT, Audio recorded consultation	Barriers of SDM	**Barrier (s)** Limited time	Descriptive and comparative statistics Logistic regression Grounded theory analysis

Table 6.13: Findings related to patient-centeredness

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Rosenberg-Yunger (2018)	Canada	Describe community pharmacists' perceptions of SDM within the context of delivering Ontario's MedsCheck for Diabetes (MCD) programme and providing general diabetes management	Qualitative telephone semi-structured interview	Community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management, and barriers and facilitators to implementing SDM	**Involvement** Pharmacists emphasised the value of offering personalised healthcare to enhance patients' concordance **Barrier (s)** Not being considered part of patient's circle of care **Facilitator (s)** Being considered part of patient's circle of care	Thematic analysis
Harris et al. (2017)	UK	To compare and synthesise mental health stakeholder views on antipsychotic prescribing in one NHS Trust, to understand potential reasons for the difficult enactment of shared decision-making in practice	Qualitative; semi-structured and focus group interview	Understand potential reasons for the difficult enactment of shared decision-making in practice	Most users did not feel involved in medication discussions Importance of SDM valued by all stakeholders, though valued discrete aspects differently	Framework analysis (both deductive and inductive approaches)

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Kayyali et al. (2018)	UK	1) Investigate hospital patients' receipt and involvement in medication counselling, patients' HCP preference for receiving medication information at the transition of care, and awareness of community pharmacy services such as the MUR. 2) Explore perceptions and experiences of patients with LTCs about the quality of care received in primary care and their awareness of the MUR service provided in the community pharmacy sector, focusing on COPD patients.	Mixed method Surveys and semi structured interview	SDM experience and medication counselling at discharge Patients perception on quality of care Patients views on SDM	**Barrier (s)** Lack of patient-centred care and of SDM	Descriptive statistics No robust statistical analysis, only Excel Thematic analysis (inductive/deductive)

Table 6.14: Findings related to paternalism

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Harris et al. (2017)	UK	To compare and synthesise mental health stakeholder views on antipsychotic prescribing in one NHS Trust, to understand potential reasons for the difficult enactment of shared decision-making in practice	Qualitative; semi-structured and focus group interview	Understand potential reasons for the difficult enactment of shared decision-making in practice	**Barrier (s)** Lack of consensus among experts on the existence of a power imbalance.	Framework analysis (both deductive and inductive approaches)

Table 6.15: Findings related to Stigma

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Chong et al. (2013)	Australia	Explored healthcare providers' perceptions of barriers and facilitators to both shared decision-making and interprofessional collaboration in mental healthcare	Qualitative; semi-structured interview	Healthcare professionals' views on SDM and collaboration among multidisciplinary team	**Factors associated with mental health consumers and healthcare providers** **Barrier (s)** Social stigma	Thematic analysis

Table 6.16: Findings related to physical environment

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Chong et al. (2013)	Australia	Explored healthcare providers' perceptions of barriers and facilitators to both shared decision-making and interprofessional collaboration in mental healthcare	Qualitative; semi-structured interview	Healthcare professionals' views on SDM and collaboration among multidisciplinary team	**Factors associated with mental health consumers and healthcare providers** **Enabler (s)** availability of designated spaces to offer SDM	Thematic analysis
Rosenberg-Yunger (2018)	Canada	Describe community pharmacists' perceptions of SDM within the context of delivering Ontario's MedsCheck for Diabetes (MCD) programme and providing general diabetes management	Qualitative telephone semi-structured interview	Community pharmacists' perceptions and awareness of SDM within their provision of general diabetes management, and barriers and facilitators to implementing SDM	**Barrier (s)** Lack of private space	Thematic analysis

Table 6.17: Findings related to regulatory hurdles

Author (s) / Year	Location	Aim	Research design	Outcome	Results	Data analysis methods
Harris et al. (2017)	UK	To compare and synthesise mental health stakeholder views on antipsychotic prescribing in one NHS Trust, to understand potential reasons for the difficult enactment of shared decision-making in practice	Qualitative; semi-structured and focus group interview	Understand potential reasons for the difficult enactment of shared decision-making in practice	**Barrier (s)** SDM complexity and guidelines have yet to recognise it	Framework analysis (both deductive and inductive approaches)

6.6.4 **Summary of evidence**

6.6.4.1 Adherence, clinical outcomes, and quality of life

Three studies (360, 361, 367) concerning medication adherence were demonstrated in the quantitative studies. Two RCTs (360, 361) **reported a positive association between adherence and a SDM consultation**. One mixed method study (367) found that patients adhere to their medications when HCPs offer SDM. Furthermore, two quantitative studies (RCT (361) and cohort (362)) found **a positive association between clinical outcomes** (weight loss, HbA1c, LDL, length of stays, and hospitalisation) **and having received a SDM consultation**, although one randomised controlled study (360) reported **no association between either severity of depression or quality of life** *vs* SDM.

6.6.4.2 Patient satisfaction

Two quantitative studies (RCT (360), pilot (363)) suggested **a positive association between patient satisfaction and competent SDM**, which was reinforced by a mixed method study (367) that found higher satisfaction ratings in the presence of SDM during the prescribing decision process.

6.6.4.3 Knowledge/awareness, and patients' willingness to participate

Two quantitative studies (cross-sectional (364) and feasibility (365)) and four qualitative research (356-359), involved pharmacists, emphasised that patients' education (knowledge) and awareness of SDM were considered valuable and could improve patients' health. Two mixed method studies (366, 368) reinforced **the importance of patients' knowledge aspects related to SDM consultation**; one mixed method study (368) reported that patients had insufficient education support from the pharmacist; the other mixed method study (366) highlighted that patients had limited awareness of pharmaceutical services such as MUR which may hinder SDM.

6.6.4.4 Communication/ collaboration

The results of three qualitative studies (356-358) identified that people perceived **a strong association between effective communication/ collaboration and effective SDM delivery**. The qualitative studies highlighted the importance of open lines of communication, competence in consultation, good communication skills, and level of HCPs' clinical documentation. Also, an inadequate or lack of integration of health services to SDM consultations was perceived as a barrier by HCPs including pharmacists (356). In addition, two mixed method studies (366, 368) found that the limited communication among HCPs and ineffective engagement between patients with the pharmacists during the consultation could impact effective SDM delivery.

6.6.4.5 Time

The results of two quantitative studies with HCPs including pharmacists (cross-sectional (364) and feasibility (365)) demonstrated **a moderate association between time constraints and SDM**. This was corroborated by two qualitative studies among HCPs including pharmacists (356, 358) and suggested that limited time led to reduced SDM delivery. One mixed method study (368) found that the pharmacists highlighted time as a barrier to offer SDM effectively.

6.6.4.6 Patients-centeredness

The findings of two qualitative studies (357, 358) highlighted the perception of pharmacists and reported positivity of patients-centeredness on SDM delivery. One mixed method study (366) conducted among patients and found that there was an **absence of patient-centred care**.

6.6.4.7 Paternalism

A qualitative study (357) conducted among service users and HCPs, including pharmacists found that service users perceived that their disease experience was not valued, and **HCPs had the ultimate decision-making**.

6.6.4.8 Stigma

A qualitative study (356) with mental health professionals including **pharmacists perceived stigma** as a barrier that prevented them from working effectively with those in different medical disciplines.

6.6.4.9 Physical environment

Two qualitative studies (356, 358) conducted among service users and HCPs including pharmacists found that the **availability of physical spaces** while offering SDM services was an enabler factor for effective SDM delivery.

6.6.4.10 Regulatory hurdles

One qualitative study (357) conducted among service users and HCPs including pharmacists found **regulatory hurdles such as the lack or limited SDM related to disease guidelines** could be associated with negative results or considered barriers to delivering the SDM approach.

The findings were evaluated using criteria specified in the GRADE guidelines: risk of bias (study limitations), inconsistency, indirectness, imprecision, publication bias. The majority of the studies were graded with a low score, indicating low confidence in the results (Table 6.18). Furthermore, the findings were evaluated using criteria specified in the GRADE-CERQual covered the studies' methodological weaknesses, the review's overall consistency, the quality of the data used to draw conclusions, and the studies' applicability to the research topic. The majority of the studies were graded with a moderate score (Table 6.19).

Table 6.18: Summary of evidence derived from quantitative and mixed methods studies synthesis

Outcome	Significant studies (No. of participants)	Not significant studies (No. of participants)	GRADE	Comments
Adherence	RCT Aljumah et al. (239) RCT Moin et al. (351) MM Wiess et al. (532)	MM Lauffenburger et al. (1555)	Low	For evidence that isn't based only on randomised controlled trials, a reduction of two grade is appropriate due to a, b. A low level of confidence; actual effect will be much different from the predicted effect.
HbA1C	MM Lauffenburger et al. (1555) Cohort Whitley et al. (69)		Low	A reduction of two grade is appropriate due to a, b, c. A low level of confidence; actual effect will be much different from the predicted effect.
Weight change	RCT Moin et al. (351)		Moderate	A reduction of one grade is appropriate due to c. A moderate level of confidence in actual effect.
Quality of life (EQ-5D)		RCT Aljumah et al. (239)	Very low	A reduction of three grade is appropriate due to a, b, c. A very low level of confidence; actual effect will be substantially different from the predicted effect.
Severity of depression		RCT Aljumah et al. (239)	Very low	A reduction of three grade is appropriate due to a, b, c. A very low level of confidence; actual effect will be substantially different from the predicted effect.
LDL	Cohort Whitley et al. (69)		Low	A reduction of two grade is appropriate due to a, b, c. A low level of confidence; actual effect will be much different from the predicted effect.
Emergency hospital visit		Cohort Whitley et al. (69)	Very Low	A reduction of one grade is appropriate due to a, c A very low level of confidence; actual effect will be substantially different from the predicted effect.
Hospital admissions	Cohort Whitley et al. (69)		Low	A reduction of two grade is appropriate due to a, c A low level of confidence; actual effect will be much different from the predicted effect.

Outcome	Significant studies (No. of participants)	Not significant studies (No. of participants)	GRADE	Comments
Lengths of hospital stay	Cohort Whitley et al.(69)		Low	A reduction of two grade is appropriate due to a, c. A low level of confidence; actual effect will be much different from the predicted effect.
Appropriateness of anticoagulation therapy	Pilot Khalil et al. (126)		Low	A reduction of one grade is appropriate due to a, c. A low level of confidence; actual effect will be much different from the predicted effect.
Patient satisfaction	RCT Aljumah et al. (239) Pilot Khalil et al. (126) MM Wiess et al. (532)		Low	A reduction of one grade is appropriate due to a. A low level of confidence; actual effect will be much different from the predicted effect.

a Most information used to generate the summary estimate of effect from studies at 'some concern or high risk of bias
b Statistical heterogeneity between positive and negative treatment effects
c Insufficient sample to meet optimal information size criteria

RCT: Randomised Controlled Trial, PP: Pre/Post study, MM: mixed-method, LDL: Low-density lipoprotein, HbA1c: The haemoglobin A1C, (EQ-5D): European Quality of Life Five Dimension

Table 6.19: Summary of evidence derived from qualitative and mixed method synthesis

Themes Summarising Barriers and Facilitators to SDM with quotations and GRADE-QUAL assessment of confidence in the evidence			
Theme	**Studies**	**Representative Quotations**	**GRADE-QUAL assessment**
Knowledge/ awareness	Verweel et al. (2017) Rosenberg-Yunger et al. (2018) Harris et al. (2017) Chong et al. (2013) Lauffenburger et al. (2019) Kayyali et al. (2018)	"We have more informational kind[s] of aids. . .we have a lot of algorithms and stuff like that, but it's more decision making on our part as opposed to for them [the patients]. So, that's more, I guess, my experience with algorithms as opposed to for the patient" [Verweel 2017] "People may have different needs or requirement for education which is not specific to their medication regimen…that's not related to this [content of the decision aid]" [Verweel 2017] "You just can't hand out these pieces of paper…because. . .their decision making is out of context... There has to be a discussion there that people understand... I think it has to be put into perspective" [Verweel 2017] "Education, I mean for sure... Sometimes it's just beliefs that are not there or not appropriate'" [Rosenberg-Yunger 2018] "It's hard to describe ... I [pharmacist] follow ... clues from the patient . . . I'm looking at the patient from a holistic point of view" [Rosenberg-Yunger 2018] "You don't know until you actually get it from the chemist and read the leaflet" [Harris 2017] "The biggest problem is that for the people we deal with, the nature of their illness is that they are often paranoid and they have a lot of ideas about medication but they don't necessarily fit with your ideas. And obviously they don't believe they have an illness, some of them" [Chong 2013] "I never knew this service was available, nobody told me about it." [Kayyali 2018]	**High confidence** 6 studies with no or low methodological limitations. Data from 4 countries across 3 continents (Australia, Europe, and North America). No or very minor concerns about coherence and adequacy.

Themes Summarising Barriers and Facilitators to SDM with quotations and GRADE-QUAL assessment of confidence in the evidence			
Theme	**Studies**	**Representative Quotations**	**GRADE-QUAL assessment**
Communication/ collaboration	Chong et al. (2013) Rosenberg-Yunger (2018) Kayyali et al. (2018) Lauffenburger et al. (2019) Harris et al. (2017)	"We organized that the medical staff wouldn't dare take anyone out of a group, because we've established that as part of our culture. And I think it's because everyone has just come to work with the idea that they're here for the patients, to do the right thing'' [Chong 2013] 'I wish that I had more information sometimes because then it would make it easier for me to communicate more specifics to that particular patient" [Rosenberg-Yunger 2018] "Communication in educating patients to help them to better understand why … medications would be beneficial" [Rosenberg-Yunger 2018] "Counselling only involved basic use of the inhalers lasted for a few seconds." [Kayyali 2018] "The consultation may not have been optimally delivered as they [patients] may not have been fully engaged in the conversation" [Lauffenburger 2019] "I think it [the process] is collaborative but it depends on obviously how well the patient is...so it can't always be totally collaborative, because if the patient's really unwell, [. . .] they can't take on board information to make a decision" [Harris 2017]	**High confidence** 5 studies with low methodological limitations. Data from 4 countries across 3 continents (Australia, Europe, and North America). No or very minor concerns about coherence and adequacy.
Time	Chong et al. (2013) Rosenberg-Yunger (2018) Lauffenburger et al. (2019)	No quotes were provided, only a narrative descriptions. [Chong 2013] No quotes were provided, only a narrative descriptions. [Rosenberg-Yunger 2018] "Several pharmacists noted that the conversation was rushed" [Lauffenburger 2019]	**Low confidence** 3 studies with low methodological limitations. Data from 3 countries across 2 continents (Australia, and North America). Moderate concerns regarding the adequacy.
Patients' centeredness and paternalism	Rosenberg-Yunger (2018) Harris et al. (2017) Kayyali et al. (2018)	"The biggest barrier ... is the willingness for physicians to change...It doesn't prohibit me from writing recommendations...But I think it's when the patient gets caught in the	**Moderate confidence** 3 studies with low methodological limitations. Data from 3 countries

Themes Summarising Barriers and Facilitators to SDM with quotations and GRADE-QUAL assessment of confidence in the evidence			
Theme	**Studies**	**Representative Quotations**	**GRADE-QUAL assessment**
		middle, that's the hard part" [Rosenberg-Yunger 2018] "They [professionals] just don't' even look up, you are done and you are out" [Harris 2017] "we have to take a paternal role with their [users'] medication [. . .] there are some clients that if you didn't stand over them and made sure they took their meds, there's a chance they might not take them and become non-compliant" [Harris, 2017] "It looked like they didn't really pay much attention to how I really felt and instead went about it their own way" [Kayyali et al. 2018]	across 2 continents (Australia, and North America). Minor concerns regarding the adequacy.
Stigma	Chong et al. (2013)	"… there is still a stigma associated with mental illness … it even exists within health. … And a lot of times mental health units are physically located, even here, separate to the main part of the hospital" [Chong 2013]	**Low confidence** due to moderate concerns regarding adequacy. Thin data.
Physical environment	Chong et al. (2013) Rosenberg-Yunger (2018)	No quotes were provided, only a narrative descriptions. [Chong 2013] No quotes were provided, only a narrative descriptions. [Rosenberg-Yunger 2018]	**Low confidence** due to moderate concerns regarding adequacy. Thin data.
Regulatory hurdles	Harris et al. (2017)	No quotes were provided, only a narrative descriptions. [Harris, 2017]	**Low confidence** due to moderate concerns regarding adequacy. Thin data.

6.7 Discussion

6.7.1 Summary of the key findings

Current physicians have been pushed to embrace SDM as a significant advancement in modern clinical practice to develop better connections with their patients. This review is the first time the effectiveness of pharmacist-led SDM on medication adherence and clinical outcomes and the perceptions of pharmacists and patients about SDM have been systematically examined, to the best of our knowledge. It was challenging to synthesise the data because of the range of interventions utilised in each study. This diversity of interventions may be used to illustrate the ambiguity of SDM during the last two decades.

Based on the quality assessment of quantitative studies in the review, concerns regarding randomisation and reporting bias (360), confounding and selection bias (362), confounding, selection, missing data, and measurement of outcomes bias (363, 365), were identified. However, the quality assessment of qualitative studies highlighted a good quality of research, though some research added conclusions based on authors' interpretation and theme analysis without the use of quotations, which raised some mild concerns with coherence and moderate concerns with adequacy. This was taken into account while determining the evidence's overall confidence.

This review found that **SDM had a positive or better effect on adherence** (three studies) (360, 361, 367), **improvement in clinical outcome** (weight loss, HbA1c, LDL, hospitalisation and length of stays) (two studies) (361, 362), **satisfaction** (three studies) (360, 363, 367). However, SDM involving pharmacists had **no impact on quality of life or severity of depression**. Barriers and enablers of SDM perceived by pharmacists and patients were highlighted in the following themes: the **knowledge/awareness** of patients or pharmacists (356-359, 364, 366, 368), **communication** among HCPs and patients-

pharmacists (356-358, 366, 368), **time constraints** (356, 358, 364, 365, 368), **patients' centeredness** during SDM delivery (357, 358, 366), **paternalism** (356, 357), **physical environment issues** (356, 358), **regulatory hurdles** (357), and **integration of care** (356).

6.7.2 Findings in relation to existing literature

With such a wide variety of disease types and outcomes being examined, it is understandable that many research results have been varied. Despite this, a review of data throughout the research suggests that some interventions may be more beneficial, such as adherence, satisfaction, and some clinical outcomes.

Adherence

It is possible to draw the following conclusion out of 2 papers (360, 367) that assessed the effects of SDM on adherence: patients obtained a higher adherence level towards their medications than those that utilised a conventional service method. Previous findings by Weiss et al. (367) highlighted one of the probable explanations for this outcome. In that study, it was proven that spending more time explaining treatment choices was connected with higher levels of adherence and higher ratings of the prescriber's empathy. 'Sharing ideas' and 'patient awareness about sickness' were shown to favour adherence to medical advice (370). In addition, a meta-analysis (371) found that adherence was linked to increased information-giving and encouraging discussion. The studies (2 out of 3) examined for this review did not cover a specified time needed to improve adherence among patients who used the SDM approach material in a manner comparable to that the conventional control group provided. Only one RCT (360) provided a time interval (3 to 6 months) showing adherence improvement among mental health patients. However, in that RCT, there was a concern of bias that the findings might have been skewed by

investigators who were aware of the intervention arm and a restricted group of pharmacists who carried out the intervention.

Satisfaction

In three research papers (360, 363, 367), it was observed in this review that users of SDM were more satisfied with SDM activity compared to non-users of SDM. Similar conclusions were observed in a review by Ong et al. (372) as it highlighted that patient satisfaction was improved by SDM implementations. Moreover, a retrospective study from the USA analysed large data from the Medical Expenditure Panel Survey (MEPS) to examine the relationship between SDM and healthcare satisfaction by performing multiple regression. The study found that patient satisfaction was 40% greater among those who participated profoundly in SDM (373). Again, this review reported a timeframe only with one RCT. It was reported that satisfaction was significant in the 3 and 6 months of delivering the SDM consultations.

Clinical outcomes

This review identified only two out of four studies with evidence related to clinical outcomes. The studies found that SDM positively impacted weight loss, haemoglobin A1C (HbA1c), LDL, hospitalisation, and length of hospital stays among diabetic patients. SDM may be suitable for diabetes care since multiple management and therapy choices exist. However, this review found in one RCT that pharmacists-led SDM had no impact on the quality of life or severity of depression. Another RCT with a sequential mixed method in this review showed that SDM had no impact on medication adherence among patients with diabetes because of the possibility of poor SDM delivery by pharmacists. Our findings echoed prior research (373) that reported that suboptimal SDM practices

were linked to inferior patient-reported health outcomes, lower documented quality indices, and increased healthcare utilisation.

Barriers and enablers of SDM

Research regarding the organisational and system-level challenges and advantages of SDM is in its beginnings (374, 375). A scoping review by Scholl et al. (374) conducted a detailed assessment of the organisational and system factors that are likely to affect SDM's deployment. Appropriate resourcing, designating SDM as precedence, integrating SDM into teams and routine, and cultural and institutional leadership were shown to be important in the successful adoption of SDM. Elements such as clinical guidelines, rewards, training and education, licencing, culture, and legislation may be found at the systemic level.

Knowledge

In our review, knowledge was the prominent theme as it emerged from six studies. The lack of knowledge about SDM among patients and pharmacists and the lack of developed tools were barriers to delivering effective SDM consultations. In addition, lack of cognitive capacity and stigma were highlighted in our review. Scholl et al. (374) highlighted the confirmation of previously described parameters, which highlighted the education issue as a systemic level barrier. However, this review differed from Scholl et al.'s findings in one aspect related to the lack of developed decision-aid tools to support patients. The training issue was another barrier that emerged from this review.

Communication

A systematic review by Légaré et al. (376) evaluated the enablers and obstacles of SDM from the perspective of clinicians from the Netherlands, Germany, the United States, and

Canada and found that the primary challenges of SDM include limited time, unique patient features, and the clinical setting. The results of this review diverge from Légaré et al. review in certain aspects. This review cited communication issues as the second most commonly stated impediment. Thus, this review demonstrated the importance of communication/collaboration among HCPs, and pharmacists-patients communication. When seeing medical professionals, patients and non-patients often struggle to put their thoughts and feelings into words. Patients might not always sense they are welcome to discuss and may be unsure what is essential to convey.

Nonetheless, the patient's perspective is the most important factor in SDM. Clinical education and training programmes should emphasise physicians' ability to actively listen to patients as a means of involving them in SDM. For example, one research found that HCPs (physicians) often cut people off after just eleven seconds, maybe because they were under so much time pressure (377). In light of the fact that most patients wish to undertake active roles (broadly construed) in health decision-making, doctors must acquire efficient methods for controlling the quality and amount of time spent on SDM (378-380).

Time issue

Successful SDM requires enough time investment from both patients and professionals; sometimes, there is simply not enough time. Patients' worries about a doctor's rushed schedule increased inadequate SDM delivery in daily healthcare settings due to medical practitioners' need to preserve brief consultation periods. Clinicians need time to build relationships with their patients, instil confidence in them, act as their advocates, and learn about their unique circumstances and needs. Effective patient-professional interactions are associated with better health outcomes (381, 382). Moreover, if SDM is performed

throughout numerous sessions instead of a solitary encounter, the time constraint of SDM may be alleviated (383). Our review identified a lack of time as a barrier to SDM. The current research findings mirrored those of previous research, which reported that time constraints are often cited as an obstacle to SDM delivery (376, 381, 384, 385). On the other hand, a Cochrane study reported that the median time of an SDM consultation was extended by only 2.55 minutes due to the usage of the decision aid tool (44).

Patients-centeredness

Patient-centred care and SDM throughout the course of a lengthy professional engagement with a patient could improve health outcomes. The current investigation results are backed up by previous studies that reported that communication or therapy decisions could affect diabetic patient outcomes. However, SDM may intercede or at least modulate this association. For instance, SDM could enhance patient satisfaction, leading to doctor trust, implementing the doctor's advice, and, eventually, better health outcomes (386). Further research is needed to evaluate the effect of motivational interviewing on patients' involvement in SDM and the health outcome benefits over time.

Paternalism

Not all patients are enthusiastic or prepared to take a proactive role in determining their treatment. In our review, paternalism was identified as a barrier to effective SDM. The paternalistic approach was reported in previous research by Charles et al. (387), which highlighted that health specialists endorse the paternalistic approach due to patients entrusting them with making choices regarding therapy rather than SDM. Though, patient preference for their participation in decision-making is dynamic. Patients who have had positive experiences with SDM were highly likely to become engaged in their care (388).

Evidence also highlighted that patients who proactively address their chronic diseases tend to have better outcomes (389).

Regulatory hurdles

In our review, pharmacists' highlighted the complexity of SDM and the lack of or limited SDM related to disease guidelines. It is unclear how to include patients' choices or set concrete standards for SDM execution. The current investigation results backed up those of previous research; research shows that despite healthcare practitioners thinking they include patients in various stages of SDM, patients do not share this perception (390). On the other hand, studies have demonstrated that SDM was carried out in primary care and mental health settings to share information about patients with mental health issues (384). However, so far, it has only attained the first phase developed by Charles et al. (175), which consists of three phases, including a) two-way exchange of information, b) elucidation of priorities concerning therapy decisions, and c) consensus on a course of therapy. This review confirmed the previous studies that highlighted the system factors, including the unavailability or disorganisation of clinical guidelines that endorse the use of SDM (7, 391, 392). Likewise, Müller et al. (393) examined several methods for educating HCPs on SDM. Evidence-based recommendations from Müller et al. proposed the establishment of worldwide guidelines consisting of a fundamental collection of anticipated outcomes to evaluate the quality of SDM training programmes. Future implementation of SDM-based guidelines is recommended to measure SDM effectiveness during consultations for COPD patients.

Integration of care

Only one study in this review highlighted that health service integration was either poor or nonexistent. A recent review of 18 papers examined decision-making challenges in

integrated care services (394). The review reported that three primary trends of decision-making challenges were observed across the wide variety of worldwide integrated care service networks, including "autonomy versus inter-dependence, diversity versus coherence, and self-interest versus common goals". The same review concluded that collaborative efforts take time to develop because they need the resolution of many thorny issues, including but not limited to competing priorities, responsibilities, degrees of dedication, and power dynamics (394). Therefore, integrating care requires initiative from care professionals, patients, and other partners to surmount other systemic hurdles, such as bureaucracy and a lack of coordination, to provide better patient care. Given that SDM and integration of care have their constraints, it is crucial to recognise the difficulties around both approaches and proactively mitigate them. Interventions on enhancing collaboration among professionals and improving patients' engagement in SDM are needed.

