HOW CAN COMMUNITY PHARMACY ENHANCE ASTHMA CARE IN ADULT PATIENTS?

A MULTIPERSPECTIVE STUDY

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A thesis submitted in partial fulfilment of the requirements of Liverpool John Moores University for the degree of Doctor of Philosophy

March 2022

Biography

The researcher graduated from the University of Jordan and qualified as a pharmacist in 2008. She worked in an independent community pharmacy in Jordan for one year; then in 2013, she completed her Master of Sciences degree in pharmacy from the University of Jordan. Since then she worked as a teaching assistant at the University of Jordan, before working as a lecturer in pharmacy practice at Isra University in Jordan. Being a community pharmacist and working in the academic field in the area of pharmacy practice made the researcher a perfect candidate for a PhD scholarship from Isra University. In 2017, the researcher moved to the UK and started her four-year PhD programme in pharmacy practice at Liverpool John Moores University (LJMU).

Abstract

Asthma is a long term condition with an episodic nature. In the UK, approximately 5.4 million people are living with asthma. The evidence showed gaps in asthma care provided to adult patients, for example, some asthma patients are not receiving basic asthma care including annual asthma reviews, asthma action plans and inhaler technique checks.

The increasing numbers of patients with long term conditions led to an increase in patients' demands, accordingly, increasing the workload on the GP practices. In 2018, NHS England stated that 26 million people in England are living with at least one long term condition and around 50% of GP appointments are provided to patients with long term conditions. The community pharmacy contractual framework confirmed the future role of community pharmacy as an integral part of the primary care pathway for patients with long term conditions. Community pharmacy offers convenient and accessible primary care premises and community pharmacists are well-educated on the management of long term conditions. Additionally, community pharmacists are in regular contact with asthma patients.

This PhD aimed to explore how community pharmacy can enhance asthma care in adult patients and suggest solutions to enhance asthma care.

The PhD study started with a narrative review of studies that were conducted to evaluate asthma interventions in community pharmacy. Only one of the studies was conducted in England. The findings showed that community pharmacy might be able to support asthma patients with inhaler technique training and asthma reviews. Additionally, there was limited evidence on the provision of an AAP in community pharmacy and none of the studies involved asthma medication change in community pharmacy. Moreover, the study highlighted some barriers to the provision of asthma

interventions in community pharmacy, mainly, difficulties in the identification of asthma patients and collecting their data.

The findings of the review were utilised to build the design of the study that involved five phases, Mixed methods research. Phase 1 involved qualitative interviews with 17 stakeholders in the North West of England. In phase 1, the participants highlighted possible opportunities to enhance asthma management in adult patients. The findings support the need to enhance engagement with AARs in adult patients, quality of AARs, access to asthma reviews and asthma patients' awareness of their condition and importance of follow-up. The participants highlighted that new interventions for asthma patients need to focus more on preventive and co-ordinated care. As well as this, health coaching might help asthma patients to self-manage their condition better.

In phase 2, a retrospective case note review was conducted in a GP practice. This phase highlighted issues with asthma management in the study sample including asthma medication use (overusing their reliever inhaler or underusing their ICS inhaler), engagement with AARs, inhaler technique check, AAPs and referral to secondary care for follow-up. The findings showed that regular checks of patients' records helped to identify patients who need review, difficulties in obtaining data regarding asthma symptoms control and inconsistency in the provision and recording of asthma action plans and inhaler technique checks.

A sample of 13 patients was identified in phase 2 and interviewed in phase 3 to explore patients' perspectives on their management of their asthma. According to some patients in phase 3, the quality of care provided to asthma patients varied among different locations, healthcare settings and different healthcare practitioners. Additionally, patients asked for continuity in their asthma care. Patients with comorbid allergic rhinitis, depression and/or anxiety showed interest in being provided with further support. Additionally, patients perceived that the ease of access to community pharmacy and the relationship of trust between patients and community pharmacists might be utilised in providing further support with their asthma.

In phase 4, the findings of phases 1-3 were triangulated, summarised and shared with HCPs to get their feedback in phase 5. The feedback from HCPs with findings from phase 4 provided the evidence to answer the research question (how can community pharmacy enhance asthma care in adult patients). The answer was:

- **Enhancement in the provision of NMS to newly diagnosed asthma patients by helping community pharmacy to identify those patients.**

- **A community pharmacy-based asthma support:** According to the findings, asthma patients who do not attend their AARs, patients with controlled asthma and patients who have a risk for a future asthma attack (patients with poorly controlled asthma symptoms and those with allergic rhinitis or who need seasonal care) can be provided by support in community pharmacy.

The study successfully suggested a possible community pharmacy-based asthma intervention that is evidence-based to discuss with stakeholders and test its feasibility.

Acknowledgements

(ربِّ زِدْنِي عِلْماً)

“My Lord increase me in knowledge"

Holy Quraan, Surah Taha ayah 114

Throughout my PhD project I have received a great deal of support and assistance from my supervisors, family and friends.

I would first like to thank my supervisory team for their guidance. Also. I would like to say a big thank you for Dr Adam Mackridge for his advice and insightful feedback.

I would like to thank everyone who participated in this research, without their involvement this thesis would not have been completed.

I am gratefully thankful for Isra University for funding my PhD studies. In particular, I would like to thank Professor Ahmad Naddaf, Dr Amjad Abu-Irmeileh, Dr Ahmad Aldissi, and everyone who supported me during my PhD journey without their support, this thesis would not have been possible.

In addition, I would like to say a special thank you for my beloved parents and sister because without their support I would not be who I am today. I would like to say big thank you for my daughters, Bana, Mirna and Sewar for their patience and sacrifices. I would also like to say sorry for my daughters for my absence during my PhD studies and especially while writing my thesis. Finally, I would like to say big thank you for Zina and Enad for their encouragement, continuous support, and motivation.

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List of Abbreviations

A&E	Accident and Emergency
AAP	Asthma Action Plan
AAR	Annual Asthma Review
ACAQ	Asthma Control Assessment Questionnaire
ACT	Asthma Control Test
ACQ	Asthma Control Questionnaire
AG	Agreement
AQLQ	Asthma Quality of Life Questionnaire
BMQ	Brief Medication Questionnaire
BTS	British Thoracic Society
CCGs	Clinical Commissioning Groups
COPD	Chronic Obstructive Pulmonary Disease
COVID-19	Coronavirus Disease
CPCF	Community Pharmacy Contractual Framework
CPCS	Community Pharmacy Consultation Service
CPF	Community Pharmacy Future
CPRD	Clinical Practice Research Data
CQ	Consumer Questionnaire
CS	Corticosteroids
DA	Disagreement
DASS	Depression Anxiety Stress Scale
DEPICT	Descriptive Elements of Pharmacist Intervention Characterisation Tool
DMA	Discharge Medicine Service

EFR	Expiratory Flow Rate
FEV1	Forced Expiratory Volume in one second
FOMM	Four Or More Medicines
FeNO	Fractional Exhaled Nitric Oxide
FYFV	Five Year Forward View
GDPR	General Data Protection Regulation
GP	General Practitioner
GRAMM	Good Reporting of A Mixed Methods Study
HCPs	Health Care Practitioners
HRA	Health Research Authority
HSR	Health Services Research
ICS	Inhaled Corticosteroids
I-MUR	Italian Medicine Use Review
INCA	The Inhaler Compliance Assessment
KAM	Knowledge of Asthma and Asthma Medicine
KASE-AQ	Knowledge Attitude and Self-Efficacy Asthma Questionnaire,
LJMU	Liverpool John Moores University
LTCs	Long Term Conditions
MARS	Medication Adherence Rating Scale
MGLS	Morisky Green Levine Scale
MMAS	Morisky Medication Adherence Scale
MURs	Medicine Use Reviews
MRC	Medical Research Council
NAC	National Asthma Council of Australia

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMS	New Medicine Service
NRADs	National Review of Asthma Deaths
NSAIDs	Non-Steroidal Anti-inflammatory Drugs
PA	Partial Agreement
PCNE	Pharmaceutical Care Network Europe Foundation
PCP	Pharmacy Care Plan
PEF	Peak Expiratory Flow
PEFR	Peak Expiratory Flow Rate
PQS	Pharmacy Quality Scheme
QOF	Quality and Outcomes Framework
QoL	Quality of Life
RCP	Royal College of Physicians
RCT	Randomised Control Trial
REC	Research Ethics Committee
RT	Randomised Trial
S	Silence
SABA	Short-Acting Beta 2 Agonist
SCR	Summary Care Records
SIGN	Scottish Intercollegiate Guideline Network
SPSS	Statistical Package for Social Sciences
SRQR	Standards for Reporting Qualitative Research
STPs	Sustainability and Transformation Partnerships

1 Introduction

This first chapter will provide an overview of the PhD study; it will outline the background surrounding asthma, asthma care and management, the National Health Services, person-centred care, community pharmacy and complex interventions. Then it will discuss the rationale, introduce the aim and objectives of the PhD study and provide an overview of the thesis.

1.1 Background

1.1.1 Asthma

Asthma is a long term condition (LTC) that is characterised by breathlessness, tightness in the chest, coughing and wheezing, along with episodes of sudden worsening in symptoms (asthma attacks or exacerbations) that can prove fatal (1).

Due to its chronic nature, asthma poses a public health concern, with an estimated 235 million people currently living with asthma globally, according to the World Health Organisation (2). A systematic review that was conducted in 2009, estimated asthma's economic burden as the highest among other LTCs (3). The mean annual cost of asthma per patient was estimated to be USD$ 1900 in European countries and USD$ 3100 per patient in the United States of America (4).

In the UK, approximately 5.4 million people are living with asthma, affecting one in every 11 people and the National Health Service (NHS) spends around £1.1 billion each year treating and caring for asthma patients (5). A major issue with asthma patients is poor levels of symptoms control (6, 7). In their annual asthma survey for 2019, Asthma UK identified that 82% of asthma patients in the UK have poorly controlled asthma symptoms (8).

In England, approximately 1000 deaths occur per year from asthma and 90% of those deaths were related to preventable causes (1, 9). Additionally, a large number of emergency admissions are related to asthma (9). Although these emergency admissions are less than those related to chronic obstructive pulmonary disease (COPD), 70% of them could be prevented if appropriate management was provided (9).

1.1.2 Asthma care and management

Asthma care is challenging to define because of the lack of a comprehensive description of it and there is no agreed upon definition on what constitutes asthma care (10-12). Moreover, there are differences in the perception of asthma care among patients and healthcare practitioners (HCPs) (13). However, some organisations and researchers defined the main elements or aims of asthma care, those are presented below in Table 1-1.

Table 1-1 Asthma care elements and aims

Reference	Asthma care basic elements
Annual asthma survey conducted by asthma UK (14).	In their Compare Your Treatment report in 2014, Asthma UK reported that the basic

	elements of asthma care are **diagnosis, annual asthma review (AAR), asthma action plan (AAP) and treatment following admission and appropriate discharge from hospital** (14).
Annual asthma survey conducted by Asthma UK (15-18).	More recently, Asthma UK highlighted that the basic elements of asthma care are **AAR, AAP and inhaler technique check** (15-18).
Primary Care Respiratory Society (PCRS) (19) based on the British Thoracic Society (BTS)/Scottish Intercollegiate Guideline Network (SIGN) asthma guidelines (11).	According to the PCRS (19), the (BTS)/(SIGN) asthma guidelines (11) includes all the asthma care elements. These elements are **diagnosis, monitoring of asthma, supported self-management, non-pharmacological treatment, pharmacological treatment, inhaler device and management of acute asthma, difficult asthma, asthma in adolescence, asthma in pregnancy and occupational asthma** (11).
A study on asthma care that was conducted by Dima, et al. in the UK and France (10).	Dima et al. 2016 (10) provided a comprehensive description of asthma care and identified three elements of asthma care that included: 1. **Asthma management process** that involves **diagnosis, monitoring, treatment assessment and reducing trigger factors** to control symptoms and reduce the risk for asthma attacks. 2. **Patients' behaviours** in terms of **trigger management, adherence to inhalers and inhaler technique, symptom monitoring and asthma exacerbation management** (10). 3. **HCPs** affect asthma management directly

	by **providing asthma review, medication and diagnosis** or indirectly by **providing supported-self management** (trigger management, AAP, inhaler technique and education) (10). The model showed that **patients' behaviour and HCPs** can affect the **asthma management process**, which can positively impact patients' outcomes.
	Aims of asthma care
Primary Care Asthma Standards (20)	Asthma care aims to **control symptoms** and **enable people to lead a normal life**.
A study on asthma care that was conducted by Lindberg et al. in Sweden (21).	Asthma care aims to **promote patient participation in their care** and to **create a partnership between HCPs and patients**.

As shown in Table 1-1, there is a lack of a precise definition of asthma care.

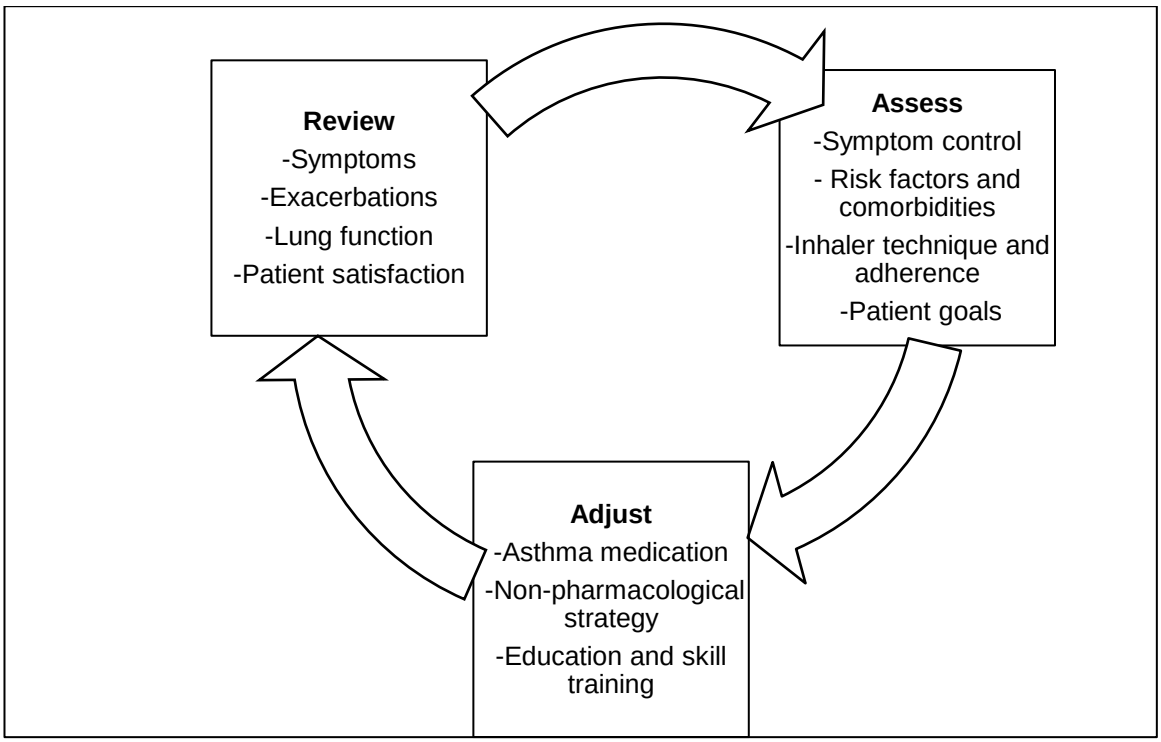
However, asthma care and asthma management are used in literature interchangeably and without precision, although asthma care includes asthma management based on asthma care elements that were presented in Table 1-1. This shows a need to be explicit about exactly what is meant by asthma care and asthma management in this thesis.

For the purpose of this thesis, the researcher identified asthma care as:

Asthma care involves three main elements that are; asthma management process, HCPs in the different healthcare settings and asthma patients. Those three elements interact with each other and can affect the quality of asthma care in patients.

The current guidance on asthma management, including the Global Initiative for Asthma (GINA), BTS/SIGN and National Institute for Health and Care Excellence (NICE) (11, 12, 22) provided definitions for asthma management. The following figure represents the asthma management process as described by Global Initiative for Asthma (GINA) guidelines for asthma management (22).

Figure 1-1 Asthma patient management cycle adapted from GINA guidelines



As shown in *Figure 1-1*, asthma management is a continuous cycle rather than a linear process.

Based on the GINA (22), BTS/SIGN (11) and NICE guidelines (12), asthma management is:

A continuous cycle of assessment (diagnosis, triggers and comorbidities, symptom control and patient goals); adjustment (of pharmacological and non-pharmacological treatment) and review of patient's response (symptoms, side effects, lung function and exacerbations) to treatment that aims to control asthma symptoms and reduce risk.

Every asthma consultation is an opportunity to assess pharmacological and non-pharmacological treatment, patient adherence to medication and to review and extend patient knowledge and skills (22, 23). Additionally, asthma management aims to control the symptoms and reduce risk by preventing exacerbations and asthma deaths.

Additionally, the researcher identified an asthma symptoms control that will be used throughout the thesis. Asthma symptoms control is defined as:

No daytime or night-time symptoms, no exacerbations and need for rescue medication, no limitations on activity, normal lung function (practically forced expiratory volume in one second (FEV1) and/or peak expiratory flow (PEF) (>80% of the predicted value) and minimal side effects (22, 23)**.**

Asthma care guidelines in the UK

There are two national guidelines: the BTS/SIGN and NICE guidelines for asthma management. The two guidelines have many similarities in their management approaches (24).

The BTS/SIGN (11) and NICE (12) guidelines recommend that asthma patients should be monitored annually in primary care in a proactive structured review, in the UK it is called the AAR (11). Benefits of the reviews include reduced school or work absence, reduced asthma attacks, improved symptom control and decreased attendance at the Accident and Emergency (A&E) department (11).

The two guidelines for asthma recommended the development and provision of an AAP that contains advice regarding how to recognise any change in asthma control (by symptoms or FEV1) and actions (seeking emergency help, increasing Inhaled Corticosteroids (ICS) use or using an oral Corticosteroid (CS)) to be taken by the patient as a response to this change (11, 12).

On the other hand, there are some differences between the two guidelines in their diagnosis and management approaches. For example, the NICE guidance (12) positioned the Fractional Exhaled Nitric Oxide (FeNO) in the diagnosis algorithm, while the BTS/SIGN guidance listed FeNO as a test that has the potential to be useful (24). The prominent role of FeNO in the diagnosis of asthma as recommended by NICE guidance may lead to more referrals to secondary care for asthma diagnosis because of the limited availability of FeNO tests in the primary care setting (19).

The two guidelines have some differences in the pharmacological management of asthma, including the use of Short-Acting Beta 2 Agonists (SABA) as first-line treatment for asthma in the NICE guidance, whereas the BTS/SIGN guideline recommends that asthma patients should be treated with a low dose of ICS in the early diagnosis and should not be treated with a SABA inhaler alone (except in patients with a very occasional short-lived wheeze) (19, 24).

Furthermore, some recommendations outlined in the BTS/SIGN guidelines are not addressed by NICE guidelines. For example, the BTS/NICE guideline includes guidance on the management of acute attacks and guidance on asthma in adolescents and in pregnant women that are not provided in the NICE guidelines (24).

These differences may have an impact on the clinical decisions made by healthcare practitioners in these areas of difference, especially because most of the Quality and Outcomes Framework (QOF) indicators are informed by NICE guidelines (12). To support HCPs to provide effective treatment for asthma patients, in 2019, NICE, BTS and SIGN announced that the three organisations will work

jointly to produce a UK-wide guideline for the diagnosis and management of chronic asthma in adults and children (25).

Asthma care in the UK

In the UK, a variety of different healthcare professionals, across different practice settings, are involved in the management of asthma patients (26). However, the general practitioner (GP) practice is central to asthma care provision.

In primary care, the patients will see their GP, practice nurse, or nurse practitioner and, more recently, a practice pharmacist for the long-term management of their asthma (26). This may include an AAR, which involves a 20-30 minute appointment to monitor and assess asthma control using a validated tool, such as the Royal College of Physicians' (RCP) 3 questions (Q1 Have you had difficulty sleeping because of your asthma symptoms?; Q2 Have you had your usual asthma symptoms during the day?; Q3 Has your asthma interfered with your usual activities?) (27), lung function, asthma attacks, inhaler technique, adherence and bronchodilator reliance, as well as the development of a Personalised AAP (11, 23).

Patients may also attend their GP practice regarding a worsening of their asthma symptoms (26). In addition, the GP may refer patients with severe or difficult-to-manage asthma to a respiratory specialist in the hospital setting (26). Patients may also attend the hospital setting as an unplanned admission for an exacerbation (26). Community pharmacy provides support to asthma patients too (see section 1.1.5).

Regardless of the availability of many published guidelines and strategies for the diagnosis and management of asthma, the evidence suggested that these guidelines appear to be poorly implemented (9) and suggested the need for better asthma care (15, 22). Additionally, a major issue with asthma patients globally and nationally is poor symptoms control (6, 7).

Why are asthma symptoms poorly controlled in patients in the UK?

The evidence highlighted some gaps in asthma care that might lead to poor asthma symptoms control. Those were based around three main issues:

1. Asthma patients in the UK are not receiving basic asthma care.

Regardless of the well-established approach for asthma reviews in the GP practices and its importance in supporting asthma patients to control their asthma symptoms, some asthma patients are not receiving their AARs. Additionally, even patients who receive their AARs might not receive an inhaler technique check and/or an AAP. Those were considered as basic elements of asthma

management that should be provided to patients with asthma to enhance their asthma symptoms control and decrease their risk for an asthma attack and accordingly their quality of life.