6.7.3 **Strengths and limitations**

This is the first systematic review of the effectiveness of SDM incorporating pharmacists on medication adherence and pharmacists' and patients perceptions concerning SDM. The preliminary design of this systematic review was related to COPD and due to the limited evidence, it was expanded to include chronic diseases. Two independent reviewers handled every aspect of this review, boosting its reliability and validity. The search strategy was performed to find the most relevant articles in seven electronic bibliographic databases (PUBMED/MEDLINE, COCHRANE, Embase, CINHAL, PsychINFO, Web of Science, CDR/DARE databases), and the Joanna Briggs Institute (JBI) database. The screening was performed on the titles and abstracts of 5503 articles, and the complete texts of 25 articles were evaluated for eligibility.

Even though the selected qualitative studies were judged to be of high quality, the procedures used in the quantitative research had various flaws. These flaws comprised a lack of blindness in some randomised trials and no measures to address the confounding variables in the cohort and cross-sectional studies. The bulk of the investigations included in this review were carried out in diabetic and mental health settings involving pharmacists, nurses, and GPs; this suggests restricting the generalisability of the findings. Moreover, the findings of this review are derived from SDM in developed nations. It is indeed possible that low and middle-income nations' unique contexts might provide different sets of challenges regarding the pharmacists-led SDM.

Only 25 papers were considered, and 12 were disqualified after being subjected to full-text assessment. Since no grey literature was incorporated into this study, it may be susceptible to publication bias. Moreover, a meta-analysis was not feasible because of the studies' varied characteristics. Despite the work focussing on primary care, it was necessary to include a diverse array of research conducted across many contexts, including hospitals, among others. The SDM approach has traditionally been used mostly in hospital settings. Moreover, the inclusion of hospitals may provide a more comprehensive understanding of the success of SDM, which has not been extensively implemented in other contexts. Furthermore, this review excluded the implementation aspect of pharmacists-led SDM; the next steps for SDM studies in chronic respiratory diseases could contemplate prospective barriers to SDM application in clinical practice and the accessibility of professional resources that promote SDM whenever this is pertinent or possibly useful to patients.

6.8 Conclusion

The SDM approach arose from the lived experiences of people with long-term illnesses who sought treatment through the formal health system. Until now, a large variety of HCPs have been involved in SDM with patients, but there has been a scarcity of information concerning the pharmacist as a part of a multidisciplinary team on SDM. The SDM has been found to boost patient adherence and satisfaction and have a positive impact on other clinical outcomes, including weight loss, HbA1c, hospital admission, and length of stays at the hospital. SDM challenges were identified, including limited resources, patients' and HCPs' knowledge and awareness, paternalism, regulatory hurdles, and a lack of integration of care. SDM enablers were also acknowledged, such as effective communication, skills to deliver the SDM effectively, and patients-centeredness. Further research is needed focusing on communication infrastructure such as electronic platforms and SDM-based guidelines to measure SDM-effectiveness during consultations for COPD patients and evaluate the accessibility of professional resources that promote SDM. Moreover, there is an urgent need for more research that is concerned with patients' education to improve their information related to the diseases (SDM phase 1: team talk), and through it, SDM (phase 3: decision) can be improved.

Chapter 7 : Discussion

7.1 Chapter overview

The research presented in this thesis explored the pharmacist's role in improving adherence to inhaled medication among COPD patients. This chapter starts by reviewing the thesis's primary aim and objectives, as well as the means through which these objectives were attained. Afterwards, each work package's results are recapitulated and evaluated in light of previous literature. Furthermore, the strengths and limitations of this thesis were highlighted. I further detail specific recommendations derived from the thesis related to practice and research. Ultimately, the value of this work to the existing body of knowledge is considered.

7.2 The main aim and objectives of the thesis

The purpose of this thesis was to explore the role of the pharmacist in improving adherence to inhaled medication among COPD patients. Thus, the following was done to achieve the overarching purpose of this thesis:

A) Undertaking a survey to ascertain the current knowledge and practice of community pharmacists and their perspectives on their role to improve inhaler adherence among COPD patients (Chapter 2).

B) Conducting a qualitative study (22 in-depth interviews) using semi-structured interviews to explore COPD patients' views about pharmacist-led consultation to improve understanding of and adherence to inhaler medications (Chapter 3).

C) Conducting a qualitative study (12 in-depth interviews) to explore Healthcare Professionals' (HCPs) views about the potential role of the pharmacist and their integration in the optimisation of medications amongst COPD patients (Chapter 4).

D) Running 12 in-depth, semi-structured interviews to explore COPD patients' and HCPs' views on COVID-19 and its impacts on health care service provided to COPD patients (Chapter 5).

E) Carrying out a systematic review to identify evidence related to the effectiveness of SDM including pharmacists on medication adherence, and views and perceptions of both pharmacists' and patients' regarding SDM (Chapter 6).

7.3 Key findings summary

7.3.1 **Objective one**

The objective was to learn more about the pharmacists' knowledge, attitudes, and skills across the UK and obtain views on their role in improving inhaler adherence among COPD patients. The survey, although limited in size, identified a potential **willingness to offer support** to COPD patients, including instruction and training on **inhaler use,** providing input on **the choice of inhaler device,** and **self-management** plans. Most community pharmacists have a solid foundation of knowledge about inhalers. Nevertheless, there is room for improvement in other areas to facilitate this role, such as **training in inhaler technique, removing financial obstacles, and improving communication with the primary care team**.

7.3.2 **Objective Two**

I adopted a qualitative methodology to conduct 22 in-depth, semi-structured interviews with COPD patients having a wide range of characteristics to explore patients' current use of pharmacists regarding their inhaler medication and to explore patients' views about an enhanced pharmacy role to improve adherence to COPD medications.

The findings revealed that those who suffer from COPD may consult their neighbourhood pharmacists for guidance on using their inhalers. Several facilitators, such as the **approachability and professionalism of pharmacists**, were shown to be significant. It was also discovered that there were noticeable **barriers, such as ineffective communication with other primary care professionals**, **a lack of prescribing authority, a lack of continuity of care, and a lack of SDM**. Patients with COPD have brought up the apprehension that pharmacists may **lack full access to their medical information**, which may lead to restricting the enhanced involvement of pharmacists in the COPD patient care pathway in improving medication adherence.

7.3.3 **Objective three**

The first objective of this study was to seek in-depth information about the role of primary HCPs in optimising patients' inhaler adherence and HCPs' views about an enhanced pharmacy role to improve adherence to COPD medication. The other objective was to explore the potential barriers and enablers to further integration of pharmacists within the patient care pathways. Twelve HCPs within the West Midlands, UK, were interviewed using semi-structured in-depth remote interviews. Interviews were guided by 18 main questions to generate extensive ideas about the current situation related to the research aim.

The qualitative findings revealed a distinctive picture of the pharmacist's role in COPD patient care pathways. It is worth noting that many HCPs believe **pharmacists' involvement in integration care would be welcomed, and patients would benefit from pharmacists' involvement in their treatment plans**. Certain enablers may influence the pharmacists' roles within the patient care pathways, **including pharmacists' knowledge,**

patients' trust in pharmacists, and collaboration between the HCPs for the patients to receive better healthcare from the pharmacists.

Insights from this study highlighted many **challenges** concerning the pharmacist's roles within the patient care pathways, including a **lack of clear lines of communication**, **pharmacists' lack of access to medical records, a lack of continuity of care, scarce resources, the culture** of general practices and health-system **external inputs such as the expanded responsibilities of CCGs (now ICSs) and PCNs** (e.g., cost-saving initiatives).

7.3.4 Objective four

This objective was to obtain COPD patients' and HCPs' views on the impact of COVID-19 on COPD patients and to explore attitudes to remote consultations as part of health services provided to COPD patients. I guided 12 in-depth semi-structured interviews with COPD patients and HCPs in the West Midlands to fulfil the study goal. The study highlighted that, as expected, as the pandemic continued to pose a risk to patients with COPD, **COVID-19 negatively affected COPD patients' lifestyles**. An additional issue clearly represented in this qualitative study was related to the **difficulty of gaining access to NHS services**.

Barriers to remote consultations were highlighted, such as **limited internet access**, **difficulty using computers and technology, patients' age, communication difficulty, and patients' inability to pick up HCPs' non-verbal cues (inhaler technique instructions)**. However, enablers that were also underlined included **patients' partial acceptance of mitigation measures and safety** from viral infections during the pandemic, and **patients better-used pharmacists during the pandemic** (e.g., better access to healthcare services).

7.3.5 **Objective five**

I appraised the existing literature to assess the effectiveness of SDM involving pharmacists on medication adherence and the perceptions of pharmacists and patients about SDM. I reviewed 13 papers (6 six quantitative, four qualitative, and three mixed-method studies). The systematic review reported that **SDM could improve patients' adherence, satisfaction, and other clinical outcomes** such as weight loss and HbA1c, hospitalisation, emergency department visits, and length of stay at the hospital. Further insights were highlighted concerning SDM barriers. These included **limited resources, patients' and HCPs' knowledge and awareness** related to SDM consultation. However, SDM enablers, such as the **capability for successful SDM delivery and communication**, were also recognised. Additionally, the review identified some **knowledge gaps** that need to be investigated concerning the patients' education to improve their information related to the disease during the SDM process.

In a nutshell, this PhD research suggests the potential advantages of in-house and community pharmacists in assisting respiratory patients, including COPD patients, with inhaler choice and training/support for their use to improve adherence. From my perspective, it seems that GPs recognise the role of GP pharmacists more than a community of pharmacists as they conduct SMR services. There is obviously a lot of effort to be undertaken and room for improvement. Despite some promising prospects, such as pharmacists' accessibility and professionalism, pharmacists' eagerness to offer premium pharmaceutical services, and patients' trust in pharmacists, some underlying hurdles have been discovered that threaten the pharmacists' roles within COPD patients' treatment pathways. Concerning the aforementioned **hurdles**, (see Section 7.4) for further discussion, including **pharmacists' capacity** to offer feasible pharmaceutical services, the **capability** of patients and HCPs, including pharmacists, **collaboration and**

communication, and regulations. Ultimately, it is important to recognise that these issues are intertwined.

7.4 Comparison of results with international literature

7.4.1 Pharmacists' capacity to offer feasible pharmaceutical services

Utilising the full potential of in-house pharmacists or in the community to aid COPD patients in selecting their inhalers or how to use them correctly is a dilemma, yet it is feasible. Pharmacy as a profession has been recognised by many entities, for example, but not limited to the GOLD guideline for COPD (1). Additionally, several pieces of literature reported the positive role of pharmacists in improving COPD patients' health outcomes. The results of Chapters 2, 3, and 4 corroborate the available literature. In this thesis (Chapter 2), community pharmacists were found to have a sufficient understanding of some aspects of inhaler usage to consult COPD patients in a very efficient manner. This is also supported by COPD patients' perceptions (Chapter 3); they highlighted an acknowledgement of the value of pharmacists' efforts during the consultation. On top of that, COPD patients perceived positive points related to pharmacists' approachability and service accessibility. HCPs (Chapter 4) also perceived positive attributes regarding the receptivity of pharmacists' roles in COPD service delivery.

However, multiple hurdles affected the pharmacists' roles in COPD service delivery. For instance, scarcity of resources (money, time, private spaces and heavy load, workforce availability) was demonstrated throughout this PhD thesis (Chapters 2, 3, 4, and 6). Regarding financial remuneration, additional pharmaceutical services offered by pharmacists are either not compensated for or are compensated at a low rate (395). This is a significant barrier in patient-centred pharmacy services, which typically take the shape of an additional service offered by pharmacists, as this thesis referred to this issue.

On the other hand, given the high-volume, low-staff pharmacy environments in which most pharmacists work, it is understandable that individual pharmacists may lack the time and effort to devote to COPD patient counselling (396) and the introduction of new tasks related to the integration of pharmacists within the patients' treatment care pathways. These findings are echoed in this thesis, where patients have cited this as an issue since they believed that pharmacists were too occupied to address their worries about COPD. There is no easy solution to this problem. However, pharmacists may take measures to implement activities that have a minimal impact on their time, such as integrating in-house or community pharmacists within primary care. This approach has two sides: either it may reduce the time burden for all HCPs or exacerbate the workload if not utilised properly. UK-based practice pharmacists currently provide medication management services in primary care settings. They perform SMRs to assess the appropriateness of patients' prescription regimens, identify potential risks, and make recommendations to improve treatment outcomes and ensure patient safety (218).

This thesis' findings are consistent with the previous literature that documented that the shortage of pharmacy staff could negatively impact the service provided to respiratory patients (396, 397).

7.4.2 Capability of patients and HCPs including pharmacists

The effective empowerment of pharmacists with COPD patients' care pathways necessitates training and education to scale up their skills to achieve successful service delivery for COPD patients. A significant obstacle to expanding pharmacists' roles to provide services to COPD patients is a paucity of training, which leads to a reduction in confidence while delivering respiratory care (250, 251, 398) (lacking the capability involving training to provide such services to COPD patients). A paucity of training causes a severe lack of qualified pharmacists to serve people with COPD (398, 399). This

PhD thesis highlighted this issue related to offering SDM to patients and pharmacists training concerning inhalers licensed for COPD. Despite worldwide proposals to prepare prospective pharmacists with an emphasis on patient care, pharmacy programs continue to place too much emphasis on fundamental sciences and not enough on clinical practice (400).

Moreover, this PhD thesis is consistent with previous research (281, 282) in which HCPs such as GPs should maintain inhaler technique training because their inhaler technique skills could be lost entirely or in large part. Surprisingly, this PhD thesis captured that some GPs do not train their patients how to use their inhalers due to insufficient training with inhalers and rely heavily on nurses to support patients with COPD. The latter could provide an opportunity for pharmacists to step up, choose the most appropriate inhalers, and share the burden of GPs and nurses to support COPD patients in using their inhalers effectively while emphasising the differences between the general practice culture and community contexts.

There have been some recent changes in practice including SCR (219), SMR (218), CCG changing to ICSs (217), and pharmacists becoming independent prescribers (401). A notable increase in the prominence and significance has been attributed to independent prescriber pharmacists in the UK. These extensively trained individuals hold the autonomy to freely prescribe medications, allowing them to offer prompt and suitable therapy to patients, hence could be leading to increased healthcare results and improved patient care (401).

In terms of education, in-house or community pharmacists are uniquely qualified to treat patients with COPD, but further education on the wide variety of approved inhalers for COPD will elevate them to a better stage to optimise pharmaceutical services. This PhD

thesis highlighted the areas for improvement for the pharmacists, for example, specific DPI devices available in the market, the cleaning periods to clean either spacers or DPI devices, crucial steps for the correct use of pMDI, medicine reconciliations, prescribing/deprescribing high-alert medications, and effective SDM. Similar to previous literature, one of the obstacles encountered by community pharmacists, as noted frequently in the literature, is inadequate knowledge in some areas of COPD therapy care (123, 146, 402). There is considerable evidence that pharmacists possessing specialised expertise are more likely to provide specialised pharmaceutical services in related disease fields than pharmacists lacking such education (299, 303, 305). Therefore, joint efforts to strengthen pharmacists' capabilities are suggested, leading to better patient health benefits.

Other points documented in this PhD thesis concerning patients' capabilities are the limited information about their diseases, inhaler technique educational materials, awareness of the SDM concept, remote consultation benefits, as well as awareness of pharmacy services provided by the pharmacists such as New Medicine Services. Acknowledging such limits to address these knowledge discrepancies effectively is very important. Evidence in the published literature shows that education may improve a patient's health outcomes (403). Additionally, in two recent systematic reviews, adherence to COPD medications has been demonstrated to improve with increased patient education about the condition and treatment options, patient confidence in healthcare providers, and pharmacist consultation services (404, 405).

7.4.3 **Communication and collaboration**

Whenever there is a communication breakdown, the potential for healthcare missteps increases; modern healthcare has brought forth a situation where patient safety is jeopardised because healthcare providers fail to properly communicate for a variety of

reasons, including but not limited to a lack of data, misunderstanding of details, ambiguous telephone instructions, and missed medication and status adjustments (406).

Practical problems in electronic or telephone contact with GPs include poor phone/online system reliability: system failure, or newer systems such as EMIS that are incompatible with the older phones are some of these issues. Moreover, the inability to acquire an answer from the HCPs is due to outdated directories information. Therefore, staff response times are worsening as they spend more time than necessary trying to locate patients using the system.

By working together, doctors, nurses, as well as various healthcare practitioners, including pharmacists, may better use the unique expertise of every individual on the healthcare team. Moreover, when all healthcare practitioners work together towards a shared objective for the patient, rather than each person being solely accountable for the tasks associated with their particular speciality, this is known as an integrated effort (407). This allows patients to communicate more straightforwardly with unified healthcare practitioners than with a large group of individuals who are all working on their care independently (408). It's indeed worth noting that there might be obstacles to confront while creating a culture of teamwork and cooperation, as reported in previous literature (408). For example, absence of autonomy, distrust or lack of reliance on the judgements of others, contrasting perspectives, egotism, and a lack of comprehension of the role of one provider or their training, experience, added working hours, and abilities possessed by teammates in other fields and type of specialisations (409).

Nevertheless, from the perspectives of COPD patients, pharmacists, and HCPs, this thesis revealed that the coordination and communication between general practitioners and pharmacists remain inadequate. The thesis' result is congruent with a previous systematic

review (410), which evaluated 37 articles (cross-sectional, retrospective, and mixed-method studies) focused on the aspects that influence community pharmacists' and GPs' interdisciplinary collaboration. The review highlighted that the inability or limited acknowledgement of other HCPs' competency is a barrier to effective communication and collaboration. Moreover, the same review reported another barrier, including the hierarchy power disparity between GPs and community pharmacists, which aligns with pharmacists' voices in this thesis (Chapter 2). Still, in this thesis, the hierarchical barrier was not mainly affecting COPD patients' choice for certain GPs, which is correlated with the availability of ancillary services such as a practice nurse.

The lack of continuity of care is another issue that may be exacerbated by ineffective communication or a lack of patients' centeredness. Continuity of care was mentioned in several parts of this thesis, where it was raised in the perceptions of pharmacists, COPD patients, and HCPs. Continuity of care is attributed to effective communication, which leads to favourable outcomes regarding COPD patients' management. With respect to our cohort of participants, this thesis elaborated concerns regarding the lack of continuity of care in which a therapeutic management plan is put on hold rather than optimised due to a lack of proper communication, such as feedback. The result of this thesis is in line with the Vale of Leven Hospital report (411), which has highlighted the significance of continuity of care as part of medical care. The Vale of Leven Hospital report documented inaccuracies and signs of missing paperwork found after reviewing patient records due to the lack of continuity of care.

From the perspective of HCPs, this thesis showed that HCPs in primary care are more likely to see community pharmacists as communicative partners if the pharmacy is close to the general practice. In addition, primary care doctors either already do or could do a better job advising their patients about the health services available from pharmacies.

Indeed, these remarks are consistent with previous systematic review results, which reported that proximity between the two professions, open and consistent lines of communication, and a mutual appreciation for each other's strengths and roles in the delivery of COPD patient care all played vital parts in fostering effective collaboration (410), eventually strengthening communication as well.

7.4.4 **Regulation**

There has likely been a shift in the dynamic between patients, physicians, and pharmacists during the last few decades. The interface care of the various healthcare sectors and levels, particularly concerning shared-integrated care among the healthcare practitioners, role identification, area of responsibility, and relations of executive power. For example, the "Time for Care program" sees surgeries throughout the country adopt new ways to work, such as allowing patients to reserve appointments within a tangible short period of time, cutting down on paperwork, and providing quicker access for various health professionals (412). A 20,000 additional staff will help GP practices to work together to provide a more excellent range of patient care-including pharmacists, physiotherapists, community paramedics, associate doctors, and staff (412). In this PhD thesis (Chapter 4), HCPs generally feel that pharmacists would benefit from a larger involvement in the whole treatment process for their patients. This opportunity is valuable; pharmacists may be integrated with GPs to share the service burden and enhance communication. Thus, medication adherence could be improved in COPD patients.

Another point regards the deal between the NHS and the Pharmaceutical Services Negotiating Committee (PSNC). In 2019, nearly £13 billion was assigned to the community pharmacy *via* its contractual arrangement, with a promise to invest £2.592 billion in each of the subsequent five fiscal years (174). This pledge ensures the existence of the community pharmacy as an integral component of the NHS, which delivers health

support in the local primary care networks as a full partner. The service offered by community pharmacies, including the Community Pharmacist Consultation Service, *via* linking patients with community pharmacists who suffer from a minor illness, continues the optimisation and safety of medications, and improves public health and prevention, as a local community agent (174). Alas, there were unprecedented difficulties due to COVID-19; the general practices and community pharmacies are under remarkable pressure. A letter (413) to the UK Prime Minister from a conglomerate representing organisations for the community pharmacy and the country's leading pharmaceutical chains has expressed their concern that the implication of the pharmaceutical service's budget being consistently slashed would soon be felt by patients. Several pharmacies have closed permanently, and numerous chemist owners are fearing for their businesses' survival by the end of 2023.

Indeed, it is not an easy task, but to ensure a successful transition to service provision and encourage successful integration in places with a dearth of pharmacies, having ready access to NHS pharmacies is of the utmost importance. As this PhD thesis demonstrated some barriers to pharmacists' integration within the COPD patient care pathways, the solutions for these barriers by ensuring funding that the government already expects to do so, optimising automation and information technology and skills mix development opportunities, and providing efficiencies in prescription time-spending services.

Moreover, the service transition requires a strong connection with PCN and in-house pharmacists. Pharmacists with clinical roles who work in PCNs are expected to complete the mandatory 18 months of training (159). Furthermore, as a part of the multidisciplinary team, pharmacists will see patients anywhere. It may be in the home of a patient, a care home, or a GP facility. System-wide incorporation ensures that PCNs will have access to expert advice from hospital pharmacists and pharmacists who will expand their

experience into primary care, including the provision of pharmacist consultation (159). Pharmacy staff have difficulty meeting the needs of the NHS regarding achieving sustainable growth and uniformity. Also, training and retaining enough pharmacists and pharmacy technicians in the most needed areas must be considered. Thus, the NHS needs a system of education and training that produces competent pharmacists, adjusts to new trends in health care and patient requirements, and reacts to shifts in both information and technology (173).

Given all that, from HCPs' perceptions in this thesis, they were worried about the CCG's and PCNs demands for the potential pharmacists' new responsibilities to clash with those of their practises, especially those related to prescription cost-saving initiatives. Hence, prior to interacting with PCNs, community pharmacies should work on strengthening their internal coordination, as this might lead to more fruitful dialogues about how each member of a PCN might participate to enhance the quality of care their patients' receive. Afterwards, balancing demands between PCNs and HCPs is suggested. Recently, the implementation of ICSs was confirmed. Assessing the potential of ICSs to effectively allocate resources across different sectors and achieve financial equilibrium within local healthcare systems is currently a challenging task. It requires further research to address this challenge.

Further challenges demonstrated in this thesis related to pharmacists' access to patients' medical records. It is not common practice for pharmacists, especially those working in the community, to gain access to patients' electronic or paper medical records. Hence, pharmacists in the community have a narrow capacity to deliver optimum service to patients, including COPD patients (414) (296). In this thesis, COPD patients and HCPs perceived that pharmacists do not have access to their records and lack prescribing

authority. This issue may hinder some patients from seeking help from pharmacists and ultimately hamper pharmacists' roles in COPD care delivery.

One recent development in healthcare is the implementation of the SCR service. This service allows authorised pharmacy personnel to access important patient information stored in a digital repository. This repository contains essential health data, such as current prescriptions, allergies, and adverse reactions. Utilising the SCR will provide the pharmacists complete clinical picture regarding the patients' status, contributing to serving the patients in the best way possible.

7.5 Limitations and strengths

Both the drawbacks and the strengths have been discussed at length in earlier chapters. Yet, the overall drawbacks and strengths are highlighted herein. The aforementioned drawbacks and strengths pertain to the entire research.

7.5.1 **Limitations**

The first and foremost limitation associated with community pharmacists who took part in this research was related to participants' responses. In the survey, I collected data during the first and second waves of the pandemic. Although several attempts to reach prospective participants, I could not receive responses from the North West region of the UK. Because of this, it is possible that some pharmacists still need to be addressed for their input on this PhD.

One other flaw lies within the participants' demographics. Despite my efforts, there was not much diversity in COPD patients' ethnic composition (Black ethnicity). Since no potential participants of Black ethnic backgrounds applied to participate in this research, this was inevitable. Moreover, geographical restrictions were embedded in three work

packages of this PhD project; there was a slim chance that the findings might not mirror in some UK regions.

Concerns about the study's capacity to be applied to other contexts are a major drawback. Results could be irrelevant outside the UK, even if local contexts are similar. However, it should be taken into account that the UK is a pioneer in health research, so it is possible to benefit somewhat and generalise the findings of this PhD research.

Since this work completed, there were some recent changes in real practice including SCR, SMR, CCG changing to ICSs. The findings presented in this thesis were constrained by a lack of comprehensive understanding of recent modifications. Moreover, there were responses from HCPs about pharmacists, some of which mentioned pharmacists' roles in a mixed way and did not differentiate among the roles of community, in-house, and CCG pharmacists.

Furthermore, it is usual for qualitative studies with just one researcher to have the constraint of the researcher's own interpretation of the findings. However, with careful oversight, this issue has been lessened as, I took the necessary steps with the supervisory team to guarantee that the findings were drawn only on the available facts. To further reduce the possibility of bias, I acknowledged my own reflexivity throughout the research process (elaborated in depth in Chapter 3, Section 3.5.5).

At last, remote interviews were held either by telephone or online video. There were a few glitches, from delayed transmission through the internet to total loss and the need to re-establish connectivity. Problems with the internet connection meant that voice quality was subpar, leading to confusion and repeated questions and responses.