The Reality of the Asthma Care report (17) that was published by Asthma UK in 2018 found that three out of five people are not receiving basic asthma care and 77% of asthma patients had an AAR. Additionally, less than 50% of asthma patients had an AAP and people without one are four times more susceptible to having an asthma attack (17). Asthma patients may fail to attend their appointments for several reasons, such as forgetting their appointments, poor health or mobility problems or feeling that their asthma does not require a review (11, 28, 29). However, some asthma patients found difficulties in booking an appointment with their GP practice for an asthma review (15).

2. Some asthma patients are not being followed up after having an asthma attack.

Every eight minutes, a person is admitted to a hospital with an asthma attack in the UK (17). After having an asthma attack, a follow-up appointment should be provided to the patients in the GP practice within 48 hours (11). This follow-up is considered an essential procedure to prevent further asthma attacks and hospital admissions (11). However, Asthma UK found that among patients who had emergency care, 65% have not had a follow-up appointment with their GP (15). Among this 65% of asthma patients, 64% of patients did not know that they can have a follow-up appointment after having emergency care and for 22% there was no available appointment to book within 48 hours (15).

3. Asthma medication use.

The NHS Long Term Plan highlighted that there is a need to support patients with respiratory conditions including asthma to use the right medications and know how to use them. As discussed in point one above, not all asthma patients are receiving an inhaler technique check, therefore they might not know how to use their inhaler. Additionally, the National Review of Asthma Deaths (NRADs) report showed that overuse of the reliever inhaler and non-adherence to the preventer inhaler were related to poor-asthma control and were highlighted as preventable causes for asthma deaths (1, 6).

Overall, the evidence suggested a lack of structured care for asthma in practice and asthma patients may fail to attend their appointments for several reasons, and one of these reasons is difficulty in booking an appointment with their GP practices (11, 28, 29). There is a need for effective asthma care that may lead to an increase in patient engagement with their appointments

and improve their control over their asthma symptoms (22). The evidence suggests the need to enhance asthma patients' access to their asthma care.

1.1.3 The National Health Service (NHS)

The NHS was founded in 1948 and many changes have been introduced since then (30). NHS England was established in 2013 and is responsible for the planning and commissioning of NHS services (30). Some services are commissioned by NHS England directly, while most are commissioned by the 135 Clinical Commissioning Groups (CCGs) that are funded by the NHS (30, 31). CCGs are NHS bodies that plan and procure services based on patients' needs in their local area from different providers in primary and secondary care, and in the community (30, 31). Working alongside NHS England is NHS Improvement, which oversees NHS Trusts to ensure better healthcare provision for patients and to ensure sustainable finances (30). Moreover, the quality of care provided is monitored by the Care Quality Commission (30).

In 2014, the NHS introduced the Five Year Forward View (FYFV) which focused on the provision of preventive care and involvement of patients in their treatment plan (32). Furthermore, it focused on the provision of new care models that provide integrated services to patients to improve the care in patients with LTCs (32). This new way of providing care aimed to support patients with LTCs to improve their physical and mental status (30). To facilitate the collaboration between different organisations, NHS England created the Sustainability and Transformation Partnerships (STPs) in 2015 (30). In England, 44 STPs are working to achieve the main aims of the FYFV (30, 32). Some STPs developed the Accountable Care System that involves working together using a set budget to deliver care to patients in certain areas (30). The STPs and Accountable Care System were developed to respond to the limited resources in the NHS and the increasing number of patients (30). Additionally, it allowed collaboration between the NHS, social care and public health (30).

Regardless of the continuous changes and improvements in the NHS, patient care is provided in primary and secondary care settings (30). However, the General Practitioner (GP) practice is the gatekeeper to accessing care and is responsible for co-ordinating patient care (26). To standardise improvements in the delivery of care to patients (including asthma patients) (33), the QOF was introduced on 1st April 2004 as part of the General Medical Services contract (34). QOF is a voluntary reward and incentive program for all GP practices in England which details a points system where GP practices score points according to their level of achievement (33). Additionally, QOF allowed for the establishment of disease registers in individual GP practices, which are lists of

registered patients with a particular condition or risk factor, for example, asthma. Overall, the QOF has changed the monitoring of patients with LTCs from reactive to proactive (35).

1.1.4 Person-centred care

As discussed earlier, the improvement in the care of patients with LTCs is one of the key priorities of the NHS FYFV, therefore new care models for patients with LTCs should be shifted to become more person-centred. Person-centred care is a holistic approach to care that provides co-ordinated care to people that is focused on their needs, respects their values and beliefs, involves them in clinical decision making and enables them to recognise their strengths and abilities (36-38). Person-centred care and approaches to it, such as **care planning, supported self-management and proactive care**, respond to the needs of patients with LTCs and allow patients to play a more active role in their treatment (38, 39). Person-centred care improves patient experience, quality of care and health outcomes (38).

To enhance the provision of person-centred care, improvement in the quality of the partnership relationship between patients and their HCPs is essential to provide person-centred care, as it allows the identification of patient preferences, enables them to make decisions and identify and achieve their treatment goals (38).

Additionally, shifting the healthcare system to become more person-centred requires changes in the care models provided to patients with LTCs, and the provision of multidisciplinary care planning (38, 39). The multidisciplinary team is "*a group of professionals from one or more clinical disciplines who together make decisions regarding recommended treatment of individual*" (40). Multidisciplinary teamwork involves a partnership between different health professions within the GP practice, and communication and cooperation with HCPs in the community and social care (41). Such an approach requires co-ordination and efficient documentation to recognise patients' needs (36). Boundaries between different healthcare settings (32), staff contracts and professional barriers all need to be overcome to facilitate the provision of multidisciplinary care planning (39, 42).

Self-management

Enabling people with LTCs to be able to make choices and decisions to manage their condition, take actions and manage factors that could affect their health could be achieved through a supported self-management approach for person-centred care (38).

It supports people with LTCs to become self-managers of their condition by providing a mix of personalised information, action plans, education and training (38, 39). To support patients to self-manage their condition, patients should be provided with a proactive, structured and comprehensive education to help them improve their health literacy and behaviour (39). Patients' engagement in their treatment decisions will increase their adherence to their treatment and improve patient knowledge and skills, as well as confidence and satisfaction with the services provided (36, 38, 39).

Care planning is essential in person-centred care and is required to support patients to self-manage their condition and enhance their engagement in their treatment decisions (39). Care planning should address patients' medical requirements and other needs, for example, their cultural background and financial needs (39). The individualised patient's needs, goals, actions, and updates on the patient's progress should all be detailed and identified in the personalised care plan (39).

A written care plan is believed to improve information sharing between different healthcare settings, decrease the number of missed appointments and reduce unnecessary tests (39, 41). It also outlines the services and interventions to be provided to the patient in the community, primary or secondary healthcare settings (39). Regardless of this emphasis on the provision of the care plan to patients with LTCs, less than 50% of patients with LTCs who spent time in a hospital have a care plan and less than 10% of patients with asthma have an AAP (39). GPs should provide a care plan to all people with LTCs and assign a named care co-ordinator (that patients can contact for advice and support) (39).

Proactive care

Providing proactive care is essential in person-centred care (39). HCPs and commissioners should run case finding and risk assessments to find people who are at risk for long term or life-threatening complications (39). Proactive screening using health checks and screening programmes, regular reviews and referrals allow for prevention, early diagnosis and intervention at the right time (39). People with LTCs should be supported with good-quality information and support to understand how lifestyle changes or service use might help them better manage their condition. A proactive approach helps patients to access services early to prevent exacerbations of their condition or to improve their health.

A proactive approach for care is important for all patients with LTCs, especially in LTCs that have an episodic or fluctuating nature, for example, asthma (35). Prevention can help to reduce the

severity and minimise the risk for more exacerbations (35, 39, 43, 44). Adults aged 40-74 are eligible for general health checks to spot any early signs of LTCs. Additionally, patients with LTCs are provided with regular reviews and medication reviews to support them manage their condition and to highlight any risk that could be reduced or avoided. Asthma patients are provided with AARs and follow-ups with their GP within 48 hours of having an asthma attack. However, there is still a need to improve asthma patients' access to the AARs and follow-up appointments and enhance the quality of those AARs.

What is happening to enhance self-management, personalised care and proactive care?

A comprehensive model of personalised care was developed by the NHS, which promotes a proactive approach through the empowerment of patients with LTCs to make decisions regarding their health and to self-manage their condition (37). Over 200,000 people had joined this personalised care programme by September 2020 (45). Although many patients with a range of health conditions are already involved in the management of their care, the NHS will provide further support for patients to self-manage their own health as outlined in the NHS Long Term Plan (45). This support will be provided for patients with LTCs, including diabetes, asthma and respiratory conditions (45).

To support more personalised care provision, support should be provided to HCPs to enable them to engage patients in decision making (45). Further improvement could be implemented by developing knowledge and skills of the HCPs to be able to assist people with LTCs and to improve access to self-management support among people with long term conditions (38, 39).

1.1.5 Community pharmacy

The third-largest healthcare workforce in the UK is pharmacists; there are 11,700 community pharmacies in England (46). The traditional role of community pharmacists was limited to dispensing medication; however, the community pharmacy role has developed over the years to include other services (46).

The Community Pharmacy Contractual Framework (CPCF) classified the services provided in the community pharmacy into essential, advanced and enhanced services (47).

Essential services must be provided in all community pharmacies, including dispensing medicines and appliances, repeat dispensing, disposal of unwanted medicines, public health, support for self-

care and signposting patients to other services (47), whereas advanced and enhanced services are optional for community pharmacists (47).

Advanced services focus mainly on medicine reviews, flu vaccination, public health, urgent medicine supply and lifestyle change. For example, Medicine Use Reviews (MURs), New Medicine Service (NMS) and the Community Pharmacists Consultation Service (CPCS) are advanced services (47).

MURs is an archived advanced service that was decommissioned in March 2021 (47). The MUR involved face-to-face, structured reviews of the patients' use of their medication by a pharmacist to help patients manage and use their medicines more effectively, highlight problematic side effects, improve adherence and reduce medicine wastage (48).

The NMS is designed to provide early support to patients with LTCs who have been newly prescribed a medicine to maximise its benefits, including patients with newly diagnosed asthma, hypertension, COPD, type 2 diabetes, and antiplatelet/anticoagulant therapy (49). The NMS involves patient engagement, intervention that include face-to-face, video or telephone discussion with the patients to increase their adherence to medication and follow-up after 14-21 days after the intervention.

The CPCS involves referring patients who have a minor illness or need an urgent medicine supply from a GP or NHS 111 to community pharmacy for urgent care (50). NHS 111 is a locally commissioned service for patients that is available 24 hours a day, 7 days a week to provide them with the right advice when needed urgently (51).

Enhanced services can be contracted by different commissioners including local authorities. Those services can be commissioned based on the needs of the local population.

These services allow community pharmacists to use their knowledge autonomously, to position community pharmacy as an integral part of the NHS organisation, and to support healthcare and self-care (52).

Community pharmacy within integral primary care provision

In the UK, there is a shift of some secondary care activities toward primary care to offer patients care closer to home that aligns with NHS FYFV (32, 53). Additionally, there are an increasing number of patients with LTCs and patients' demands and activities that are carried out in the GP practices are increasing, for example, new services including expansion of immunisation, new

medicines and provision of primary and secondary prevention of diseases (53). These have led to an increase in the workload in the GP practice (53).

"***The primary care pathway for patients with LTCs is the healthcare route that patients take for the treatment and management of their condition***" (42). GPs are central to this primary care pathway.

With increasing demands of patients and increasing pressure on the GPs, the policymakers in the UK recognised the potential for community pharmacy to support patients with LTCs and alleviate the increasing pressure in the GP practices. Community pharmacy offers convenient primary care premises that provide long opening hours and easy access (54, 55). Community pharmacists are well trained and their skills could be utilised to support patients with LTCs.

The advanced and enhanced services provided community pharmacy with the opportunity to support patients with LTCs and extend their role beyond medication supply. Regardless of all the efforts that have been made to expand the community pharmacy role in patient care, community pharmacy services remained separated from other healthcare settings due to many barriers (46, 56). These barriers include organisational factors, as community pharmacies are owned and managed by different organisations and professional differences exist, and there is a lack of support from GP practices that might have an impact on patients' uptake of the services (46, 56).

In 2016, Wright (57) reviewed the evidence surrounding clinical services in the community pharmacy setting, including the MURs. The evidence reviewed highlighted that the implementation and delivery of the MURs were affected by the GPs' negative perception of them (57), as they perceived that MURs were a duplication of their work (58). This resulted in a lack of collaboration between GPs and community pharmacists in the delivery of the MURs (58). For example, a randomised control trial (RCT) in the Isle of Wight showed that 70% of asthma patients who received a MUR, had their asthma review in the GP practice (59). Additionally, non-targeted MURs caused duplication of work and loss of NHS resources, which could have been avoided by better collaboration between community pharmacies and the GP practices (57).

The NMS was commissioned in 2011 (49) and a study was conducted as part of the implementation process to evaluate the effectiveness and cost-effectiveness of the service (60, 61). The results of the study (62) suggested that the NMS is effective in improving adherence and is cost-effective. The study results showed a 10% improvement in adherence for patients who received the NMS after 10 weeks compared to usual care (62). The availability of a cost-

effectiveness estimation of the NMS supported the adoption of the service (57). Despite enhanced uptake of the NMS and the positive response from the GPs, issues with the collaboration between community pharmacists and GPs were identified in the delivery of the NMS, as found in the MUR service (57, 61).

Another barrier that has kept community pharmacy separated is the lack of communication and information sharing. Over the years, many efforts have been made to connect community pharmacies in England to the other parts of the NHS (56). For example, the Electronic Prescriptions Service forwards prescriptions from the GP practice to the community pharmacy electronically (56, 63). More recently, community pharmacists were provided with read-only access to Summary Care Records (SCR) (56, 64). The SCR contains data that is extracted from the GP practice's system, including information regarding medication, allergies, adverse reactions, and the medical history of the patient (64). In addition, web-based pharmacy systems, including PharmOutcomes and Sonar Informatics Solutions, were developed to record the services provided in the community pharmacy and notify the GP automatically (56). In addition, the NHSmail system is a secured email service that allows patient information to be shared safely between different healthcare settings, including community pharmacy. Currently (56), the NHSmail could not be considered as an efficient and reliable way of communication between the community pharmacy and GP practices, because of its limited use by community pharmacy in sharing information with the GP practices, and the fact it is not monitored regularly by GP practices (56). Regardless of the availability of many systems to connect community pharmacy, there is still a lack of availability in the information provided to the community pharmacy and communication with them, which needs further improvement and solutions (56).

All those barriers affected the uptake of services by community pharmacies and slowed down the integration of community pharmacy into the primary care pathway for patients with LTCs. However, the CPCF in 2019 supported the expansion of the future of community pharmacy and focused on positioning community pharmacy as an integral part of the NHS organisations (65).

Recent changes in the role of community pharmacy

In 2019, the CPCF (65) initiated a five-year investment that facilitates the expansion of the clinical role of the community pharmacy to support the NHS Long Term Plan, by securing adequate funding and improving the utilisation of technology (65, 66). This includes funding of £2.592 billion per year for dispensing and delivery of services; the funding plan will be reviewed to amend the

money spent on dispensing and service delivery, towards an increase in funding for the delivery of services (66).

In 2019, the CPCF focused on facilitating the expansion of the role of community pharmacy by launching more services and supporting the community pharmacy with their increasing workload (65). Additionally, it has confirmed the future of community pharmacy as an official and integral part of the NHS by delivering clinical services as a full partner in the local primary care networks (PCNs). PCNs allow GP practices to work together with other professionals in primary care including community pharmacy by building on existing services and enabling the provision of more integrated care. In the future, community pharmacy will have an integral role in supporting the GPs to face this increasing demand and workload (65).

The CPCF (65) introduced a new scheme, commencing October 2019: the Pharmacy Quality Scheme (PQS) which replaced the Community Pharmacy Quality Payments Scheme that was introduced earlier in 2016 (65, 66). The PQS was designed to reward community pharmacies for delivering quality criteria within six domains (66). These domains are risk management and safety, medicines safety audits, prevention, PCNs, asthma and digital enablers (66, 67). Each domain is worth a number of points and to collect points, community pharmacies must meet the domains included in the PQS by achieving all the quality criteria in the domain (67). A budget of £75 million has been assigned to the PQS, which will be divided between community pharmacies based on the points they have achieved by meeting the domains of the PQS (66, 67).

As outlined in the CPCF, community pharmacists will begin to provide new services over the next five years (65). These services will be developed to utilise community pharmacy in the provision of preventive and urgent care to patients and support them after discharge from the hospital (65). The first service that was introduced in October 2019, was the CPCS (66). To facilitate the delivery of the CPCS, MURs have been decommissioned and NMSs will be expanded over the next five years, whilst new services will be implemented to further integrate pharmacists into the prevention and diagnosis of diseases (66). More recently, in November 2020, the CPCS has expanded to include referrals from the GP practices into community pharmacy for minor illness (68). This service connects patients who have minor illnesses or need an urgent supply with a community pharmacy (68).

In February 2021, the discharge medicine service (DMS) became a new essential service. In this service, NHS trusts will refer patients who might benefit from guidance around new medicines to

community pharmacy for guidance. The referral from NHS trusts to community pharmacy will be via an electronic system, for example, PharmOutcome or NHSmail.

Those changes enhanced the role of community pharmacy as an integral part of the NHS. Additionally, it will put in place processes and IT structures for better communication between community pharmacy and NHS trusts and GP practices. These processes might be utilised to support patients with LTCs and to facilitate patients' referrals from GPs to community pharmacy.

Community pharmacy and asthma care

Community pharmacy has an established role in supporting asthma patients (46). They dispense asthma patients' prescriptions, educate them about their medications and provide advice regarding smoking cessation (26). Community pharmacy also supports asthma patients by offering services that review their medication, including NMS and asthma referrals (69).

Asthma is one of the PQS domains which community pharmacies can meet by providing an asthma referrals service for adults and children (70). The asthma referrals service involves the identification of asthma patients who have had six short-acting inhalers and no CS inhalers in the last six months and referring them to their GP practice for a review (70). To help the community pharmacist provide asthma referrals, community pharmacies were provided access to the asthma referrals on PharmOutcomes (70, 71). Community pharmacists' access to PharmOutcomes allows patients' data to be recorded and then an automatic referral to the patients' GP practice could be sent via an NHS email address that is saved on PharmOutcomes (70).

Many efforts were made by community pharmacy to support asthma patients by delivering locally commissioned services in different cities in England (72). For example, a community pharmacy-based inhaler technique check service was commissioned in 2019 in Leeds for COPD and asthma patients (72). The service mainly aims to optimise the inhaler technique in asthma patients to improve the control of their symptoms and involves two appointments that are six to eight weeks apart (72). Additionally, it involves asthma assessment, education on asthma medication and smoking cessation advice. According to the Pharmaceutical Services negotiating Committee, such a service can replace the MURs in asthma patients (72). However, its provision is local.

Studies on community pharmacy-based services for patients with LTCs (including asthma)

This section will discuss some studies that were conducted to evaluate interventions provided to patients with LTCs in the community pharmacy setting, with a focus on asthma. These

interventions were provided as part of commissioned services or a service that was developed for pilot or research purposes.

In response to the increasing age of the population in the UK and the number of patients with LTCs and complex conditions, the Community Pharmacy Future (CPF) team conducted research that focuses on the development, implementation and evaluation of new care models for patients with LTCs in community pharmacy (73-75). The CPF team developed new services in the community pharmacy setting to support the primary care team with the current workload and to ensure the provision of more person-centred care to patients with LTCs (73-75).

The CPF team developed, implemented and evaluated the Four or More Medicines (FOMM) support service for patients aged over 65 years in community pharmacy (74). The service was person-centred and involved medication review and discussion of the risk of falls, pain management, adherence and general health by conducting regular consultations with the patient in community pharmacy (74). During the service, patients' medications were discussed with their GP and they were referred by the community pharmacist to public health interventions if needed (74). Additionally, the community pharmacist made decisions in conjunction with patients on which intervention(s) they should receive (74). A service evaluation study was conducted to evaluate the FOMM service by analysing the patients' data over six months of receiving the service (74). The findings showed that FOMM service had a positive impact on patient outcomes including improvement in Quality of Life (QoL) and medication adherence and risk reduction (74). The sustainability of the service was not evaluated because the analysis utilised data for six months only (74).

A COPD support service was developed and implemented in community pharmacy by the CPF team and evaluated in a study that was conducted by Wright et al. (73). Patients with COPD were recruited and provided a 10-week COPD service that aimed to improve medication adherence, support patients with COPD to stop smoking and help patients to manage their symptoms (73). The community pharmacist assessed the patients' condition and appropriateness of their inhaler, then discussed the assessment with them and provided them with necessary interventions based on the assessment (73). The interventions involved medication counselling to improve their adherence, stop smoking service or signposting to smoking cessation service and lifestyle advice that included weight management (73). Overall, the findings showed that the community-pharmacy based COPD support service improved medication adherence, resulted in a 4.1% decrease in the percentage of smokers among the recruited patients and showed a reduction in the NHS costs (73). However, the

sustainability of the service was not evaluated because the patients' data was collected over a six month period only (73).

More recently in 2015, the Pharmacy Care Plan (PCP) service, which was targeted to patients over 50 years of age and prescribed one or more medicines and at least one of them for cardiovascular disease or diabetes, was developed by the CPF team (75). Furthermore, the service was evaluated in a study that was conducted by Twigg et al. (75). The PCP service involved regular consultations in community pharmacy over 12 months (75). The initial consultation involved medication review, calculating cardiovascular risk, adherence advice, development of a personalised care plan (included the agreed goals for their condition management), referral to the GP or other services if needed (75). In the following visits, the community pharmacist discussed with the patients their progress with the agreed goals and new goals were identified (75). The findings of the study showed that the PCP service had a positive impact on patients' outcomes including adherence and QoL (75).