7.5.2 **Strengths**

The study's primary aim is its strongest point- to pragmatically explore the pharmacist's role in improving adherence to inhaled medication among COPD patients in the UK. This PhD project consists of multiple studies, including two quantitative studies (systematic review and cross-sectional) and three qualitative studies. Strengths reflect on each study's insights in the PhD project by addressing certain questions related to pharmacists' role in improving adherence among COPD patients.

The ability to recruit effectively is another area of strength. This PhD project obtained pharmacists', GPs', nurses', and COPD patients' voices. Because of this, I was able to have a holistic understanding of the current situation. Another strength of this PhD project is the broad diversity of COPD and HCPs characteristics, including the age group, gender, qualifications, HCPs' length of experience, patients' disease severity, and deprivation level of the area.

Lastly, the remote interviews were twofold. Despite the disadvantages described above in the limitation section, the benefits of remote interviews outweigh the disadvantages, mainly when it comes to scheduling an interview with HCPs in person due to the stringent time available to conduct a 60-minute interview during working hours. The remote interviews provided more flexibility, as some HCPs were interviewed during weekends or out-of-office times. Furthermore, since most COPD patients experience breathing problems, having in-person interviews could exhaust their energy levels due to travel, for instance, and cause them to run out of breath before finalising the interviews. Additionally, it may put them at a more elevated risk of contracting COVID-19 during interviews.

7.6 Recommendations

The recommendations derived from this doctoral research are summarised in the succeeding subheadings. Specifically, the recommendations are broken down into the following three subheadings: a) recommendation for practice; b) recommendation for policymakers; c) recommendation for research which may contribute to improving adherence to inhaled medication among COPD patients.

7.6.1 **Recommendation for practice**

a) Community pharmacists need more information and training on the wide variety of approved inhalers for COPD.

b) The urge for pharmacists to enhance their communication skills is growing, especially when interacting with patients and medical staff as well as the support of primary care physicians for expanded pharmacy services, but also, the proper infrastructure to do it.

c) Further efforts are needed to promote the pharmacists' capabilities and skills among HCPs to maximise the benefits generated from the integration approach and optimised services provided to patients.

d) Distribute educational resources for example webinars, videos, and shared learning sessions to all clinicians throughout the patient's care route in order to promote collaborative learning.

e) Patients with COPD have adjusted well to the current state of pandemic, but the new approach of providing consultation about medical treatment remotely must be assessed thoroughly in the near future especially those related to inhaler

technique demonstration. It should be used cautiously due to the possibility of unintended consequences in some areas of healthcare, including patient dissatisfaction and the potential widening of socioeconomic inequalities.

f) A standardised tool is recommended to assess the severity of COPD while recording data collection through remote communication.

g) SDM required holistic training and development for HCPs including pharmacists before utilisation. Also, integrate pharmacists into SDM about inhalers at an early stage, then accommodate individual preferences of patients.

h) Incorporate SDM and decision support into recommendation-based guidelines, and make SDM-tools available to users.

7.6.2 Recommendation for policy makers

a) Ensure sustainable funding from the government, and to optimise automation and information technology and skills mix development opportunities, and to provide efficiencies in prescription time-spending services.

b) Integration of care is involving transition, this transition requires a strong connection with all stakeholders including PCN, in-house and community pharmacists, nurses, GPs, and other HCPs.

c) To ensure a successful transition to service provision and encourage successful integration, it is vital in areas where there are fewer pharmacies to secure access to local physical NHS pharmaceutical services.

d) Ensuring sustainability and consistency across the country while ensuring the provision and development of workers is the challenge to pharmacy personnel, so

the NHS requires an educational and training model that provides the right pharmacy staff, adapts to the evolving health treatment environment, and patient's needs, responds to technological and data change.

e) Retain national key performance indictors up-to-date to guarantee reliable pharmaceutical service information provision.

7.6.3 **Recommendation for research**

a) Addressing the impact of multidisciplinary meeting sessions at the primary care setting on the COPD patient care.

b) Addressing the scarcity of continuity of care including pharmacists' turnover or rotation on the management of COPD patients.

c) Exploring multidisciplinary professionals' perceptions on encompassing COPD patients in the process of SDM focusing on the inhaler technique improvement.

d) Investigating the healthcare advantages of incorporating pharmacists into general practice settings, including quantifying pharmacists' efforts to improve COPD patients' health outcomes.

e) Further research is needed to assess the potential of ICSs to effectively allocate resources across different sectors and achieve financial equilibrium within local healthcare systems.

f) In-depth investigation on the potential advantages and disadvantages of remote consultation, particularly video consultation, within the primary care context on a larger scale and evaluate the cost-effectiveness of this approach.

g) Assessing the benefits of remote consultations concerning patients with severe or very severe COPD who are using multiple inhaler medications.

h) A well-designed study of SDM involving pharmacists in COPD management.

7.7 Contributions to the literature

This thesis contributes to our understanding of pharmacists' roles in improving adherence among COPD patients by demonstrating a wealth of detail and variety of why understanding the current practice is crucial to help COPD patients in order to improve their adherence to medications.

I conducted the first survey of UK pharmacists to establish their current knowledge and practice and their views on being involved in the inhaler choice and support for COPD patients, findings were generally keen, but there were some barriers to overcome.

I conducted the first in-depth exploration of the views of both patients and primary care healthcare professionals on incorporating pharmacists into the care pathway for COPD patients, which was again generally positive, although there were also barriers to overcome.

I explored the views of both patients and primary care healthcare professionals on the impact of COVID-19 on COPD patients and raised the need to explore how COPD patients are best consulted with post-pandemic; the role of remote consultation needs to be explored further in this group, especially with regards to improving their treatment adherence.

I identified the current lack of a role for pharmacists in decision-making about inhalers and thus reviewed the available evidence suggesting that SDM involving pharmacists

could be beneficial for patients with a variety of chronic diseases, although more research is needed in this area because of the limited quality of the data and the well-designed study of SDM involving pharmacists in COPD management.

7.8 Dissemination plan

The results will be shared with the COPD patients and HCPs involved in this PhD who requested to receive a summary of findings. Also, the summary of the findings will be available for different stakeholders, such as GPs, nurses, and pharmacists. Moreover, I will create an infographic of the thesis findings for patients and public engagement. The COVID-19 study presented in this thesis is now being prepared for publication in an academic journal. Also, I will be preparing a number of the other chapters for publication. Moreover, poster presentations for studies (Chapters 2, 3, 4, and 5) were presented at national and international conferences. In addition, I will present some findings reported in this PhD thesis as a scientific lecture and interactive workshop in Saudi Arabia. Lastly, this PhD will be deposited in the University of Birmingham library's digital archive.

7.9 Conclusion

COPD is a degenerative illness that progressively worsens over time and requires multifaceted interventions to manage such a complex disease. Inhaler adherence is crucial, and the ineffective inhaler technique's significance is recognised in health-related literature and clinical practice. Evidence highlighted the potential pharmacists' roles in supporting COPD care delivery.

Numerous work packages were accomplished to fulfil the aim of the PhD thesis, including two quantitative studies (systematic review and cross-sectional) and three qualitative studies. This PhD thesis reaffirmed the importance and enthusiasm for in-house and community pharmacists in supporting COPD patients with their inhaler adherence.

However, the results showed some barriers which need to be overcome before successful implementation. Pharmacists currently have limited capacity to offer feasible pharmaceutical services, collaboration and communication between HCPs and pharmacists as well as HCPs and patients requires improvement, and regulatory hurdles need to be overcome. Hence, this research proposes that future work should concentrate on these aspects to make it more possible to step up the pharmacists' roles and eventually improve adherence to inhaled medication among COPD patients within the UK.

References

1. Global Initiative for Chronic Obstructive Lung Disease-2023 Gold Report [Internet]. GOLD. 2022 [cited 15 Nov 2022]. Available from: https://goldcopd.org/2023-gold-report-2.
2. Castillo D, Burgos F, Guayta R, Giner J, Lozano P, Estrada M, et al. Airflow obstruction case finding in community-pharmacies: a novel strategy to reduce COPD underdiagnosis. Respir Med. 2015;109(4):475-82.
3. Gardener AC, Ewing G, Kuhn I, Farquhar M. Support needs of patients with COPD: a systematic literature search and narrative review. Int J Chron Obstruct Pulmon Dis. 2018;13:1021-35.
4. Chronic obstructive pulmonary disease in over 16s: Diagnosis and management [Internet]. NICE; 2018 [cited 15 Jan 2019]. Available from: https://www.nice.org.uk/guidance/ng115/resources/chronic-obstructive-pulmonary-disease-in-over-16s-diagnosis-and-management-pdf-66141600098245.
5. Adeloye D, Song P, Zhu Y, Campbell H, Sheikh A, Rudan I. Global, regional, and national prevalence of, and risk factors for, chronic obstructive pulmonary disease (COPD) in 2019: a systematic review and modelling analysis. Lancet Respir. Med. 2022;10(5):447-58.
6. Abdulsalim S, Unnikrishnan MK, Manu MK, Alrasheedy AA, Godman B, Morisky DE. Structured pharmacist-led intervention programme to improve medication adherence in COPD patients: A randomized controlled study. Res Social Adm Pharm. 2018;14(10):909-14.
7. Allen KM, Dittmann KR, Hutter JA, Chuang C, Donald ML, Enns AL, et al. Implementing a shared decision-making and cognitive strategy-based intervention: Knowledge user perspectives and recommendations. J Eval Clin Pract. 2020;26(2):575-81.
8. May SM, Li JT. Burden of chronic obstructive pulmonary disease: healthcare costs and beyond. Allergy Asthma Proc. 2015;36(1):4-10.
9. COPD (chronic obstructive pulmonary disease) - british lung foundation [Internet]. Asthma + Lung UK. 2022 [cited 11 Sep 2022]. Available from: https://www.blf.org.uk/support-for-you/copd
10. Snell N, Strachan D, Hubbard R, Gibson J, Gruffydd-Jones K, Jarrold I. S32 Epidemiology of chronic obstructive pulmonary disease (COPD) in the uk: findings from the british lung foundation's 'respiratory health of the nation' project. Thorax. 2016;71(Suppl 3):A20-A.
11. Chronic obstructive pulmonary disease (COPD): update, prioritised quality improvement areas for development [Internet]. NICE. 2015 [cited 15 Jan 2019]. Available from: https://www.nice.org.uk/guidance/qs10/documents/briefing-paper.
12. Stolz D, Mkorombindo T, Schumann DM, Agusti A, Ash SY, Bafadhel M, et al. Towards the elimination of chronic obstructive pulmonary disease: a Lancet Commission. Lancet. 2022;400(10356):921-72.
13. Hajiro T, Nishimura K, Tsukino M, Ikeda A, Oga T, Izumi T. A comparison of the level of dyspnea vs disease severity in indicating the health-related quality of life of patients with COPD. Chest. 1999;116(6):1632-7.
14. Nishimura K, Izumi T, Tsukino M, Oga T. Dyspnea is a better predictor of 5-year survival than airway obstruction in patients with COPD. Chest. 2002;121(5):1434-40.
15. Celli BR, Fabbri LM, Aaron SD, Agusti A, Brook R, Criner GJ, et al. An Updated Definition and Severity Classification of Chronic Obstructive Pulmonary Disease Exacerbations: The Rome Proposal. Am J Respir Crit Care Med. 2021;204(11):1251-8.
16. Rodriguez-Roisin R. Toward a consensus definition for COPD exacerbations. Chest. 2000;117(5 Suppl 2):398s-401s.
17. Merinopoulou E, Raluy-Callado M, Ramagopalan S, MacLachlan S, Khalid JM. COPD exacerbations by disease severity in England. Int J Chron Obstruct Pulmon Dis. 2016;11:697-709.
18. Seemungal TA, Donaldson GC, Bhowmik A, Jeffries DJ, Wedzicha JA. Time course and recovery of exacerbations in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med. 2000;161(5):1608-13.

19. Seemungal TA, Donaldson GC, Paul EA, Bestall JC, Jeffries DJ, Wedzicha JA. Effect of exacerbation on quality of life in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med. 1998;157(5 Pt 1):1418-22.
20. Seemungal TAR, Hurst JR, Wedzicha JA. Exacerbation rate, health status and mortality in COPD--a review of potential interventions. Int J Chron Obstruct Pulmon Dis. 2009;4:203-23.
21. Van Boven JF, Ryan D, Eakin MN, Canonica GW, Barot A, Foster JM, et al. Enhancing respiratory medication adherence: the role of health care professionals and cost-effectiveness considerations. J Allergy Clin Immunol Pract. 2016;4(5):835-46.
22. Leiva-Fernández J, Leiva-Fernández F, García-Ruiz A, Prados-Torres D, Barnestein-Fonseca P. Efficacy of a multifactorial intervention on therapeutic adherence in patients with chronic obstructive pulmonary disease (COPD): a randomized controlled trial. BMC Pulm Med. 2014;14(1):70.
23. Hamrin V, Sinclair VG, Gardner V. Theoretical approaches to enhancing motivation for adherence to antidepressant medications. Arch Psychiatr Nurs. 2017;31(2):223-30.
24. Anthonisen NR, Connett JE, Kiley JP, Altose MD, Bailey WC, Buist AS, et al. Effects of smoking intervention and the use of an inhaled anticholinergic bronchodilator on the rate of decline of FEV1. The Lung Health Study. JAMA. 1994;272(19):1497-505.
25. Tønnesen P. Smoking cessation and COPD. Eur Respir Rev. 2013;22(127):37.
26. Hoogendoorn M, Feenstra TL, Hoogenveen RT, Rutten-van Molken MP. Long-term effectiveness and cost-effectiveness of smoking cessation interventions in patients with COPD. Thorax. 2010;65(8):711-8.
27. Jordan RE, Majothi S, Heneghan NR, et al. Supported self-management for patients with moderate to severe chronic obstructive pulmonary disease (COPD): an evidence synthesis and economic analysis. Health Technol Assess. 2015;19(36):1-516.
28. Puhan MA, Gimeno-Santos E, Scharplatz M, Troosters T, Walters EH, Steurer J. Pulmonary rehabilitation following exacerbations of chronic obstructive pulmonary disease. Cochrane Database Syst. Rev. 2011(10).
29. Yang J, Lin R, Xu Z, Zhang H. Significance of Pulmonary Rehabilitation in Improving Quality of Life for Subjects With COPD. Respir Care. 2019;64(1):99-107.
30. Effing TW, Vercoulen JH, Bourbeau J, Trappenburg J, Lenferink A, Cafarella P, et al. Definition of a COPD self-management intervention: International Expert Group consensus. Eur Respir J. 2016;48(1):46-54.
31. Zwerink M, Brusse-Keizer M, van der Valk PD, Zielhuis GA, Monninkhof EM, van der Palen J, et al. Self management for patients with chronic obstructive pulmonary disease. Cochrane Database Syst. Rev. 2014(3):Cd002990.
32. Sidhu MS, Daley A, Jordan R, Coventry PA, Heneghan C, Jowett S, et al. Patient self-management in primary care patients with mild COPD - protocol of a randomised controlled trial of telephone health coaching. BMC Pulm Med. 2015;15:16.
33. Jolly K, Sidhu MS, Hewitt CA, Coventry PA, Daley A, Jordan R, et al. Self management of patients with mild COPD in primary care: randomised controlled trial. BMJ. 2018;361:k2241.
34. Cranston JM, Crockett AJ, Moss JR, Alpers JH. Domiciliary oxygen for chronic obstructive pulmonary disease. Cochrane Database Syst. Rev. 2005(4):Cd001744.
35. Gallefoss F, Bakke PS. Impact of patient education and self-management on morbidity in asthmatics and patients with chronic obstructive pulmonary disease. Respir Med. 2000;94(3):279-87.
36. Gregory K, Elliott M, Dunne P. Guide to aerosol delivery systems for physicians, nurses, pharmacists and other health care professionals [Internet]. American Association for Respiratory Care. 2017 [cited 17 Oct 2018]. Available from: https://www. https://www.aarc.org/wp-content/uploads/2018/01/aerosol-guide-for-hcp-3rd.pdf.
37. Pritchard JN. Industry guidance for the selection of a delivery system for the development of novel respiratory products. Expert Opin Drug Deliv. 2015;12(11):1755-65.
38. Lavorini F, Usmani OS. Correct inhalation technique is critical in achieving good asthma control. Prim Care Respir J. 2013;22(4):385-6.
39. Wright J, Brocklebank D, Ram F. Inhaler devices for the treatment of asthma and chronic obstructive airways disease (COPD). Qual Saf Health Care. 2002;11(4):376-82.

40. Price D, Marshall J, Turner R. Inhaler Use in Five European Countries: Analysis of Sales Data From Q4 2005 to Q4 2011. Value Health. 2012;15(7):A361.
41. Price D, Roche N, Christian Virchow J, Burden A, Ali M, Chisholm A, et al. Device type and real-world effectiveness of asthma combination therapy: an observational study. Respir. Med. 2011;105(10):1457-66.
42. Lavorini F, Fontana GA, Usmani OS. New inhaler devices-the good, the bad and the ugly. Respiration. 2014;88(1):3-15.
43. Barrons R, Wheeler J, Woods JA. Review: Opportunities for inhaler device selection in elderly patients with asthma or COPD. Patient Intell. 2015;7:53-65.
44. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane database of systematic reviews. 2017(4).
45. Wolfe A. Institute of Medicine Report: Crossing the Quality Chasm: A New Health Care System for the 21st Century. Policy, Politics, & Nursing Practice. 2001;2(3):233-5.
46. World Health Organization. Adherence to long-term therapies: evidence for action [Internet]. World Health Organization; 2003 [cited 2018 Sep 14]. Available from: https://apps.who.int/iris/bitstream/handle/10665/42682/9241545992.pdf.
47. Sanduzzi A, Balbo P, Candoli P, Catapano GA, Contini P, Mattei A, et al. COPD: adherence to therapy. Multidiscip Respir Med. 2014;9(1):60.
48. Vrijens B, Dima AL, Van Ganse E, van Boven JFM, Eakin MN, Foster JM, et al. What We Mean When We Talk About Adherence in Respiratory Medicine. J Allergy Clin Immunol Pract. 2016;4(5):802-12.
49. Bourbeau J, Bartlett S. Patient adherence in COPD. Thorax. 2008;63(9):831-8.
50. Krigsman K, Nilsson JL, Ring L. Adherence to multiple drug therapies: refill adherence to concomitant use of diabetes and asthma/COPD medication. Pharmacoepidemiol Drug Saf. 2007;16(10):1120-8.
51. Bryant J, McDonald VM, Boyes A, Sanson-Fisher R, Paul C, Melville J. Improving medication adherence in chronic obstructive pulmonary disease: a systematic review. Respir Res. 2013;14(1):109.
52. Holmes MS, D'arcy S, Costello RW, Reilly RB. Acoustic analysis of inhaler sounds from community-dwelling asthmatic patients for automatic assessment of adherence. IEEE J Transl Eng Health Med. 2014;2:1-10.
53. Goeman DP, Douglass JA. Optimal Management of Asthma in Elderly Patients. Drugs Aging. 2007;24(5):381-94.
54. Banning M. Older people and adherence with medication: a review of the literature. Int J Nurs Stud. 2008;45(10):1550-61.
55. Horne R. Compliance, adherence, and concordance: implications for asthma treatment. Chest. 2006;130(1 Suppl):65s-72s.
56. George J, Kong DC, Thoman R, Stewart K. Factors associated with medication non-adherence in patients with COPD. Chest. 2005;128.
57. McDonald VM, Higgins I, Gibson PG. Managing older patients with coexistent asthma and chronic obstructive pulmonary disease: diagnostic and therapeutic challenges. Drugs Aging. 2013;30(1):1-17.
58. Dolce JJ, Crisp C, Manzella B, Richards JM, Hardin JM, Bailey WC. Medication adherence patterns in chronic obstructive pulmonary disease. Chest. 1991;99(4):837-41.
59. Montes de Oca M, Menezes A, Wehrmeister FC, Lopez Varela MV, Casas A, Ugalde L, et al. Adherence to inhaled therapies of COPD patients from seven Latin American countries: The LASSYC study. PLOS ONE. 2017;12(11):e0186777.
60. Taylor DR, Kinney CD, McDevitt DG. Patient compliance with oral theophylline therapy. Br J Clin Pharmacol. 1984;17(1):15-20.
61. Bosley CM, Parry DT, Cochrane GM. Patient compliance with inhaled medication: does combining beta-agonists with corticosteroids improve compliance? Eur Respir J. 1994;7(3):504-9.
62. Make BJ. Chronic obstructive pulmonary disease: developing comprehensive management. Respir Care. 2003;48(12):1225-37.

63. Garcia-Aymerich J, Barreiro E, Farrero E, Marrades RM, Morera J, Anto JM. Patients hospitalized for COPD have a high prevalence of modifiable risk factors for exacerbation (EFRAM study). Eur Respir J. 2000;16(6):1037-42.
64. Mehuys E, Van Bortel L, De Bolle L, Van Tongelen I, Annemans L, Remon JP, et al. Effectiveness of pharmacist intervention for asthma control improvement. Eur Respir J. 2008;31(4):790-9.
65. Bryant L, Bang C, Chew C, Hee Baik S, Wiseman D. Adequacy of inhaler technique used by people with asthma or chronic obstructive pulmonary disease. J Prim Health Care. 2013;5(3):191-8.
66. Cully JA, Graham DP, Stanley MA, Ferguson CJ, Sharafkhaneh A, Souchek J, et al. Quality of life in patients with chronic obstructive pulmonary disease and comorbid anxiety or depression. Psychosomatics. 2006;47(4):312-9.
67. Qian J, Simoni-Wastila L, Rattinger GB, Zuckerman IH, Lehmann S, Wei YJ, et al. Association between depression and maintenance medication adherence among Medicare beneficiaries with chronic obstructive pulmonary disease. Int J Geriatr Psychiatry. 2014;29.
68. Sin DD, McAlister FA, Man SF, Anthonisen NR. Contemporary management of chronic obstructive pulmonary disease: scientific review. JAMA. 2003;290(17):2301-12.
69. Le TT, Bilderback A, Bender B, Wamboldt FS, Turner CF, Rand CS, et al. Do asthma medication beliefs mediate the relationship between minority status and adherence to therapy? J Asthma. 2008;45(1):33-7.
70. Duarte-de-Araujo A, Teixeira P, Hespanhol V, Correia-de-Sousa J. COPD: understanding patients' adherence to inhaled medications. Int J Chron Obstruct Pulmon Dis. 2018;13:2767-73.
71. Foster JM, Jenkins CR, Toelle BG, Smith L, Reddel HK. “It must be doing something”: COPD patients’ rationales for using combination ICS/LABA treatment. Am J Respir Crit Care Med. 2015;257:A6175.
72. Sherman J, Patel P, Hutson A, Chesrown S, Hendeles L. Adherence to oral montelukast and inhaled fluticasone in children with persistent asthma. Pharmacotherapy. 2001;21(12):1464-7.
73. Chambers CV, Markson L, Diamond JJ, Lasch L, Berger M. Health beliefs and compliance with inhaled corticosteroids by asthmatic patients in primary care practices. Respir Med. 1999;93(2):88-94.
74. Boulet LP. Perception of the role and potential side effects of inhaled corticosteroids among asthmatic patients. Chest. 1998;113(3):587-92.
75. Bosnic-Anticevich S, Chrystyn H, Costello RW, Dolovich MB, Fletcher MJ, Lavorini F, et al. The use of multiple respiratory inhalers requiring different inhalation techniques has an adverse effect on COPD outcomes. Int J Chron Obstruct Pulmon Dis. 2017;12:59-71.
76. Rootmensen GN, van Keimpema ARJ, Jansen HM, de Haan RJ. Predictors of Incorrect Inhalation Technique in Patients with Asthma or COPD: A Study Using a Validated Videotaped Scoring Method. J Aerosol Med Pulm Drug Deliv. 2010;23(5):323-8.
77. Khassawneh BY, Al-Ali MK, Alzoubi KH, Batarseh MZ, Al-Safi SA, Sharara AM, et al. Handling of inhaler devices in actual pulmonary practice: Metered-dose inhaler versus dry powder inhalers. Respir Care. 2008;53(3):324-8.
78. Bjerg A, Lundbäck B, Lötvall J. The future of combining inhaled drugs for COPD. Curr Opin Pharmacol. 2012;12(3):252-5.
79. Toy EL, Beaulieu NU, McHale JM, Welland TR, Plauschinat CA, Swensen A, et al. Treatment of COPD: Relationships between daily dosing frequency, adherence, resource use, and costs. Respir Med. 2011;105(3):435-41.
80. Sulaiman I, Cushen B, Greene G, Seheult J, Seow D, Rawat F, et al. Objective assessment of adherence to inhalers by patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med. 2017;195(10):1333-43.
81. Cazzola M, Rogliani P. Inhaled medication: which device for which patient? ERS Monogr. 2015;69:213-23.
82. Viswanathan M, Golin CE, Jones CD, Ashok M, Blalock SJ, Wines RC, et al. Interventions to improve adherence to self-administered medications for chronic diseases in the United States: a systematic review. Ann Intern Med. 2012;157(11):785-95.