The services developed by the CPF team involved the provision of person-centred, holistic care that involved shared decision making with patients and supported self-management approaches in the community pharmacy setting and was targeted to patients with LTCs (73-75). The findings of the three studies (73-75) showed that such intervention had a positive impact on patient outcomes including QoL, medication adherence and lifestyle. Overall, the findings suggested that community pharmacists can enhance the care in patients with LTCs through the provision of person-centred services (73-75).

As mentioned earlier, the NMS could be targeted to patients who are newly prescribed an asthma medication (49). A study (76) was conducted to evaluate the implementation of the Belgium NMS for asthma patients in community pharmacy. In this study (76), Fraeyman et al. used a systematic approach to assess the implementation process and its fidelity. Implementation fidelity is used to measure if an intervention was implemented as intended or not (76). Fraeyman et al. (76) evaluated two main factors to describe the Implementation Fidelity of the NMS targeted to asthma patients. The first factor was: pharmacists' adherence to the NMS (assessed by counting the number of NMS interventions performed and the NMS delivery duration). The second factor was the moderators that affected the NMS implementation (76). These moderators were mainly related to the pharmacists, patients, the NMS protocol software tool used to facilitate NMS implementation and collaboration with other HCPs (76). The overall results of this study (76) showed a 25.8% uptake of the NMS by Belgian community pharmacists. This low uptake was caused by many

implementation barriers, including pharmacists' low engagement due to a lack of time or lack of collaboration with the GP and a lack of knowledge amongst patients and GPs regarding the benefits of the NMS (76).

Another study (77) conducted a pilot to evaluate the feasibility of an asthma Local Enhancement Service in Scotland. This service involved the delivery of an asthma review by the community pharmacist to adult patients who had not attended their AAR appointments in the GP practice in the last 12 months (78). The service involved multidisciplinary work and partnership with the GPs to support the identification and referral of patients for review in the community pharmacy (78, 79). The patients were identified by the GPs by writing a message on their prescriptions or by the community pharmacists (77). Although the pharmacists showed a positive reception to the service, the pilot highlighted many barriers in its delivery (77). These barriers were similar to the limitations identified for the implementation of any service in community pharmacy settings and included: limited time to deliver the service, community pharmacists needing the training to provide asthma reviews, difficulties in identifying patients and a lack of communication with the GPs (77). Moreover, patients' engagement with the service was low because the pilot was conducted in asthma patients who do not attend their annual asthma reviews and those patients are considered as "*hard to reach patients*" (77).

Another study (80) was conducted to test the provision of asthma reviews in community pharmacy to asthma patients who did not attend their AARs in England. The patients were identified by the GPs and their names were shared with the community pharmacy (80). The service included the delivery of asthma reviews to these patients and the recording of the review using PharmOutcomes, which notified the patients' GP practice if they received the review in community pharmacy (80). The results showed relatively high satisfaction with the service amongst the patients involved and improved the relationship between the community pharmacists and their patients (80). Although the ease of access to community pharmacy helped to engage patients with the review, others showed a negative response to using the pharmacy consultation room for the service, because it had been used for other services, for example, methadone dispensing (80). In addition, conducting the reviews in the community pharmacy decreased the workload on the nurse in the GP practice (80). However, the study (80) highlighted some barriers, including different IT systems between community pharmacy and GPs which limited the community pharmacists' access to the patients' medical records.

Summary

The evidence discussed earlier, highlighted successful services in community pharmacy that supported patients with LTCs including asthma and improved their outcomes including medication adherence and QoL and decreased risk for exacerbations in patients with LTCs.

However, the evidence highlighted limitations in the implementation of interventions in the community pharmacy setting that were related to the patients including low engagement and lack of knowledge among patients about the benefits of services in community pharmacy. Moreover, limitations that are related to community pharmacists include variability in uptake by community pharmacists due to time restrictions, workload and differences in skill-mix between community pharmacies.

Other limitations are related to the current organisational structure of the health care system including lack of communication between GPs and community pharmacy, inequity in access to care and limitations in the community pharmacies' access to patients' data.

As the GPs are central for primary care provided to patients with LTCs but community pharmacy services are traditionally separated from other healthcare settings (46), it seems that GPs might have concerns about competencies and encroachment on professional boundaries. Therefore, there is a need to identify how community pharmacy could be better utilised and integrated as an effective collaboration between community pharmacy and GP practices to optimise patient care. A possible way to better utilise community pharmacy is to include community pharmacy as a part of care planning for patients with LTCs within the primary care that might prevent duplication of work (42). Additionally, developing services with clear specifications and a focus on a particular problem could enhance consistency and quality in the provision of community pharmacy service and encourage GPs to support the service (42).

1.1.6 Complex intervention development and evaluation

In 2000, the Medical Research Council (MRC) published a framework for the complex intervention development that was updated later in 2008 and most recently in 2021 (81-83). Complex interventions contain several interacting components. The MRC outlined the constituents that made an intervention a complex one (82, 83), those constituents are:

- Number of interacting components within experimental and control interventions.
- Number of difficulties and behaviours required by those delivering or receiving the intervention.

- Number of groups or organisational levels targeted by the intervention.
- Number and variability of the outcomes.
- Degree of flexibility or tailoring of the intervention permitted.

The MRC framework identified four phases of the intervention development and evaluation process that includes development, feasibility and piloting, evaluation and implementation (82).

The intervention development phase was further enriched and comprehensively described by other researchers using the MRC framework alongside evidence from other approaches for intervention development (84, 85). The development phase includes **the actions that are taken by the developers to design the intervention before conducting formal pilot testing in practice** (84). Figure 1-2 presents the elements of the development phase as described by the MRC with additional elements from other approaches for the development of complex interventions (82, 85).

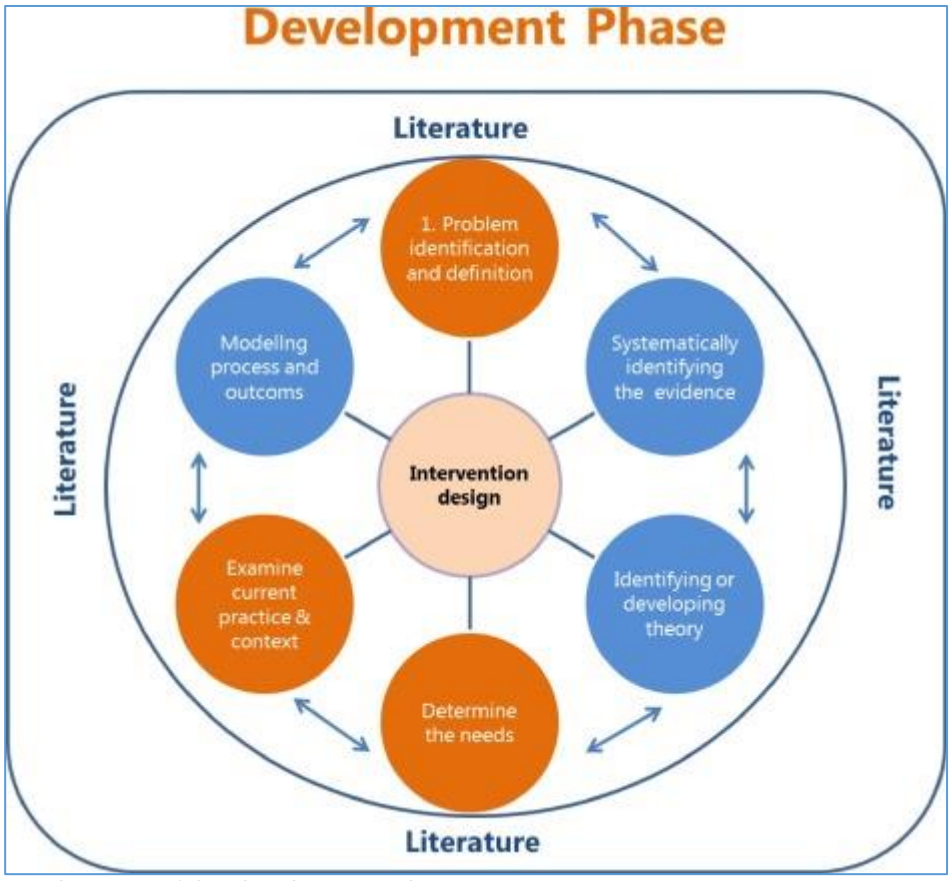


Figure 1-2 Elements of the development phase.

This figure was copied from Bleijenberg et al., 2008 (85), according to the Creative Commons Attribution-NonCommercial-No Derivatives License.

As shown in *Figure 1-2*, the development phase starts with problem identification and definition by an in-depth understanding of the problem, identifying the problem in a specific context and

providing insights into current gaps (84, 85). This can be achieved by reviewing the published research evidence considered suitable to allow for a better understanding of the problem, the context in which the problem exists, define barriers and facilitators for intervention delivery and uncertainties that need to be addressed in the primary data collection (82, 84, 85).

It is necessary to involve stakeholders who might use or deliver the intervention throughout the development process to allow for better insights into the problem (84, 85). The involvement of stakeholders not only allows for a better understanding of the problem but it helps to investigate the care needs by conducting primary data collection (84, 85). Mixed methods including qualitative, surveys or observational methodologies could be used to collect data from stakeholders to address the uncertainties that were identified from the literature review (84, 85).

Based on the definition of asthma care that breaks it down into three components, conducting the study in the context of the MRC framework and the available guidance and descriptions of the development phase of an intervention (81, 82, 84, 85) is thought to enhance the quality of the evidence that will be provided in the end regarding asthma care. Additionally, it might be of benefit for conducting research that focuses on patient's care in community pharmacy.

1.2 Rationale

Recently, the NHS FYFV stated that the improvement of the management of patients with LTCs is a key priority of the NHS, to meet the needs of an ageing population and the increasing number of people with LTCs (32). Among multiple LTCs, asthma is a national health concern; affecting one in every 11 in the UK, 82% of them with uncontrolled asthma (5, 15). Asthma is a complex and episodic condition (16), which needs innovative approaches to improve its management (16, 80). Despite the BTS/SIGN (11) and NICE (12) guidelines, there is a lack of evidence to inform the best way to organise structured asthma care in practice. Overall, the evidence highlighted that there is a need to improve asthma symptoms control in adult patients (17, 22, 28). The evidence discussed throughout this chapter highlights that there is a need to enhance asthma patients' access and engagement with their AARs, enhance the provision of structured asthma care in the GP practices that involve the basic elements of asthma care and improve medication use and adherence in asthma patients.

The current increasing workload and pressure on the GP practices and the effect of Coronavirus Disease of 2019 (COVID-19) might have a negative impact on asthma care (53, 86). As discussed earlier, some asthma patients have not been able to book an appointment with their GP practice for

an AAR or a follow-up after having emergency care. Additionally, less than 50% of asthma patients have an AAP and only 77% have been provided with an inhaler technique check by an HCP (17). This can explain the poor asthma symptoms in asthma patients. Community pharmacists might be able to play a role in filling those gaps in asthma care as they have the expertise and are in regular contact with patients with LTCs including asthma patients. Being the most accessible healthcare professional to patients with LTCs across the healthcare system (46, 69), community pharmacists might be utilised to provide further support to asthma patients.

Additionally, the high uptake of the NMS and its successful implementation (49, 61, 87) highlights that community pharmacy might provide further support for asthma patients, especially with their medication use. The studies that were discussed earlier showed that the provision of person-centred services in community pharmacy that were targeted to patients with LTCs including COPD, diabetes and cardiovascular diseases improved patient outcomes (73-75). Community pharmacy might enhance the support provided by pharmacists to patients with LTCs, improve the quality of care in patients with LTCs and overcome the barriers that have restricted the role of community pharmacy in the past (46). Utilising community pharmacy to support patients with LTCs is believed to improve health outcomes, patient engagement and improve communication between community pharmacy and GPs (42, 88). Furthermore, targeting asthma patients who do not attend their AAR in community pharmacy showed a positive impact on their health outcomes, experience and engagement (39).

Utilising community pharmacy to enhance asthma care is within the context of the CPCF that aims to extend the clinical role of community pharmacy and position it as an integral part of the NHS organisation (65). The utilisation of community pharmacy could help to provide multidisciplinary care planning to patients with asthma that facilitates the provision of person-centred care including holistic and preventive care and supports the NHS in delivering the outcomes in the NHS outcomes framework (9, 41, 42, 46, 88, 89). Community pharmacy integration into the patient's care could prevent duplication of services because it will enhance the communication between community pharmacy and other HCPs (42, 73, 88). The evidence showed that patients with LTCs including asthma could benefit from services in community pharmacy (59, 77, 80).

As discussed earlier, asthma care requires improvement and community pharmacy might play a role in the enhancement of asthma care, therefore, our question is:

How can community pharmacy enhance asthma care in adult patients?

This thesis aims **to explore how community pharmacy can enhance asthma care in adult patients and to suggest solutions to enhance asthma care** with an emphasis on highlighting asthma patients who might benefit the most from community pharmacy-based interventions to improve their engagement and asthma symptoms control. For this purpose, the PhD has been conducted in the context of the key elements of the development phase of the intervention (85), which was explained previously.

Accordingly, the thesis will start by reviewing the available literature to get better insights into asthma intervention in community pharmacy, then data collection will be conducted to better understand the problem with asthma management and address any uncertainties that will be highlighted in the literature review. The data collection will use Mixed methods and engage stakeholders who might be involved in delivering or receiving the intervention. Finally, the PhD study intends to use the cumulated evidence to answer the question of how community pharmacy can enhance asthma care in adult patients.

1.3 Aim and objectives of the PhD study

To explore how community pharmacy can enhance asthma care in adult patients and suggest solutions to enhance asthma care.

Objectives of the PhD study:

- To review international and UK-based studies that evaluated asthma interventions provided in community pharmacy. (Literature review)
- To explore healthcare practitioners and commissioners' perspectives on asthma management in adult patients. (phase 1)
- To assess asthma management in a sample of adult patients in a general practice in England using a validated tool. (phase 2)
- To explore patients' perceptions on the management of their asthma. (phase 3)
- To compare and connect the findings from the interviews with HCPs and commissioner (phase 1) and patients (phase 3) and case note review (phase 2) to increase understanding of the findings. (phase 4)
- To get HCPs' feedback on the findings from phase 4. (phase 5)

1.4 Overview of the thesis

The thesis begins with **a narrative review** followed by the presentation of a multiphase (**five phases**) study.

The thesis includes nine chapters; **chapter one** (this chapter) presented a background on asthma and asthma care and management and discussed the improvements in the care in patients with LTCs and patients with asthma. Moreover, it discussed the role of community pharmacy in the management of asthma along with some studies on community pharmacy-based services and described the rationale for using the community pharmacy setting to enhance asthma care in adult patients. Additionally, it described the MRC framework for the development of complex interventions and ended with a conclusion that stated the rationale and aim of the thesis.

Chapter 2 covers the literature review; this chapter outlines the methods and results, drawing conclusions from the literature. This is followed by **Chapter 3** that describes the methodology of the PhD study, the Mixed methods research used, theoretical framework and overview of the PhD study. The following five chapters present the five phases of the PhD. Each chapter will present the aim and objectives, methods, findings, discussion, conclusions and implications for the thesis.

Chapter 4 covers qualitative interviews with HCPs and commissioners that were conducted in phase 1, whereas **chapter 5** presents phase 2 that involves a case note review of the asthma patients' medical records held in a GP practice.

Chapter 6 covers phase 3 that involves qualitative interviews with asthma patients, **chapter 7** presents phase 4 that involves the triangulation of the data collected from phases 1 to 3 and **chapter 8** will involve qualitative interviews with HCPs and final results of the PhD.

The final chapter of the thesis discusses the overall findings of the PhD study.

2 Literature review of community pharmacy-based asthma interventions in adult patients

The PhD study started with a literature review. This second chapter will present the aim and objectives, methods, findings, discussion and implications.

Publication developed from this chapter:

Mahmoud A, Mullen R, Penson PE, Morecroft C. The management of asthma in adult patients in the community pharmacy setting: Literature review. *Research in Social and Administrative Pharmacy.* 2021. Available from: https://doi.org/10.1016/j.sapharm.2021.04.001

2.1 Introduction

As discussed earlier in chapter 1, asthma care involves the interaction of asthma management, asthma patients and HCPs and the PhD study aims to **explore how community pharmacy can enhance asthma care in adult patients and suggest solutions to enhance asthma care**.

The evidence has shown that intervention development and evaluation involves examining the literature and collecting data to get a better understanding of the research problem and the context of the intervention (82, 84, 85). Therefore, in this narrative review, the researcher examined studies that evaluated asthma interventions provided to adult asthma patients by community pharmacies in the UK and worldwide.

A narrative review, rather than a systematic, was conducted because the research question was too broad to fit into an explicit statement of questions regarding participants, interventions, comparisons, outcomes and study design (PICOS) (90). However, a consistent approach was used to describe the components of the interventions that were evaluated in the included studies. For this purpose, the data extraction and analysis during this review was informed by the improved version of the Descriptive Elements of Pharmacist Intervention Characterisation Tool (DEPICT 2), which was developed in 2015 (91, 92).

DEPICT 2 was developed to facilitate the analysis of studies in the pharmacy field and to ensure an in-depth description of pharmacy intervention (93). DEPICT 2 consists of 142 elements related to the characterisation of the interventions that are classified under 11 domains. The tool was developed by analysing pharmacists' interventions in 269 RCT studies that were included in 49 systematic reviews (91). DEPICT 2 was selected because it is a reliable, reproducible tool that allows retrospective analysis of published studies (91, 93). Additionally, DEPICT 2 is considered as a valid tool for pharmacy complex interventions of any type, not like other tools that are specific for certain types of interventions, for example, complex interventions for elderly people (91, 94). Moreover, 2 domains of DEPICT 2 were used previously in a systematic review that was conducted in 2017 by Crespo-Gonzalez, et al. (95) to analyse intervention provided by pharmacists in asthma management and the use of DEPICT 2 allowed the authors to extract data on the interventions' components.

The review provided a summary regarding the studies that were conducted to evaluate asthma interventions and assessed their quality using a quality assessment tool that was developed by the researcher. This provided insights into asthma management interventions, opportunities for

community pharmacists to enhance asthma care and barriers to its provision in the community pharmacy setting. The review helped to highlight gaps in the research regarding community pharmacy-based asthma interventions that could be addressed in future research.

2.2 Aim and objectives

The literature review aimed to review international and UK-based studies that evaluated asthma interventions provided in community pharmacy.

The objectives were to identify:

- The design, population and quality of the studies that evaluated asthma interventions.
- The characteristics of asthma interventions provided by community pharmacy.
- The training provided to community pharmacists to deliver asthma interventions.
- The factors affecting the implementation of asthma interventions in community pharmacy.
- The effectiveness of asthma interventions provided by community pharmacy.

2.3 Method

2.3.1 Literature search and screening

A literature search was undertaken to identify relevant articles published before March 2018 using previously identified search terms (listed in section 2.3.2). More recently, the search was updated to include any papers published from March 2018 to Feb 2021. The following electronic databases were searched: Cochrane Central Registers of Controlled Trials, PubMed, CINAHL, SCOPUS and PsychInfo. A hand search was then performed in the Research in Social and Administrative Pharmacy Journal and International Journal of Pharmacy Practice. These journals were selected because their topics of interest are based around pharmacy and include an outcomes evaluation of interventions, which is relevant to the aim of the review. Additionally, the International Journal of Pharmacy Practice was included in the hand search because it is not on PubMed.

Once identified, the articles were downloaded to the EndNote® referencing programme for further screening and duplicates were removed. Screening of the potential studies' titles and abstracts was performed to remove articles that did not comply with the inclusion criteria. Following this, the full texts of the potentially relevant studies were downloaded to the EndNote® referencing program for further detailed screening. Those texts that could not be resourced directly, were obtained via the University inter-library loan system. The full-text reading was performed by the researcher; the inclusion and exclusion criteria were applied to identify the articles eligible for inclusion. Further

discussion was conducted with the research team regarding the included studies to ensure that all the included studies were relevant and met the inclusion/exclusion criteria. Reports from the same study were linked together. Finally, articles from the citations of the included studies were included in the review if considered relevant.

2.3.2 Search terms

The search terms were identified using the PICOS identified earlier, by searching two related systematic reviews (7, 96) and PubMed MeSH terms. Subsequently, the search terms were discussed with the supervisory team before the search was undertaken.

The following search terms were used and combined for the literature search in the following Boolean form: ((Pharm* OR Pharmacis* OR (CHEMIST)) AND ((Community) OR (High street) OR (Pharmacy distribution) OR (RETAIL)) AND (Asthma* OR Respiratory disease* OR Bronchial disease*) AND ((Medicine optimisation) OR (medicine management) OR (patient-centred care) OR (patient care management) OR (medic* use review*)) AND ((asthma management) OR (asthma control))).

Each search term or combination was searched for in the title, keywords and abstract listed in the Scopus and Cochrane Central Registers of Controlled Trials databases, but not in the other databases because their search limits did not permit this. Neither the publication type nor the publication year filters were used.

2.3.3 Inclusion criteria

This literature review looked to review international and UK-based studies that evaluated asthma interventions provided in community pharmacy. In this literature review and throughout the thesis, community pharmacy is defined as a pharmacy or retail unit that allows public access to medications and pharmacy-based interventions, including any type or size of community pharmacy, such as large chains and small community pharmacies that are located on the high street, in supermarkets or neighbourhood centres (50). Therefore, the inclusion criteria for this review were studies undertaken in the community pharmacy setting, providing an intervention to improve asthma symptoms control in adult asthma patients, which was mainly provided by a community pharmacist. Based on the NICE guidelines (12) for asthma management, adults were identified as over 17 years of age. Moreover, studies were included if they were conducted in asthma and COPD or more than one age group, as long as the results were separately outlined for asthma patients or adult patients.

Further, the studies were included only if the measured outcomes were related to asthma control, quality of life, lung function, healthcare utilisation, drug-related problems, and/or symptoms improvement, practitioner related and/or cost, either as a primary or secondary outcome. These outcomes were chosen due to their importance in the measurement of asthma management in most of the previous studies, and the evaluation of pharmaceutical interventions provided by community pharmacy. All types of research design and methodology were included because the review sought to examine the largest possible number of interventions provided by community pharmacy for managing adult asthma patients. Only original research papers that were written in English were included.

2.3.4 Exclusion criteria

Studies were excluded if the intervention was delivered to children rather than adults, if the intervention was delivered in any setting other than community pharmacy and if the outcomes measured were different from those mentioned earlier in the inclusion criteria. Literature and systematic reviews were not included in the review. Finally, studies were excluded if the full text or English version could not be sourced.

2.3.5 Data extraction and analysis

The data collected was based around the study method, intervention provided in the study, pharmacy training, outcomes measured and results. The interventions undertaken in community pharmacy were described in order to provide an overview of the asthma interventions provided to adult patients in community pharmacy.

To ensure consistency in data extraction, the DEPICT 2 tool was utilised by the researcher to guide data extraction regarding the components of the interventions that were tested in the included studies. For guidance the researcher used the instruction manual published on the DEPICT project website (92).

Eight domains of DEPICT 2 were used in this review because some of the domains were not applicable for use. For example, the setting domain was not used because all the interventions assessed in this review were conducted in the community pharmacy setting. Some of the elements of DEPICT 2 were modified by the researcher as appropriate to be more specific to asthma intervention in the community pharmacy setting.

The modifications included the removal of some elements of the domains of the intervention if they did not apply to asthma interventions. On the other hand, some elements were amended, for

example, the element of the study population domain included different categories of asthma patients. The tool was developed and used to ensure consistent assessment of the interventions included in the literature review. The eight main domains of DEPICT 2 that are specific to asthma interventions in the community pharmacy setting, their description and elements are detailed in Table 2-1,

Table 2-1 DEPICT 2 domains that were used to extract data in this review

Domains	Description and elements
1. Study population	a. Any adult asthma patient
	b. Adult patients with poorly controlled asthma symptoms.
	c. Adult patients with controlled asthma symptoms.
	d. Other
2. Actions taken by community pharmacy	a. Education
	b. Patient counselling
	c. Check that patients have an AAP and/or provide them with one.
	d. Referral to other HCPs
	e. Change or suggestion for therapy change
	f. Inhaler technique
	g. Other
3. Intervention frequency	a. Number of contacts with patients
	b. Intervention duration per patient
4. Delivery methods	a. Face-to-face
	b. Written (email or letter)
	c. Telephone
	d. Video conference
5. Variables assessed	a. Drug selection/prescription analysis
	b. Asthma control
	c. Drug-related problems

	d. Patient education needs and beliefs
	e. Medication adherence
	f. Medication history
	g. Other
6. The clinical data sources that were used for patient assessment	a. Pharmacy records/pharmacy computer system
	b. Peak flow monitoring
	c. Patient self-monitoring data
	d. Adherence measuring tool
	e. Patient interview
	f. Direct contact with the GP
	g. Other sources
7. Measured outcomes	a. Asthma control
	b. Occurrence of asthma exacerbations
	c. Medication related
	d. Inhaler technique
	e. AAP
	f. Others
8. The intervention materials	a. Referral letter
	b. Educational materials including leaflets or written Asthma Action Plan (AAP)
	c. Patient diary (asthma symptoms self-monitoring)
	d. Guidelines/clinical protocol provided to pharmacists
	e. Self-monitoring device (peak flow meter)
	f. Label
	g. Other

2.3.6 Quality assessment

The review included a variety of study designs that included randomised, controlled and observational studies. Because no satisfactory published method exists for the combined quality assessment of observational, randomised and nonrandomised studies, a quality assessment system was developed by the researcher and reviewed by the research team. The developed quality assessment system was influenced by the Newcastle-Ottawa Scale for assessing the quality of non-randomised studies in meta-analysis (97).

The assessment used a star system that assessed the quality of the studies included in terms of the quality of research and the intervention provided. The quality of the research was assessed using three factors:

1. Study design, which was grouped into a cohort, qualitative, controlled trials and randomised control trials (three stars).

2. Inclusion criteria, which was classified into any asthma patients, asthma patients who were using certain inhalers and asthma patient groups.

3. Study period, which was classified into two months, over two months and less than six months.

The interventions provided in the study were assessed using three components:

1. Contents of the intervention, which were classified into one, two or more than two components.

2. Exposure to the intervention, which included one session, two or more and less than six months and two or more and period of six months or more.

3. The outcomes assessment method, which included self-report, interviews with patients, review of their medical records and/or a validated assessment tool. The results of each factor assessment were combined to assess the overall quality of the study and the intervention provided. The quality assessment tool is detailed below in *Table 2-2*.

Assessment factors and ratings	
Quality of research methods	Quality of the intervention provided
Study design	Content of the intervention

Table 2-2 Quality assessment tool

Observational ★	CT ★★	RCT ★★★	One component ★	Two components ★★	More than two components ★★★
Inclusion criteria			Exposure to the intervention		
Any asthma patient ★	Patients using a certain type of inhaler devices ★★	Patients with poorly controlled asthma or other ★★★	One session only ★	Two or more sessions and less than 6 months period ★★	Two or more sessions and more than 6 months period ★★★
Study period			Outcomes assessment method		
Two months or less ★	More than 2 months and less than 6 months ★★	6 months or more ★★★	Self-report ★	Interviews with patients or patients' medical records ★★	Validated tool or measured as part of the intervention ★★★
Overall quality			Overall quality		
Five or less stars	Six stars	Seven to nine stars	Five or less stars	Six stars	Seven or more stars
Fair	Moderate	Good	Fair	Moderate	Good
CT: Controlled Trial, RCT: Randomised Control Trial.					

2.4 Results

This review included 20 studies (98-114) that assessed asthma interventions for adult asthma patients in the community pharmacy setting.

2.4.1 Search results

The database search identified 290 potentially relevant studies which were published in peer-reviewed journals. The numbers of hits for each search term, the combinations of search terms and databases are detailed below in Table 2-3.

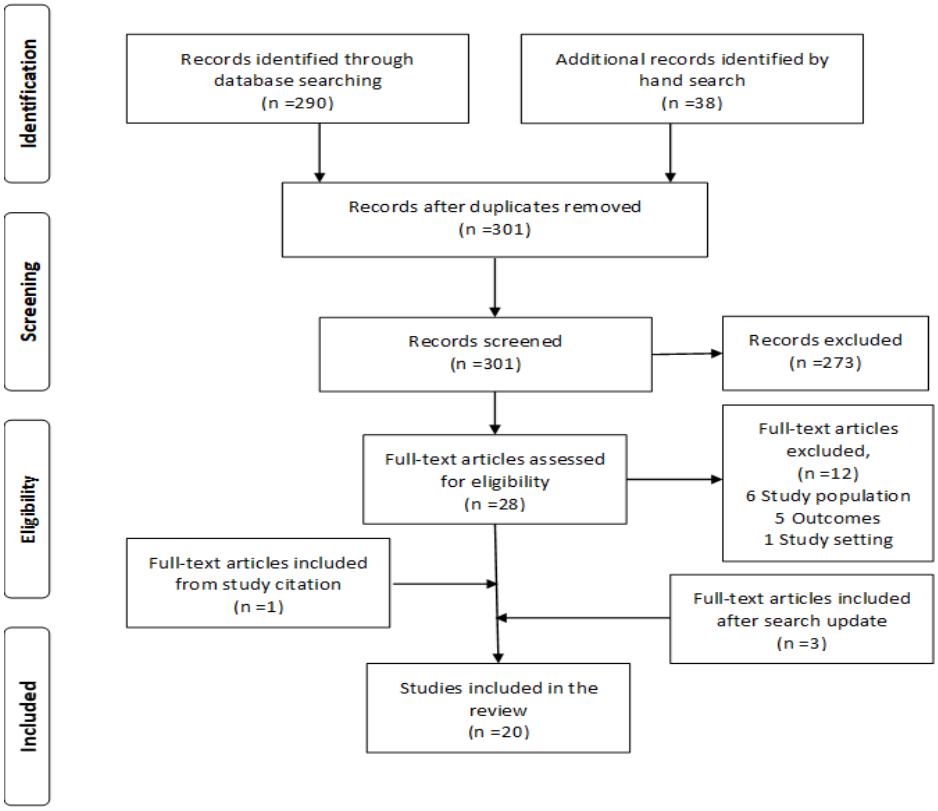
Table 2-3 Search terms and results

Number	Search Term	PubMed	Cochrane	CINHAL	Psych INFO	Scopus
1	Pharm*	646,404	101,362	229,825	44,844	1,378,009
2	Pharmacis*	31,361	2,642	16,785	3,115	786,850
3	Chemist	1,842	52	283	436	43,368
4	1 OR 2 or 3	660,432	101,405	230,051	46,050	141,8075
5	Community	628,484	27,991	229,710	365,664	1,273,817
6	High street	57,430	11	167	3,923	29,783
7	Pharmacy distribution	30,935	121	82	778	5,094
8	Retail	7,389	166	6,772	5,602	48,290
9	5 OR 6 OR 7 OR 8	713,826	28,396	234,845	374,435	1,320,509
10	4 AND 9	32,412	2,344	10,870	4,098	31,566
11	Asthma*	173,550	27,422	34,884	7,847	240262
12	Respiratory disease*	38,116	16,651	8,585	6,582	389,011
13	Bronchial disease*	8,677	1,807	1,076	346	51,184
14	11 OR 12 OR 13	212,621	42,338	42,791	13,830	275,422
15	10 AND 14	575	11	220	74	848
16	Medicine optimisation	1,362	136	71	768	10,967
17	Medicine management	640,708	4,238	1,713	46,220	183,984
18	Patient-centred care	3,667	1,348	1,173	1,092	20,868
19	Patient care management	765,489	21,294	4,253	37,513	393,184
20	Medic* use	96	12,993	636	35,981	936,656

	review*					
21	16 OR 17 OR 18 OR 19 OR 20	1,251,931	36,128	7,741	80,716	22,850
22	15 AND 21	201	70	6	15	602
23	Asthma control	34,238	13,622	4,527	1,937	40,882
24	Asthma management	21,779	2,470	2,901	1,613	3,720
25	23 OR 24	49,450	14,240	6,612	3,030	8,793
26	22 AND 25	181	48	3	13	45

Through hand searching, 38 articles were identified, which increased the total number of results to 328 articles. After duplicates were removed and the titles of the potential articles were screened for inclusion/exclusion criteria, 192 studies were retrieved for further screening. The abstracts of these 192 studies were screened and all the studies that did not meet the inclusion criteria were excluded; 45 articles were identified for the full-text screening. After the full-text screening, 28 articles were excluded and one study was included from citations in the full-text studies. Based on the inclusion/exclusion criteria, 17 studies were considered eligible to be reviewed. Recently, the search was updated and three more studies were included. Overall, 20 studies were included in the review. The detailed screening process and numbers of included and excluded studies are detailed below in Figure 2-1.

Figure 2-1 Flow chart of studies included in the literature review



Included studies

This section provides details regarding the studies that were included in the review after the full-text screening. Detailed searching retrieved 31 studies for full-text review to identify those that were eligible for inclusion. Based on the inclusion/exclusion criteria, 20 studies were considered eligible to be reviewed (detailed in sections 2.3.3 and 2.3.4).

This review included 20 studies (98-117) that assessed the provision of community pharmacy-based interventions for adult asthma patients. A study (98) conducted in Serbia was considered eligible because the results from adults and children were separated. Two other studies (100, 111) were included, even though it was conducted on patients with asthma or COPD because the results of the studies were displayed separately for each condition.

Included studies were conducted in community pharmacy settings in the period from 2001-2020, in different countries. A range of methods was used among the included studies to assess the interventions provided to asthma patients including four RCTs (105, 108, 110, 111), three cluster RCTs (99, 104, 106), one pragmatic cluster Randomised Trial (RT) (102), one cluster RT (103), one Controlled Trial (CT) (112), two parallel control design (109, 116) and eight observational

studies (98, 100, 101, 107, 113-115, 117), in which the study participants were not randomised to the intervention. The eight studies included five prospective observational intervention (98, 100, 107, 114, 115), one prospective comparative observational (117), a cross-sectional study (101) and one effectiveness-implementation hybrid design (113). The latest was considered observational because the study was conducted with no randomisation, no control group and involved testing the implementation strategy of the intervention while observing its impact on the outcomes (113, 118).

All the 20 studies were conducted in adult asthma patients, and in two (100, 111) of the studies, COPD patients were included too. However, 13 studies (100, 102-107, 109-111, 113, 114, 116) were provided to a certain group of asthma patients. These asthma patient groups included poorly controlled asthma patients (98, 100, 103-105, 113), patients at risk of poor asthma control (102, 116), patients receiving certain ICS (106, 114), patients receiving a certain type of inhaler device (107) and patients receiving any preventer inhaler (109-111).

There was variability in the methods used to identify patients with poorly controlled asthma among the studies. Two studies (100, 113) used validated asthma control assessment tools, the Asthma Control Assessment Questionnaire (ACAQ) and the Asthma Control Test (ACT). Another study (103) identified patients with poorly controlled asthma as those who were using the reliever inhaler more than three times a week, had frequent attacks and/or night or day asthma symptoms. Patients with poor asthma control were only identified based on the number of reliever inhalers they had used during the last six or 12 months (104, 105).

An Australian study (102) in 2013 targeted patients who were at risk of poor asthma control, identifying them as patients who used the reliever inhaler more than three times a week, had not had an asthma review in the previous six months or had one or more criterion from the revised Jones Morbidity Index (119). This index is used in UK general practice and is made of three simple, clinically relevant questions to categorise asthma patients into low, medium, or high morbidity related to lung function (119). Some studies (102, 108, 110, 111) considered regular visits to community pharmacy as an additive inclusion criterion for the patients to be recruited into the study. Another Australian study (103) also considered patients eligible for inclusion only if they had not visited the GP during the six months before the study commenced, along with the other inclusion criteria.

The details of the included studies are presented in Table 2-4 along with the quality assessment results.

Table 2-4 Included studies and their quality rating

First author, year and country	Study design	Star rating for study design	Star rating for inclusion criteria	Star rating for study period	Quality of the research method	Content of the intervention and exposure	Outcomes Assessment Method	Quality of The Intervention
Kovacevic 2017, Serbia (98)	Prospective intervention study	★	★	★★	Fair	★★★★★	★★	Good
Manfrin 2017, Italy (99)	Cluster RCT	★★★	★	★★	Moderate	★★★	★★★	Moderate
Apikoglu-Rabus 2016, Turkey (100)	Prospective intervention study	★	★★★	★	Fair	★★★★	★★★	Good
Watkins 2016, Australia (101)	Cross-sectional	★★★	★	★	Fair	★★	★★★	Fair
Armour 2013, Australia	Pragmatic cluster RT	★★★	★★★	★★★	Good	★★★★★★	★★★	Good

(102)								
Bereznicki 2013, Australia (104)	Cluster RCT	★★★	★★★	★	Good	★★★	★	Fair
Garcia-Cardenas 2013, Spain (106)	Cluster RCT	★★★	★★	★★★	Good	★★★★★	★★	Good
Ovchinikova 2011, Belgium (107)	Prospective intervention study	★	★★	★	Fair	★★★★	★★★	Good
Bereznicki 2008, Australia (105)	RCT	★★★	★★★	★	Good	★★★	★	Fair
Mehuys 2008,	RCT	★★★	★	★★★	Good	★★★★★	★★★	Good

Australia (108)								
Armour 2007, Australia (103)	Cluster RCT	★★★	★★★	★★★	Good	★★★★★★	★★★	Good
Smith 2007, Australia (109)	Controlled parallel	★★	★★	★★★	Good	★★★★★★	★★	Good
Barbanel 2003, UK (110)	RCT	★★★	★★	★★	Good	★★★★★	★★	Good
Weinberger 2002, America (111)	RCT	★★★	★★	★★★	Good	★★★★★	★★	Good
Schulz 2001, Germany (112)	CT	★★	★	★★★	Moderate	★★★★★★	★★	Good

Fuller 2017, Australia (113)	Effectiveness-implementation hybrid design	★	★★★	★★★	Good	★★★★★	★★	Good
Giraud 2011, France (114)	Prospective intervention	★	★★	★	Fair	★★★	★★	Fair
Paoletti 2020, Italy (117)	Prospective comparative study	★	★★	★★★	Fair	★★★★★	★★★	Good
Nastaravicius 2018, Lithuania (116)	Parallel CT	★★	★★★	★★★	Good	★★★★★★	★★★	Good
Narhi 2002, Finland (115)	Prospective intervention	★	★	★★★	Fair	★★★★★★	★★	Good

Quality assessment of the included studies

The quality of the included studies varied due to the difference in study design, intervention provision and evaluation. Table 2-4 showed the detailed rating for the quality of the research design and the overall rating of the interventions provided. Of the studies, 11 (55%) showed a 'good' quality rating and included eight RCTs, two CTs and one observational study. The limitations of the observational study compared to the RCT were strengthened by the long period of the study. Among the remaining nine studies; two (10%) showed a 'moderate' quality rating and seven (35%) showed a 'fair' quality rating.

Excluded studies

This section provides details regarding the studies that were excluded as a result of assessing their eligibility based on the inclusion/exclusion criteria (detailed in sections 2.3.3 and 2.3.4). Of the studies, 14 were excluded, the rationale for exclusion is discussed for each of the 14 studies below.

In an Indian study (120), the intervention was delivered by a community pharmacist, but it was excluded because it was conducted in a clinic rather than in a community pharmacy. This study was excluded because it may not reflect the current intervention provision in community pharmacies in the UK. Six studies (76, 121-125) were excluded based on the population included in the studies. An American study (121) was conducted in patients who were using an inhaler medication and not specifically in patients with asthma; whilst the other five studies (76, 122-125) did not meet the age criteria.

Five studies (126-129) were excluded based on the study aim and measured outcomes. One of these studies (126) was conducted in Northwest Ethiopia; it aimed to test the pharmacists' knowledge and experience in demonstrating the inhalation technique. Two studies from Canada (127) and Australia (128) were excluded because the studies aimed to explore asthma burden and severity. Additionally, an Australian study (129) was excluded as it was conducted to test the performance of an asthma control screening tool in community pharmacy. Another Australian study (130) was excluded because it aimed to evaluate the reliability of spirometry that was conducted in community pharmacy.

2.4.2 Intervention characteristics

A variety of interventions were provided to asthma patients by community pharmacists and assessed by the studies included in this review. The quality of the intervention in each study was

assessed and the results were presented in Table 2-4. Overall, 15 (75%) of them were rated as good quality, one (5%) were moderately rated and four (20%) showed fair quality.

The intervention characterisation tool was used to characterise the interventions provided in community pharmacy among the included studies. The interventions that were provided among the different studies are summarised in Table 2-5 below.

Table 2-5 Interventions provided in the included studies

Study first author and year	Actions taken by the community pharmacists	Frequency of the intervention	Method of delivery
Kovacevic 2017 (98)	Patient education and counselling, inhaler technique, self-management, Asthma Action Plan (AAP)	2-3 sessions (around 30 minutes each)/3 months study period	Face-to-face
Manfrin 2017 (99)	Patient education and counselling and referral to a health care practitioner	Once (around 26 minutes)/9 months study period	Face-to-face
Apikoglu-Rabus 2018 (100)	Patient education and counselling and inhaler technique	3 sessions (10-50 minutes each)/2 months study period	Face-to-face
Watkins 2016 (101)	The patients were interviewed to assess their needs	Once (duration was not mentioned)/2 weeks	Face-to-face
Armour 2013 (102)	Patient education and counselling, inhaler technique and referral to a health care practitioner	Three or 4 sessions (20-75 minutes each)/6 months study period	Face-to-face
Berezinicki 2013 (104)	Patient education and counselling and referral to a health care practitioner	Once (duration of the session was not mentioned)	Face-to-face or mail
Garcia	Patient education and	Three sessions	Face-to-face

Cardenas 2013 (106)	counselling, inhaler technique	(duration of the session was not mentioned)/6 months study period	
Ovchinikova 2011 (107)	Patient education and counselling, inhaler technique	Two visits (duration of the session was not mentioned)/1-month study period	Face-to-face
Berezinicki 2008 (105)	Patient education and counselling and referral to a health care practitioner	Once (duration of the session was not mentioned)	Mail
Mehuys 2008 (108)	Patient education and counselling, inhaler technique	Three visits (duration of the session was not mentioned)/6 months study period	Face-to-face
Armour 2007 (103)	Patient education and counselling, inhaler technique and referral to a health care practitioner	Three or four visits (duration of the session was not mentioned)/6 months study period	Face-to-face
Smith 2007 (109)	Patient education and counselling, self-management and referral to a health care practitioner	Six (20-45 minutes) visits/9 months study period	Face-to-face
Barbanel 2003 (110)	Patient education and counselling, inhaler technique, self-management and referral to a health care practitioner	One session (45-60 minutes), and then follow-up of the patients by telephone for 3 months	Face-to-face and telephone
Weinberger 2002 (111)	Patient education and counselling, and referral to a	Three sessions (duration of the	Face-to-face

	health care practitioner	session was not mentioned)/one-year study period and follow-up monthly by telephone	
Schulz 2001 (112)	Patient education and counselling, inhaler technique and self-management	Nine visits (duration of the session was not mentioned)one-year study period	Face-to-face
Fuller 2017 (113)	Patient education and counselling, inhaler technique	Four visits (duration of the session was not mentioned)/6 months period	Face-to-face
Giraud 2011 (114)	Patient education and counselling, inhaler technique	Once (30 minutes)	Face-to-face
Narhi 2002 (115)	Patient education and counselling and referral to a health care practitioner	Four visits (15-120 minutes)/one-year study period	Face-to-face
Nastaravicius 2018 (116)	Patient education, inhaler technique training and AAP	Two visits (duration of the session was not mentioned) /6 months period	Face-to-face
Paoletti 2020 (117)	Patient education and inhaler technique training	Two visits (duration of the session was not mentioned)/6 months period	Face-to-face

As shown in Table 2-5 above, there was variability in the constituents of the interventions provided among the studies and the frequency of the interventions.