83. Fraser C, Hadjimichael O, Vollmer T. Predictors of adherence to glatiramer acetate therapy in individuals with self-reported progressive forms of multiple sclerosis. J Neurosci Nurs. 2003;35(3):163-70.
84. Dassa D, Boyer L, Benoit M, Bourcet S, Raymondet P, Bottai T. Factors associated with medication non-adherence in patients suffering from schizophrenia: a cross-sectional study in a universal coverage health-care system. Aust N Z J Psychiatry. 2010;44(10):921-8.
85. Olfson M, Mechanic D, Hansell S, Boyer CA, Walkup J, Weiden PJ. Predicting medication noncompliance after hospital discharge among patients with schizophrenia. Psychiatr Serv. 2000;51(2):216-22.
86. Van Boven JFM, Lavorini F, Dekhuijzen PNR, Blasi F, Price DB, Viegi G. Urging Europe to put non-adherence to inhaled respiratory medication higher on the policy agenda: a report from the First European Congress on Adherence to Therapy. Eur Respir J. 2017;49(5).
87. Lam WY, Fresco P. Medication Adherence Measures: An Overview. Biomed Res Int. 2015;2015:217047.
88. Mardby AC, Akerlind I, Jorgensen T. Beliefs about medicines and self-reported adherence among pharmacy clients. Patient Educ Couns. 2007;69(1-3):158-64.
89. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Med Care. 1986:67-74.
90. Daniels T, Goodacre L, Sutton C, Pollard K, Conway S, Peckham D. Accurate assessment of adherence: self-report and clinician report vs electronic monitoring of nebulizers. Chest. 2011;140(2):425-32.
91. Zelikovsky N, Schast AP. Eliciting accurate reports of adherence in a clinical interview: development of the Medical Adherence Measure. Pediatr Nurs. 2008;34(2):141-6.
92. Byerly MJ, Nakonezny PA, Rush AJ. The Brief Adherence Rating Scale (BARS) validated against electronic monitoring in assessing the antipsychotic medication adherence of outpatients with schizophrenia and schizoaffective disorder. Schizophr Res. 2008;100(1-3):60-9.
93. Lavsa SM, Holzworth A, Ansani NT. Selection of a validated scale for measuring medication adherence. J Am Pharm Assoc. 2011;51(1):90-4.
94. Garfield S, Clifford S, Eliasson L, Barber N, Willson A. Suitability of measures of self-reported medication adherence for routine clinical use: a systematic review. BMC Med Res Methodol. 2011;11:149.
95. Dolder CR, Lacro JP, Warren KA, Golshan S, Perkins DO, Jeste DV. Brief evaluation of medication influences and beliefs: development and testing of a brief scale for medication adherence. J Clin Psychopharmacol. 2004;24(4):404-9.
96. Horne R, Weinman J, Hankins M. The beliefs about medicines questionnaire: The development and evaluation of a new method for assessing the cognitive representation of medication. Psychol Health. 1999;14(1):1-24.
97. Lewis S. Development and evaluation of the Adherence Attitude Inventory. Res Soc Work Pract. 2002;12(1):107-123.
98. George J, Mackinnon A, Kong DC, Stewart K. Development and validation of the Beliefs and Behaviour Questionnaire (BBQ). Patient Educ Couns. 2006;64(1-3):50-60.
99. Thompson K, Kulkarni J, Sergejew AA. Reliability and validity of a new Medication Adherence Rating Scale (MARS) for the psychoses. Schizophr Res. 2000;42(3):241-7.
100. Kripalani S, Risser J, Gatti ME, Jacobson TA. Development and evaluation of the Adherence to Refills and Medications Scale (ARMS) among low-literacy patients with chronic disease. Value Health. 2009;12(1):118-23.
101. Brooks CM, Richards JM, Kohler CL, Soong SJ, Martin B, Windsor RA, et al. Assessing adherence to asthma medication and inhaler regimens: a psychometric analysis of adult self-report scales. Med Care. 1994;32(3):298-307.
102. Chisholm MA, Lance CE, Williamson GM, Mulloy LL. Development and validation of an immunosuppressant therapy adherence barrier instrument. Nephrol Dial Transplant. 2005;20(1):181-8.
103. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. J Clin Hypertens (Greenwich). 2008;10(5):348-54.

104. Knobel H, Alonso J, Casado JL, Collazos J, Gonzalez J, Ruiz I, et al. Validation of a simplified medication adherence questionnaire in a large cohort of HIV-infected patients: the GEEMA Study. AIDS. 2002;16(4):605-13.
105. Karve S, Cleves MA, Helm M, Hudson TJ, West DS, Martin BC. Good and poor adherence: optimal cut-point for adherence measures using administrative claims data. Curr Med Res Opin. 2009;25(9):2303-10.
106. Sattler EL, Lee JS, Perri M, 3rd. Medication (re)fill adherence measures derived from pharmacy claims data in older Americans: a review of the literature. Drugs Aging. 2013;30(6):383-99.
107. Sulaiman I, Seheult J, MacHale E, D'Arcy S, Boland F, McCrory K, et al. Irregular and Ineffective: A Quantitative Observational Study of the Time and Technique of Inhaler Use. J Allergy Clin Immunol Pract. 2016;4(5):900.
108. Chan AHY, Harrison J, Black PN, Mitchell EA, Foster JM. Using Electronic Monitoring Devices to Measure Inhaler Adherence: A Practical Guide for Clinicians. J Allergy Clin Immunol Pract. 2015;3(3):335-49.e5.
109. Holmes MS, Seheult JN, Geraghty C, D'Arcy S, O'Brien U, O'Connell GC, et al. A method of estimating inspiratory flow rate and volume from an inhaler using acoustic measurements. Physiol Meas. 2013;34(8):903.
110. New Medicine Service (NMS) [Internet]. PSNC Website. 2013 [cited 10 Feb 2020]. Available from: https://psnc.org.uk/national-pharmacy-services/advanced-services/nms.
111. New Medicine Service (NMS) [Internet]. NHS choices. NHS; [cited 10 Feb 2020]. Available from: https://www.nhs.uk/nhs-services/prescriptions-and-pharmacies/pharmacies/new-medicine-service-nms.
112. Elliott RA, Boyd MJ, Salema N-E, Davies J, Barber N, Mehta RL, et al. Supporting adherence for people starting a new medication for a long-term condition through community pharmacies: a pragmatic randomised controlled trial of the New Medicine Service. BMJ Qual Saf. 2016;25(10):747.
113. Pharmacy- helping provide better quality and resilient urgent care [Internet]. 2013 [cited 13 Feb 2020]. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/11/comm-pharm-better-quality-resilient-urgent-care.pdf.
114. Van der Molen T, Van Boven JF, Maguire T, Goyal P, Altman P. Optimizing identification and management of COPD patients–reviewing the role of the community pharmacist. Br J Clin Pharmacol. 2017;83(1):192-201.
115. Fathima M, Naik-Panvelkar P, Saini B, Armour CL. The role of community pharmacists in screening and subsequent management of chronic respiratory diseases: a systematic review. Pharm Pract (Granada). 2013;11(4):228-45.
116. Visacri MB, Figueiredo IV, Lima TdM. Role of pharmacist during the COVID-19 pandemic: A scoping review. Res Social Adm Pharm. 2021;17(1):1799-806.
117. The role of a pharmacist during Covid-19: University of Sunderland; 2022 [Available from: https://www.sunderland.ac.uk/study/explore/health-sciences-wellbeing/pharmacist-covid19.
118. Improving health and patient care through community pharmacy: a call to action – what now? [Internet]. NHS choices. NHS; 2014 [cited 13 Feb 2023]. Available from: https://www.england.nhs.uk/blog/clare-howard-3.
119. Van Boven JF, Stuurman-Bieze AG, Hiddink EG, Postma MJ, Vegter S. Medication monitoring and optimization: a targeted pharmacist program for effective and cost-effective improvement of chronic therapy adherence. J Manag Care Spec Pharm. 2014;20(8):786-92.
120. Jones R. Primary Care Respiratory Society UK. Self Management of Chronic Obstructive Pulmonary Disease (COPD) in Primary Care 2010 [Available from: https://www.pcrs-uk.org/sites/pcrs-uk.org/files/os11_copd_self_man.pdf.
121. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns. 2002;48(2):177-87.
122. Wright D, Twigg M, Barton G, Thornley T, Kerr C. An evaluation of a multi-site community pharmacy–based chronic obstructive pulmonary disease support service. Int J Pharm Pract. 2015;23(1):36-43.

123. Tommelein E, Mehuys E, Van Hees T, Adriaens E, Van Bortel L, Christiaens T, et al. Effectiveness of pharmaceutical care for patients with chronic obstructive pulmonary disease (PHARMACOP): a randomized controlled trial. Br J Clin Pharmacol. 2014;77(5):756-66.
124. Gorgas MT, Pàez FV, Camós JR, Jolonch PS, Homs EP, Schoenenberger JA, et al. Integrated pharmaceutical care programme in patients with chronic diseases. Farm Hosp. 2012;36(4):229-39.
125. Khdour MR, Agus AM, Kidney JC, Smyth BM, McElnay JC, Crealey GE. Cost-utility analysis of a pharmacy-led self-management programme for patients with COPD. Int J Clin Pharm. 2011;33(4):665-73.
126. Jarab AS, AlQudah SG, Khdour M, Shamssain M, Mukattash TL. Impact of pharmaceutical care on health outcomes in patients with COPD. Int J Clin Pharm. 2012;34(1):53-62.
127. Khdour MR, Kidney JC, Smyth BM, McElnay JC. Clinical pharmacy-led disease and medicine management programme for patients with COPD. Br J Clin Pharmacol. 2009;68(4):588-98.
128. Zhong H, Ni XJ, Cui M, Liu XY. Evaluation of pharmacist care for patients with chronic obstructive pulmonary disease: a systematic review and meta-analysis. Int J Clin Pharm. 2014;36(6):1230-40.
129. Davis E, Marra C, Gamble J-M, Farrell J, Lockyer J, FitzGerald JM, et al. Effectiveness of a pharmacist-driven intervention in COPD (EPIC): study protocol for a randomized controlled trial. Trials. 2016;17(1):502.
130. Hesso I, Gebara SN, Kayyali R. Impact of community pharmacists in COPD management: Inhalation technique and medication adherence. Respir Med. 2016;118:22-30.
131. Milosavljevic A, Aspden T, Harrison J. Community pharmacist-led interventions and their impact on patients' medication adherence and other health outcomes: a systematic review. Int J Pharm Pract. 2018;26(5):387-97.
132. Ngo CQ, Phan DM, Vu GV, Dao PN, Phan PT, Chu HT, et al. Inhaler Technique and Adherence to Inhaled Medications among Patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease in Vietnam. Int J Environ Res Public Health. 2019;16(2):185.
133. Impact of a pharmacist-led asthma and COPD respiratory clinic in general practice [Internet]. NICE. NHS City and Hackney CCG; 2016 [cited 15 Aug 2020]. Available from: https://pharmaceutical-journal.com/article/letters/impact-of-a-pharmacist-led-asthma-and-copd-respiratory-clinic-in-general-practice.
134. Van Boven JF, Tommelein E, Boussery K, Mehuys E, Vegter S, Brusselle GG, et al. Improving inhaler adherence in patients with chronic obstructive pulmonary disease: a cost-effectiveness analysis. Respir Res. 2014;15(1):66.
135. Andreevska K, Petkova V, Jordanova S, Grekova D, Madjarov V, Dimitrova M, et al. Effect of education on patients with chronic obstructive pulmonary disease. WJPPS. 2014;3(3):01-9.
136. Bosnic-Anticevich SZ, Sinha H, So S, Reddel HK. Metered-dose inhaler technique: the effect of two educational interventions delivered in community pharmacy over time. J Asthma. 2010;47(3):251-6.
137. Basheti IA, Armour CL, Bosnic-Anticevich SZ, Reddel HK. Evaluation of a novel educational strategy, including inhaler-based reminder labels, to improve asthma inhaler technique. Patient Educ Couns. 2008;72(1):26-33.
138. Ottenbros S, Teichert M, de Groot R, Griens F, Sodihardjo F, Wensing M, et al. Pharmacist-led intervention study to improve drug therapy in asthma and COPD patients. I Int J Clin Pharm. 2014;36(2):336-44.
139. Kovačević SV, Miljković B, Vučićević K, Ćulafić M, Kovačević M, Golubović B, et al. Elderly polypharmacy patients' needs and concerns regarding medication assessed using the Structured Patient-Pharmacist Consultation Model. Patient Educ Couns. 2017;100(9):1714-9.
140. De Tullio PL, Corson ME. Effect of pharmacist counseling on ambulatory patients' use of aerosolized bronchodilators. Am J Health Syst Pharm. 1987;44(8):1802-6.
141. Ruud KW, Ronningen SW, Faksvag PK, Ariansen H, Hovland R. Evaluation of a structured pharmacist-led inhalation technique assessment service for patients with asthma and COPD in Norwegian pharmacies. Patient Educ Couns. 2018;101(10):1828-37.

142. Wright D, Twigg M, Thornley T. Chronic obstructive pulmonary disease case finding by community pharmacists: a potential cost-effective public health intervention. Int J Pharm Pract. 2015;23(1):83-5.
143. Hämmerlein A, Müller U, Schulz M. Pharmacist-led intervention study to improve inhalation technique in asthma and COPD patients. J Eval Clin Pract. 2011;17(1):61-70.
144. Takemura M, Mitsui K, Ido M, Matsumoto M, Koyama M, Inoue D, et al. Effect of a network system for providing proper inhalation technique by community pharmacists on clinical outcomes in COPD patients. Int J Chron Obstruct Pulmon Dis. 2013;8:239.
145. Beauchesne MF, Bercier D, Julien-Baker F, Lalonde L, Boileau R, Blais L. Community pharmacy-based medication assessment program for asthma and chronic obstructive pulmonary disease. Can Pharm J. 2012;145(2):70-1.
146. Hesso I, Kayyali R, Nabhani-Gebara S. Supporting respiratory patients in primary care: a qualitative insight from independent community pharmacists in London. BMC Health Serv Res. 2019;19:12.
147. Beloin-Jubinville B, Joly-Mischlich T, Rouleau ED, Noiseux P, Blais L, Forget A, et al. Does hospitalization influence patients' medication adherence and community pharmacists' interventions? Ann Pharmacother. 2013;47(9):1143-52.
148. Giner J, Roura P, Torres B, Burgos F, Castillo D, Tarragona E, et al. Knowledge, attitudes and preferences among spanish community pharmacists regarding inhaled therapy. Int J Pharm Pharm Sci. 2016;8(9):53-60.
149. Heikkilä JM, Parkkamäki S, Salimäki J, Westermarck S, Pohjanoksa-Mäntylä M. Community pharmacists' knowledge of COPD, and practices and perceptions of medication counseling of COPD patients. Int J Chron Obstruct Pulmon Dis. 2018;13:2065-74.
150. Abdulameer SA. Knowledge and pharmaceutical care practice regarding inhaled therapy among registered and unregistered pharmacists: an urgent need for a patient-oriented health care educational program in Iraq. Int J Chron Obstruct Pulmon Dis. 2018;13:879-88.
151. Sanii Y, Torkamandi H, Gholami K, Hadavand N, Javadi M. Role of pharmacist counseling in pharmacotherapy quality improvement. J Res Pharm Pract. 2016;5(2):132-7.
152. McMillan SS, Kelly F, Sav A, King MA, Whitty JA, Wheeler AJ. Australian community pharmacy services: a survey of what people with chronic conditions and their carers use versus what they consider important. BMJ Open. 2014;4(12):e006587.
153. Lowrie R, Johansson L, Forsyth P, Bryce SL, McKellar S, Fitzgerald N. Experiences of a community pharmacy service to support adherence and self-management in chronic heart failure. International Journal of Clinical Pharmacy. 2014;36(1):154-62.
154. Naik-Panvelkar P, Armour C, Rose JM, Saini B. Patient preferences for community pharmacy asthma services: a discrete choice experiment. Pharmacoeconomics. 2012;30(10):961-76.
155. Chen YC, Tarn YH, Kreling DH. Public views of community pharmacists in Taiwan. Int J Pharm Pract. 2012;20(3):203-6.
156. You JH, Wong FY, Chan FW, Wong EL, Yeoh E-K. Public perception on the role of community pharmacists in self-medication and self-care in Hong Kong. BMC Clin Pharmacol. 2011;11:19.
157. López-Campos JL, Quintana Gallego E, Carrasco Hernández L. Status of and strategies for improving adherence to COPD treatment. Int J Chron Obstruct Pulmon Dis. 2019;14:1503-15.
158. Melzer AC, Ghassemieh BJ, Gillespie SE, Lindenauer PK, McBurnie MA, Mularski RA, et al. Patient characteristics associated with poor inhaler technique among a cohort of patients with COPD. Respir Med. 2017;123:124-30.
159. Primary care networks: A briefing for pharmacy teams [Internet]. NHS choices. NHS; 2019 [cited 19 Sep 2019]. Available from: https://www.england.nhs.uk/wp-content/uploads/2019/06/pcn-briefing-for-pharmacy-teams.pdf.
160. Arya V, Pinto S, Singer J, Khan T. Understanding awareness of pharmacist-led medication therapy management among primary care physicians in New York City using qualitative methods: part I. J Med Pract Manage. 2013;29(2):84-8.

161. Arya V, Pinto S, Singer J. Understanding awareness of pharmacist-led medication therapy management among primary care physicians in New York City, Part II: Findings and implications. J Med Pract Manage. 2013;29(3):187-94.
162. Latif A, Waring J, Watmough D, Barber N, Chuter A, Davies J, et al. Examination of England's New Medicine Service (NMS) of complex health care interventions in community pharmacy. Res Social Adm Pharm. 2016;12(6):966-89.
163. Russell S, Ogunbayo OJ, Newham JJ, Heslop-Marshall K, Netts P, Hanratty B, et al. Qualitative systematic review of barriers and facilitators to self-management of chronic obstructive pulmonary disease: views of patients and healthcare professionals. NPJ Prim Care Respir Med. 2018;28(1):2.
164. Young HML, Apps LD, Harrison SL, Johnson-Warrington VL, Hudson N, Singh SJ. Important, misunderstood, and challenging: a qualitative study of nurses' and allied health professionals' perceptions of implementing self-management for patients with COPD. Int J Chron Obstruct Pulmon Dis. 2015;10:1043-52.
165. Twigg MJ, Wright DJ. Community pharmacy COPD services: what do researchers and policy makers need to know? Integr Pharm Res Pract. 2017;6:53.
166. Ekenga V, Bailey-Wheeler J, Hart T, Sarpong D, Earls M. Patients' perception of community pharmacists as healthcare providers and willingness to participate in pharmacist services: a pilot study. Pharm Health Serv Res. 2018;9(4):297-300.
167. Wickware C, Robinson J. Asthma inhaler stocks low after COVID-19 linked demand spike, government says. Pharm J. 2020;10.
168. Wickware C. Pharmacies' dispensing increases by up to a third as a result of covid-19, survey finds [Internet]. Pharmaceutical J. 2021 [cited 27 Oct 2022]. Available from: https://pharmaceutical-journal.com/article/news/pharmacies-dispensing-increases-by-up-to-a-third-as-a-result-of-covid-19-survey-finds.
169. Bragazzi NL, Mansour M, Bonsignore A, Ciliberti R. The Role of Hospital and Community Pharmacists in the Management of COVID-19: Towards an Expanded Definition of the Roles, Responsibilities, and Duties of the Pharmacist. Pharmacy (Basel). 2020;8(3).
170. Margusino-Framiñán L, Illarro-Uranga A, Lorenzo-Lorenzo K, Monte-Boquet E, Márquez-Saavedra E, Fernández-Bargiela N, et al. Pharmaceutical care to hospital outpatients during the COVID-19 pandemic. Telepharmacy. Farm Hosp. 2020;44(7):61-5.
171. Peat G, Olaniyan J, Fylan B, Breen L, Grindey C, Hague I, et al. Mapping the resilience performance of community pharmacy to maintain patient safety during the Covid-19 pandemic. Res Social Adm Pharm. 2022;18(9):3534-41.
172. Li H, Zheng S, Liu F, Liu W, Zhao R. Fighting against COVID-19: Innovative strategies for clinical pharmacists. Research in social & administrative pharmacy : RSAP. 2021;17(1):1813-8.
173. Kovačević M, Ćulafić M, Vezmar Kovačević S, Borjanić S, Keleč B, Miljković B, et al. Telepharmacy service experience during the COVID-19 pandemic in the Republic of Srpska, Bosnia and Herzegovina. Health Soc Care Community. 2022;30(5):e1639-e50.
174. Community Pharmacy Contractual Framework 2019-2024 [Internet]. NHS choices. NHS; 2019 [cited 14 Sep 2019]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/819601/cpcf-2019-to-2024.pdf.
175. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: What does it mean? (or it takes at least two to tango). Social Science & Medicine. 1997;44(5):681-92.
176. Kew KM, Malik P, Aniruddhan K, Normansell R. Shared decision-making for people with asthma. Cochrane Database of Systematic Reviews. 2017;2017(10):CD012330.
177. Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. Patient Educ Couns. 2006;60(3):301-12.
178. Elwyn G, Durand MA, Song J, Aarts J, Barr PJ, Berger Z, et al. A three-talk model for shared decision making: multistage consultation process. BMJ. 2017;359:j4891.
179. Blaiss MS, Steven GC, Bender B, Bukstein DA, Meltzer EO, Winders T. Shared decision making for the allergist. Ann Allergy Asthma Immunol. 2019;122(5):463-70.

180. Montori VM, Gafni A, Charles C. A shared treatment decision-making approach between patients with chronic conditions and their clinicians: the case of diabetes. Health Expect. 2006;9(1):25-36.
181. Joosten EA, DeFuentes-Merillas L, de Weert GH, Sensky T, van der Staak CP, de Jong CA. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. Psychother Psychosom. 2008;77(4):219-26.
182. Global strategy for asthma management and prevention [Internet]. Global Initiative for Asthma (GINA); 2022 [cited 10 Dec 2022]. Available from: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf.
183. Wieringa TH, Rodriguez-Gutierrez R, Spencer-Bonilla G, De Wit M, Ponce OJ, Sanchez-Herrera MF, et al. Decision aids that facilitate elements of shared decision making in chronic illnesses: a systematic review. Syst Rev. 2019;8(1):121.
184. The pharmacopeia of the United States of America. The United States pharmacopeia. 15th ed. Rockville (US): United States Pharmacopeial Convention; 1979.
185. Gums TH, Carter BL, Milavetz G, Buys L, Rosenkrans K, Uribe L, et al. Physician-pharmacist collaborative management of asthma in primary care. Pharmacotherapy. 2014;34(10):1033-42.
186. Stacey D, Légaré F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev. 2014(1):Cd001431.
187. Shay LA, Lafata JE. Where Is the Evidence? A Systematic Review of Shared Decision Making and Patient Outcomes. Med Decis Making. 2015;35(1):114-31.
188. Shared decision making [Internet]. NICE. 2021 [cited 15 May 2022]. Available from: https://www.nice.org.uk/guidance/ng197/resources/shared-decision-making-pdf-66142087186885
189. Matthias MS, Salyers MP, Rollins AL, Frankel RM. Decision making in recovery-oriented mental health care. Psychiatr Rehabil J. 2012;35(4):305.
190. Foot C, Gilburt H, Dunn P, Jabbal J, Seale B, Goodrich J, et al. People in control of their own health and care. London (GB): King's Fund; 2014.
191. Kilbourne AM, Beck K, Spaeth-Rublee B, Ramanuj P, O'Brien RW, Tomoyasu N, et al. Measuring and improving the quality of mental health care: a global perspective. World psychiatry. 2018;17(1):30-8.
192. Priebe S, Miglietta E. Assessment and determinants of patient satisfaction with mental health care. World Psychiatry. 2019;18(1):30.
193. Update to the GP contract agreement 2020/21 – 2023/24 [Internet]. NHS-England; 2020 [cited 16 Mar 2020]. Available from: https://www.england.nhs.uk/wp-content/uploads/2020/03/update-to-the-gp-contract-agreement-v2-updated.pdf
194. Souheil H, Rouba Karen Z, Sylvia S, Aline H, Rabih H, Charbel Y, et al. Knowledge, Attitude and Practice of Lebanese Community Pharmacists toward Chronic Obstructive Pulmonary Disease. J Epidemiol Glob Health. 2020;10(1):86-95.
195. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implementation Sci. 2012;7(1):37.
196. Costa FA, Scullin C, Al-Taani G, Hawwa AF, Anderson C, Bezverhni Z, et al. Provision of pharmaceutical care by community pharmacists across E urope: Is it developing and spreading? J Eval Clin Pract. 2017;23(6):1336-47.
197. Integration and innovation: Working together to improve health and social care for all [Internet]. GOV.UK. Department of Health & Social Care; 2021 [cited 17 Jun 2022]. Available from: https://www.gov.uk/government/publications/working-together-to-improve-health-and-social-care-for-all/integration-and-innovation-working-together-to-improve-health-and-social-care-for-all-html-version.
198. Sestini P, Cappiello V, Aliani M, Martucci P, Sena A, Vaghi A, et al. Prescription bias and factors associated with improper use of inhalers. J Aerosol Med. 2006;19(2):127-36.
199. Mickle TR, Self TH, Farr GE, Bess DT, Tsiu SJ, Caldwell FL. Evaluation of pharmacists' practice in patient education when dispensing a metered-dose inhaler. Dicp. 1990;24(10):927-30.