One of the studies (99) evaluated interventions that were delivered as part of the Italian Medicine Use Reviews (I-MUR). The study (99) was undertaken to evaluate the I-MURs provided to asthma

patients in community pharmacy, which included a structured interview with patients to assess their asthma control, medication use and adherence. The other studies evaluated interventions that were developed and delivered for study purposes. The following sections will discuss the elements of the interventions (as described earlier in the intervention characterisation tool) including the action taken by pharmacists, intervention frequency, delivery method, measured outcomes, pharmacist training, intervention materials and intervention implementation and sustainability.

Action taken by pharmacists

Although there was variability in the action taken by pharmacists among the 20 studies, all of the interventions assessed involved an educational element as part of the intervention. Patient education was based around: asthma, (98, 102-105, 108, 110) asthma management and monitoring, including self-management skills, for example, monitoring of peak flow readings, symptoms and exacerbations, (98, 103, 104, 109, 110, 112, 115) asthma medication and/or adherence (98, 102-106, 108, 111, 113) and inhaler technique (98, 100, 102, 103, 106-108, 110, 112-117).

Within the studies included in this review, six (98, 109, 110, 112, 115, 116) assessed person-centred self-management interventions. During these studies, (98, 109, 110, 112, 115, 116) the patient's needs were identified, and a self-management plan was developed by the community pharmacist and the patient; this was then provided as advice or as a written plan.

Barbanel's study (110) was the only one that was conducted in the UK among the included studies. In this study (110), a self-management plan was provided to asthma patients by community pharmacy. Patients' inhaler technique was reviewed by the community pharmacist, they were then educated about their asthma, inhaler technique, non-pharmacological factors, and self-management skills (110). As part of their self-management plan, patients were instructed to alter their ICS dose in response to their symptoms and/or Peak Expiratory Flow Rate (PEFR) and educated on when to request an oral corticosteroid prescription or urgent intervention from their GP (110). Patients were also followed up weekly via the telephone by the community pharmacist for three months (110).

Another controlled study (109) that was conducted in Australia in 2007, involved a self-management intervention that was developed based on patients' behaviour and needs. Asthma patients involved in the study were interviewed to identify the problems they have with their asthma

management, goals to be achieved and strategies to achieve the goals (109). The findings of the study showed that the most repeated goals among patients were related to asthma triggers; this highlighted the importance of trigger identification and avoidance in asthma management (109). In Smith's study (109), community pharmacists motivated patients to manage their condition by helping them to identify their goals and providing them with guidance and support to choose the best method to achieve their goals (109). Six studies (98, 109, 110, 112, 115, 116) provided person-centred self-management interventions that improved asthma patients' outcomes.

Furthermore, three studies (98, 103, 110) focused on the non-pharmacological factors that may affect asthma management, including asthma triggers, nutrition, physical activity and sleep. Asthma patients were also educated regarding smoking cessation as part of the educational interventions in four of the included studies (98, 100, 108, 110). Overall, there was variation in asthma education provided to the patients among the studies. More focus on non-pharmacological management of asthma, especially asthma triggers management might help to provide preventive care to asthma patients (109).

The inhaler technique training process used in the studies varied. In six of the studies, (106, 107, 113, 114, 116, 117) community pharmacists provided asthma patients with a physical demonstration of inhalation technique along with verbal and written instructions on how to use their inhaler(s). Other studies involved physical demonstration only (98, 102, 103) or verbal and written instructions (100). Assessment of the inhaler technique and correction were conducted in three of these studies (108, 112, 116). On the other hand, the study that was conducted in the UK mentioned the inhaler technique education as part of the intervention provided to patients, without explaining the technique used (110).

In one of these studies (114), which was conducted in France in 2011, previous training on inhaler technique was evaluated by the community pharmacist. In this study (114), the findings showed that 67% of the participants were previously educated on how to use their inhaler by an HCP including pharmacists, however, only 35% of the participants had demonstrated their inhaler technique to an HCP (114). Previous training on inhaler use was assessed in another study in 2010 in Australia (107), which showed that 96% of the participants were previously educated on how to use their inhaler (mostly by their GP), and physical demonstration was performed in 53% of the participants. However, reinforcement of the inhaler technique education by an HCP occurred only in 10% of the participants (107). Variability in the provision of inhaler technique training was evident

in the findings of the review. Additionally, physical demonstration of the inhaler technique was not always performed in all asthma patients.

Edward Bartlett defined patient counselling as "*an individualised process involving guidance and collaborative problem-solving to help the patient to better manage the health problem*" (131),[p323]. In seven of the studies (98, 99, 102, 103, 109, 113, 115), patient counselling was provided regarding their condition, asthma management and/or their attitudes toward their medication to improve their adherence and/or inhaler technique.

In the UK, community pharmacists check if patients have an AAP and may refer those who do not have one to their GP (70). An expansion of the clinical role of community pharmacists in the care of asthma patients was suggested in a cross-sectional study; Watkins et al. (101) suggested that pharmacists could develop an AAP, regularly review and increase or decrease a patient's medication. In Australia, a cluster RCT (103) was conducted in 2007 to evaluate an asthma pharmacy care programme for patients with uncontrolled asthma in community pharmacy to improve their symptoms. The study (103) was conducted on 396 asthma patients from 57 community pharmacies over a six-month period, and each patient was seen in community pharmacy three to four times. During the study period, the intervention group was provided with an educational intervention based on medication adherence and inhaler technique, and their medication was reviewed to highlight any drug-related problems (103). Consequently, patients' management goals were identified, and some patients were referred to the GP (103). Although the results of the study were promising and improved asthma control and patients' adherence to their treatment, 80% of patients in the intervention group were referred to the GP, most of which (90%) were referred because they did not have an AAP (103). Although the intervention increased the number of patients with an AAP among the study participants from 23% to 64% over a six-month period (103), not all of the patients were provided with an AAP by the end of the study. The provision of an AAP by the community pharmacist was assessed by the Serbian study (98) that was conducted in 2017. In this study (98), a counselling intervention was provided to asthma patients by community pharmacy through a systematic, structured, face-to-face interview with patients along with the development and provision of an AAP. In Lithuania, a parallel controlled study (116) was conducted to evaluate an intervention model that involved patient education and the provision of an AAP. The results of the study showed that asthma control was increased in the

intervention group (who received the intervention) from 32.6% to 47.7%, however, the improvement in asthma control was related to enhancement in inhaler technique and patient education (116).

Another intervention that was assessed in nine of the included studies (99, 102-105, 109-111, 115) involved the referral to another HCP. Patients' needs and asthma control were assessed before the pharmacists decided to refer the patient to another HCP. Referral to another HCP was undertaken as the main action of the intervention or as part of a complex intervention. Although community pharmacists referred patients to another HCP, they played a role in the assessment of asthma control and patients' needs. Further research could be conducted to explore if this intervention could be improved to involve further action by the community pharmacists.

Among the 20 studies, none included a change in medication, dosage, or laboratory test by the pharmacist. In one observational intervention study (115) that was conducted in Finland in 2002, the intervention provided by community pharmacists involved patient education, recommendation of dosage or medication change by contacting a physician or nurse and/or referral to a specialist if needed (115). The intervention consisted of four visits over a one-year study period and involved unstructured interviews with the patients to assess and solve any self-management related problems perceived by the patient or identified by the pharmacist (115). The results of the study (115) showed that 50% of the patients had no self-management problems at the end of the study period. Unfortunately, the authors of the study (115) have not mentioned explicit data regarding the number of patients who needed a medication or dose change and if the intervention helped to decrease this problem. However, the patients involved in the study perceived that receiving advice regarding asthma medication adjustment according to the symptoms was one of the most useful areas of the intervention (115). The undertaking of this type of intervention in community pharmacy was suggested to expand the role of community pharmacists by Watkins et al. (101) in their cross-sectional study.

Intervention frequency

The duration and frequency of interventions varied among the studies included in this review. Some of the interventions, including patient counselling, written education material, referral to another HCP and/or inhaler technique training, were provided to the patient on one occasion during the study period. However, the other educational and self-management interventions frequency ranged from one to nine visits during the study period. The length of the follow-up period in the included studies also varied from two weeks up to a year.

In Australia, Armour, et al. (102, 103) assessed patients' outcomes (asthma control, inhaler technique and AAP) improvement in two groups of asthma patients, one received the intervention in three visits and the other group received the intervention in four visits in six month period. The findings showed no significant difference in the outcomes between the two groups and suggested that an asthma intervention provided in the community pharmacy consisting of three visits could be more feasible than four visits; due to the lower cost and amount of time required (102, 103). There is a lack of evidence to recommend an optimal or preferred frequency for community pharmacy-based asthma intervention. This might be caused by the variability of the interventions provided among the different studies and the costs.

Delivery method

A common factor in the interventions assessed in 18 of the included studies (98-103, 106-117) was the face-to-face method used to deliver the intervention. Only Bereznicki et al. (105) assessed an intervention that included educational material that was sent to the patients by mail from community pharmacy. Later on, Bereznicki, et al. (104) conducted a study in 2013 to compare face-to-face and mail methods of delivering the intervention in community pharmacy. The pharmacists delivered the intervention to 89.4% (414/463) of patients in the mail group and 66.6% (235/353) of patients in the face-to-face group (104). The two methods were assessed by comparing the use of SABA and ICS inhalers in each group to the control group (104). The results suggested that the largest decrease in SABA usage was in the mail intervention group, followed by the face-to-face intervention group; the lower uptake of the face-to-face intervention by the community pharmacists affected the overall outcomes (104). More delivery methods that utilise technology could be used and assessed to improve patients' engagement with asthma interventions and ensure a higher uptake by community pharmacists.

Variables assessed and clinical data sources

Data was collected at baseline in all of the included studies (98-117) to assess certain patient variables that were related to asthma control, patients' knowledge, asthma management and asthma medication. Some studies (98-103, 106-109, 112-114, 116, 117) collected the data directly from patients through systematically structured interviews and/or a validated tool or questionnaire; while some studies (100, 104, 105, 108, 111) used the patient's medical records to collect the data. One of the studies used unstructured interviews with patients to collect data through the study period (115). The data collected was analysed to identify individual patients' needs to inform the

development of an individualised intervention or education material to be provided to the patient, or to assess their baseline characteristics (115).

In a German study (112), asthma patients were recruited through community pharmacy, but their diagnosis of asthma was assessed and confirmed by a physician before the intervention was provided to them by the community pharmacist. This joined work between the community pharmacist and the physician facilitated the identification of asthma patients who met the inclusion criteria for the study (112).

In a one-year study in Indiana (111), community pharmacists strived to collect data regarding medication use and to check any hospitalisation or A&E visits that were related to asthma. The community pharmacists had access to an integrated network linking data from Indianapolis' major hospital and/or contacting the site of care, phoning the patients monthly for updates (111).

Measured outcomes.

A variety of outcomes were measured to evaluate the interventions provided in community pharmacy among the included studies, using different measurement tests or tools. The outcomes were asthma control, lung function, the occurrence of asthma exacerbation, medication use, medication adherence, inhaler technique, AAP, patient beliefs self-efficacy and knowledge, quality of life, cost-effectiveness and patient satisfaction. The outcomes measured, measurement tools and the effect of the intervention on the outcomes will be presented in Table 2-6 and discussed below.

Table 2-6 Effect of the interventions on the measured outcomes

Outcomes measured	Measurement method	Effect of interventions on outcomes	Studies that showed 'good' quality rating of the research design and intervention
Asthma control	**ACT (98-101, 108, 116, 117) **ACQ (102, 106, 107, 109, 113, 114) Tool adapted from **NAC (103) North of England asthma symptoms scale (110)	13 studies (98, 99, 101-103, 106, 108-110, 113, 114, 116, 117) measured the effect of the pharmacist's intervention on asthma control and 10 of them (98, 99, 102, 103, 106, 109, 110, 113, 114, 116) reported improvement in asthma control. One study (101) showed no relation between asthma control and other patients' outcomes and the other two studies (108, 117) showed no significant improvement in asthma control after receiving the intervention.	Among the 13 studies, six (102, 106, 108-110) studies showed good quality rating of the research design and the intervention compared to the other included studies.
Lung function	** FEV1 and/or**PEFR (111, 112, 117)	Three studies (111, 112, 117) measured lung function as an outcome. Only one study (111) reported significant improvement of lung function as a result of a pharmaceutical care programme intervention compared to usual care.	Among the three studies, only one study (111) showed good quality rating of the research design and the intervention compared to the other included studies.

Exacerbations	Questionnaire (101) Self-reported by patients (108) A&E visits and hospital admissions from patients' medical records (111)	Three studies (101, 108, 111) measured the effect of the intervention on asthma exacerbations; one study (108) found no significant difference in the occurrence of asthma exacerbations in the intervention group compared to the control group, the second study (111) reported a higher number of A&E visits and hospitalisation in the intervention group. Finally, Watkins et al. (101) highlighted a relationship between poor control and hospital admission and A&E visits in asthma patients.	Two studies (108, 111) showed good quality rating of the research design and the intervention compared to the other included studies, whilst the third one showed fair quality rating of the research design and the intervention.
Medication use	Directly from patients (99) Questionnaire (101-103) Preventer/reliever ratio was calculated from patients' medical records (104, 105)	Medication use was assessed in six studies (99, 101-105). The studies found a decrease in the number of active ingredients used (99) or the reliever inhaler used by patients.	Among the six studies, two studies (102, 103) showed good quality rating of the research design and the intervention compared to the other included studies.
Medication adherence	**MMAS (98-100, 114) **MARS (107, 109) 4-item **MGLS (106) **BMQ (103)	Nine studies (98, 99, 102, 103, 106, 108, 109, 114, 117) assessed the medication adherence in asthma patients after receiving intervention and seven of these studies (98, 99, 102, 103, 106, 114,	Among the nine studies, five studies (102, 103, 106, 108, 109) showed good quality rating of the research design and the intervention compared to the other included

	**TAI (117) Self-reported by patients (108, 116)	117) found positive impact of the intervention on medication adherence in asthma patients. Two studies (108, 109) found no impact of the intervention on medication adherence in asthma patients during the study period.	studies.
Medication and self-management related problems	**PCNE classification scheme (100) Structured interviews with patients (115)	Apikoglu-Rabus and colleagues (100) reported a decrease in medication-related problems among asthma patients at the end of the study. Narhi et al. (115) reported a decrease in patients with self-management related problems.	The two studies showed fair quality rating of the research design and good quality rating of the intervention.
Inhaler technique	10-Step Turbohaler checklist (106) 11-item inhaler device-specific checklist (107) Device-specific checklist (103, 108, 112-114, 116) Tool not mentioned (102)	The nine studies (102, 103, 106-108, 112-114, 116) that assessed inhaler technique reported improvement in inhaler technique after receiving the intervention.	Among the nine studies, six studies (102, 103, 106, 108, 113, 116) showed good quality rating of the research design and the intervention compared to the other included studies.
AAP	Questionnaire (101) Self-reported by patients (102, 103)	Three studies (101-103) reported the proportion of patients who had an AAP among asthma patients. One study (101) reported that less than 20% of	Two studies (102, 103) showed good quality rating of the research design and the intervention compared to the other included

		asthma patients in the study had an AAP. Two studies(102, 103) reported an increase in patients who had an AAP among patients in the intervention group(s).	studies.
Patient beliefs, self-efficacy and knowledge	BMQ (98, 103, 106) **KASE-AQ (109) Self-efficacy scale (112) *KAM (98) **CQ (101, 102) Questionnaire (108, 112)	One of the studies reported improvements in patient beliefs toward their medication (98). Two studies (109, 112) showed an improvement in asthma patients' self-efficacy. Six studies (98, 101-103, 108, 112) reported the impact of the pharmacist's intervention on asthma patient knowledge. Improvement in asthma patients' knowledge was reported in four studies (98, 102, 103, 112). Two studies (101, 108) showed no improvement in asthma knowledge among the study participants.	Four studies (102, 103, 108, 109) showed good quality rating of the research design and the intervention compared to the other included studies.
Quality of life	**AQLQ (102, 103, 108, 109) **QoL (111, 112) Questionnaire (101)	Seven studies (101-103, 108, 109, 111, 112) reported the impact of the intervention on the QoL of asthma patients. Five studies (102, 103, 109, 111, 112) reported	Among the five studies, four studies (102, 103, 109, 111) showed good quality rating of the research design and the intervention compared to the other included studies.

		significant improvement in the QoL of patients after receiving the intervention, while one study (108) reported no impact of the intervention on the QoL. One study(101) showed that poor asthma control had a negative impact on QoL.	
Cost-effectiveness	Cost/ **QALY (99)	Manfarin's 2017 (99) study results showed a 100% probability of the Italian MURs being more cost-effective than the usual care.	The study showed moderate quality rating of the research design and the intervention compared to the other included studies.
Patient's satisfaction with the intervention	4-item global measure (111) Interview with patients (100, 115)	Three studies (100, 111, 115) assessed patients' satisfaction with the intervention provided to them and all showed high satisfaction with the intervention provided by the community pharmacist among asthma patients.	Only one study (111) showed good quality rating of the research design and the intervention compared to the other included studies.
Intervention implementation, provision and/or sustainability	Systematically structured tool and patients uptake of the intervention (113) Developed by the researchers (102)	Fuller's 2017 (113) study results showed that only seven (40%) of the involved pharmacies delivered the intervention and 41% of patients completed the intervention by the end of the study. Armour 2013 (102) study reported sustainability on asthma control. Knowledge and quality of life for 12	The two studies showed good quality rating of the research design and the intervention compared to the other included studies.

		months (follow-up period) after the intervention.	
****ACT: Asthma Control Test, ACQ: Asthma Control Questionnaire, NAC: National Asthma Council of Australia, BMQ: Brief Medication Questionnaire, FEV1: Forced Expiratory Volume, EFR: Expiratory Flow Rate, PEFR: Peak Expiratory Flow Rate, MMAS: Morisky Medication Adherence Scale, MGLS: Morisky Green Levine Scale, MARS: Medication Adherence Rating Scale, TAI: Test of Adherence to Inhalers, PCNE: Pharmaceutical Care Network Europe Foundation, KASE-AQ: Knowledge Attitude And Self-Efficacy Asthma Questionnaire, KAM: Knowledge Of Asthma And Asthma Medicine, CQ: Consumer Questionnaire, AQLQ: Asthma Quality Of Life Questionnaire, QoL: Quality Of Life Questionnaire, DASS: Depression Anxiety Stress Scale.**			

Asthma control.

There were 13 studies (98, 99, 101-103, 106, 108-110, 113, 114, 116, 117) that measured the effect of the pharmacist's intervention on asthma symptoms control. Except for one study that included interviews with patients to identify their needs (101). Most of the studies used validated tools to measure asthma symptoms control, mainly ACT and Asthma Control Questionnaire (ACQ).

Four of these studies (98, 99, 106, 116) reported a significant increase in the number or proportion of patients with controlled asthma symptoms or for whom asthma symptoms control was improved after receiving the intervention. In the Spanish cluster RCT, (106) the number of patients with controlled asthma symptoms increased from 28% to 58.1%, while in the Italian one (99) the proportion of patients with controlled asthma was increased by 40.2% and 45% for the two MUR intervention groups compared to the control group. The third study (116) used a parallel controlled design and the results showed an increase in the proportion of patients with controlled asthma symptoms from 32.56% to 47.6% in the intervention group. The findings of the fourth study (98), which was a prospective intervention study, showed a significant increase in asthma control (measured by ACT score) in 60% of the patients.

One study (114), which was conducted in France using a prospective observational study, reported a significant improvement in the mean ACQ score from 1.8 to 1.4 after one month of the intervention that involved inhaler technique training in community pharmacy. A further study (102) that was conducted in Australia reported significant improvement in asthma control in both of the study groups who received three and four visits intervention. However, there was no significant difference in the improvement in asthma control and ACQ scores between the two groups (102). Furthermore, an RCT (110) assessed the effect of the intervention on asthma control using the North of England Asthma Symptoms score and reported a significant improvement in the mean score of asthma symptoms in the intervention group.

Moreover, a cluster RCT (103) reported a significant decrease in the proportion of patients with severe asthma in the intervention group from 87.9% to 52.7% and no change in the control group. Fuller et al. (113), reported a decrease in the proportion of patients with poorly controlled asthma symptoms from 73% to 56% as a result of receiving the intervention. Another Australian study (109), which used a controlled parallel design, reported significant improvement in asthma control over time in both the control and intervention group who received a self-management intervention.

Further study revealed no significant improvement in asthma control in the intervention group compared to the control group (usual care) (108).

The interventions provided in those studies involved patient education and counselling and/or inhaler technique, self-management, AAP, referral to an HCP. However, due to the variability in the interventions provided, study designs and the way they measured asthma control, it was hard to conclude which component of the interventions caused the improvement in asthma control. Nevertheless, one study (101) assessed some factors that could affect asthma control (including medication adherence, asthma knowledge, AAP and gender) but the findings revealed no significant relationship between asthma control and any of these factors. However, this might be caused by the tools used in the study to measure the outcomes that limited the study ability to highlight the relationship between asthma control and other outcomes. Because these tools are subjective and depend on the patients' memory and willingness to report poor adherence. This limitation could be overcome by qualitative interviewing, where the researcher can probe the interviewees and encourage them to describe their experiences.

Lung function

Three studies (111, 112, 117) reported measurements of lung function as an outcome of the intervention provided, these measurements included FEV1 and/or Expiratory Flow Rate (EFR). One of the studies (112) reported an 11.7% increase in FEV1 after six months in the intervention group but no significant improvement in the lung function in the intervention group compared to the control group at the end of the study. Another study in Italy (117) reported improvement in the mean FEV1 from 80% to 85% and EFR from 75.7% to 82.9% in the intervention group and no change in the control group. Finally, the American study (111) results showed an increase in EFR of patients in the pharmaceutical care programme group and the peak flow monitoring group compared to the usual care group. The three studies assessed interventions that involved different components and intervention frequency, however, there was an improvement in lung function in the three studies. In the American study (111), patients were using a peak flow meter to monitor their lung function, interestingly; the findings highlighted a duplication in the number of breathing-related A&E visits among patients in the intervention group compared to the usual care group. This might highlight that enhancement of patients' involvement in the monitoring of their asthma might increase their utilisation of health care (111). That could be related to an increase in patients' awareness of their asthma (111). Looking at this, one can question if the improvement in lung

function was related to the intervention provided or action taken by HCPs in the A&E department. However, further research could be conducted to investigate if asthma patients who are more involved in their treatment plan are seeking help for appropriate clinical reasons or not. Additionally, the provision of patient education regarding treatment adjustment in response to symptoms, which was highlighted by the findings of the Finland study (115), might decrease the utilisation of secondary care among asthma patients.

Occurrence of asthma exacerbations

Three studies (101, 108, 111) using different methods, measured the number of exacerbations as one of the outcomes. Two of the studies (101, 111) reported the occurrence of asthma exacerbation by the number of visits to the A&E or admissions to the hospital, while Mehyus et al. (108) defined asthma exacerbation as an asthma attack that required an oral CS, visit the A&E or hospital admission. The American study (111) found that visits to accident and emergency were higher in the intervention group, which received a pharmaceutical care program, compared to the usual care group. On the other hand, the Mehuys et al. study (108) reported no effect of the intervention on the occurrence of asthma exacerbations. As discussed earlier, the enhancement of patients' involvement in the monitoring of their asthma might increase their utilisation of healthcare. Furthermore, the Watkins et al. cross-sectional study in 2016 (101) showed a relation between poor-asthma control and the occurrence of asthma exacerbations.

Medication use

Medication use was assessed in six studies (99, 101-105) and the impact of the intervention on it was reported using different methods. Watkins et al. (101) found that 22% of asthma patients in the study were using the reliever only without ICS, which is against the GINA and BTS/SIGN guidance on asthma management. This might not highlight poor practice among HCPs because patients could prefer to buy the reliever inhaler only to save the cost of the preventer inhaler (101).

The Italian RCT study (99) reported a 7.9% reduction in the number of active ingredients used by asthma patients after receiving the I-MUR and it was maintained for six months. A threefold increase in the preventer to reliever inhalers ratio used by patients in the intervention group compared to the control group in an RCT that was conducted in Australia (105).

The other three Australian cluster RCTs (102-104) reported a decrease in the reliever inhaler use in the patients after receiving the intervention. One of the studies (103) reported a 5.7% decrease

in reliever inhaler use. Armour, et al. (102) found a decrease in the reliever inhaler use in the two interventions groups, however, no significant difference was found between the three and four visit intervention groups. A decrease in the reliever inhaler use was found in the three study groups in the Berezniki et al. study (104) but the highest decrease was in the mailed intervention group compared to the usual care and face-to-face intervention groups. In all of those studies, the participants' asthma medications were reviewed and patients were referred to an HCP for a review of their asthma. However, the variability in the duration, frequency and delivery method of the interventions provided in the studies make it impossible to make recommendations on the frequency of such intervention in the community pharmacy setting.

Medication adherence

Nine studies (98, 99, 102, 103, 106, 108, 109, 114, 117) assessed the medication adherence in asthma patients after receiving intervention by pharmacists using many tools. These studies assessed an intervention that involved the provision of patient education and counselling and other components. Seven studies (98, 99, 102, 103, 106, 114, 117) showed a positive impact on medication adherence, regardless of the variability of the components and frequency of the interventions that were provided to the participants.

An increase in the percentage of patients who were adherent to their asthma medication was used to report the impact of the intervention on medication adherence in four studies (98, 103, 106, 114). One study (103) found that the percentage of patients who were adherent to their preventer medication increased from 54% to 71% after receiving the intervention. Another study (106) reported a 75.8% increase in the proportion of patients who were adherent to their asthma medication compared to 50% in the control group. The proportion of patients with very good to moderate adherence to their asthma medication was increased from 58% to 66.2% in one study in France (114). Further, Kovacevic et al. (98) reported that the number of patients with high adherence to their medication was increased after three months of the study.

Two Italian studies (99, 117) reported improvement in overall adherence among asthma patients after receiving the intervention; Manfrin et al. (99) found that medication adherence was improved by 40% six months after receiving the I-MUR. Finally, Armour et al. (102) measured the risk of non-adherence using the Brief Medication Questionnaire (BMQ) and found that the risk of non-adherence was decreased in the two study groups with no significant difference between the three-visit and four-visit intervention groups.

Two studies (108, 109) found no significant difference in medication adherence in asthma patients during the study period. This might be related to the study population and their receptiveness to the interventions or the measurement tools used for medication adherence.

Medication and self-management related problems

One study in the review assessed the impact of the intervention provided on medication-related problems including treatment effectiveness, adverse reactions, cost and the causes for the problems using the Pharmaceutical Care Network Europe Foundation (PCNE) classification scheme (100). At the beginning of the study, 59 medication-related problems were identified and after receiving the intervention, 32 (54.2%) problems were solved.

Another study (115) assessed self-management related problems before and after receiving the intervention by conducting systematic interviews with the patients. After receiving the intervention, 50% of patients reported that they have no problems related to the self-management of their asthma. Both studies used observational intervention design and were conducted in a small sample number, however it showed that community pharmacists might help to identify medication-related problems and support asthma patients to solve them.

Inhaler technique

Inhaler technique was assessed as an outcome in nine studies (102, 103, 106-108, 112-114, 116) using device-specific, 10-step or 11-step checklists and improvement in inhaler technique in asthma patients after receiving the intervention, which involved inhaler technique training, was reported in the nine studies.

The impact of the intervention on the inhalation techniques was reported in one study (116) by a decrease in the mean number of mistakes of the inhalation technique from 2.03 to 1.12 after receiving the intervention. The other eight studies (102, 103, 106-108, 112-114) used the proportion of patients with the correct inhaler technique to report the impact of the intervention on the inhalation technique. The proportion of patients with the correct inhaler technique increased from 17 to 33% and 57 to 72% in the three and four visits intervention groups in the Armour et al. study (102) and no significant difference was reported between the two groups. Another Australian RCT (103) reported a 48.6% increase in patients with correct inhaler technique in the intervention group but it was not measured in the control group. A 75.8% increase in the proportion of patients with correct inhaler technique in the intervention group compared to 50% in the control group was

reported in the Spanish study (106). The Fuller et al. study (113) results showed a significant increase in patients with correct inhaler technique from 12% to 57%, Mehuys et al. (108) reported a 40% increase in the proportion of patients with correct inhaler technique in the intervention group and Giraud et al. (114) also found an increase in the proportion of patients with correct inhaler technique.

Two other studies (107, 112) assessed the inhaler technique and the maintenance of the correct inhaler technique. The first study (112) found improvement in the inhaler technique in asthma patients at six months and the improvement was maintained at 12 months of receiving the intervention, which involved nine visits in a one-year period. The second study (107) found that 100% of patients had correct inhaler technique after receiving a two visits intervention compared to 17% at baseline. After a one-month follow-up, only 61% maintained the correct inhaler technique (107). These studies showed that community pharmacists can provide inhaler technique training to asthma patients and that maintaining a correct inhaler technique in asthma patients require frequent patient education.

Asthma action plan

Three studies (101-103) reported the proportion of patients who had an AAP among the participants. One cross-sectional study (101) reported that less than 20% of the 248 patients in the study had an AAP. The other two studies (102, 103) were conducted in Australia and referred patients who needed an AAP to the GP. The findings of the two studies reported a 40% (103) and 37% (102) increase in patients who have an AAP among patients in the intervention group(s) but it was not compared to usual care. Armour et al. (102) found no difference between the number of patients who had an AAP in the three-visit and four-visit intervention groups. The findings highlighted the need to improve the provision of AAPs among adult asthma patients and that community pharmacists can play a role to enhance the provision of AAPs.

Patient's beliefs, self-efficacy and knowledge

The impact of the pharmacists' interventions on asthma patients' beliefs and self-efficacy was assessed in three of the studies (98, 109, 112). Many tools were used in the assessment and included: beliefs about medicines questionnaire, (98) Knowledge Attitude and Self-Efficacy (KASE) (109), and another study (112) used the Self-efficacy scale. One of the studies reported improvements in patients' attitudes and beliefs toward their medication as a result of the

pharmacist intervention (98). Two additional studies (109, 112) showed an improvement in asthma patients' self-efficacy that was caused by the interventions provided by the community pharmacists.

Six studies (98, 101-103, 108, 112) reported the impact of the pharmacist's intervention on asthma patient knowledge of asthma, asthma medication and/or asthma exacerbations using different tools One of the studies (98) used Knowledge of Asthma and Asthma Medication (KAM), three studies (101-103) used Consumer Questionnaire (CQ) and the other two studies (108, 112) used a questionnaire to assess patients knowledge. Improvement in the asthma patients' knowledge was reported in four studies (98, 102, 103, 112). For example, in one of the studies (98), the KAM score was increased by 15.2% in the intervention group after receiving an educational intervention. Another study (102) reported improvement in asthma patients' knowledge in the two study groups who received three or four visits interventions with no significant difference between the two groups. On the other hand, Mehuys et al. (108) found no effect of the intervention on asthma patients' knowledge and the cross-sectional study that was conducted by Watkins et al. (101) showed no relation between asthma control and patient knowledge among the study participants.

This variation on the effect of different asthma interventions might be caused by the variability of the assessment methods. Additionally, although employing quantitative tools to assess the improvement in asthma patients' knowledge might be useful in terms of comparison between the study participants, it might not provide patients with enough freedom to express their needs and thoughts.

Quality of life

Seven studies (101-103, 108, 109, 111, 112) reported the impact of the intervention on the Quality of Life (QoL) of asthma patients. The QoL was assessed using the asthma quality of life and QoL questionnaires. Amongst the seven studies, a cross-sectional study (101) reported a relation between poor asthma control and asthma quality of life. The study (101) showed that asthma has a more negative impact on QoL in patients with poorly controlled asthma. Five other studies (102, 103, 109, 111, 112) reported significant improvement in the QoL of patients after receiving the intervention. In one of the five studies (112), the overall QoL in the intervention group increased from 58.1 to 66.6 %. Two other studies (103, 109) reported improvement in the QoL in the intervention group during the study period compared to the control group. In the other two studies, (102, 111) that used RCT study design, QoL was improved in all of the study groups. The American one (111) reported sustained improvement in the QoL in patients in both intervention

groups and the usual care group and the Australian study (102) reported no significant difference in QoL improvement between patients who received three or four visits intervention.

Only one study (108) reported no impact of the intervention on the QoL of asthma patients.

Cost-effectiveness

Only one study (99) measured the cost-effectiveness of the pharmacist's intervention. In this study (99), the quality of adjusted life years was used to measure the cost-effectiveness of the Italian MURs. The findings suggested that the Italian MURs, which were targeted to asthma patients in community pharmacy, were effective and showed a 100% probability of being more cost-effective than the usual care (99). This highlighted the need to conduct more studies to evaluate the cost-effectiveness of community pharmacy-based asthma interventions.

Patient satisfaction with the intervention

Patient satisfaction with the intervention provided to them was assessed in three studies (100, 111, 115). Two observational intervention studies used a questionnaire to assess patients' satisfaction with the intervention. In the first study (100), 97.4% (37 out of 38 patients) of asthma patients were satisfied with the intervention provided to them by the pharmacist, compared to 90% (25 out of 28 patients) in the second study (115). In the third study (111), which was a RCT, patient satisfaction with the two interventions provided in the study was assessed using the 4-item global measure. The results showed that patients in the intervention groups were satisfied with the healthcare provided to them more than patients in the usual care group (111). Additionally, patients who received the pharmaceutical care program were more satisfied with their pharmacist than patients in the other intervention and usual care groups (111).

Intervention materials

Written material was provided to the patients in 10 of the studies (98, 100, 106-109, 111-114). These materials were based on inhaler use, smoking cessation and specific issues related to asthma treatment. Of the 10 studies, a Turkish study (100), which was conducted in 2016, assessed interventions provided to asthma patients by community pharmacy; patients were provided with written instructions and demonstration aids on how to use their inhalers, along with a smoking cessation leaflet if needed. In two of the studies (107, 114), a label or sticker containing the inhaler-use instructions was applied or attached to the patient's inhaler device. Among these 10 studies, a written self-management plan was developed and provided to asthma patients in the

Serbian study (98) that was discussed earlier. Moreover, a diary was provided to the patients in three of the studies (108, 109, 112) as part of self-management interventions, to record their asthma symptoms and peak expiratory flow readings to help them monitor their condition. The provision of written educational material or a management plan was not compared to the verbal method. Therefore, there is no evidence to conclude which method is better, however, written materials might help patients to overcome memory recall.

Apart from the written materials, a peak flow meter was provided to patients in one of the studies (108) and was used by the patients to monitor their lung function. In addition, pharmacists were provided with the EasyOne® spirometer in two of Armour's studies (102, 103) in Australia, to monitor the patient's lung function. The EasyOne® device was chosen because it could maintain calibration within routine use (102, 103). These devices were provided to ensure that all patients' readings were taken using the same device to exclude variability that could have resulted from using different devices.

Pharmacist training

All of the studies included in this review provided training to the pharmacists before delivering the intervention, except the Turkish (100) and Finland (115) studies. The training, in general, was based around asthma, medication and/or asthma control and management. Other studies also focused on asthma treatment guidelines (102, 108), inhaler technique (98, 106, 107, 114, 116, 117) and spirometry or PEFR (102, 103, 111, 117). In addition, in some of the studies (99, 102, 103, 113), the training covered patient behaviour and clinical skills to provide the intervention to the patient. However, in 17 studies (98, 99, 101-114, 116), the pharmacists were trained on the study protocol, resources to use and software if applicable.

The pharmacists' training was provided face-to-face in workshops, courses, training sessions (98, 101-114, 116, 117) or via self-study material (99, 102). Moreover, in one of the studies, (99) the training included a role-play or mock interview. The training duration in the studies ranged from two hours up to two days and was provided by a pharmacist, respiratory specialist or more than one HCP.

Pharmacists were provided with a protocol or detailed instructions to deliver the intervention to the patients effectively. In most of the studies, the instructions to deliver the interventions were included in the participant information sheet provided to the pharmacist. In one of the studies (111),

intervention guidance was printed on coloured, laminated paper and displayed in front of the study computers to be easily used by the pharmacists. This variation in the training provided to pharmacists might be related to the variability in knowledge, skills and experience of the community pharmacists across different countries where the studies were conducted, as well as, the variability of the interventions provided among the included studies, study period and funding.

Intervention implementation and sustainability

Most of the experimental studies were conducted to evaluate the interventions rather than to assess the implementation process or the sustainability of the interventions (132). In this review, an Australian study (113) was conducted in 2017 to evaluate the implementation of an asthma intervention in community pharmacy using a systematic approach. In this study (113), Fuller et al. used a Framework for Implementation of Services in Pharmacy model as guidance to implement the asthma intervention. The implementation of the intervention in community pharmacy was assessed using an asthma intervention evaluation model (113). This is a systematic structured model that is used to assess the implementation by an evaluation of the intervention provision and patient outcomes (113). The findings of the study showed variability in the implementation progress among different community pharmacies; seven (40%) pharmacies out of 18 reached the stage of delivering the intervention (113). By the end of the study period, only three pharmacies completed the intervention delivery (113). The implementation process used in the study allowed the pharmacists to overcome any identified barriers before implementation and allowed continuous assessment and identification of any barriers that arose during this process (113). The sustainability of the intervention effects on asthma outcomes cannot be measured from the study because of low uptake by patients (41% of patients completed the intervention) and there was variability in implementation progress among community pharmacies. The variability in sustainability in intervention delivery among community pharmacies was related to financial issues (113).

Another study (102) evaluated the sustainability of the intervention provided to asthma patients in Australia, by following up a subgroup of patients for a further 12 months. The findings showed sustainability in the improvement of asthma control, knowledge and quality of life among the subgroup of patients (102). The limited sample number might affect the findings (102). As mentioned earlier, only a few studies assessed the feasibility of the interventions in terms of frequency and cost-effectiveness, as well as, implementation and sustainability of community

pharmacy-based asthma interventions. This could be an area for future research on asthma interventions in the community pharmacy setting. However, these studies highlighted low patient engagement and financial issues as barriers to the implementation of community pharmacy-based asthma interventions.

2.5 Discussion

The review identified 20 studies that assessed asthma interventions in the community pharmacy setting. The studies included in the review used different study designs, assessed different asthma interventions and measured a variety of outcomes. Accordingly, there was variability in the quality of the studies in terms of the study design and intervention provided. Of the included studies, 55% showed a good quality rating of the study design and 75% of the studies provided good quality rated asthma interventions. Most of the included studies had many strengths including the use of validated tools to measure the outcomes (98-103, 106-109, 111-114), comparison of the intervention with usual care (99, 104-110, 112, 114, 116, 117) and a study period of six months or more (99, 102, 103, 106, 108, 109, 111-113, 116, 117). On the other hand, the limited sample number in some studies limited the generalisability of the result (100, 110, 113, 115, 117).

The process for patient identification was based on collecting data from patients or from their medication record in the community pharmacy. In most of the studies, patient identification was time-consuming and required more than one step or confirmation with another HCP in a different setting. This suggests difficulties in the identification of asthma patients who need support in community pharmacy. The limited access of community pharmacy to the patients' medical records was highlighted previously in the literature as a barrier for delivery of community-pharmacy based intervention (46, 56, 133). More collaboration between patients medical practice and community pharmacy may overcome this problem in identification of patients (134).

The included studies assessed their interventions using a variety of outcomes. Only the Italian study (99) evaluated the cost-effectiveness of the I-MURs conducted in community pharmacy and reported that the intervention was cost-effective. Other studies were conducted to evaluate the cost-effectiveness of community pharmacy-based interventions for patients with COPD (73) and other LTCs (75) but not for asthma. This finding suggest that more studies could be conducted to evaluate the cost-effectiveness of community pharmacy-based asthma interventions.

There was variability in the tools used to measure the outcomes among the studies. The measurement tools were quantitative and only one study used qualitative methodology. Although the study used qualitative methodology to interview HCPs but not asthma patients. Using qualitative methodology that involves asthma patients can help to explore patients' needs and thoughts.

Additionally, the tools used are subjective and depends on patients' memory recall. For example, asthma control was measured using validated tools or by counting the number of inhalers prescribed or dispensed to the patient using their medical records. The Berezinicki, et al. study (104) suggested that community pharmacy records might be used to identify patients with poorly controlled asthma. Patient medication records held in the community pharmacy setting could be used as a source of information to identify patients with asthma who need management and patients with a risk of non-adherence to their medication (135). Although counting the number of dispensed inhalers in patients who regularly visit the community pharmacy could help to identify patients who are overusing their SABA inhalers, patients who get their prescription from different community pharmacies may not be identified. Additionally, poor medication adherence, as determined by the number of inhalers collected by the patients, might not necessarily indicate poor symptoms control.

Only one of the studies was conducted in the UK (110). Although the study showed good quality rated asthma intervention and study method, the limited sample number affected the generalisability of the results (110). On the other hand, the review highlighted several successful international community pharmacy-based interventions that were provided to asthma patients to improve their asthma management. These interventions consisted of one or more components and included: patient education that was based around inhaler technique improvement, patient counselling, person-centred self-management plans, development and provision of AAPs and referral to other HCPs.

A person-centred self-management intervention was assessed in six of the studies and had positive impacts on many of the outcomes including improvement in asthma control (98, 110, 116); medication adherence (98); inhaler technique (112, 116); patients' attitude and beliefs toward their disease and medication (98); self-efficacy (116); and QoL (109, 112). As well as this, 90% of patients were satisfied by the self-management intervention provided to them by the community

pharmacist in one of the studies (115). The improvement in those outcomes can be related to the support that was provided to asthma patients among those studies to manage their condition.

The results of this review showed that inhaler technique education and training in the community pharmacy setting improved inhaler technique and asthma control in adult patients in all the studies that involved inhaler technique training. The variability in the methods used to evaluate the inhaler technique made it hard to conclude which intervention caused more improvement in inhaler technique among the studies. Further improvement of inhaler technique training and the provision of more frequent education on inhaler technique could improve control of asthma and medication adherence in adult patients (98, 107, 114, 116). However, more studies could be conducted to identify a feasible inhaler technique training intervention and its frequency that could allow patients to maintain the correct inhaler technique.