200. Guide to reducing the carbon footprint of Inhaler prescribing [Internet]. Greener Practice. 2021 [cited 2021 December 29]. Available from: https://s40639.pcdn.co/wp-content/uploads/Reducing-Carbon-Footprint-of-Inhaler-Prescribing-v3.3.2.pdf.
201. Gregory PAM, Austin Z. How do patients develop trust in community pharmacists? Res Social Adm Pharm. 2021;17(5):911-20.
202. Todd A, Copeland A, Husband A, Kasim A, Bambra C. The positive pharmacy care law: an area-level analysis of the relationship between community pharmacy distribution, urbanity and social deprivation in England. BMJ Open. 2014;4(8):e005764.
203. Seston EM, Schafheutle EI, Willis SC. "A little bit more looking…listening and feeling" A qualitative interview study exploring advanced clinical practice in primary care and community pharmacy. Int J Clin Pharmacy. 2021.
204. Stewart DC, Maclure K, Bond CM, Cunningham S, Diack L, George J, et al. Pharmacist prescribing in primary care: the views of patients across Great Britain who had experienced the service. Int J Pharm Pract. 2011;19(5):328-32.
205. Hadi MA, Alldred DP, Briggs M, Marczewski K, Closs SJ. Effectiveness of a community based nurse-pharmacist managed pain clinic: A mixed-methods study. Int J Nurs Stud. 2016;53:219-27.
206. van der Molen T, van Boven JFM, Maguire T, Goyal P, Altman P. Optimizing identification and management of COPD patients – reviewing the role of the community pharmacist. Br J Clin Pharmacol. 2017;83(1):192-201.
207. Astbury JL, Gallagher CT. Moral distress among community pharmacists: causes and achievable remedies. Res Social Adm Pharm. 2020;16(3):321-8.
208. Murphy AL, Phelan H, Haslam S, Martin-Misener R, Kutcher SP, Gardner DM. Community pharmacists' experiences in mental illness and addictions care: a qualitative study. Subst Abuse Treat Prev Policy. 2016;11(1):6.
209. Weir NM, Newham R, Dunlop E, Bennie M. Factors influencing national implementation of innovations within community pharmacy: a systematic review applying the Consolidated Framework for Implementation Research. Implementation Sci. 2019;14(1):21.
210. Hindi AMK, Schafheutle EI, Jacobs S. Patient and public perspectives of community pharmacies in the United Kingdom: A systematic review. Health Expect. 2018;21(2):409-28.
211. Bradley F, Ashcroft DM, Noyce PR. Integration and differentiation: a conceptual model of general practitioner and community pharmacist collaboration. Res Social Adm Pharm. 2012;8(1):36-46.
212. Stevenson FA, Cox K, Britten N, Dundar Y. A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance. Health Expect. 2004;7(3):235-45.
213. Borrill C, West M, Shapiro D, Rees A. Team working and effectiveness in health care. Br J Health Care Manag. 2000;6(8):364-71.
214. Hinata M, Miyazaki K, Okada H, Nakayama T. Mindset modification of community pharmacists in a collaborative relationship between a major hospital and neighboring community pharmacies: a qualitative study. BMC Health Serv Res. 2019;19(1):487.
215. Hindi AMK, Jacobs S, Schafheutle EI. Solidarity or dissonance? A systematic review of pharmacist and GP views on community pharmacy services in the UK. Health Soc Care Community. 2019;27(3):565-98.
216. Smith MG, Shea CM, Brown P, Wines K, Farley JF, Ferreri SP. Pharmacy characteristics associated with the provision of medication management services within an integrated care management program. J Am Pharm Assoc. 2017;57(2):217-21.e1.
217. Integrated care [Internet]. NHS England. 2022 [cited 15 May 2023]. Available from: https://www.england.nhs.uk/integratedcare/what-is-integrated-care/.
218. Structured medication reviews and medicines optimisation [Internet]. NHS England. 2022 [cited 15 May 2023]. Available from: https://www.england.nhs.uk/primary-care/pharmacy/smr/.
219. Summary Care Record in community pharmacy [Internet]. NHS Digital. 2022 [cited 15 May 2023]. Available from: https://digital.nhs.uk/services/summary-care-records-scr/summary-care-record-scr-in-community-pharmacy#future-access.

220. Fisher RJ. Social Desirability Bias and the Validity of Indirect Questioning. J Consum Res. 1993;20(2):303-15.
221. Eynon T, Conroy S. The state of social care: the reality of a fragmented system. Br J Gen Pract. 2017;67(658):200.
222. Panch T, Mattie H, Celi L. The “inconvenient truth” about AI in healthcare. npj Digital Med 2: 77. 2019.
223. Adab P, Fitzmaurice DA, Dickens AP, Ayres JG, Buni H, Cooper BG, et al. Cohort Profile: The Birmingham Chronic Obstructive Pulmonary Disease (COPD) Cohort Study. Int J Epidemiol. 2017;46(1):23.
224. McLennan D, Noble S, Noble M, Plunkett E, Wright G, Gutacker N. English indices of deprivation 2019 [Internet]. GOV.UK. Ministry of Housing, Communities and Local Government; 2019 [cited 20 Feb 2020]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/833951/IoD2019_Technical_Report.pdf.
225. Plaza V, Fernández-Rodríguez C, Melero C, Cosío BG, Entrenas LM, de Llano LP, et al. Validation of the ‘Test of the Adherence to Inhalers’ (TAI) for Asthma and COPD Patients. J Aerosol Med Pulm Drug Deliv. 2015;29(2):142-52.
226. Lincoln Y, Guba E. Naturalistic inquiry. Newbury Park (US): SAGE Publications; 2006.
227. Shenton AK. Strategies for ensuring trustworthiness in qualitative research projects. Educ Inf. 2004;22(2):63-75.
228. Elliott R, Fischer CT, Rennie DL. Evolving guidelines for publication of qualitative research studies in psychology and related fields. Br J Clin Psychol. 1999;38(3):215-29.
229. Harper D, Thompson AR. Qualitative research methods in mental health and psychotherapy: A guide for students and Practitioners. Chichester (GB): John Wiley & Sons; 2012.
230. Patton MQ. Enhancing the quality and credibility of qualitative analysis. Health Serv Res. 1999;34(5 Pt 2):1189-208.
231. Polit DF, Beck CT. Essentials of nursing research: Appraising evidence for nursing practice. Philadelphia (US): Wolters Kluwer; 2022.
232. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349-57. International journal for quality in health care. 2007;19(6):349-57.
233. Berger R. Now I see it, now I don’t: researcher’s position and reflexivity in qualitative research. Qual Res. 2013;15(2):219-34.
234. Malterud K. Qualitative research: standards, challenges, and guidelines. Lancet. 2001;358(9280):483-8
235. Adams E. The joys and challenges of semi-structured interviewing. Community Pract. 2010;83(7):18-21.
236. Braun V, Clarke V. What can "thematic analysis" offer health and wellbeing researchers? Int J Qual Stud Health Well-being. 2014;9:26152.
237. QSR International Pty Ltd. (2018); NVivo (Version 12), https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home2018.
238. Creswell JW, Poth CN. Qualitative inquiry and research design: Choosing among five approaches. London (GB): SAGE publications; 2016.
239. Ismail A, Gan YN, Ahmad N. Factors associated with patient satisfaction towards pharmacy services among out-patients attending public health clinics: Questionnaire development and its application. PLoS One. 2020;15(11):e0241082.
240. Jordan JN, Wadsworth TG, Robinson R, Hruza H, Paul A, O'Connor SK. Patient Satisfaction with Pharmacist-Provided Health-Related Services in a Primary Care Clinic. Pharmacy (Basel). 2021;9(4):187.
241. Ayalew MB, Taye K, Asfaw D, Lemma B, Dadi F, Solomon H, et al. Patients'/Clients' Expectation Toward and Satisfaction from Pharmacy Services. J Res Pharm Pract. 2017;6(1):21-6.
242. Mahase E. Covid-19: Increased demand for steroid inhalers causes “distressing” shortages. BMJ. 2020;369:m1393.

243. All About Health. Out of Stock Notice Board. 07 April 2020 [Available from: https://www.gpni.co.uk/wp-content/uploads/2020/04/aah-out-of-stock-pharmacy-and-dispensing-doctors-data-1.pdf.
244. Twigg MJ, Poland F, Bhattacharya D, Desborough JA, Wright DJ. The current and future roles of community pharmacists: views and experiences of patients with type 2 diabetes. Res Social Adm Pharm. 2013;9(6):777-89.
245. Tinelli M, Ryan M, Bond C. Patients' preferences for an increased pharmacist role in the management of drug therapy. Int J Pharm Pract. 2009;17(5):275-82.
246. Torjesen I. More People Live Within a 20-minute Walk of a Pharmacy than a GP surgery. Pharmaceutical J. 2015. [cited 18 April 2021]. Avilable from https://pharmaceutical-journal.com/article/news/more-people-live-within-a-20-minute-walk-of-a-pharmacy-than-a-gp-surgery.
247. Boivin A, Lehoux P, Lacombe R, Burgers J, Grol R. Involving patients in setting priorities for healthcare improvement: a cluster randomized trial. Implementation science : IS. 2014;9:24.
248. Porteous T, Ryan M, Bond C, Watson M, Watson V. Managing minor ailments; the public's preferences for attributes of community pharmacies. A discrete choice experiment. PLoS One. 2016;11(3):e0152257.
249. The community pharmacy offer for improving the public's health [Internet]. Local Government Association; 2016 [cited 22 Dec 2021]. Available from: https://www.healthylondon.org/wp-content/uploads/2017/10/L16-44-The-community-pharmacy-offer-for-improving-the-public-health.pdf.
250. Abuzour AS, Lewis PJ, Tully MP. A qualitative study exploring how pharmacist and nurse independent prescribers make clinical decisions. J Adv Nurs. 2018;74(1):65-74.
251. Frankel GEC, Austin Z. Responsibility and confidence: identifying barriers to advanced pharmacy practice. Can Pharm J. 2013;146(3):155-61.
252. Rosenthal M, Austin Z, Tsuyuki RT. Are pharmacists the ultimate barrier to pharmacy practice change? Can Pharm J. 2010;143(1):37-42..
253. O'Riordan M, Dahinden A, Aktürk Z, Ortiz JMB, Dagdeviren N, Elwyn G, et al. Dealing with uncertainty in general practice: an essential skill for the general practitioner. Qual Prim Care. 2011;19(3):175.
254. Nearly a quarter of PCNs did not claim NHS funding to hire extra pharmacists. Pharmaceutical J. 2020 [cited 14 March 2022]. Avilable from https://pharmaceutical-journal.com/article/news/nearly-a-quarter-of-pcns-did-not-claim-nhs-funding-to-hire-extra-pharmacists.
255. PCNs – positive impact on practice staffing or untapped potential? GP Practice Management Blog. 2022 [cited 12 March 2022]. Available from: https://practiceindex.co.uk/gp/blog/pcns-positive-impact-practice-staffing-untapped-potential.
256. Ibrahim OM, Ibrahim RM, Z Al Meslamani A, Al Mazrouei N. Role of telepharmacy in pharmacist counselling to coronavirus disease 2019 patients and medication dispensing errors. J Telemed Telecare. 2020;29(1):18–27.
257. Famiyeh IM, MacKeigan L, Thompson A, Kuluski K, McCarthy LM. Exploring pharmacy service users' support for and willingness to use community pharmacist prescribing services. Res Social Adm Pharm. 2019;15(5):575-83.
258. Roberts MF, Reeves K, Divine H. Community pharmacists' lack of access to health records and its impact on targeted MTM interventions. J Am Pharm Assoc. 2019;59(4s):S81-s4.
259. Gidman W, Ward P, McGregor L. Understanding public trust in services provided by community pharmacists relative to those provided by general practitioners: a qualitative study. BMJ open. 2012;2(3):e000939.
260. Boonen LH, Schut FT, Donkers B, Koolman X. Which preferred providers are really preferred? Effectiveness of insurers' channeling incentives on pharmacy choice. Int J Health Care Finance Econ. 2009;9(4):347-66.
261. Shah J, Dickinson CL. Establishing which factors patients value when selecting urology outpatient care. Br J Med Surg Urol. 2010;3(1):25-9.

262. Dahlgren C, Dackehag M, Wändell P, Rehnberg C. Simply the best? The impact of quality on choice of primary healthcare provider in Sweden. Health Policy. 2021;125(11):1448-54.
263. MacLure K, George J, Diack L, Bond C, Cunningham S, Stewart D. Views of the Scottish general public on non-medical prescribing. Int J Clin Pharm. 2013;35(5):704-10.
264. Hobson RJ, Scott J, Sutton J. Pharmacists and nurses as independent prescribers: exploring the patient's perspective. Fam Pract. 2010;27(1):110-20.
265. Bissell P, Blenkinsopp A, Short D, Mason L. Patients' experiences of a community pharmacy-led medicines management service. Health Soc Care Community. 2008;16(4):363-9.
266. Officer TN, McBride-Henry K. Perceptions of underlying practice hierarchies: Who is managing my care? BMC health services research. 2021;21(1):911.
267. Ngwenya N, Crang C, Farquhar M, Rintoul RC, Mahadeva R, Calvert LD, et al. Communicating uncertainty: contrasting the communication experiences of patients with advanced COPD and incurable lung cancer. Fam Pract. 2021;38(5):637-43.
268. Booker R. Effective communication with the patient. Eur Respir Rev. 2005;14(96):93.
269. Asher R. Talk, tact, and treatment. Lancet. 1955;265(6867):758-60.
270. Choi E, Lee I-H. Relational continuity of care in community pharmacy: A systematic review. Health Soc Care Community. 2022;30(1):e39-e50.
271. Granados-Santiago M, Valenza MC, López-López L, Prados-Román E, Rodríguez-Torres J, Cabrera-Martos I. Shared decision-making and patient engagement program during acute exacerbation of COPD hospitalization: A randomized control trial. Patient Educ Couns. 2020;103(4):702-8.
272. Fowler FJ, Gerstein BS, Barry MJ. How patient centered are medical decisions?: Results of a national survey. JAMA Intern Med. 2013;173(13):1215-21.
273. Couët N, Desroches S, Robitaille H, Vaillancourt H, Leblanc A, Turcotte S, et al. Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the OPTION instrument. Health Expect. 2015;18(4):542-61.
274. Brenner AT, Malo TL, Margolis M, Lafata JE, James S, Vu MB, et al. Evaluating shared decision making for lung cancer screening. JAMA Intern Med. 2018;178(10):1311-6.
275. Friedberg MW, Van Busum K, Wexler R, Bowen M, Schneider EC. A demonstration of shared decision making in primary care highlights barriers to adoption and potential remedies. Health Aff. 2013;32(2):268-75.
276. Waddell A, Lennox A, Spassova G, Bragge P. Barriers and facilitators to shared decision-making in hospitals from policy to practice: a systematic review. Implement Sci. 2021;16(1):1-23.
277. Apikoglu-Rabus S, Yesilyaprak G, Izzettin FV. Drug-related problems and pharmacist interventions in a cohort of patients with asthma and chronic obstructive pulmonary disease. Respir Med. 2016;120:109-15.
278. Alton S, Farndon L. The impact of community pharmacy-led medicines management support for people with COPD. Br J Community Nurs. 2018;23(6):214-9.
279. Pharmacists in primary care networks [Internet]. Royal College of General Practitioners. 2019 [cited 13 Feb 2023]. Available from: https://www.rcgp.org.uk/representing-you/policy-areas/pharmacists.
280. Baverstock M, Woodhall N, Maarman V. P94 Do healthcare professionals have sufficient knowledge of inhaler techniques in order to educate their patients effectively in their use? Thorax. 2010;65(Suppl 4):A117-A8.
281. Jackevicius CA, Chapman KR. Inhaler education for hospital-based pharmacists: how much is required? Can Respir J. 1999;6(3):237-44.
282. Resnick DJ, Gold RL, Lee-Wong M, Feldman BR, Ramakrishnan R, Davis WJ. Physician's metered dose inhaler technique after a single teaching session. Ann Allergy Asthma Immunol. 1996;76(2):145-8.
283. Coluccio M, Maguire P. Collaborative practice: Becoming a reality through primary nursing. Nurs Adm Q. 1983;7(4):59-63.
284. Vermeir P, Vandijck D, Degroote S, Peleman R, Verhaeghe R, Mortier E, et al. Communication in healthcare: a narrative review of the literature and practical recommendations. Int J Clin Pract. 2015;69(11):1257-67.

285. Weissenborn M, Haefeli WE, Peters-Klimm F, Seidling HM. Interprofessional communication between community pharmacists and general practitioners: a qualitative study. Int J Clin Pharm. 2017;39(3):495-506.
286. Hasan Ibrahim AS, Barry HE, Hughes CM. General practitioners' experiences with, views of, and attitudes towards, general practice-based pharmacists: a cross-sectional survey. BMC Prim Care. 2022;23(1):6.
287. Santschi V, Chiolero A, Burnand B, Colosimo AL, Paradis G. Impact of pharmacist care in the management of cardiovascular disease risk factors: a systematic review and meta-analysis of randomized trials. Arch Intern Med. 2011;171(16):1441-53.
288. Weeks G, George J, Maclure K, Stewart D. Non-medical prescribing versus medical prescribing for acute and chronic disease management in primary and secondary care. Cochrane Database Syst Rev. 2016;11(11):Cd011227.
289. Nabhani-Gebara S, Fletcher S, Shamim A, May L, Butt N, Chagger S, et al. General practice pharmacists in England: Integration, mediation and professional dynamics. Res Social Adm Pharm. 2020;16(1):17-24.
290. Butterworth J, Sansom A, Sims L, Healey M, Kingsland E, Campbell J. Pharmacists' perceptions of their emerging general practice roles in UK primary care: a qualitative interview study. Br J Gen Pract. 2017;67(662):e650.
291. Number of clinical pharmacists expected to work in PCNs rises to 7,500 by 2023/2024 - The Pharmaceutical Journal [Internet]. Pharmaceutical J. 2022 [cited 25 August 2022]. Available from: https://pharmaceutical-journal.com/article/news/number-of-clinical-pharmacists-expected-to-work-in-pcns-rises-to-7500-by-2023-2024.
292. Francetic I, Gibson J, Spooner S, Checkland K, Sutton M. Skill-mix change and outcomes in primary care: Longitudinal analysis of general practices in England 2015–2019. Soc Sci Med. 2022;308:115224.
293. O'Connor R, Mannix M, Mullen J, Powys L, Mannion M, Nolan HA, et al. Structured care of diabetes in general practice: a qualitative study of the barriers and facilitators. Irish medical journal. 2013;106 3:77-80.
294. Pinnock H, Huby G, Tierney A, Hamilton S, Powell A, Kielmann T, et al. Is multidisciplinary teamwork the key? A qualitative study of the development of respiratory services in the UK. J R Soc Med. 2009;102(9):378-90.
295. Wallman A, Vaudan C, Sporrong SK. Communications training in pharmacy education, 1995-2010. Am J Pharm Educ. 2013;77(2):36.
296. Pharmacists should have read and write access rights to patient records, says RPS - The Pharmaceutical Journal [Internet]. Pharmaceutical J. 2022 [cited 25 August 2022]. Available from: https://pharmaceutical-journal.com/article/news/pharmacists-should-have-read-and-write-access-rights-to-patient-records-says-rps.
297. Information Governance Framework for Integrated Health and Care: Shared Care Records [Internet]. 2022 [cited 25 August 2022]. Available from: https://transform.england.nhs.uk/information-governance/guidance/summary-of-information-governance-framework-shared-care-records.
298. Benson H, Lucas C, Williams KA. Establishing consensus for general practice pharmacist education: A Delphi study. Currents in pharmacy teaching & learning. 2020;12(1):8-13.
299. Jacobi J. Clinical pharmacists: practitioners who are essential members of your clinical care team. Revista Médica Clínica Las Condes. 2016;27(5):571-7.
300. Morcos P, Dalton K. Exploring pharmacists' perceptions of integrating pharmacists into the general practice setting. Exploratory Research in Clinical and Social Pharmacy. 2021;2:100027.
301. Alshehri AA, Cheema E, Yahyouche A, Haque MS, Jalal Z. Evaluating the role and integration of general practice pharmacists in England: a cross-sectional study. Int J Clin Pharm. 2021;43(6):1609-18.
302. Who director-general's opening remarks at the media briefing on COVID-19 - 11 march 2020 [Internet]. World Health Organization; 2020 [cited 2021Apr15]. Available from: https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-11-march-2020.

303. Gilchrist M, Wade P, Ashiru-Oredope D, Howard P, Sneddon J, Whitney L, et al. Antimicrobial Stewardship from Policy to Practice: Experiences from UK Antimicrobial Pharmacists. Infectious diseases and therapy. 2015;4(Suppl 1):51-64.
304. Buttery S, Philip KEJ, Williams P, Fallas A, West B, Cumella A, et al. Patient symptoms and experience following COVID-19: results from a UK-wide survey. BMJ Open Respiratory Research. 2021;8(1):e001075.
305. Emmerton LM, Smith L, LeMay KS, Krass I, Saini B, Bosnic-Anticevich SZ, et al. Experiences of community pharmacists involved in the delivery of a specialist asthma service in Australia. BMC health services research. 2012;12:164.
306. Subramanian A, Nirantharakumar K, Hughes S, Myles P, Williams T, Gokhale K, et al. Assessment of 115 symptoms for Long COVID (post-COVID-19 condition) and their risk factors in non-hospitalised individuals: a retrospective matched cohort study in UK primary care. Res Sq; 2022.
307. Gerayeli FV, Milne S, Cheung C, Li X, Yang CWT, Tam A, et al. COPD and the risk of poor outcomes in COVID-19: A systematic review and meta-analysis. eClinicalMedicine. 2021;33.
308. Guan WJ, Liang WH, Zhao Y, Liang HR, Chen ZS, Li YM, et al. Comorbidity and its impact on 1590 patients with COVID-19 in China: a nationwide analysis. Eur Respir J. 2020;55(5).
309. Alqahtani JS, Oyelade T, Aldhahir AM, Alghamdi SM, Almehmadi M, Alqahtani AS, et al. Prevalence, severity and mortality associated with COPD and smoking in patients with COVID-19: a rapid systematic review and meta-analysis. PloS One. 2020;15(5):e0233147.
310. Talic S, Shah S, Wild H, Gasevic D, Maharaj A, Ademi Z, et al. Effectiveness of public health measures in reducing the incidence of covid-19, SARS-CoV-2 transmission, and covid-19 mortality: systematic review and meta-analysis. BMJ. 2021;375:e068302.
311. Lawless M, Burgess M, Bourke S. Impact of COVID-19 on Hospital Admissions for COPD Exacerbation: Lessons for Future Care. Medicina. 2022;58(1).
312. Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Peer Reviewed: Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. Prev Chronic Dis. 2021;18.
313. McAuley H, Hadley K, Elneima O, Brightling CE, Evans RA, Steiner MC, et al. COPD in the time of COVID-19: an analysis of acute exacerbations and reported behavioural changes in patients with COPD. ERJ Open Res. 2021;7(1).
314. Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, et al. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. Lancet. 2020;395(10227):912-20.
315. Hedima EW, Adeyemi MS, Ikunaiye NY. Community Pharmacists: On the frontline of health service against COVID-19 in LMICs. Res Social Adm Pharm. 2021;17(1):1964-6.
316. Kretchy IA, Asiedu-Danso M, Kretchy J-P. Medication management and adherence during the COVID-19 pandemic: Perspectives and experiences from low-and middle-income countries. Res Social Adm Pharm. 2021;17(1):2023-6.
317. Khan Z, Muhammad K, Ahmed A, Rahman H. Coronavirus outbreaks: prevention and management recommendations. Drugs Ther Perspect. 2020:1-3.
318. Hughes O. EMIS makes GP Video Consultation Service Free in coronavirus fight [Internet]. Digital Health; 2020 [cited 19Aug 2021]. Available from: https://www.digitalhealth.net/2020/03/emis-makes-gp-video-consultation-service-free-in-coronavirus-fight.
319. Evans M. Covid-19 pandemic: What to do if you need to see a GP or get medication [Internet]. Patient; 2021 [cited 16 May 2021]. Available from: https://patient.info/news-and-features/covid-19-coronavirus-what-to-do-if-you-need-to-see-a-gp-or-get-medication.
320. Joy M, McGagh D, Jones N, Liyanage H, Sherlock J, Parimalanathan V, et al. Reorganisation of primary care for older adults during COVID-19: a cross-sectional database study in the UK. Br J Gen Pract. 2020;70(697):e540-e7.
321. Majeed A, Maile EJ, Bindman AB. The primary care response to COVID-19 in England's National Health Service. J R Soc Med. 2020;113(6):208-10.

322. Gerada C. Primary care has transformed into a 'dial-in' or 'click first' service [Internet]. Health Serv J; 2020 [cited 29 Mar 2021]. Available from: https://www.hsj.co.uk/technology-and-innovation/primary-care-has-transformed-into-a-dial-in-or-click-first-service/7027249.
323. Gerayeli FV, Milne S, Cheung C, Li X, Yang CWT, Tam A, et al. COPD and the risk of poor outcomes in COVID-19: A systematic review and meta-analysis. EClinicalMedicine. 2021;33:100789.
324. Ammar A, Brach M, Trabelsi K, Chtourou H, Boukhris O, Masmoudi L, et al. Šimunič B, Pišot R, Gaggioli A, Bailey SJ, Steinacker JM, Driss T, Hoekelmann A. 2020. Effects of COVID-19 home confinement on eating behaviour and physical activity: results of the ECLB-COVID19 international online survey. Nutrients. 2020;12(6):1583.
325. de Oliveira Neto L, Elsangedy HM, Tavares VD, Teixeira CV, Behm DG, Da Silva-Grigoletto ME. Training in home - home-based training during COVID-19 (SARS-COV2) pandemic: Physical exercise and behavior-based approach. Rev Bras Prescr Fisiol Exerc. 2020;19(2):9-19.
326. Houchen-Wolloff L, Steiner MC. Pulmonary rehabilitation at a time of social distancing: prime time for tele-rehabilitation? Thorax. 2020;75(6):446-447.
327. Mauro V, Lorenzo M, Paolo C, Sergio H. Treat all COVID 19-positive patients, but do not forget those negative with chronic diseases. Intern Emerg Med. 2020;15(5):787-90.
328. Chudasama YV, Gillies CL, Zaccardi F, Coles B, Davies MJ, Seidu S, et al. Impact of COVID-19 on routine care for chronic diseases: a global survey of views from healthcare professionals. Diabetes Metab Syndr. 2020;14(5):965-7.
329. McGowan A, Laveneziana P, Bayat S, Beydon N, Boros P, Burgos F, et al. International consensus on lung function testing during the COVID-19 pandemic and beyond. ERJ Open Res. 2022;8(1).
330. Next steps on transitioning from COVID-19 response to recovery [Internet]. NHS choices. NHS; [cited 15 Jul 2022]. Available from: https://www.england.nhs.uk/coronavirus/next-steps-on-transitioning-from-covid-19-response-to-recovery.
331. Cliffe S, Stevenson K. Patient experiences of virtual consultation during COVID 19: a musculoskeletal service evaluation. Musculoskeletal Care. 2021;19(3):380-3.
332. Vusirikala A, Ensor D, Asokan AK, Lee AJ, Ray R, Tsekes D, et al. Hello, can you hear me? Orthopaedic clinic telephone consultations in the COVID-19 era-a patient and clinician perspective. World J Orthop. 2021;12(1):24.
333. Gilbert AW, Mentzakis E, May CR, Stokes M, Jones J. Patient preferences for use of virtual consultations in an orthopaedic rehabilitation setting: Results from a discrete choice experiment. J Health Serv Res Policy. 2022;27(1):62-73.
334. Jones MT, Arif R, Rai A. Patient experiences with telemedicine in a national health service rheumatology outpatient department during coronavirus disease-19. J Patient Exp. 2021;8:23743735211034973.
335. Raynor DT. Health literacy. BMJ. 2012;344:e2188.
336. Parker S, Prince A, Thomas L, Song H, Milosevic D, Harris MF. Electronic, mobile and telehealth tools for vulnerable patients with chronic disease: a systematic review and realist synthesis. BMJ open. 2018;8(8):e019192.
337. Bryce C, O'Connell MD, Dale J, Underwood M, Atherton H. Online and telephone access to general practice: a cross-sectional patient survey. BJGP open. 2021;5(4).
338. Donaghy E, Atherton H, Hammersley V, McNeilly H, Bikker A, Robbins L, et al. Acceptability, benefits, and challenges of video consulting: a qualitative study in primary care. Br J Gen Pract. 2019;69(686):e586-e94.
339. Greenhalgh T, Rosen R. Remote by default general practice: must we, should we, dare we? Br J Gen Pract; 2021;71(705):149-150.
340. Press VG, Pincavage AT, Pappalardo AA, Baker DC, Conwell WD, Cohen JC, et al. The Chicago Breathe Project: a regional approach to improving education on asthma inhalers for resident physicians and minority patients. J Natl Med Assoc. 2010;102(7):548-55.
341. NHS Long Term Plan [Internet]. NHS choices. NHS; 2019 [cited 10 Sep 2019]. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/08/nhs-long-term-plan-version-1.2.pdf.