Another intervention that was provided to asthma patients in two of the studies (98, 116) was the development and provision of an AAP. The provision of an AAP improved asthma control, self-efficacy and knowledge in asthma patients in one study (98). Other studies (102, 103) referred patients to the GP if they didn't have an AAP, which increased the AAP ownership in asthma patients, but not all of them had an AAP by the end of the study. Community pharmacy could develop AAPs and review patient medications (101) instead of referring more patients to the GP. In this way, ownership of AAP in adult asthma patients could be improved without increasing the workload on GP practices.

Also, other studies (99, 102-105, 109-111, 115) referred asthma patients to other HCPs including a GP or a specialist for review if needed. It was not possible to conclude the impact of referral to another HCP based on these outcomes because of the complexity of the interventions provided among the studies, however, the two studies that were conducted by Bereznicki and colleagues (104, 105) showed improvement in the preventer to reliever ratio in patients after receiving education and referral to the GP practice intervention. Further research could be conducted to explore if community pharmacy can provide more interventions to asthma patients, rather than referring them to the GP practice for an intervention. For example, there was an absence of medication adjustment as a constituent of the interventions among the 20 studies and this is might be because community pharmacists do not adjust asthma patients' medications in routine practice. This suggested the need to explore further opportunities to enhance community pharmacists' clinical role to support asthma patients (46).

The interventions were delivered to the patients in community pharmacy, face-to-face, over the phone or by mail. Bereznicki, et al. (104) suggested that sending study materials or recommending referral to the GP via mail, was more effective than face-to-face interventions because of the higher uptake of mailed intervention by the pharmacists. The findings suggested that choosing an appropriate delivery method is important in enhancing the uptake of the intervention by the community pharmacists and improving patient engagement (104).

None of the studies assessed video calls as a method of delivery, although it is an accessible method that could save time and cost (136). The Royal Pharmaceutical Society's policy document that was published during the COVID-19 pandemic recommended that *"pharmacists in all care settings must have access to virtual consultation tools and equipment." (133), p3* Providing virtual care by pharmacists, including community pharmacists, might improve patients' access to pharmacy services and their engagement by reducing the travel needed to get to a service (133). The use of technology could allow remote patient monitoring using telepharmacy, from which electronic data collection and devices can be used by pharmacists to monitor and review patient medication and provide counselling to patients remotely (137). Telepharmacy could improve asthma patient engagement with the services and improve their condition but there is limited evidence on the impact of telepharmacy on asthma control and other outcomes in asthma patients (138, 139). Further exploration of the utilisation of technology and telepharmacy to support asthma patients could be undertaken in future research (136, 138).

All the interventions in this review were provided by community pharmacists. Training was provided to the pharmacists to improve their knowledge regarding patient education, asthma guidelines, inhaler technique, spirometry and/or AAP. To further develop their skills to deliver the intervention, some studies provided self-study materials whilst others delivered face-to-face training. Interestingly, only one study used role-plays and mock interviews for the training (99), although this may enhance the practitioner's knowledge and their adherence to research protocols (140). Providing the pharmacists with written instructions for counselling or inhaler technique could help to ensure the consistency of the intervention delivered.

Regardless of the outcomes assessment tools, the sustainability of the improvement in asthma control, medication adherence, inhaler technique or other outcomes cannot be assessed unless patients were followed-up for longer than six months. Fuller, et al. (113), discussed earlier, attempted to test the sustainability of an asthma intervention in community pharmacy, but the

variation in patient outcomes over the six months made it difficult to evaluate if the intervention was sustainable or not. On the other hand, Armour, et al. (102) provided an intervention over a six-month period and followed up 31% of patients for 12 months to test the sustainability of the intervention. The findings showed a sustainability of the improvements in asthma control, quality of life and knowledge, however, the small sample size limited the generalisability of the results (102).

2.6 Strengths and limitations

An extensive search strategy of the literature was performed, covering a large number of databases. The review aimed to answer a question that was too broad to fit into an explicit statement of questions regarding participants, interventions, comparisons, outcomes and study design (PICOS) (90). Additionally, the study design and type of the intervention was not limited to reviewing a larger number of studies examining a community pharmacy-based intervention. Accordingly, the review cannot be considered a systematic review, despite using a systematic approach to searching and screening of studies.

Although the review was not a systematic review, it included many elements of the systematic review according to the PRISMA 2009 checklist (90) and PROSPERO register for systematic reviews (141). Firstly, the search method outlined the search strategy clearly and the review method used eligibility criteria to select studies for inclusion in the review. Secondly, a structured approach was not only used for study selection, but also data collection. Using the DEPICT 2 allowed the researcher to highlight the multiple components of the complex health interventions that interacted together to improve patient outcomes (91). Some of the domains of the DEPICT 2 tool were amended to be more specific for asthma interventions. Although the tool was not validated, it allowed consistent assessment of the interventions in all of the studies.

The variability in the interventions provided and measured outcomes among the included studies made it impossible to run a quantitative analysis of the findings. A narrative synthesis of the findings from the included studies was conducted and was based around intervention, target population, outcomes measured and intervention components.

The study identification and data extraction were undertaken by the first author only, however, the selection of the studies was based on inclusion and exclusion criteria and was further discussed by the research team to decrease the selection bias. Additionally, the DEPICT 2, quality assessment tool and consistent review of the findings by the researcher and the research team helped to

decrease the bias in the findings as much as possible for a narrative review. Finally, the studies included in the review were assessed and compared to each other. The methodological heterogeneity of the included studies made it impossible to apply a single validated or published tool to assess the quality of the included studies. Because no satisfactory published method exists for the combined quality assessment of randomised and nonrandomised studies, the quality of studies was assessed using a quality assessment tool that was developed by the researcher. The tool was influenced by the Newcastle-Ottawa Scale[22] and reviewed by the research team.

2.7 Implications for research

This review supports the evidence that there is a need for validated tools to report and evaluate interventions in pharmacy practice due to the variation in reporting interventions and their complexity (142). The use of reliable, reproducible tools such as DEPICT 2 could help to enhance the consistency in reporting and evaluating complex interventions in the community pharmacy setting. Moreover, the developed quality assessment tool allowed a combined quality assessment of the included studies that could be of use to other pharmacy researchers.

The review provided useful insights into the asthma interventions provided to adult patients in community pharmacy and the impact of these interventions on the measured outcomes. The review found limited evidence regarding the implementation, sustainability and cost-effectiveness of asthma interventions in community pharmacy. These areas should be taken into consideration in future research that aims to evaluate the effectiveness of asthma interventions in community pharmacy.

2.8 Implications for thesis

This literature review supports utilising community pharmacy to enhance adult patients' management of their condition, as community pharmacy-based asthma interventions showed positive impacts on adult patients' outcomes.

There was variability in the interventions provided to asthma patients among the studies, for example, not all the interventions covered the same aspects for asthma education or focused on self-management. This variability made it harder to compare the interventions but it helped to identify intervention components that could be provided in the community pharmacy setting.

As discussed in the introduction (chapter 1), there are three gaps in asthma care (asthma patients are not receiving basic asthma care, medication use and asthma patients are not followed up after

using emergency care). In this review, the findings showed that community pharmacists provided asthma reviews and an inhaler technique check and many of the studies found a positive impact of the interventions provided on medication adherence. However, only two studies involved the delivery of an AAP, whereas, the rest of the studies referred patients to the GP to get an AAP. Some of the studies resulted in a high referral to the GP practice, this is against the current view of the NHS to decrease the workload on the GP practice.

Only one study was conducted in England and there was therefore no sufficient evidence to enhance asthma care in adult patients in community pharmacy. However, five main findings were highlighted from the review that will be utilised and used in the PhD study, those findings were:

1. Improvement of **patient identification** and **collecting patients' data** in the community pharmacy setting was highlighted by the findings of the review. Three studies showed difficulties in patient identification and the process was time-consuming and required many steps.

2. The provision of regular reviews in community pharmacy for asthma patients may help to improve patient outcomes and improve the partnership between patients and community pharmacists (103, 106, 110). However, more research on the feasibility of the **frequency** of the pharmacist's intervention, **follow-up period** and **method of delivery** should be conducted. In the study that was conducted in England, patients were followed up monthly by the telephone. As discussed in the introduction, there is an increasing workload on the community pharmacy and funding limitations that need to be taken into consideration.

3. None of the studies in the review involved a **medication dosage change** by the community pharmacists.

4. Although community pharmacists can support patients to improve their inhaler technique, there was variability in the provision of an **inhaler technique check** and training among the studies.

5. Utilising quantitative tools to collect data from patients' directly in the studies provided comprehensive data and allowed comparison of measured outcomes between the study participants. However, the data collected might be affected by patients' memory recall and might limit patients' ability to describe their experience. Only one study involved unstructured interviews with patients and it was not conducted in England. **Qualitative data collection** might help to **explore patients' experiences**, **acceptance o**f getting support in community pharmacy and **willingness of community pharmacists** to support asthma patients.

The findings from the review were taken forward and used to inform the data collection in the next phases of the PhD. This literature review was followed by five-phased Mixed methods research to explore the question: **how can community pharmacy enhance asthma care in adult patients?**

The following chapter will present the methods utilised in the thesis to achieve the aim and objectives of the study.

3 Methodology

This chapter will discuss the methodological approach used in this PhD study and the underpinning philosophical approach. The chapter will discuss the rationale for using Mixed methods research and design. Finally, it will discuss the ethical issues related to the PhD study and how the researcher ensured the quality of Mixed methods research.

3.1 Introduction

Health research as defined by Ann Bowling is:

"a systematic and rigorous process of enquiry that aims to improve health, health outcomes and health services" (143).

In the UK, there is a focus on health services research (HSR) (143). HSR is defined as:

"health research that uses a set of techniques to seek knowledge and evidence in order to improve health, health care and its delivery" (144).

HSR has a narrower focus than health research, studying the relationship between the population's demand and the health service delivery with a direct focus on patient care (143). This PhD study involved a research question regarding asthma care that is complex and results in diverse research questions that could be answered by different methods, which is common in HSR (145, 146).

As discussed in chapter 1, the evidence highlighted that there is a need to enhance asthma care in adult patients and improve asthma patient engagement with the care provided to them. Being the most accessible healthcare professionals to patients with LTCs across the healthcare system (46, 69), community pharmacists might be utilised to provide further support to asthma patients. Therefore, this PhD study aims **to explore how community pharmacy can enhance asthma care in adult patients and suggest solutions to enhance asthma care**.

The PhD study started with a literature review (chapter 2) that discussed studies that assessed asthma interventions provided in the community pharmacy setting. Although all the included studies were conducted in the community pharmacy setting, only one of the studies included in the review was conducted in England. The evidence from international studies might apply to community pharmacy in England but the different regulations and health policies across different countries that can affect the community pharmacy role within the healthcare system across different countries should be taken into consideration (147). For example, there is a range of services that can be provided to patients in community pharmacy in the European countries that differ from one country to another, whereas, in other countries, their role is limited to medication supply (147, 148). Accordingly, there was not sufficient evidence to identify how community pharmacy can enhance asthma care in adult patients in England.

Moreover, the evidence and the literature review (chapter 2) highlighted barriers for the implementation of asthma intervention in the community pharmacy setting. Some of these barriers are organisational and/or related to HCPs, while others are related to asthma patients. Many of those barriers comply with findings from other studies on services and interventions in community pharmacy in England (46, 57), so they can be taken into consideration when implementing an asthma intervention in community pharmacy. However, there could be other barriers that are specific to the implementation of asthma interventions in community pharmacy in England that are related to the differences in skills or education of community pharmacists across different countries, regulations and other issues.

The literature review highlighted variability in the measured outcomes across the studies and the measurement tools used but the measurement tools were quantitative. The measurement tools used in the studies depends on patients' memory recall and because of the episodic nature of asthma, patients are susceptible to forgetting about their asthma symptoms (149). For example, patients can have symptoms on more than one occasion per week then they might have no symptoms for one month, when those patients are asked about their asthma they tend to extrapolate their experience in the last month to three or more months (149). Using qualitative methodologies can help in the conceptualisation of patients' needs and experiences because they will be able to freely express their perceptions (145, 149). Utilising qualitative methodology is considered useful in the development, design and implementation of interventions and products for patients including those with asthma (150). Only one of the studies included in the literature review utilised qualitative methodology in the development of the intervention to explore patients' needs, however, the qualitative interviews were conducted with pharmacists and not with patients (116). Therefore, the PhD study utilised qualitative methodology and involved both asthma patients and HCPs.

Additionally, the studies included in the literature review included patients in the evaluation of the intervention and not in the early stages of development. However, having patients' voices in the early stages of development is considered essential to enhance the person-centeredness of intervention that might enhance their effectiveness (38, 43). Overall, there is a need for evidence-based and person-centred asthma interventions in community pharmacy that aim to satisfy patients' needs.

Mixed methods research was selected to address the complexity of asthma care that required a range of methodologies to allow better understanding (10, 145, 146). Using mixed method research will help to address the different aspects of the overall research question regarding asthma care in adult patients in a comprehensive way (82, 145, 146). The PhD study will utilise qualitative and quantitative methodologies that will allow a better understanding of issues with asthma care provision in different settings (82, 145, 146).

The PhD study will utilise five phases that involve interviews with HCPs and a commissioner, quantitative data collection and qualitative interviews with patients in the first three phases that provided a full picture regarding asthma management in adult patients (82, 84, 85, 146). In phase four, the qualitative and quantitative data from phases one , two and three will be triangulated to connect the findings to be able to answer the research question by combining the multi-perspectives across the three phases. The findings of triangulation will be summarised and discussed with HCPs in phase five to get their feedback on the findings from triangulation.

The overall design of the PhD is within the context of the MRC framework development phase for interventions (82, 85). The MRC framework is well-known, cited in the literature and intended to guide researchers to choose appropriate methods, taking into account the currently available evidence, resources and the nature of the intervention (82, 83, 85). Following the MRC framework helped to provide good quality evidence (82, 85).

The following sections will discuss the philosophical approach, explore Mixed methods research and discuss the design used in the PhD study and rationale for using it.

3.2 Philosophical approach

Quantitative research is usually theory-driven because it intends to test the validity of an existing theory (151). On the other hand, qualitative research might intend to develop a theory (151, 152). Developed by Glasser and Strauss, grounded theory is a methodology that aims to develop theory from data (153), in which qualitative researchers collect the data and then search for themes and patterns in the data that are grounded in the theory (151-153). Moreover, qualitative researchers might bring a strong orienting theoretical framework in ethnography and phenomenology research (152).

In Mixed methods research, the use of theory depends on the strategy for enquiry or design of the study (151, 152, 154). For example, the transformative Mixed methods strategy for enquiry should

be led by a theoretical framework or a specific ideology (151, 152). On the other hand, sequential mixed methods design and case studies might or might not be framed by an explicit theoretical approach (151, 152). Different Mixed methods research designs will be discussed later in this chapter (section 3.3.2).

A thesis might not fit into an explicit theory, philosophy or a restricted theoretical framework (151). Moreover, no theory or framework provides a perfect explanation of what is being studied (151, 152). However, a research framework that frames the PhD study should be identified (152, 155). Trying to identify and explain the theoretical framework underpinning the design of Mixed methods research in this PhD study, the researcher followed Creswell guidance (152). Creswell highlighted that research design involves the interaction between the philosophical worldview, strategies of inquiry and methods (152). Worldview was identified by Guba as:

"*A basic set of beliefs that identify action*" (152).

According to Creswell, "*researchers bring their own worldview into their research"*, therefore he described four different worldviews that will be discussed in this section (152). The researcher thought about those three components of research design (philosophical approach, strategies of inquiry and methods) during planning for the study and identified each component to define an appropriate framework for the study (151, 152, 155). Identifying those three components, including philosophical worldview(s) that influenced the practice of research in this study was sufficient to frame the PhD study because no explicit theory was thought to be suitable to lead the study (151). This resulted from the complexity of the research question that required Mixed methods research, which is common in HSR (152, 155).

The following section will discuss four different worldviews based on Creswell guidance and discuss the rationale for inclusion in or exclusion from the PhD study.

3.2.1 Post positivist worldview

Post-positivism holds the traditional form of research (152). This worldview holds a deterministic philosophy, in which causes determine the outcomes (152). Moreover, it is reductionist because it aims to decrease the question into small discrete ideas (variables) that could be tested (152). In this worldview, the researcher sets a theory, collects data to test the theory and then makes revisions before conducting more tests (152). Post-positivism suits quantitative rather than

qualitative enquiry, therefore, it was not considered suitable for the Mixed methods research in this PhD (152).

3.2.2 Constructivist

In this worldview, the research aim is to rely as much as possible on the participants' views and ideas and it suits qualitative inquiry (152). Therefore, the researchers tend to use open-ended questions to collect participants' views and focus on the specific contexts in which people live or work (152). However, the researchers' background and experience shape their interpretation (152). Although the PhD study involved three qualitative phases, in which the researcher used open-ended questions and intended to explore the participants' views and explanations, none of the phases aimed to generate a theory or pattern of social meanings as in constructivist worldview (152). Overall, the PhD study was not aiming to generate theory and therefore constructivism was not considered applicable for the PhD aim and objectives.

3.2.3 Participatory

This worldview focuses on the needs of groups and individuals in our society (152). Therefore, in participatory research, the participants are involved or engaged in the research as active collaborators who can make decisions (152). In this PhD, participants will be engaged to explore their opinions, experiences and perceptions but not as active collaborators.

Moreover, the research enquiry in this PhD regarding asthma care has nothing related to empowerment, inequality and other social issues that are usually targeted in participatory research (152). Participatory research is ideally suited to qualitative enquiry that aims to advance an action agenda or policy change for marginalised people, which researchers think cannot be addressed by constructivism (152). Finally, the participatory worldview was not considered applicable to the aim and objectives of the research in this PhD study or any of the qualitative phases.

3.2.4 Pragmatism

Pragmatism is a "*problem-centred, pluralistic and real-world practice-oriented philosophy, at which the researchers are free to choose methods, techniques and procedures to answer the research question"* (152). This approach applies to Mixed methods research in which "*the researcher draws liberally from both quantitative and qualitative"* (152). Following the philosophy of pragmatism, the researcher does not stick to one philosophy or method in conducting the research (82, 152).

Because no explicit theory was thought to be suitable to lead the study due to the complexity of the research question (151, 152, 155), a pragmatic approach was considered appropriate to answer the research question of this PhD, as it commonly leads the Mixed methods in HSR (84, 146, 152). Moreover, the pragmatic approach provided freedom for the researcher to select methods that suit the research question (152). The research question regarding asthma care was not based around any social issues, behaviour change or theory development that might be answered by adopting specific theories. However, because the study question is related to health interventions, the research was conducted within the context of the MRC framework (152).

3.2.5 Conducting the research in the context of the MRC framework

The choice of approach to develop an intervention is usually led by its aim (84), for example, Salisbury and colleagues used the intervention mapping and MRC framework to guide the development and evaluation of an intervention that aimed to change behaviour in patients with depression or increased risk for cardiovascular disease (156).

In this PhD, the MRC framework was followed because it is an evidence-based approach for intervention development and evaluation, and there is sufficient guidance on the development of complex interventions using the MRC framework (82, 84, 85, 157). Additionally, the MRC framework was utilised in other studies in community pharmacy (134). Therefore, conducting the research in the context of the MRC framework was considered suitable to provide good quality evidence from the PhD to be used in future research and by other researchers.

According to the MRC framework the researcher should use evidence to inform the study design. The researcher used the assumption that community pharmacy can enhance asthma care in adult patients to build the research question that was how can community pharmacy enhance asthma care in adult patients. The literature review that was discussed in chapter 2 supported the assumption that community pharmacy can enhance asthma care in adult patients.

The existing evidence was used to inform the design of the PhD study to answer the research question. Based on the definition of asthma care that was developed by the researcher in the introduction and the findings from the literature review and other studies, three main issues were highlighted by the researcher that, if addressed, could answer the research question. The three issues were based on the three components of asthma care that includes asthma management, asthma patients and HCPs.

Figure 3-1 below presents the evidence utilised to build the research question and identify those three issues and how the issues are connected to each other.