342. Evidence review for effectiveness of approaches and activities to increase engagement in shared decision making and the barriers and facilitators to engagement. [Internet]. NICE. 2021. [cited 15 May 2022]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK572433/
343. Pluye P, Gagnon M-P, Griffiths F, Johnson-Lafleur J. A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in mixed studies reviews. Int J Nurs Stud. 2009;46(4):529-46.
344. Stern C, Lizarondo L, Carrier J, Godfrey C, Rieger K, Salmond S, et al. Methodological guidance for the conduct of mixed methods systematic reviews. JBI Evid Synth. 2020;18(10).
345. Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, Welch VA. Cochrane Handbook for Systematic Reviews of Interventions. 2nd edition. Chichester (UK): John Wiley & Sons, 2019.
346. Downes MJ, Brennan ML, Williams HC, Dean RS. Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS). BMJ open. 2016;6(12):e011458.
347. Allen MS, Walter EE, Swann C. Sedentary behaviour and risk of anxiety: A systematic review and meta-analysis. Journal of Affective Disorders. 2019;242:5-13.
348. Wong JN, McAuley E, Trinh L. Physical activity programming and counseling preferences among cancer survivors: a systematic review. Int J Behav Nutr Phys Act. 2018;15(1):48.
349. Critical Appraisal Skills Programme. CASP checklist [Internet] Oxford: CASP UK; 2018 [Available from: https://casp-uk.net/wp-content/uploads/2018/01/CASP-Systematic-Review-Checklist_2018.pdf.
350. Pace R, Pluye P, Bartlett G, Macaulay AC, Salsberg J, Jagosh J, et al. Testing the reliability and efficiency of the pilot Mixed Methods Appraisal Tool (MMAT) for systematic mixed studies review. Int J Nurs Stud. 2012;49(1):47-53.
351. Bloomfield JG, While AE, Roberts JD. Using computer assisted learning for clinical skills education in nursing: integrative review. J Adv Nurs. 2008;63(3):222-35.
352. Rowe M, Frantz J, Bozalek V. The role of blended learning in the clinical education of healthcare students: a systematic review. Medical teacher. 2012;34(4):e216-21.
353. Lucas PJ, Baird J, Arai L, Law C, Roberts HM. Worked examples of alternative methods for the synthesis of qualitative and quantitative research in systematic reviews. BMC Med Res Methodol. 2007;7(1):1-7.
354. Dixon-Woods M, Agarwal S, Jones D, Young B, Sutton A. Synthesising qualitative and quantitative evidence: a review of possible methods. J Health Serv Res Policy. 2005;10(1):45-53.
355. Noyes J, Booth A, Flemming K, Garside R, Harden A, Lewin S, et al. Cochrane Qualitative and Implementation Methods Group guidance series-paper 3: methods for assessing methodological limitations, data extraction and synthesis, and confidence in synthesized qualitative findings. J Clin Epidemiol. 2018;97:49-58.
356. Chong WW, Aslani P, Chen TF. Shared decision-making and interprofessional collaboration in mental healthcare: a qualitative study exploring perceptions of barriers and facilitators. J Interprof Care. 2013;27(5):373-9.
357. Harris K, Brooks H, Lythgoe G, Bee P, Lovell K, Drake RJ. Exploring service users', carers' and professionals' perspectives and experiences of current antipsychotic prescribing: A qualitative study. Chronic Illness. 2017;13(4):275-87.
358. Rosenberg-Yunger ZRS, Verweel L, Gionfriddo MR, MacCallum L, Dolovich L. Community pharmacists' perspectives on shared decision-making in diabetes management. Int J Pharm Pract. 2018;26(5):414-22.
359. Verweel L, Gionfriddo MR, MacCallum L, Dolovich L, Rosenberg-Yunger ZRS. Community Pharmacists' Perspectives of a Decision Aid for Managing Type 2 Diabetes in Ontario. Can J Diabetes. 2017;41(6):587-95.
360. Aljumah K, Hassali MA. Impact of pharmacist intervention on adherence and measurable patient outcomes among depressed patients: a randomised controlled study. BMC psychiatry. 2015;15:219.
361. Moin T, Duru OK, Turk N, Chon JS, Frosch DL, Martin JM, et al. Effectiveness of Shared Decision-making for Diabetes Prevention: 12-Month Results from the Prediabetes Informed Decision and Education (PRIDE) Trial. J Gen Intern Med. 2019;34(11):2652-9.

362. Whitley HP, Smith WD, Hanson C, Parton JM. Interdisciplinary speed dating augments diabetes self-management education and support to improve health outcomes. Patient Educ Couns. 2020;103(11):2305-11.
363. Khalil V, Blackley S, Subramaniam A. Evaluation of a pharmacist-led shared decision-making in atrial fibrillation and patients' satisfaction-a before and after pilot study. Ir J Med Sci. 2020.
364. Chung MC, Juang WC, Li YC. Perceptions of shared decision making among health care professionals. J Eval Clin Pract. 2019;25(6):1080-7.
365. Schafer KM, Gionfriddo MR, Boehm DH. Shared decision making and medication therapy management with the use of an interactive template. J Am Pharm Assoc. 2016;56(2):166-72.
366. Kayyali R, Gebara SN, Hesso I, Funnell G, Naik M, Mason T, et al. Shared decision making and experiences of patients with long-term conditions: has anything changed? BMC Health Serv Res. 2018;18(1):763.
367. Weiss MC, Platt J, Riley R, Chewning B, Taylor G, Horrocks S, et al. Medication decision making and patient outcomes in GP, nurse and pharmacist prescriber consultations. Prim Health Care Res Dev. 2015;16(5):513-27.
368. Lauffenburger JC, Ghazinouri R, Jan S, Makanji S, Ferro CA, Lewey J, et al. Impact of a novel pharmacist-delivered behavioral intervention for patients with poorly-controlled diabetes: The ENhancing outcomes through Goal Assessment and Generating Engagement in Diabetes Mellitus (ENGAGE-DM) pragmatic randomized trial. PLoS One. 2019;14(4):e0214754.
369. Simmons M, Hetrick S, Jorm A. Shared decision-making: benefits, barriers and current opportunities for application. Australas Psychiatry. 2010;18(5):394-7.
370. Carter WB, Inui TS, Kukull WA, Haigh VH. Outcome-based doctor-patient interaction analysis: II. Identifying effective provider and patient behavior. Med Care. 1982:550-66.
371. Roter DL. Which facets of communication have strong effects on outcome-a meta-analysis. Nurs Stand. 1989:183-96.
372. Ong LM, De Haes JC, Hoos AM, Lammes FB. Doctor-patient communication: a review of the literature. Soc Sci Med. 1995;40(7):903-18.
373. Milky G, Thomas J. Shared decision making, satisfaction with care and medication adherence among patients with diabetes. Patient Educ Couns. 2020;103(3):661-9.
374. Scholl I, LaRussa A, Hahlweg P, Kobrin S, Elwyn G. Organizational- and system-level characteristics that influence implementation of shared decision-making and strategies to address them — a scoping review. Implement. Sci. 2018;13(1):40.
375. Elwyn G, Frosch DL, Kobrin S. Implementing shared decision-making: consider all the consequences. Implement Sci. 2016;11(1):114.
376. Légaré F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. Patient Educ Couns. 2008;73(3):526-35.
377. Singh Ospina N, Phillips KA, Rodriguez-Gutierrez R, Castaneda-Guarderas A, Gionfriddo MR, Branda ME, et al. Eliciting the Patient's Agenda- Secondary Analysis of Recorded Clinical Encounters. J Gen Intern Med. 2019;34(1):36-40.
378. Kiesler DJ, Auerbach SM. Optimal matches of patient preferences for information, decision-making and interpersonal behavior: evidence, models and interventions. Patient Educ Couns. 2006;61(3):319-41.
379. Tamirisa NP, Goodwin JS, Kandalam A, Linder SK, Weller S, Turrubiate S, et al. Patient and physician views of shared decision making in cancer. Health Expect. 2017;20(6):1248-53.
380. Schulman-Green DJ, Naik AD, Bradley EH, McCorkle R, Bogardus ST. Goal setting as a shared decision making strategy among clinicians and their older patients. Patient Educ Couns. 2006;63(1-2):145-51.
381. Hack TF, Degner LF, Watson P, Sinha L. Do patients benefit from participating in medical decision making? Longitudinal follow-up of women with breast cancer. Psycho-Oncology. 2006;15(1):9-19.

382. Hughes TM, Merath K, Chen Q, Sun S, Palmer E, Idrees JJ, et al. Association of shared decision-making on patient-reported health outcomes and healthcare utilization. Am J Surg. 2018;216(1):7-12.
383. Thomas EC, Ben-David S, Treichler E, Roth S, Dixon LB, Salzer M, et al. A systematic review of shared decision–making interventions for service users with serious mental illnesses: state of the science and future directions. Psychiatr Serv. 2021;72(11):1288-300.
384. Loh A, Simon D, Hennig K, Hennig B, Härter M, Elwyn G. The assessment of depressive patients' involvement in decision making in audio-taped primary care consultations. Patient Educ Couns. 2006;63(3):314-8.
385. Torrey WC, Drake RE. Practicing shared decision making in the outpatient psychiatric care of adults with severe mental illnesses: redesigning care for the future. Community Ment Health J. 2010;46(5):433-40.
386. Lafata JE, Morris HL, Dobie E, Heisler M, Werner RM, Dumenci L. Patient-reported use of collaborative goal setting and glycemic control among patients with diabetes. Patient Educ Couns. 2013;92(1):94-9.
387. Charles CA, Whelan T, Gafni A, Willan A, Farrell S. Shared Treatment Decision Making: What Does It Mean to Physicians? J Clin Oncol. 2003;21(5):932-6.
388. Thornton H. Evidence-based health care: what roles for patients? Shared Decision-making in Health Care. New York (US); Oxford University Press; 2009:37-41.
389. Wagner EH, Austin BT, Davis C, Hindmarsh M, Schaefer J, Bonomi A. Improving Chronic Illness Care: Translating Evidence Into Action. Health Aff. 2001;20(6):64-78.
390. Mistler LA, Drake RE. Shared decision making in antipsychotic management. J Psychiatr Pract. 2008;14(6):333-44.
391. Schoenfeld EM, Goff SL, Elia TR, Khordipour ER, Poronsky KE, Nault KA, et al. The Physician-as-Stakeholder: An Exploratory Qualitative Analysis of Physicians' Motivations for Using Shared Decision Making in the Emergency Department. Acad Emerg Med. 2016;23(12):1417-27.
392. Thompson JS, Matlock DD, Morris MA, McIlvennan CK, Allen LA. Organic Dissemination and Real-World Implementation of Patient Decision Aids for Left Ventricular Assist Device. MDM Policy Pract. 2018;3(1):2381468318767658.
393. Müller E, Strukava A, Scholl I, Härter M, Diouf NT, Légaré F, et al. Strategies to evaluate healthcare provider trainings in shared decision-making (SDM): a systematic review of evaluation studies. BMJ Open. 2019;9(6):e026488.
394. Michgelsen J, Glimmerveen LM, Pittens CA, Minkman MM. Decision-Making Dilemmas within Integrated Care Service Networks: A Systematic Literature Review. Int J Integr Care. 2022;22(4).
395. Community Pharmacy at a glance 2021: Regulation, scope of Practice, remuneration, and distribution of medicines through community pharmacy premises and other outlets (2021) [Internet]. FIP Development Goals. 2022 [cited 12 Jan 2023]. Available from: https://developmentgoals.fip.org/resources/community-pharmacy-at-a-glance-2021-regulation-scope-of-practice-remuneration-and-distribution-of-medicines-through-community-pharmacy-premises-and-other-outlets-2021.
396. Kritikos VS, Reddel HK, Bosnic-Anticevich SZ. Pharmacists' perceptions of their role in asthma management and barriers to the provision of asthma services. Int J Pharm Pract. 2010;18(4):209-16.
397. René-Henri N, Khamla Y, Nadaira N, Ouellet C, Blais L, Lalonde L, et al. Community pharmacists' interventions in asthma care: a descriptive study. Ann Pharmacother. 2009;43(1):104-11.
398. Emiru YK, Hammeso WW, Adelo ES, Siraj EA, Bizuneh GK, Adamu BA, et al. Role of community pharmacists in educating asthmatic patients: A multi-centered cross-sectional study in Ethiopia. Chron Respir Dis. 2020;17:1479973120952679.
399. Scahill S. Barriers to effective pharmacy practice in low-and middle-income countries. Integr Pharm Res Pract. 2014;3:25.
400. Nunes-da-Cunha I, Arguello B, Martinez FM, Fernandez-Llimos F. A Comparison of Patient-Centered Care in Pharmacy Curricula in the United States and Europe. Am J Pharm Educ. 2016;80(5):83.

401. Roberts J, Jaam M, Paudyal V, Hadi MA. Minimizing prescribing errors: A phenomenological exploration of the views and experiences of independent prescribing pharmacists. Br J Clin Pharmacol. 2023; 1-10.
402. Doucette WR, Nevins JC, Gaither C, Kreling DH, Mott DA, Pedersen CA, et al. Organizational factors influencing pharmacy practice change. Res Social Adm Pharm. 2012;8(4):274-84.
403. Zimmerman E, Woolf SH. Understanding the relationship between education and health. NAM Perspectives. 2014;4(6).
404. Bhattarai B, Walpola R, Mey A, Anoopkumar-Dukie S, Khan S. Barriers and Strategies for Improving Medication Adherence Among People Living With COPD: A Systematic Review Respir Care. 2020;65(11):1738.
405. Jia X, Zhou S, Luo D, Zhao X, Zhou Y, Cui YM. Effect of pharmacist-led interventions on medication adherence and inhalation technique in adult patients with asthma or COPD: A systematic review and meta-analysis. J Clin Pharm Ther. 2020;45(5):904-17.
406. Smith IJ. The Joint Commission Guide to improving staff communication. 2nd ed. Oakbrook Terrace (US): Joint Commission Resources; 2009.
407. Christensen C, Larson JR, Jr. Collaborative medical decision making. Med Decis Making. 1993;13(4):339-46.
408. Singleton JK, Green-Hernandez C. Interdisciplinary Education and Practice: Has Its Time Come? J Nurse Midwifery. 1998;43(1):3-7.
409. Catlett C, Halper A. Team approaches: working together to improve quality. Qual Improv Digest. 1992:1.
410. Sim TF, Hattingh HL, Sunderland B, Czarniak P. Effective communication and collaboration with health professionals: A qualitative study of primary care pharmacists in Western Australia. PLoS One. 2020;15(6):e0234580.
411. The Vale of Leven Hospital Inquiry Report [Internet]. 2014 [cited 11 Jan 2023]. Available from: https://hub.careinspectorate.com/media/1415/vale-of-leven-hospital-inquiry-report.pdf.
412. Access improvement support [Internet]. NHS choices. NHS; [cited 13 Jan 2023]. Available from: https://www.england.nhs.uk/gp/improvement-support/access-improvement-support.
413. Pharmacy leaders urge Rishi Sunak to invest in Sector [Internet]. PSNC Website. 2023 [cited 13 Feb 2023]. Available from: https://psnc.org.uk/wp-content/uploads/2023/01/Pharmacy-Letter-to-Prime-Minister_January-2023.pdf.
414. Torjesen I. Access to patient records: Britain lags behind other countries [Internet]. Pharmaceutical J. 2021 [cited 12 Jan 2023]. Available from: https://pharmaceutical-journal.com/article/feature/access-to-patient-records-britain-lags-behind-other-countries.

Appendices

Appendix 1: Cross-sectional study ethical approval

Subject: Application for Ethical Review ERN_20-0315
Date: Monday, 20 April 2020 at 3:26:48 PM British Summer Time
From: Susan Cottam (Research Support Services)
To: Rachel Jordan (Institute of Applied Health Research)
CC: Andy Dickens (Applied Health Research), James Hodgkinson (Applied Health Research), Abdullah Aljahan (PhD App Health Resea FT (A900))
Attachments: image001.jpg

Dear Dr Jordan

Re: "Cross-sectional study with community pharmacists across the UK to assess knowledge, attitudes and skills and obtain their views on potential interventions to improve medication adherence among COPD patients"
Application for Ethical Review ERN_20-0315

Thank you for your application for ethical review for the above project, which was reviewed by the Science, Technology, Engineering and Mathematics Ethical Review Committee.

On behalf of the Committee, I confirm that this study now has full ethical approval.

I would like to remind you that any substantive changes to the nature of the study as described in the Application for Ethical Review, and/or any adverse events occurring during the study should be promptly brought to the Committee's attention by the Principal Investigator and may necessitate further ethical review.

Please also ensure that the relevant requirements within the University's Code of Practice for Research and the information and guidance provided on the University's ethics webpages (available at https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Links-and-Resources.aspx) are adhered to and referred to in any future applications for ethical review. It is now a requirement on the revised application form (https://intranet.birmingham.ac.uk/finance/accounting/Research-Support-Group/Research-Ethics/Ethical-Review-Forms.aspx) to confirm that this guidance has been consulted and is understood, and that it has been taken into account when completing your application for ethical review.

Please be aware that whilst Health and Safety (H&S) issues may be considered during the ethical review process, you are still required to follow the University's guidance on H&S and to ensure that H&S risk assessments have been carried out as appropriate. For further information about this, please contact your School H&S representative or the University's H&S Unit at healthandsafety@contacts.bham.ac.uk.

Kind regards

Susan Cottam
Research Ethics Manager
Research Support Group
C Block Dome
Aston Webb Building
University of Birmingham
Edgbaston B15 2TT
Tel:
Email:
Web: https://intranet.birmingham.ac.uk/finance/RSS/Research-Support-Group/integrity-ethics-governance/Research-Ethics/index.aspx

Appendix 2: Community pharmacists' invitation letter and PIS

UNIVERSITY OF BIRMINGHAM

INVITATION LETTER

Dear <colleague>,

Research study to assess the role of the community pharmacist in optimising the medication of COPD patients

We are writing to invite you take part in a short research study about improving the adherence of COPD patients to their inhaled medication, and particularly about exploring the role of the community pharmacist in this.

We realise that the COVID-19 pandemic is uppermost in your minds and you may not be able to participate, but if you are able to take the time we would be grateful. The research consists of a short survey to describe your current practice in the management of COPD patients and your views on how best to help COPD patients choose, understand and use their medications. Please find (attached) the participant information sheet for further information. The survey is completely anonymous, and will take around 15 minutes to complete.

As a token of appreciation, there is an opportunity for you to enter **a prize draw and win an Apple iPad**. In order to enter the competition, you will need to submit your contact details on the final page of the questionnaire, but your answers will be unlinked to your details.

Please click on the link to access the online questionnaire:

https://bham.onlinesurveys.ac.uk/cp-adh-copd

In order to be eligible for the prize draw, please return your questionnaire by 30/01/2021

Thank you for taking part; your response is important in order to gauge views from a representative sample of community pharmacists. Please contact me if you have any queries.

Kind regards

Abdullah Aljahan

PhD student

University of Birmingham

Rachel Jordan

Reader in Epidemiology & Primary Care

University of Birmingham

A survey to assess the role of the community pharmacist in optimising the medication of COPD patients.

Invitation and brief summary

Inhaler medications for COPD patients are an essential part of their treatment, but we know that adherence is sub-optimal, thus limiting the potential benefit. Patients may find it difficult to understand how and when to take their inhalers, or their long-term benefits. The community pharmacist is encouraged to play a stronger role in helping patients to choose, understand and use their medications. We want to understand current practice and obtain your views on how best to perform this role. This will enable us to consider possible interventions to support your practice.

What is involved?

You are invited to participate in this first research study, which is a short questionnaire to describe your knowledge and current practice in the management of COPD patients and your views on how best to help COPD patients choose, understand and use their medications. The survey is completely anonymous, and will take around 15 minutes to complete.

As a token of appreciation, there is an opportunity for you to enter **a prize draw and win an Apple iPad**. In order to enter the competition, you will need to submit your contact details on the final page of the questionnaire, but your answers will be not linked to your details.

Your consent will be implied through the completion of this questionnaire. You can withdraw consent at any time by exiting the survey before the end. It will not be possible to provide individuals with feedback as the data collection is anonymous. All data will be anonymised and securely stored, within the University of Birmingham IT systems and in accordance with GDPR rules and policies. All submitted personal email addresses will be destroyed once the iPad winner has been notified. This means that once you submit your anonymous responses you are then unable to withdraw your data from the study.

What are the benefits of participating?

This will encourage us to gain a broader understanding the role of the community pharmacist in optimising the medication of COPD patients and what this role can do nationally. This will enable us to take possible measures to help your practice that are very helpful to COPD patients and other healthcare professionals.

What are the possible disadvantages and risks of taking part?

As the survey is not provided with any personally identifiable information, it is entirely anonymous and confidential. The involvement in this research involves no risks.

Where can I find more information?

Ethical approval for this study (Ref. number: ERN_20-0315) was obtained from the University of Birmingham ethics committee. Tel: 0121414803?

For further information, please contact: **Abdullah Aljahan** (BSc, MSc-HCM)

PhD Student – University of Birmingham, Institute of Applied Health Research

Email:

Appendix 3: The Theoretical Domains Framework (TDF)

The Refined Theoretical Domains Framework

Reproduced from Cane, Connor & Michie, *Implementation Science*, 2012

Domain/Definition*	Constructs
Knowledge *An awareness of the existence of something*	- Knowledge (including knowledge of condition/ scientific rationale) - Procedural knowledge - Knowledge of task environment
Skills *An ability or proficiency acquired through practice*	- Skills - Skills development - Competence - Ability - Interpersonal skills - Practice - Skill assessment
Social/Professional Role and Identity *A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting*	- Professional identity - Professional role - Social identity - Identity - Professional boundaries - Professional confidence - Group identity - Leadership - Organisational commitment
Beliefs about Capabilities *Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use*	- Self-confidence - Perceived competence - Self-efficacy - Perceived behavioural control - Beliefs - Self-esteem - Empowerment - Professional confidence
Optimism *The confidence that things will happen for the best or that desired goals will be attained*	- Optimism - Pessimism - Unrealistic optimism - Identity
Beliefs about Consequences *Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation*	- Beliefs - Outcome expectancies - Characteristic of outcome expectancies - Anticipated regret - Consequents
Reinforcement *Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus*	- Rewards (proximal/distal, valued/not valued, probably/improbable) - Incentives - Punishment - Consequents - Reinforcement - Contingencies - Sanctions
Intentions *A conscious decision to perform a behaviour or a resolve to act in a certain way*	- Stability of intentions - Stages of change model - Transtheoretical model and stages of change
Goals *Mental representations of outcomes or end states that an individual wants to achieve*	- Goals (distal/proximal) - Goal priority - Goal/target setting - Goals (autonomous/controlled) - Action planning - Implementation intention
Memory, Attention and Decision Processes *The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives*	- Memory - Attention - Attention control - Decision making - Cognitive overload/tiredness
Environmental Context and Resources *Any circumstance of a persons' situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour*	- Environmental stressors - Resources/material resources - Organisational culture/climate - Salient events/critical incidents - Person x environment interaction - Barriers and facilitators
Social Influences *Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours*	- Social pressure - Social norms - Group conformity - Social comparisons - Group norms - Social support - Power - Intergroup conflict - Alienation - Group identity - Modelling
Emotion *A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event*	- Fear - Anxiety - Affect - Stress - Depression - Positive/negative affect - Burn-out
Behavioural Regulation *Anything aimed at managing or changing objectively observed or measured actions*	- Self-monitoring - Breaking habit - Action planning

Appendix 4: Survey questions linked to TDF

Questions	TDF domains
The main source of your current knowledge about inhaler use is:	*Knowledge*
What extent you are aware of the different inhaler devices available:	
Please identify the Dry Powder inhaler (DPI) devices from the following list:	
Patients can stop taking their long-acting breathing medications (inhalers) when their COPD symptoms get better.	
In your opinion, the most important step for correct pressurized metered-dose inhaler (pMDI) inhalation is:	
When using the pressurized metered-dose inhaler (pMDI), a rapid inspiration is recommended.	
Spacer use results in a significant reduction in the amount of aerosol that is deposited in the mouth and throat.	
In your opinion, the most important step for correct dry powder inhaler (DPI) inhalation is:	
It is OK if the patient does not feel the dry powder inhaler (DPI) powder go down.	
How long should you tell patients to wait before taking a second puff?	
How long should you tell patients to hold their breath after taking a puff?	
How often should you tell patients to clean their spacer?	
How often should you tell patients to clean their DPI mouthpiece?	
Inhaled steroid effectiveness is improved by taking a β-agonist first.	
When health care practitioners prescribe an inhaler device, which of the following variables do you consider the most important?	
Which inhaled device is most commonly prescribed in your pharmacy for COPD patients.	*Skills*
Which inhaled device is the second most commonly prescribed in your pharmacy for COPD patients.	
Do you provide input into the choice of device for COPD patients in your community?	
Please indicate the electronic devices you use to check inhaler technique from the following list:	
When dispensing an inhaler device, do you assess the patients' inhalation technique?	
How often you use the electronic devices to check inhaler technique for COPD patients?	
At your pharmacy, who trains the patients on the inhalation technique of the prescribed device?	
Do you check at least once a year the inhalation technique used by your patients treated with inhaled therapy?	
What tools do you use when counselling or conducting services like MUR or NMS for COPD patients?	
What educational material, if any, do you provide to patients to take home?	
As a pharmacist, regular checking inhaler technique and intervening where necessary would be useful to optimise inhaler adherence in COPD patients.	
As a pharmacist, additional training to develop the knowledge needed for the new pharmaceutical services is important to provide better services for COPD patients.	

Questions	TDF domains
It is meaningful to provide counselling for COPD patients to improve adherence.	*Beliefs about Capabilities*
The Pharmacist may be able to support COPD patients to improve the self-management of their disease.	
In the treatment pathway for patients with COPD, the pharmacist should have an important role in advising patients on which type of inhalers they should use.	*Social/Professional Role and Identity*
The pharmacist should have an important role in educating patients on how to use their inhalers.	
The pharmacist should have an important role in monitoring patients' adherence to inhalers.	
Can you think of ways in which community pharmacists and GPs could work more closely together to optimise inhaler use among COPD patients? Please specify in your own words	
When dispensing an inhaler device, do you assess the patients' inhalation technique?	
How often you use the electronic devices to check inhaler technique for COPD patients?	
It would be useful to assistant pharmacists to play a role in improving inhaler adherence in COPD patients.	
As a pharmacist, the main barriers to providing input on the choice of the inhaler are:	*Environmental Context and Resources*
As a pharmacist, better electronic communication system with primary care would improve inhaler adherence among COPD patients.	
As a pharmacist, better methods (e.g. Point-of-care meters –FeNO-) would help to monitor the use of both maintenance and rescue medications.	
As a pharmacist, better access to patients' medical records would improve inhaler adherence in COPD patients.	
As a pharmacist, the approaches to improve inhaler adherence in COPD patients:	*Memory, Attention and Decision Processes* *Beliefs about Capabilities* *Skills* *Social influence*
As a pharmacist, financial incentives are important to provide better services for COPD patients.	*Reinforcement*
How do you perceive patients' acceptance of the services offered in your pharmacy? Please specify in your own words	*Beliefs about Consequences*

Appendix 5: Cross-sectional survey

UNIVERSITY OF BIRMINGHAM

Community pharmacist interventions to improve inhaler adherence amongst COPD patients: a cross-sectional survey

A survey to assess the role of the community pharmacist in optimising the inhaled medication adherence amongst COPD patients.

Are you a pharmacist working in the community with a minimum of 3 months experience?

- ☐ Yes
- ☐ NO

Brief participant information

Inhaler medications for COPD patients are an essential part of their treatment, but we know that adherence is sub-optimal, thus limiting the potential benefit. Patients may find it difficult to understand how and when to take their inhalers, or their long-term benefits. The community pharmacist is encouraged to play a stronger role in helping patients to choose, understand and use their medications. We want to understand current practice and obtain your views on how best to perform this role. This will enable us to consider possible interventions to support your practice. This study forms part of a PhD award, being supervised by Dr Rachel Jordan, Dr Andy Dickens, and Dr James Hodgkinson and has been awarded ethical approval from the University of Birmingham.

As a practising community pharmacist, you are being asked to complete a short questionnaire on your usual practice and your views about how pharmacists can best support COPD patients. The survey is entirely anonymous. Please provide responses about your usual practice in non-pandemic times.

As a token of appreciation, there is an opportunity for you to enter **a prize draw and win an Apple iPad**. To enter the competition, you will need to submit your desired contact email address on the final page of the questionnaire. This is not linked to your survey data, meaning your answers will remain anonymous. If you wish to remove your 'opt-in' to the competition after you have submitted your email details, please email the study contact (below) within one week of survey completion.
Please only complete one questionnaire.
Please do not spend too long thinking about your answers. The questionnaire is made up of three sections and should take no longer than 15 minutes to complete. You do not have to answer the whole questionnaire at once, and can return to it at a later stage. You need to click "Finish later" at the bottom of the pages to do this before exiting the survey.
Your consent will be implied through the completion of this questionnaire. You can withdraw consent at any time by exiting the survey before the end. All data will be anonymised and securely stored, within the University of Birmingham IT systems and in accordance with GDPR rules and policies. All submitted personal email addresses will be destroyed once the iPad winner has been notified (approximately 24 weeks after study commencement). This means that once you submit your anonymous responses, you are then unable to withdraw your data from the study. The results from this study will be analysed and written up and published.

Thanks again your participation in this research and completing the questionnaire at this difficult time. If you have any queries or concerns about this study, please contact:

Abdullah Aljahan
(BSc, MSc-HCM) PhD Student – University of Birmingham, Institute of Applied Health Research
Email: [redacted]

Section one: About you and your pharmacy

Please indicate your sex: *Required*

- ☐ Male
- ☐ Female
- ☐ Prefer not to say

What is your age? *Required*

- ☐ 20-29
- ☐ 30-39
- ☐ 40-49
- ☐ 50-59
- ☐ 60-69

What is the highest level of education that you hold? *Required*

- ☐ Diploma
- ☐ Bachelors degree
- ☐ Masters degree
- ☐ PhD
- ☐ Other

What (if any) respiratory qualification do you hold? *Required*

- ☐ Diploma in Respiratory Medicine
- ☐ Masters in Respiratory Medicine
- ☐ COPD specialist pharmacists
- ☐ Asthma specialist pharmacists
- ☐ ARTP qualifications
- ☐ Respiratory Disease Management
- ☐ Other
- ☐ None of these

How many years of experience do you have as a pharmacist? *Required*

- ☐ <1 year
- ☐ 1-4 years
- ☐ 5-9 years
- ☐ 10-14 years
- ☐ ≥15 years

What is your current job title? *Required*

- ☐ Assistant pharmacist
- ☐ Pharmacist
- ☐ Senior pharmacist
- ☐ Consultant pharmacist
- ☐ Other

Please indicate your ethnicity: *Required*

- ☐ White
- ☐ Mixed/Multiple ethnic groups
- ☐ Asian/Asian British
- ☐ Black/ African/Caribbean/Black British
- ☐ Other ethnic group
- ☐ Prefer not to say

Please provide the health region of your pharmacy? *Required*

- ☐ London
- ☐ East of England
- ☐ South East
- ☐ South West
- ☐ West Midlands
- ☐ East Midlands
- ☐ North East
- ☐ North West
- ☐ Yorkshire and the Humber
- ☐ Wales
- ☐ Scotland
- ☐ Northern Ireland

Please indicate the type of your pharmacy: *Required*

- ☐ Independent
- ☐ Chain
- ☐ Other

Please indicate the average number of prescriptions per day: *Required*

- ☐ 1-50 prescriptions per day
- ☐ 51-99 prescriptions per day
- ☐ 100-199 prescriptions per day
- ☐ 200-299 prescriptions per day
- ☐ ≥300 prescriptions per day

What is your current working pattern? *Required*

- ☐ Full-time
- ☐ Part-time

Is your pharmacy located in or adjacent to a primary care practice? *Required*

- ☐ Yes, within primary care practice
- ☐ Yes, adjacent to primary care practice
- ☐ Neither

What services do your pharmacy usually offer for COPD patients? **(TICK ANY THAT APPLY)** *Required*

- ☐ Medication use review (MUR)
- ☐ New medicine service (NMS)
- ☐ Vaccination
- ☐ Smoking cessation service
- ☐ Inhaler technique training
- ☐ Pulmonary rehabilitation referral
- ☐ Other

Section two: Your current knowledge, and practice about COPD inhaler medication

Instructions: Please respond to the following questions, statements, and true/false statements.

CURRENT KNOWLEDGE:

The main source of your current knowledge about inhaler use is: **(TICK ANY THAT APPLY)** *Required*

- ☐ From your formal education e.g. University course
- ☐ From a specialist website
- ☐ From the Right Breathe app
- ☐ From attendance at meetings, courses, or workshops organized by pharmaceutical companies or scientific societies
- ☐ From reading the inhaler device leaflet
- ☐ From personal experience and common sense
- ☐ Other

What extent you are aware of the different inhaler devices available? **(CHOOSE ONE OPTION)** *Required*

- ☐ Not at all aware
- ☐ Slightly aware
- ☐ Moderately aware
- ☐ Very aware
- ☐ Extremely aware

Please identify all of the **Dry Powder inhaler (DPI)** devices from the following list: **(TICK ANY THAT APPLY)** *Required*

- ☐ Accuhaler™
- ☐ Autohaler™
- ☐ Breezhaler™
- ☐ Handihaler™
- ☐ Nexthaler™
- ☐ Novolizer™
- ☐ Respimat™
- ☐ Twithaler™
- ☐ pMDI
- ☐ Easi-Breathe™
- ☐ Ellipta™
- ☐ Genuair™
- ☐ Easyhaler™
- ☐ Turbohaler™
- ☐ I do not know

Patients can stop taking their long-acting inhalers when their COPD symptoms get better. **(CHOOSE ONE OPTION)** *Required*

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

In your opinion, the most important step for correct pressurized metered-dose inhaler (pMDI) inhalation is: **(CHOOSE ONE OPTION)** *Required*

- ☐ To shake the device before inhalation
- ☐ To exhale deeply before inhalation
- ☐ To fire the device during inhalation
- ☐ To inhale deeply and forcefully
- ☐ To inhale slowly and progressively
- ☐ I do not know

When using the pressurized metered-dose inhaler (pMDI), a rapid inspiration is recommended? **(CHOOSE ONE OPTION)** *Required*

- ☐ True
- ☐ False
- ☐ I do not know

Spacer use results in a significant reduction in the amount of aerosol that is deposited in the mouth and throat. **(CHOOSE ONE OPTION)** *Required*

- ☐ True
- ☐ False
- ☐ Depends on the inhaler type
- ☐ I do not know

In your opinion, the most important step for correct dry powder inhaler (DPI) inhalation is: **(CHOOSE ONE OPTION)** *Required*

- ☐ To shake the device before inhalation
- ☐ To exhale before inhalation
- ☐ To fire the device during inhalation
- ☐ To breathe in deeply and forcefully
- ☐ To inhale slowly and progressively
- ☐ I do not know

It is acceptable if the patient does not feel the dry powder inhaler (DPI) powder go down. **(CHOOSE ONE OPTION)** *Required*

- ☐ True
- ☐ False
- ☐ Depends on the inhaler type
- ☐ I do not know

How long should you tell patients to wait before taking a second puff? **(CHOOSE ONE OPTION)** *Required*

- ☐ At least 5 seconds
- ☐ At least 10 seconds
- ☐ At least 20 seconds
- ☐ I do not know

How long should you tell patients to hold their breath after taking a puff? **(CHOOSE ONE OPTION)** *Required*

- ☐ At least 4 seconds
- ☐ At least 6 seconds
- ☐ At least 8 seconds
- ☐ I do not know

How often should you tell patients to clean their spacer? **(CHOOSE ONE OPTION)** *Required*

- ☐ After each use
- ☐ Every day
- ☐ Every week
- ☐ I do not know

How often should you tell patients to clean their DPI mouthpiece? **(CHOOSE ONE OPTION)** *Required*

- ☐ After each use
- ☐ Every day
- ☐ Every 2 to 3 weeks
- ☐ I do not know

Inhaled steroid effectiveness is improved by taking a β-agonist first. **(CHOOSE ONE OPTION)** *Required*

- ☐ True
- ☐ False
- ☐ Depends on the dose
- ☐ I do not know

When health care practitioners prescribe an inhaler device, which of the following variables do you consider the most important? **(CHOOSE ONE OPTION)** *Required*

- ☐ Patients' preferences
- ☐ Patients' age
- ☐ Patients' experience with a specific device
- ☐ Patients' educational level
- ☐ Other

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CURRENT PRACTICE:

Which inhaled device is the **first** most commonly prescribed in your pharmacy for COPD patients? **(CHOOSE ONE OPTION)** *Required*

- ☐ Accuhaler™
- ☐ Autohale™
- ☐ Breezhaler™
- ☐ Handihaler™
- ☐ Breezhaler™
- ☐ Handihaler™
- ☐ Nexthaler™
- ☐ Novolizer™
- ☐ Respimat™
- ☐ Twithaler™
- ☐ pMDI
- ☐ Easi-Breathe™
- ☐ Ellipta™
- ☐ Genuair™
- ☐ Easyhaler™
- ☐ Turbohaler™
- ☐ I don't know

Which inhaled device is the **second** most commonly prescribed in your pharmacy for COPD patients? **(CHOOSE ONE OPTION)** *Required*

- ☐ Accuhaler™
- ☐ Autohale™
- ☐ Breezhaler™
- ☐ Handihaler™
- ☐ Breezhaler™
- ☐ Handihaler™
- ☐ Nexthaler™
- ☐ Novolizer™
- ☐ Respimat™
- ☐ Twithaler™
- ☐ pMDI
- ☐ Easi-Breathe™
- ☐ Ellipta™
- ☐ Genuair™
- ☐ Easyhaler™
- ☐ Turbohaler™
- ☐ I don't know

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Please indicate the electronic devices you use to check inhaler technique from the following list: **(TICK ANY THAT APPLY)** *Required*

- ☐ Inhaler Compliance Assessment Device (INCA™)
- ☐ Aerosol Inhalation Monitor (AIM™)
- ☐ In-Check™
- ☐ Mag-Flo™
- ☐ SmartMist™
- ☐ pMDI datalogger™
- ☐ Other
- ☐ Not appropriate

Do you provide input into the choice of device for COPD patients in your community? *Required*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

When dispensing an inhaler device, do you assess the patients' inhalation technique? *Required*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

How often you use the electronic devices to check inhaler technique for COPD patients? *Required*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

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At your pharmacy, who trains the patients on the inhalation technique of the prescribed device? **(CHOOSE ONE OPTION)** *Required*

- ☐ Only the pharmacists
- ☐ Only the assistant pharmacists
- ☐ Either the pharmacist or assistant pharmacist, it depends
- ☐ Nobody, patients receive written information
- ☐ Nobody, patients do not receive written information
- ☐ Other

Do you provide input into the choice of device for COPD patients in your community? *Required*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

When dispensing an inhaler device, do you assess the patients' inhalation technique? *Required*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

How often you use the electronic devices to check inhaler technique for COPD patients? *Required*

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Always

At your pharmacy, who trains the patients on the inhalation technique of the prescribed device? **(CHOOSE ONE OPTION)** *Required*

- ☐ Only the pharmacists
- ☐ Only the assistant pharmacists
- ☐ Either the pharmacist or assistant pharmacist, it depends
- ☐ Nobody, patients receive written information
- ☐ Nobody, patients do not receive written information
- ☐ Other

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Do you check at least once a year the inhalation technique used by your patients treated with inhaled therapy? *Required*

- ☐ Yes, I do
- ☐ No, I do not

What tools do you use when counselling or conducting services like MUR or NMS for COPD patients? **(TICK ANY THAT APPLY)** *Required*

- ☐ Verbal instructions
- ☐ Leaflets
- ☐ YouTube videos
- ☐ Mobile Apps
- ☐ Guidelines
- ☐ Pictographs (pictures and graphs)
- ☐ Other
- ☐ Not appropriate

What educational material, if any, do you provide to patients to take home? **(TICK ANY THAT APPLY)** *Required*

- ☐ Inhaler technique brochure
- ☐ COPD self-management leaflet
- ☐ Digital (QR code) COPD overview leaflet
- ☐ Digital App (e.g. my mhealth:myCOPD or RightBreathe)
- ☐ Only verbal instructions
- ☐ Other
- ☐ Not appropriate

Attitudes:

Please respond to the following: *Required*

It is meaningful to provide counselling for COPD patients to improve adherence.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

The Pharmacist may be able to support COPD patients to improve the self-management of their disease.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

In the treatment pathway for patients with COPD, the pharmacist should have an important role in advising patients on which type of inhalers they should use.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

The pharmacist should have an important role in educating patients on how to use their inhalers.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

The pharmacist should have an important role in monitoring patients' adherence to inhalers.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

Section three: Your views on how to improve inhaler adherence in COPD patients

Instructions: Please respond to the following:

As a pharmacist, the main barriers to providing input on the choice of the inhaler are: **(TICK ANY THAT APPLY)** *Required*

- ☐ Time constraints
- ☐ Lack of training
- ☐ Lack of resources (e.g. placebo inhalers or inhaler technique checking devices)
- ☐ Financial constraints
- ☐ Lack of communication between the pharmacist and other health care professionals
- ☐ Lack of access to patients' medical records
- ☐ Lack of engagement from patients with pharmacists
- ☐ Lack of public recognition of the role of community pharmacists due to patients' perception of the status of the pharmacist in the health professional hierarchy
- ☐ Lack of knowledge
- ☐ Other

Thinking about your role as a pharmacist, in the below table please tick the **3 most important** and **3 least important** approaches to improving inhaler adherence in COPD patients. *Required*

Providing reminders

- ☐ Most important
- ☐ Least important

Shared decision making

- ☐ Most important
- ☐ Least important

Motivational interviewing

- ☐ Most important
- ☐ Least important

Switching regimen or inhaler

- ☐ Most important
- ☐ Least important

Discussing side effects

- ☐ Most important
- ☐ Least important

Linking inhaler use to the daily habit

- ☐ Most important
- ☐ Least important

Using smart inhalers

- ☐ Most important
- ☐ Least important

Linking inhaler use to personal goals

- ☐ Most important
- ☐ Least important

Simplifying regimen

- ☐ Most important
- ☐ Least important

If you know other approaches not mentioned above, please specify: *Optional*

Please respond to the following: *Required*

As a pharmacist, regular checking inhaler technique and intervening where necessary would be useful to optimise inhaler adherence in COPD patients.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

As a pharmacist, better electronic communication system with primary care would improve inhaler adherence among COPD patients.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

As a pharmacist, additional training to develop the knowledge needed for the new pharmaceutical services is important to provide better services for COPD patients.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

As a pharmacist, better methods (e.g. Point-of-care meters –FeNO-) would help to monitor the use of both maintenance and rescue medications.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

It would be useful for assistant pharmacists to play a role in improving inhaler adherence in COPD patients.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

As a pharmacist, financial incentives are important to provide better services for COPD patients.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

As a pharmacist, better access to patients' medical records would improve inhaler adherence in COPD patients.

- ☐ Strongly Disagree
- ☐ Disagree
- ☐ Neither agree nor disagree
- ☐ Agree
- ☐ Strongly Agree

How do you perceive patients' acceptance of the services offered in your pharmacy? **Please specify in your own words** *Required*

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Can you think of ways in which community pharmacists and GPs could work more closely together to optimise inhaler use among COPD patients? **Please specify in your own words** *Required*

THANKS

I greatly appreciate your help filling out this survey.

WAIT !!!!

As a token of appreciation, there is an opportunity for you to enter a prize draw and win an **Apple iPad**. To proceed click yes, if not click no and again thank you so much.

- ☐ Yes, I would like to enter the prize draw
- ☐ No, I would like not to enter the prize draw

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Prize Draw Entry Form

If you would like to be considered for the prize draw for an iPad, please provide your details below.

NOTE: This is not linked to your survey data, meaning your answers will remain anonymous. If you wish to withdraw from the prize draw after submitting your details, please email me (axa1407@student.bham.ac.uk) within 1 week of survey completion.

All submitted personal details will be destroyed once the iPad winner has been notified (approximately 24 weeks after study commencement).

Please fill out the following details: Title, Surname, Forename, and Email Address.

Best of luck

Title *Required*

Please select:

- ☐ Mr.
- ☐ Mrs.
- ☐ Ms.
- ☐ Miss
- ☐ Dr.
- ☐ Other

Surname *Required*

Forename *Required*

Email *Required*

Click finish to submit your response

☐ **Finish**

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Final page

Thank you for taking part; your feedback is appreciated.

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Appendix 6: REC approval

NHS
Health Research Authority

South Central - Oxford A Research Ethics Committee
Ground Floor
Temple Quay House
2 The Square
Bristol
BS1 6PN

17 March 2021

Mr Abdullah Aljahan
[redacted]

Dear Mr Aljahan

Study title:	**A qualitative study in the West Midlands; exploring the views of COPD patients and Health care professionals about the role of pharmacists in supporting patients inhaler medication use and the integration of pharmacists in the management of COPD patients to promote inhaler adherence.**
REC reference:	**21/SC/0047**
Protocol number:	**RG_20-158**
IRAS project ID:	**288175**

Thank you for your letter of 12 March 2021, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved on behalf of the PR sub-committee.

Confirmation of ethical opinion

On behalf of the Research Ethics Committee (REC), I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four

Appendix 7: Amendment REC approval

Subject: ?spam? IRAS PROJECT ID 288175, REC Reference 21/SC/0047 Confirmation of favourable opinion for substantial amendment

Date: Monday, 20 September 2021 at 11:36:11 AM British Summer Time

From: noreply@harp.org.uk

To: Abdullah Aljahan (PhD App Health Resea FT (A900)), Abdullah Aljahan (PhD App Health Resea FT (A900)), researchgovernance@contacts.bham.ac.uk, Abdullah Aljahan (PhD App Health Resea FT (A900))

Attachments: Favourable opinion 21.SC.0047.AM01 288175.pdf

Dear Mr Aljahan,

IRAS project ID:	288175
REC reference:	21/SC/0047
Short Study title:	Qualitative study with COPD Patients and Health care professionals.
Date complete amendment submission received:	08 September 2021
Amendment No./ Sponsor Ref:	RG_20-158 SA_01
Amendment Date:	16 August 2021
Amendment Type:	**Substantial**
Outcome of HRA Assessment	**This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.**

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

HRA and HCRW Approval Status

As detailed above, **this email also constitutes HRA and HCRW Approval for the amendment.** No separate confirmation of HRA and HCRW Approval will be issued.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

If you require further information, please contact me.

Kind regards

Anfal El-Awaisi
Ground Floor | Temple Quay House | Health Research Authority | BS1 6PN
E. oxforda.rec@hra.nhs.uk
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

Appendix 8: TAI licence approval



Sublicencia en BiblioPRO

Se le ha otorgado la sublicencia de *Test of adherence to inhalers*

Estado de la sublicencia: Otorgada el 27 de February de 2020 a las 14:02

Válida hasta: 30 de December de 2022 a las 23:59

Información sobre el pago

- **Precio de la sublicencia:**
  - **Base imponible:** 0 €
  - **IVA:** 21% (0 €)
  - **Total:** 0 €
- **Número de la factura:**
- **Fecha de la factura:** No emitida
- **Número de albarán interno:** 3953_2020-02-27-SUBL-1708-19632
- **IBAN:**
- **SWIFT:**

Información sobre la sublicencia

- **Nombre:** Abdullah Aljahan
- **Email:** [redacted]
- **País:** Reino Unido
- **Fecha de solicitud:** 27 de February de 2020 a las 12:01
- **Número de administraciones:** 1
- **Financiación mayoritaria por una entidad:** Académica
- **Entidad desde la que solicita la sublicencia:** University of Birmingham
- **Promotor del proyecto:** University of Birmingham

Información sobre el estudio

- **Nombre:** Patients' views/perceptions about pharmacist-led inhaler medication consultations to improve adherence
- **Uso:** Cribado de problemas de salud
- **Ojetivos:** To use TAI as an extra source of descriptive data so the researcher can classify participants as having low/mod/high adherence
- **Período:** 2020-03-01 - 2022-12-30
- **Diseño:** Otros
- **Población:** 20
- **Enfermedad o síntoma:** Sistema respiratorio
- **Modo de administración:** Por entrevistador
- **Soporte técnico:** Papel impreso

Datos de facturación

- **Razón social:** No indicado
- **CIF:** No indicado
- **Dirección:** No indicado
- **Código postal:** No indicado
- **Población:** No indicado
- **País:** No indicado
- **Teléfono:** No indicado
- **Correo electrónico:** No indicado

Appendix 9: Research passport

UNIVERSITY OF BIRMINGHAM

Occupational Health Unit
Workplace Wellbeing

14th January 2021

Mr Abdullah Aljahan
[redacted]
Birmingham
[redacted]

Dear Abdullah
Re: Clearance for none clinical work in the NHS

Name: Abdullah Aljahan
Date of birth: [redacted]

I confirm that, in accordance with the 2007 Guidelines for Clearance of New Healthcare Workers, you have been cleared to work in the NHS in a none clinical role.

Yours sincerely

[redacted]

Sophie Gask
RGN, DipOH
Occupational Health Adviser

PLEASE KEEP THIS RECORD SAFE.
RE-ISSUE OF YOUR IMMUNISATION HISTORY REPORT WILL INCUR A £10 CHARGE.

University of Birmingham 13 Pritchatts Road Edgbaston Birmingham B15 2QU United Kingdom
T: +44 (0)121 414 5116 F: +44 (0) 121 414 4602 E: occupationalhealth@bham.ac.uk

Appendix 10: COPD patients' invitation letter

UNIVERSITY OF BIRMINGHAM

COPD patients invitation letter.

Dear <name of patients>,

Research study exploring the views of COPD patients about the role of pharmacists in supporting their inhaler medication use.

We are inviting you to take part in a new study, as you previously took part in Birmingham Lung Improvement StudieS (BLISS) and were happy to be contacted about future similar studies. The new study aims to explore how pharmacists might be involved in the choice of your inhaler medication and how they might support you to use it effectively.

Your participation is voluntary, not participating will not affect your rights and you can withdraw at any time. The study would involve one interview to ask your views about using your inhalers and any related support you get from health professionals (GPs, nurses, pharmacists). We hope to use the information from this research to help patients make the most of their prescribed treatments. If you would like to know more, we have included more information about this study in an enclosed information sheet.

We realise that the COVID-19 pandemic is uppermost in your minds and you may not be able to participate, but if you are able to take the time we would be grateful. If you take part in this study, a researcher will arrange an online video or telephone interview based on your preference. The interview will take around one hour to complete.

Please complete the attached reply slip and return it by email if you would like to take part. If you have any questions about the study, please contact the lead researcher (Abdullah Aljahan) at

Dr Rachel Jordan

Reader in Epidemiology & Primary Care

BLISS Research Team

University of Birmingham

Appendix 11: COPD Patients Information Sheet

UNIVERSITY OF BIRMINGHAM

Abdullah Aljahan [redacted]

PATIENT INFORMATION SHEET

Study Title: Exploring the views of COPD patients about the role of pharmacists in supporting their inhaler medication use.

We would like to invite you to take part in a research study. Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you. Your participation is voluntary, not participating will not affect your rights and you can withdraw at any time. The study is part of a PhD award degree where the University of Birmingham takes on the sponsor role for this study. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

What is the purpose of the study?

- Inhaler medications for COPD patients are an essential part of their treatment, but we know that compliance is still low, thus limiting the potential benefit.
- Community pharmacists could be encouraged to play a greater role in helping patients to choose, understand and use their medications.
- We need to understand what patients think about pharmacists talking to them about their inhaler medication.

Why have I been invited?

- You are receiving this material either because you previously took part in Birmingham Lung Improvement Studies (BLISS) and were happy to be contacted about future similar studies.

Do I have to take part?

- You do not need to take part in this study. But, if you decide to take part, you will be asked to sign a consent form.
- You will be asked about your view on the role of pharmacists in choosing and supporting your inhaler medications.

What will happen to me if I decide to take part?

- All interviews will be conducted by Abdullah Aljahan, who is a PhD student and the main researcher on this study.
- The interview will last no longer than one hour and will be audio recorded with your approval (all identifying information will be anonymised).
- The interview will be conducted remotely (e.g. Zoom).
- You can withdraw from the study at any time and up to one month after the interview date without giving a reason.

What should I consider?

- You should be living within the West Midlands area and previously participate in Birmingham Lung Improvement Studies (BLISS).
- You can participate in this study even though you are involved in other research studies.

Are there any possible disadvantages or risks from taking part?

- The interviews will not ask any sensitive questions, so there are no anticipated risks associated with your involvement in this study.

What are the possible benefits of taking part?

- Your treatment will not be affected. We are only asking for your opinion.

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- Taking part in this research will not benefit you personally, however being involved in the study may contribute to the improvement of healthcare services that are helpful to other COPD patients and healthcare professionals in the future.

Will my taking part in the study be kept confidential?

- Yes. The information about you will only be known to members of the research team. All collected information (e.g. audio recording of interviews), will be confidential, and stored in a locked filing cabinet and protected computer folder, kept securely at University of Birmingham server.
- Data will only be accessed by the researcher & the research team, until it is no longer required, when it will be safely shredded or erased.
- This study has gained ethical approval from the University of Birmingham.
- Responsible members of the University of Birmingham may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

- Taking part in the interview will not result in any expenses for you. None of the participants will receive any payment.

What will happen to my data?

- Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Birmingham is the data controller and is responsible for looking after your information and using it properly.
- We will keep identifiable information about you for up to 6 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Birmingham for 10 years after the end of the study.

What will happen if I don't want to carry on with the study?

- As it stated earlier, participation is voluntary and you may change your mind at a later stage. Withdrawal is permitted at any time and up to one month after the interview date without giving any reason, or legal rights being affected. If the withdrawal occurred after one month after the interview, data obtained from the interview only will be used in the analysis.

What happens at the end of the study?

- After the end of the study, the findings will be presented at conferences, published in a journal and as part of a PhD thesis.

Where can you find out more about how your information is used?

- You can find out more about how University of Birmingham uses your information by contacting our Data Protection Officer, Legal Services, University of Birmingham, B15 2TT Email: dataprotection@contacts.bham.ac.uk

What if there is a problem?

- The University of Birmingham, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.
- If you wish to complain about any aspect of the way in which you have been approached, or how your information is handled during the course of this study, you should contact the lead researcher (axa1407@student.bham.ac.uk) or you may contact Dr Birgit Whitman, Head of Research Governance and Integrity on 0121 405 8011 email (researchgovernance@contacts.bham.ac.uk).

How have patients and the public been involved in this study?

- In designing this study we have taken into account COPD patient opinions on the role of pharmacists to optimise inhaler adherence.

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Who is organising and funding the study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by a NHS REC Research Ethics Committee.

Further information and contact details:

Please contact: Mr. Abdullah Aljahan (PhD Student – University of Birmingham) by Email: (axa1407@student.bham.ac.uk)

Thank you for considering taking part.

Appendix 12: Reply slip / Consent to contact (COPD patients/HCPs)

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Reply slip / Consent to Contact

1. **Please tick one of these boxes:**

☐ I would like to take part in the study. ☐

☐ I would prefer not to take part in the study. ☐

(It would be very helpful for improving our future work, if you could provide a reason for why you do not wish to take part in this):

2. **If you <u>do wish</u> to take part, please fill in the following details:**

Mr/Mrs/Miss

First name

Surname

Full address

Telephone number (include area code)

Mobile telephone number

Email address

So that we can arrange an appointment, please tick one of the following:

I am happy to be contacted by telephone	Yes	No
I am happy to be contacted by email	Yes	No

PLEASE RETURN THIS FORM ASAP BY EMAIL TO: (axa1407@student.bham.ac.uk
THANK YOU FOR TAKING THE TIME TO REPLY!

Appendix 13: COPD Consent form

UNIVERSITY OF BIRMINGHAM

Conser

Study Number: UoB-QL002

Participant Identification Number for this study:

CONSEN

Title of Project: Exploring the views of COPD patien inhaler medication use.

1. I confirm that I have read the information sh consider the information, ask questions and h
2. I understand that my participation is voluntar up to one month after the interview date with legal rights being affected.
3. I wish to receive a summary of the conclusio
4. I understand that the information collected ab other research in the future, and may be share
5. I agree to the interview being recorded and fo University of Birmingham servers.
6. I agree to take part in the above study.

Name of Participant	Date
Name of Person taking consent	Date

PLEASE RETURN THIS FORM ASAP IN THE

IRAS Project number: 288175

Appendix 14: COPD Interview topic guide

UNIVERSITY OF BIRMINGHAM

1. How long have you been registered with your GP practice?
2. Approximately how long ago were you diagnosed with your lung condition?
3. How does your lung condition affect you (e.g. regular daily activities)?
4. What inhaler medication are you currently taking? [TDF: knowledge]
5. When you start to feel unwell, which health professional (e.g. GP, nurse or pharmacist) would you usually choose to see first? [TDF: Social/professional role and identity]
6. Who initially prescribed your inhalers? Did they talk with you about your choice of inhalers?
7. Do you usually discuss your inhaler medication with health professionals? [TDF: Beliefs and capability]
    a) If so, which professionals e.g. doctors, nurses, pharmacists?
    b) How do you decide which health professionals to talk to about inhaler medication?
    c) What choices about inhaler medication were offered?
    d) What did you discuss about the benefits and harms and any difficulties with taking the medications, if anything?
    e) To what extent did you feel your choice/feelings were taken into consideration when choosing the type of inhaler?
    f) How did the doctor describe your medications risks?
    g) How do you feel about being given choices about medications?
    h) How would you feel about the pharmacist playing a role in discussing your choices with you?
    i) How would this best be done?
8. If you have spoken to the pharmacist about inhaler medication: [TDF: Beliefs and consequences + Emotion]
    a) Did you find it useful?
    b) What issues did you discuss?
9. If you have not spoken to the pharmacist about inhaler medication:
    a) Why not?
    b) Is there a pharmacist close to your house?
10. Would you be willing to have more discussions about your inhaler medications with a pharmacist? [TDF: Beliefs and consequences + Emotion]
    a) Do you feel that talking to the pharmacist will make any difference on how to take your inhalers and adhere to medication?
11. In your view, what do you think would be the main differences between talking to your GP or your pharmacist about your lung health and treatment, if any? [TDF: Beliefs and capability]
12. If a pharmacist was involved in your care, how would this work best for you? [TDF: Environmental Context, Resources, Social/Professional Role and Identity, and Beliefs about Capabilities]

    Prompts

- Communication (**waiting times**, **length of appointments**).
- Professionalism (**friendly** and understanding, treating people with **respect**, **honesty**, knowledge and management of your medicines -**confidence**-).
- Privacy (**private consultation room**).

13. Overall, what do you think about the service provided by the pharmacist?

Do you have any other comments/ remarks you would like to make on the topic?

Thank you for your contribution. I appreciate your time and thoughts.

Appendix 15: COPD patients-Test of Adherence Inhaler





	Score
1. How often did you forget to take your regular inhalers in the last 7 days? ☐1. Always ☐2. More than half ☐3. About half ☐4. Less than half ☐5. None	
2. You forget to take your inhalers: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
3. When you are feeling well, you stop taking your inhalers: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
4. At the weekend or when you go on holiday, you stop taking your inhalers: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
5. When you are anxious or sad, you stop taking your inhalers: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
6. You stop taking your inhalers out of fear of potential side effects: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
7. You stop taking your inhalers because you believe that they are of little help in treating your condition: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
8. You take fewer inhalations than prescribed by your doctor: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
9. You stop taking your inhalers because you believe that they interfere with your day-to-day or work life: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	
10. You stop taking your inhalers because you have trouble paying for them: ☐1. Always ☐2. Almost always ☐3. Sometimes ☐4. Almost never ☐5. Never	

TOATAL SCORE =

Appendix 16: COPD patients' reminder letter

UNIVERSITY OF BIRMINGHAM

COPD patients reminder letter

Dear BLISS participant

Research study exploring the views of COPD patients about the role of pharmacists in supporting their inhaler medication use.

We wrote to you a few weeks ago and want to give you another opportunity to take part in our research study at the University of Birmingham. Please ignore this letter if you have already participated in this research study.

We are inviting you to take part in a new study, as you previously took part in Birmingham Lung Improvement StudieS (BLISS) and were happy to be contacted about future similar studies. The new study aims to explore how pharmacists might be involved in the choice of your inhaler medication and how they might support you to use it effectively.

Your participation is voluntary, not participating will not affect your rights and you can withdraw at any time. The study would involve one interview to ask your views about using your inhalers and any related support you get from health professionals (GPs, nurses, pharmacists). We hope to use the information from this research to help patients make the most of their prescribed treatments. If you would like to know more, we have included more information about this study in an enclosed information sheet.

We realise that the COVID-19 pandemic is uppermost in your minds and you may not be able to participate, but if you are able to take the time we would be grateful. If you take part in this study, a researcher will arrange an online video or telephone interview based on your preference. The interview will take around one hour to complete.

Please complete the attached reply slip and return it by post or email if you would like to take part. If you have any questions about the study, please contact the lead researcher (Abdullah Aljahan) at (

Yours sincerely,

Dr Rachel Jordan

Reader in Epidemiology & Primary Care

BLISS Research Team

University of Birmingham

Appendix 17: HCPs invitation letter

UNIVERSITY OF BIRMINGHAM

Health Care Professionals invitation letter

Dear < primary healthcare practitioners >,

Research study exploring health care professionals' views about an enhanced pharmacist role to optimise COPD patient adherence to inhaler medication.

We are conducting a research study at the University of Birmingham to explore how to improve the adherence of COPD patients to their inhaler medication, and are keen to understand health care professionals' views about the proposed enhanced role that pharmacists may play in this.

We would therefore like to invite you to participate in this research study, which would involve a one-off interview at your convenience. The main areas we would like to explore are the current role of primary healthcare professionals in inhaler adherence and the potential enablers/barriers to integrating pharmacists within the patient care pathway. More information about the study is available in the Participant Information Sheet.

Your participation is voluntary, not participating will not affect the individual's rights and you can withdraw at any time. We would be grateful if you would read the Participants Information Sheet, and then complete and return the reply slip to indicate your interest in the study. If you agree to take part in this study, a researcher will arrange an online video or telephone interview based on your preference. The interview will take around one hour to complete.

Thank you for taking the time to read this information, and please do contact me if you have any queries.

Kind regards

Dr Rachel Jordan
Reader in Epidemiology & Primary Care
BLISS Researcher Team
University of Birmingham

Appendix 18: HCPs information sheet

UNIVERSITY OF BIRMINGHAM

HCPs- Participant Information Sheet (PIS)

Abdullah Aljahan (Email: [redacted])

PARTICIPANT INFORMATION SHEET

Study Title: Exploring health care professionals' views about an enhanced pharmacist role to optimise COPD patient adherence to inhaler medication.

We would like to invite you to take part in a research study. Before you decide whether to take part, you need to understand why the research is being done and what it would involve for you. Your participation is voluntary, not participating will not affect your rights and you can withdraw at any time. The study is part of a PhD award degree where the University of Birmingham takes on the sponsor role for this study. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

What is the purpose of the study?

- Inhaler medications for COPD patients are an essential part of their treatment, but we know that compliance is still low, thus limiting the potential benefit.
- Community pharmacists could be encouraged to play a greater role in helping patients to choose, understand and use their medications.
- This study aims to understand the current role of primary healthcare professionals in inhaler devices adherence and the potential enablers/barriers to integration of the pharmacists within the patient care pathway.

Why have I been invited?

- You are receiving this material either because your GP practice previously took part in the Birmingham Lung Improvement Studie5 (BLISS) study, or you received an invitation either via Clinical Research Network newsletter (Participate) or the Primary Care Respiratory Society newsletter (Fortnightly), or Local Pharmacy Committee in West Midlands covering Birmingham and Solihull, or Local Medical Committee for Birmingham, or Birmingham and Solihull CCG, or Birmingham and Solihull STP, or The Black Country and West Birmingham STP, or Coventry STP, or social media and researcher network.

Do I have to take part?

- **You do not need to take part in this study**. But, if you decide to take part, you will be asked to sign a consent form.
- You are invited to participate in an interview to explore your views about the current role of primary healthcare professionals in patients' adherence to inhaler devices, and the potential enablers/barriers to integrate the pharmacists within the patient care pathway.

What will happen to me if I decide to take part?

- All interviews will be conducted by Abdullah Aljahan, who is a PhD student and the main researcher on this study.
- The interview will last no longer than one hour and will be audio recorded with your approval (all identifying information will be anonymised).
- The interview will be conducted remotely (e.g. Zoom/ telephone).
- You can withdraw from the study at any time and up to one month after the interview date without giving a reason.

UNIVERSITY OF BIRMINGHAM

What should I consider?

- You should be a Healthcare professionals practicing within the West Midlands area.

Are there any possible disadvantages or risks from taking part?

- The interviews will not ask any sensitive questions, so there are no anticipated risks associated with your involvement in this study.

What are the possible benefits of taking part?

- Being involved in the study will contribute to understanding HCPs' views regarding current and future practices related to patient inhaler device adherence.

Will my taking part in the study be kept confidential?

- **Yes**, the information about you will only be known to members of the research team. All collected information will be confidential (e.g. audio recording of interviews) will be confidential, and stored in a locked filing cabinet and protected folder, kept securely at University of Birmingham server.
- All data will be made anonymous using an ID code only known by the research team, and the data will only be accessed by the researcher & the research team, until it is no longer required, when it will be safely shredded or erased.
- This study has gained ethical approval from the University of Birmingham.
- Responsible members of the University of Birmingham may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

- If you take part in the interview we will cover 1 hour of clinical time, using rates advised by the primary care CRN (min £23- max £90).

What will happen to my data?

- Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest'. The University of Birmingham is the data controller and is responsible for looking after your information and using it properly.
- We will keep identifiable information about you for up to 6 months after the study has finished. This excludes any research documents with personal information, such as consent forms, which will be held securely at the University of Birmingham for 10 years after the end of the study.

What will happen if I don't want to carry on with the study?

- As it stated earlier, participation is voluntary and you may change your mind at a later stage. Withdrawal is permitted at any time and up to one month after the interview date without giving any reason, or legal rights being affected. If the withdrawal occurred after one month after the interview, data obtained from the interview only will be used in the analysis.

What happens at the end of the study?

- After the end of the study, the findings will be presented at conferences, published in a journal and as part of a PhD thesis.

IRAS Project number: 288175

UNIVERSITY OF BIRMINGHAM

Where can you find out more about how your information is used?

- You can find out more about how University of Birmingham uses your information by contacting our Data Protection Officer, Legal Services, University of Birmingham, B15 2TT Email: dataprotection@contacts.bham.ac.uk

What if there is a problem?

- The University of Birmingham, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.
- If you wish to complain about any aspect of the way in which you have been approached, or how your information is handled during the course of this study, you should contact the lead researcher (axa1407@student.bham.ac.uk) or you may contact Dr Birgit Whitman, Head of Research Governance and Integrity on 0121 405 8011 email (researchgovernance@contacts.bham.ac.uk).

How have patients and the public been involved in this study?

- In designing this study we have taken into account COPD patient opinions on the role of pharmacists to optimise inhaler adherence.

Who is organising and funding the study?

- All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by a NHS REC Research Ethics Committee.

Further information and contact details.

Please contact: Mr. Abdullah Aljahan (PhD Student – University of Birmingham) by Email: (axa1407@student.bham.ac.uk)

Thank you for considering taking part.

IRAS Project number: 288175

Appendix 19: HCPs consent form

UNIVERSITY OF BIRMINGHAM

Study Number: UoB-QL003

Participant Identification Number for this study:

CONSENT FORM

Title of Project: Exploring health care professionals' views about an enhanced pharmacist role to optimise COPD patient adherence to inhaler medication.

1. I confirm that I have read the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time up to one month after the interview date without giving any reason.

3. I wish to receive a summary of the conclusions at the end of the research study. (**OPTIONAL**)

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

5. I agree to the interview being recorded and for the recording to be securely stored on University of Birmingham servers.

6. I agree to take part in the above study.

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

PLEASE RETURN THIS FORM ASAP P IN THE SELF-ADDRESSED ENVELOPED PROVIDED

Appendix 20: HCPs topic guide

UNIVERSITY OF BIRMINGHAM

Opening

Thank you for taking part in this interview.

General Questions

1. How long have you been a GP, nurse, or in-house pharmacist? [TDF: Knowledge and Skills]
2. How many COPD patients do you have?
3. Are you mainly responsible for choosing their inhalers? [TDF: Knowledge, Skills, and Intention]
4. How do you decide which inhaler to recommend to your COPD patients? [TDF: Knowledge, Skills, and Intention]
5. To what extent do you discuss different options for patients in terms of types of inhalers?
6. How do you do this?
7. How much do you consider the preferences of the patient?
8. To what extent do you think the pharmacists might be able to engage in eliciting patients preferences?
9. How well do you think COPD patients adhere to their medication?
10. Do you train and monitor your patients in terms of their medication adherence and inhaler technique?

Integration Questions

11. There is a recent report indicating that some CCGs are implementing integrating pharmacists into the patients' treatment pathway, whereby pharmacists would play a bigger role in the choosing, monitoring, supporting and providing advice regarding inhaled medication. What are your thoughts on this? [TDF: Beliefs and capability]
12. What is relatively do you currently have with such pharmacists? [TDF: Social/professional role and identity]
13. What is the current role of pharmacists within your practice? [TDF: Beliefs and capability]
14. How do you feel about pharmacists taking on more responsibilities for this role? [TDF: Beliefs and consequences + Decision process]
15. How do you think this approach would impact your practice? [TDF: Beliefs and consequences + Decision process]
16. In regards to an integrated service, what impact do you think may have on your GP practice? [TDF: Emotion]

➢ Prompts

- (Improved communication, patient adherence, and understanding of inhaler treatment).

17. Do you think the patients are likely to benefit from it? Why? Why not? [TDF: Social influence]
18. Do you think there are any barriers to pharmacists taking on a more integrated role in prescribing or monitoring inhaler use?

➢ Prompts

- Environment: Do you think pharmacists possess the appropriate skills/knowledge to support and advise patients about their inhaled medication?
- Communication: Would communication between your GP practice and the pharmacist need to change? If so, how?
- Medical records
- Patient confidentiality: Do you think patients are willing to discuss their medication with pharmacists instead of primary care staff?

19. What needs to be put in place to make this work?

End of interview:

Conclusion questions

• Do you have any other comments/remarks you would like to make on the topic?

Thank you for your contribution. I appreciate your time and thoughts.

Appendix 21: HCPs reminder letter

UNIVERSITY OF BIRMINGHAM

Health Care Professionals reminder letter

Dear < primary healthcare practitioners >,

Research study exploring health care professionals' views about an enhanced pharmacist role to optimise COPD patient adherence to inhaler medication.

We wrote to you a few weeks ago and want to give you another opportunity to take part in our research study at the University of Birmingham. Please ignore this letter if you have already participated in this research study.

We are conducting a research study at the University of Birmingham to explore how to improve the adherence of COPD patients to their inhaler medication, and are keen to understand health care professionals' views about the proposed enhanced role that pharmacists may play in this.

We would therefore like to invite you to participate in this research study, which would involve a one-off interview at your convenience. The main areas we would like to explore are the current role of primary healthcare professionals in inhaler adherence and the potential enablers/barriers to integrating pharmacists within the patient care pathway. More information about the study is available in the Participant Information Sheet.

Your participation is voluntary, not participating will not affect the individual's rights and you can withdraw at any time. We would be grateful if you would read the Participants Information Sheet, and then complete and return the reply slip to indicate your interest in the study. If you agree to take part in this study, a researcher will arrange an online video or telephone interview based on your preference. The interview will take around one hour to complete.

Thank you for taking the time to read this information, and please do contact me if you have any queries.

Kind regards

Dr Rachel Jordan
Reader in Epidemiology & Primary Care
BLISS Researcher Team
University of Birmingham

Appendix 22: HCPs advert



Qualitative interview study exploring the role of community pharmacists in COPD management.

The University of Birmingham would like to interview GPs, nurses and pharmacists about the current and future role of community pharmacists in COPD patient care. This study will contribute towards a PhD award. Participants will be reimbursed for their time. More information is available on request

IRAS Project number: 288175

Appendix 23: COPD and HCPs topic guide— COVID-19

UNIVERSITY OF BIRMINGHAM

1. How long have you been registered with your GP practice?
2. Approximately how long ago were you diagnosed with your lung condition?
3. How does your lung condition affect you (e.g. regular daily activities)?
4. What inhaler medication are you currently taking? [TDF: knowledge]
5. When you start to feel unwell, which health professional (e.g. GP, nurse or pharmacist) would you usually choose to see first? [TDF: Social/professional role and identity]
6. Who initially prescribed your inhalers? Did they talk with you about your choice of inhalers?
7. Do you usually discuss your inhaler medication with health professionals? [TDF: Beliefs and capability]
    a) If so, which professionals e.g. doctors, nurses, pharmacists?
    b) How do you decide which health professionals to talk to about inhaler medication?
    c) What choices about inhaler medication were offered?
    d) What did you discuss about the benefits and harms and any difficulties with taking the medications, if anything?
    e) To what extent did you feel your choice/feelings were taken into consideration when choosing the type of inhaler?
    f) How did the doctor describe your medications risks?
    g) How do you feel about being given choices about medications?
    h) How would you feel about the pharmacist playing a role in discussing your choices with you?
    i) How would this best be done?
8. If you have spoken to the pharmacist about inhaler medication: [TDF: Beliefs and consequences + Emotion]
    a) Did you find it useful?
    b) What issues did you discuss?
9. If you have not spoken to the pharmacist about inhaler medication:
    a) Why not?
    b) Is there a pharmacist close to your house?
10. Would you be willing to have more discussions about your inhaler medications with a pharmacist? [TDF: Beliefs and consequences + Emotion]
    a) Do you feel that talking to the pharmacist will make any difference on how to take your inhalers and adhere to medication?
11. In your view, what do you think would be the main differences between talking to your GP or your pharmacist about your lung health and treatment, if any? [TDF: Beliefs and capability]
12. If a pharmacist was involved in your care, how would this work best for you? [TDF: Environmental Context, Resources, Social/Professional Role and Identity, and Beliefs about Capabilities]

    Prompts

- Communication (**waiting times**, **length of appointments**).
- Professionalism (**friendly** and understanding, treating people with **respect**, **honesty**, knowledge and management of your medicines -**confidence**-).
- Privacy (**private consultation room**).

13. Overall, what do you think about the service provided by the pharmacist?

Do you have any other comments/ remarks you would like to make on the topic?

Thank you for your contribution. I appreciate your time and thoughts.

Appendix 24: Search strategies

exp chronic obstructive lung disease/

(COPD or COAD or COBD or AECB).mp,ti,kw,tw,ab.

(obstruct* adj3 (pulmonary or lung* or airway* or airflow* or bronch* or respirat*)).mp.

exp Bronchiectasis/ or (bronchiect* or emphysema*).mp.

exp Chronic Disease/ exp chronic illness

exp heart failure/ exp heart disorders

exp diabetes

exp shared decision making/

(shared decision or sharing decision or informed decision or informed choice or decision aid).ti,ab. or ((share* or sharing* or informed*) and (decision* or deciding* or choice*)).ti.

exp clinical decision making/ or exp decision making/ or exp decision support system/ or exp ethical decision making/ or exp family decision making/ or exp medical decision making/ or exp patient decision making/ or (decision making or decision support or choice behaviour).ti,ab. or ((decision* or choice*) and (making* or support* or behaviour*)).ti.

exp Medication Adherence/ or exp Patient Acceptance of Health Care/

(complian* or noncomplian* or non-complian* or adhere* or nonadhere* or non-adhere* or persist* or refusal or refuse* or concord* or accept* or comply* or cooperate* or conform* or patient* dropout).tw,ti,ab,kw,mp.

inhaler adherence.mp,ti,kw,tw,ab,kw.

exp health personnel/ or exp nurses/ or exp pharmacists/ (GP* or general practitioner* or respiratory nurse* or pharmac*).mp,ti,kw,tw,ab.

exp community pharmacist/ or exp clinical pharmacist/ or exp pharmacist/ or exp hospital pharmacist/

exp patient preference/ or exp patient outcomes

patient* preference*.mp,ti,ab,tw,kw./ or patient* satisfaction*.mp,ti,ab,tw,kw.

exp patient views/ or exp patient perception

exp pharmacist views/ or exp pharmacist perception

exp qualitative research/

(interview* or qualitative research or semistructure or structure* or focus group* or ground or phenomena* or theme* or thematic*).ti,ab,tw,kw,mp

Appendix 25: JBI data extraction form

Study Details	
Author/year	
objectives	
Participants (characteristics/total	
number)	
Setting/context	
Description of Interventions/	
phenomena of interest	
Search Details	
Sources searched	
Range (years) of incl studies	
Number of studies included /	
Types of studies included	
Country of origin of incl. studies	
Appraisal	
Appraisal instruments used	
Appraisal rating	
Analysis	
Method of analysis	
Outcome assessed	
Results/Findings	
Significance/direction	
Heterogeneity	
Comments	