Figure 3-1 Theoretical framework of the PhD study

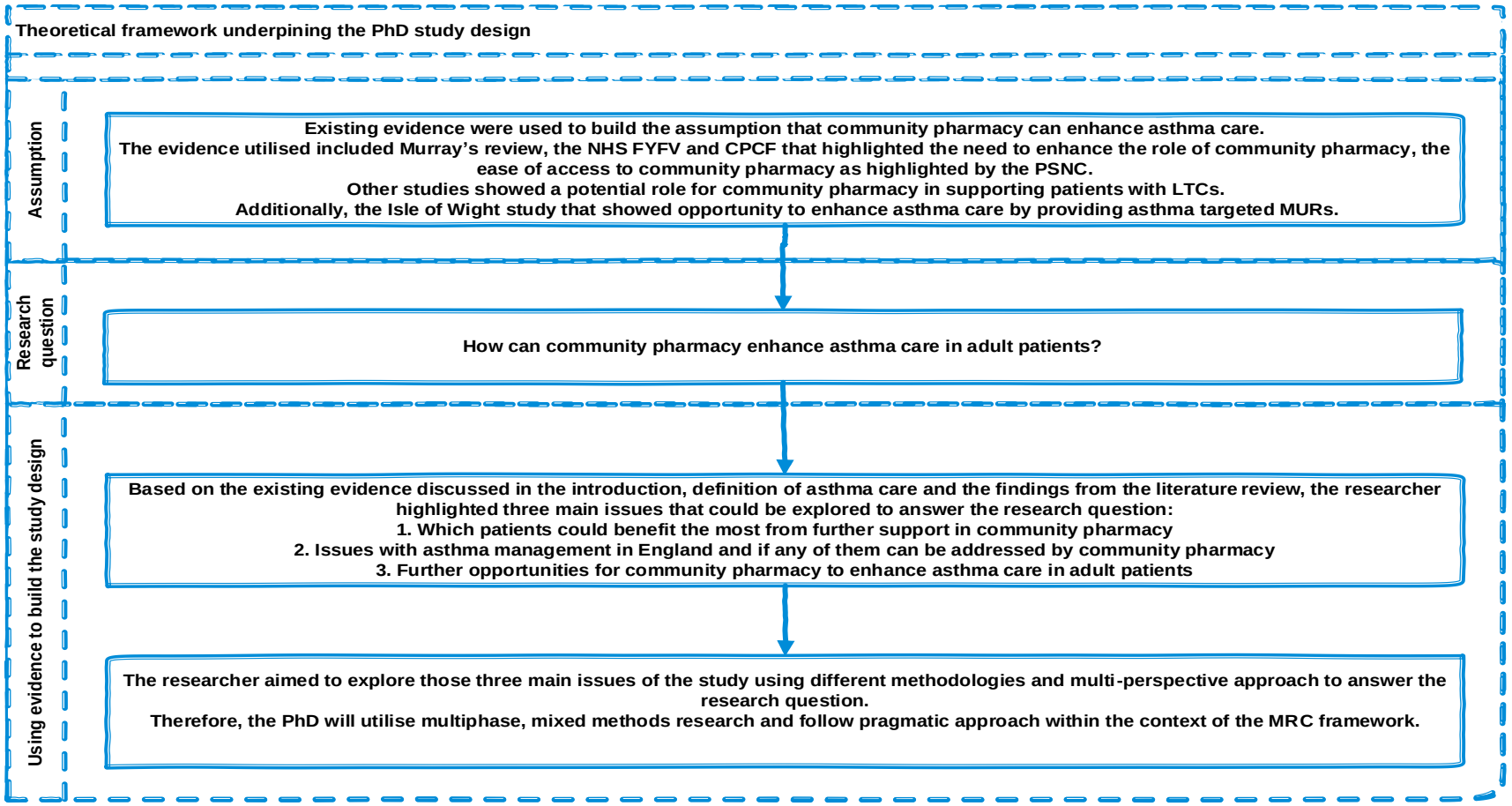


Figure 3-1 showed that the literature review, asthma care definition and existing evidence were utilised to highlight three main issues that could be investigated to answer the research question.

Firstly, issues with asthma management and if any of them could be addressed by community pharmacy. The literature review supported the evidence that there are issues with asthma care internationally and in the UK. The rationale for including this is that asthma management is an element of asthma care and investigating issues with asthma care will help the researcher to get insights into which issues can be addressed in community pharmacy.

The second issue was further opportunities for community pharmacy to enhance asthma care in adult patients. The studies reviewed in the literature review supported the evidence that community pharmacy can enhance asthma care. The evidence discussed in the introduction showed that the community pharmacy role could be enhanced and they can provide support for patients with LTCs. However, there is a need to explore further opportunities for community pharmacy to enhance asthma care in England.

The third issue was which patients could benefit the most from support in community pharmacy. There was a study in England that provided a review for asthma patients who do not attend their AARs and showed a potential role for community pharmacy to enhance asthma care in those patients. The researcher aimed to explore whether some asthma patients might benefit from support in community pharmacy other than those who do not attend their AARs. The studies included in the literature review were targeted at patients who were using a certain inhaler, others were targeted at patients with poorly controlled asthma symptoms or any asthma patients. However, the variability in the interventions provided and the evaluation of those interventions made it hard to identify which asthma patients could benefit the most from interventions in community pharmacy. Moreover, there were issues in the identification of those patients by community pharmacy that were highlighted in some studies in the review.

Those three issues were considered essential to answer the research question and will be investigated using different methodologies to allow comprehensive understanding and thick description of the research problem. Further discussion of Mixed methods research, rationale and design will be presented in the following section.

3.3 Mixed methods research

Many terms were used to describe mixing methods in research including integrating; multimethod; Mixed methodology; and more recently, the Mixed methods term, which was used in the literature and will therefore be used throughout this thesis (152). Mixed methods research as defined by Creswell is:

"*an approach to inquiry that combines both qualitative and quantitative forms, which involves philosophical assumptions, the use of quantitative and qualitative approaches and the mixing of both approaches in a study"* (152).

"*It involves the use of both approaches in tandem so that overall strength of a study is greater than either qualitative or quantitative research"* (152).

In 1959, Campbell and Fiski introduced the concept of mixing methods as multimethod/multitrait or convergent validation that was used to combine the data resulting from measuring the validity of psychological traits using multimethod (158). Campbell and Fiski promoted other researchers to conduct studies that utilise multiple methods and data sources to enhance validity (158). Later in 1970, Denzin focused on the combination of methods to converge qualitative and quantitative data using triangulation (159). The following sections will discuss the rationale for using Mixed methods research and the design of the PhD study.

3.3.1 Rationale for using Mixed methods research

In Mixed methods research, the results from different methods could be merged, connected or used side by side to reinforce each other (146, 152). Utilising Mixed methods research and following a pragmatic approach, the researcher in this PhD focused on the research question and tried to get knowledge by utilising multiple methodologies and different forms of data collection and analysis (84, 146, 152).

There is established evidence about mixed methods research, especially in social and educational research (145, 146, 152, 160). In HSR, the quantitative methodology was dominant in the UK (146). More recent, qualitative methodology was introduced to HSR to involve the voices of patients and service providers (146). As well as this, health service researchers started to use Mixed methods in their research by collecting qualitative data along with RCTs to improve the design and conduct of the trial (146). In this PhD, Mixed methods research will be used in a phased approach to address the complexity of the research question (146). The Mixed methods research

will allow for the complementary use of qualitative and quantitative data that enhanced the researcher's ability to discover, understand and communicate the findings (146). Moreover, Mixed methods will help to introduce new perspectives to answer the same research question (145, 146, 152).

Involving different methodologies, a range of stakeholders across different phases of the PhD study and triangulation help to enhance the confidence in and trustworthiness of the findings (82, 84, 85, 146). In this PhD study, the use of both qualitative and quantitative methodologies will enhance the quality of the findings (146, 152). Mixed methods research will strengthen the outcomes of the research and help to gain a better understanding of the research question (152). Triangulation will allow for the mixing and connecting of the qualitative and quantitative methodologies whilst ensuring the integrity of each approach (144).

Regardless of all the advantages of Mixed methods research, it is time-consuming and requires quantitative and qualitative skills to conduct the data collection and analysis (152, 160). Moreover, using both qualitative and quantitative data can encourage confidence in the results, but this could be limited if the researcher has not chosen appropriate and efficient methods, analysis and mixing approach to provide meaningful results (146, 160). Therefore, in this PhD, the researcher will use pragmatic approach that utilises Mixed methods research taking into consideration timing to conduct the research and mixing of the findings (82, 84, 85, 145, 146, 152, 158).

3.3.2 Mixed methods research design

In this PhD, choosing appropriate methodologies in each phase and how to mix them will be led by the research question and influenced by available literature on the design of Mixed methods (145, 146, 152, 154, 161) and other studies in HSR that utilised Mixed methods research (116, 134, 156, 162, 163).

The MRC framework for intervention development encourages health services researchers to understand the research problem using different methods and by including multiple perspectives (82, 84, 85). After the researcher identified five objectives (see section 1.3) that should be addressed to answer the research question, she chose the methodologies that were considered appropriate to achieve the objectives. The PhD study will involve five phases and stakeholders who deliver or receive asthma interventions will be involved in phases 1, 3 and 5 to investigate care needs and perceptions of stakeholders (82).

The mixing of different methodologies can be for the purpose of triangulation that allows to ensure convergence and/or complementarity; or highlight divergence that might provide explanations (154, 161, 164). Another purpose for the combination is development to guide the rest of the data collection and analysis, from which, one method can guide the researcher to choose participants to recruit and what information to obtain from them (154).

The three general strategies for designing Mixed methods research that were presented by Creswell (152) aided the researcher in designing the PhD study, those include sequential, concurrent and transformative Mixed methods.

Sequential Mixed methods

In sequential design, when one method is completed the second method takes place (152). In this design the researcher can expand the findings of one method with another method; one method inspires the second method or confirms it (145, 152).

Concurrent Mixed methods

In concurrent design, the researchers merge the qualitative and quantitative data to provide comprehensive findings (145, 152). The two methods are undertaken at the same time and the integration occurs in the interpretation of the overall findings (145).

Transformative Mixed methods

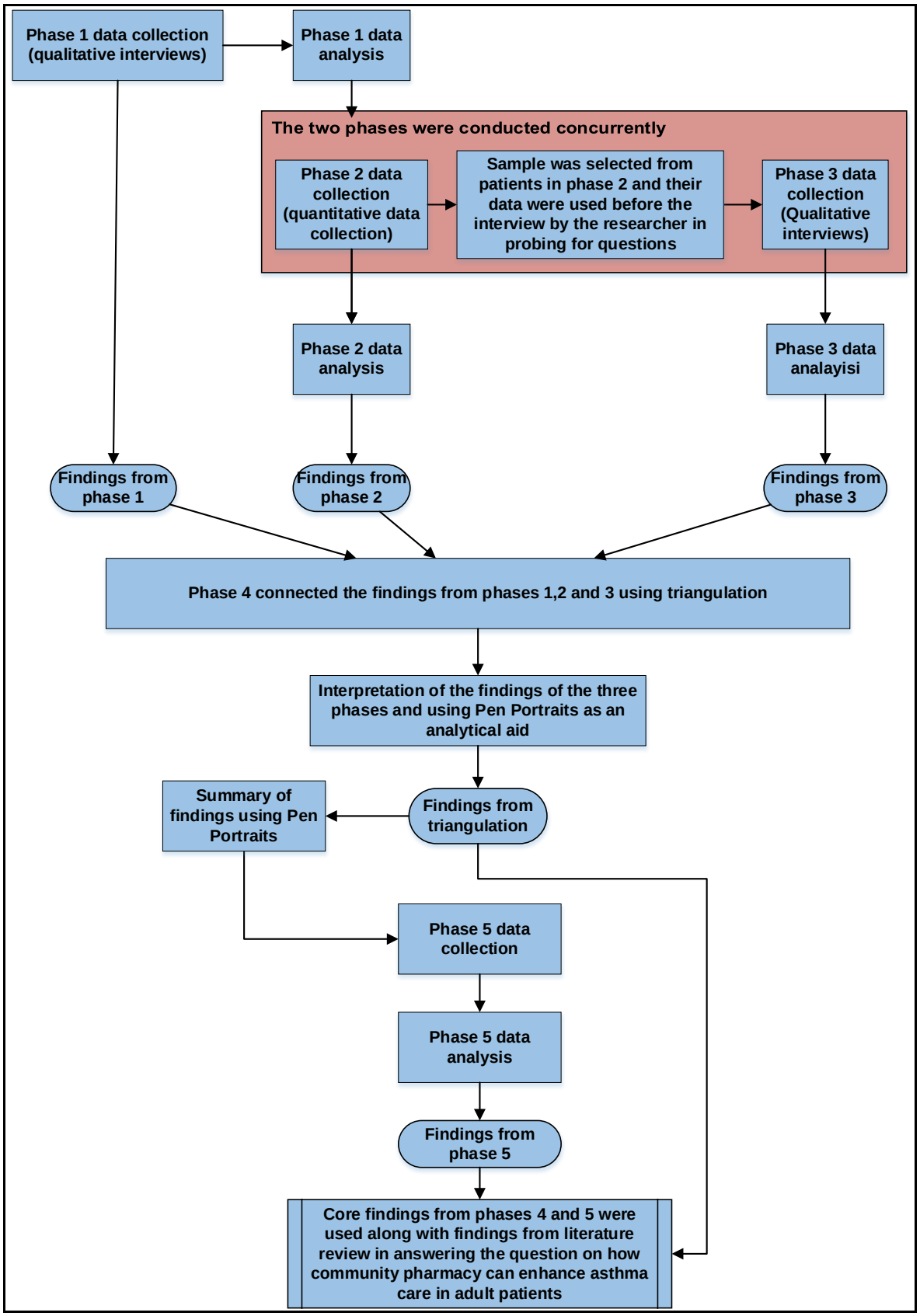
In this procedure, data collection and analysis utilise sequential or concurrent design but it is all covered by a theoretical lens (152). In this technique, the theoretical lens influences the data collection, analysis and outcomes by providing a framework for the topic of interest (152). This strategy of enquiry should be led by a theory. As the PhD was not led by a theory, the transformative design was not considered appropriate to conduct the research.

Many studies in HSR adopted the sequential and/or concurrent design in a multiphase approach to address the complexity of designs in practice (145, 146) (116, 156, 162, 163). For example, a sequential three phases study regarding variation in patients who are not transported to hospital by ambulance (162). The first phase involved qualitative interviews with stakeholders to address the issues related to the variation (162). The second phase involved three concurrent studies that included two quantitative data studies to assess the factors that lead to the variation and a qualitative study that involved observation and interviews with call-handlers, clinicians and clinician managers (162). The third phase integrated all the data collected (162). The study involved a

variety of stakeholders, observations and patient's data that all were used to answer the research question successfully.

This PhD study will adopt a multiphase sequential Mixed methods research design that included exploratory qualitative, explanatory quantitative methods and triangulation. The qualitative and quantitative phases were connected at different levels including sampling, data collection and/or interpretation of the findings (154, 161). The sequence and connection of the phases are presented in Figure 3-2 below.

Figure 3-2 Flow chart of the design of the Mixed methods research in the PhD study



As shown in Figure 3-2, the first phase will involve qualitative interviews with HCPs and a commissioner to highlight issues with asthma management. Involving HCPs, to get a better understanding of the research problem, was conducted by other researchers who utilised Mixed

methods research and helped to inform intervention or services development in community pharmacy (116, 163).

The use of qualitative method (semi-structured interviews) in phase 1 will allow exploration of the perceptions of HCPs and a service commissioner on issues with asthma management and opportunities to utilise community pharmacy to further support asthma patients (143). Phase 1 will be followed by quantitative data collection used to assess asthma management in a general practice in England as a part of a case series study.

Case series study is:

> "*one of many epidemiological research methods and study designs; which focuses on the circumstances, dynamics and complexity of a single case or a small number of cases"* (143).

In this PhD, the case series study will utilise two concurrent phases (2 and 3) to allow a comprehensive understanding of asthma care by involving patients and reviewing their medical records. A purposive sample of patients in phase 2 will be selected and interviewed in phase 3. Identifying issues with asthma management, enablers for improving care and gaps in the delivery of care were sought to be achieved by collecting quantitative data (84). Collecting quantitative data was considered appropriate to highlight issues with asthma management in the general practice that might be addressed to enhance asthma care in adult patients. Additionally, interviewing patients in phase 3 will be conducted to explore patients' experience with their management to be able to conceptualise their experiences and perceptions (163).

Phases 2 and 3 will be conducted concurrently to allow the researcher to collect quantitative and qualitative data at the same time while she was in the GP practice. This will save time and travel costs. Additionally, this will ensure a short time between reviewing the patients' records and interviewing them so their condition won't have changed, as asthma is an episodic condition.

Moreover, in phase 4, the findings from phases 1, 2 and 3 will be connected using triangulation to ensure complementarity in the findings from the different phases (123, 154, 161, 164-168). The mixing of the phases using triangulation to connect the findings was considered suitable to the sequential approach in conducting the phases (in terms of the timing) and because the PhD study will start with an exploratory phase, so the findings could be connected but cannot be embedded as in explanatory sequential designs (152). Additionally, the way the phases will be connected will be taken into consideration in weighing the phases in triangulation (152).

Consequently, findings of triangulation in phase 4 will be shared with participants in phase 5 to get their feedback, so the phases will be conducted sequentially. Overall, the phases will be conducted sequentially, while phases 2 and 3 will be conducted concurrently, however, the first three phases will be connected using triangulation and findings from phase 4 were utilised in phase 5.

Finally, the findings of phases 4 and 5 will be utilised along with the findings from the literature review to answer the research question on how community pharmacy can enhance asthma care in adult patients.

Using the Mixed methods research approach, the researcher will be able to address the complexity of the research question (146). Such an approach will help the researcher to provide a comprehensive description of the research problem by addressing the same question using different methodologies (162).

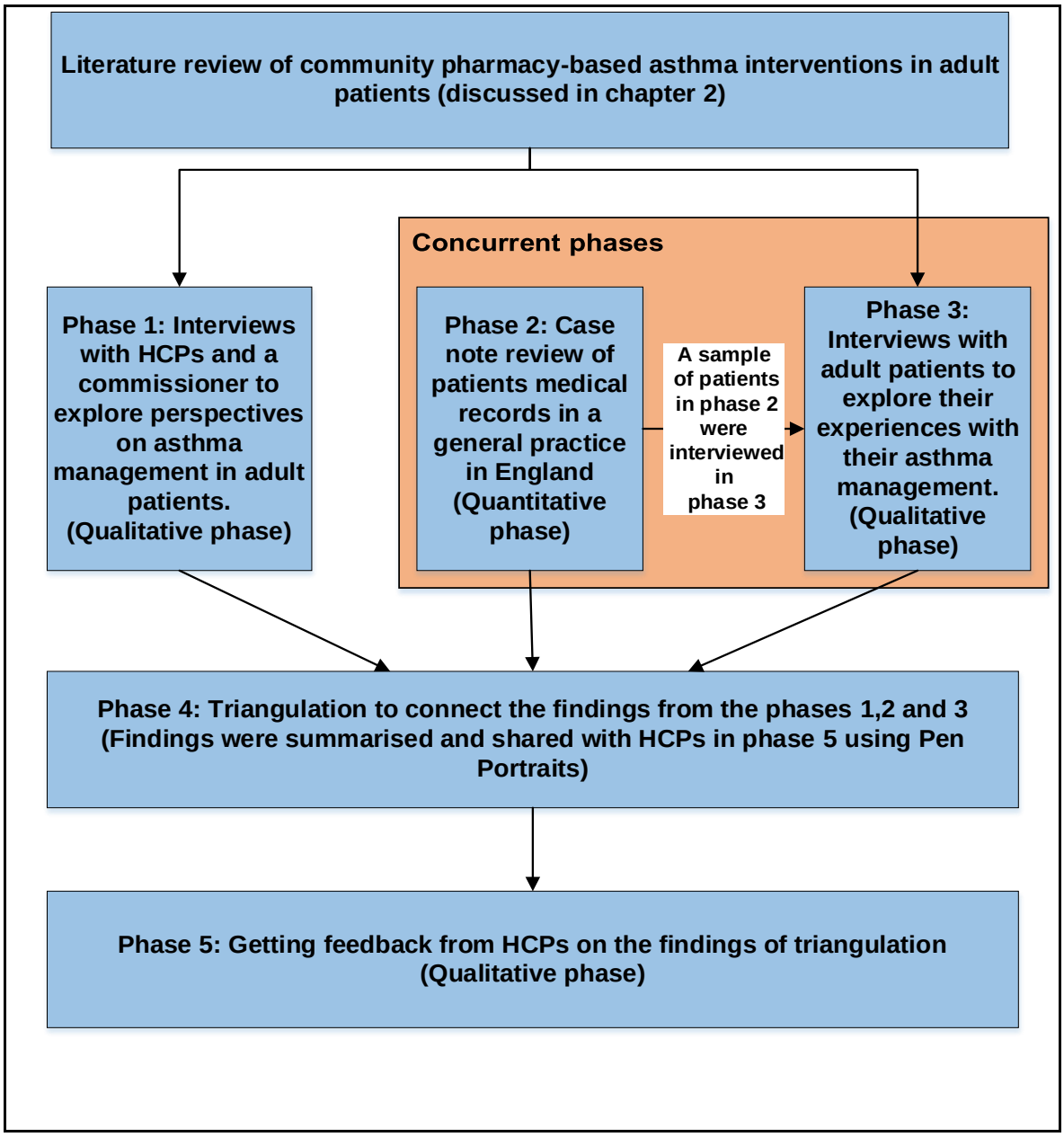
3.4 Overview of the overall methods used in the PhD study

This PhD Study will involve five phases that will be as follows:

- **Phase 1:** Face-to-face or telephone interviews with stakeholders in England.
- **Phase 2:** A case note review of patients' medical records in a GP practice in England.
- **Phase 3:** Face-to-face or telephone interviews with adult asthma patients from a GP practice in England.
- **Phase 4:** Triangulation of the findings from phases 1, 2 and 3.
- **Phase 5:** Telephone interviews with HCPs.

The overview of the PhD study is outlined in Figure 3-3 below. It also illustrates how the phases are linked together.

Figure 3-3 Overview of the PhD study



The PhD study began with a literature review (discussed in chapter 2) that was comprehensive (143). Furthermore, an evaluation tool was developed to assess the quality of the papers included in the review (for details, see chapter 2). Consequently, the findings of the literature review were utilised to guide the data collection in phases 1 and 3.

The five phases are complementary to each other (144). For example, the qualitative findings of phase 1 will be used to inform the data collection in phase 3. Although the data sets for each phase will be kept separate, the phases will be connected at some point (152). The qualitative and quantitative data will be combined during the final interpretation of the findings using triangulation to maintain the integrity of each method.

The methods and the findings of each phase will be presented and discussed in **chapters 4-8**.

3.5 Ethical issues

Researchers should be aware of the regulations and codes of ethics during the design and conduct of research (143). There are many international codes for ethical issues in medical research (144) including, for example, the Declaration of Helsinki (169). Among the different ethical codes and regulations, there are common principles that should be followed by health researchers. For example, harm should not be caused to any participant as a result of participation in the research (144). Based on this, the PhD study was designed to ensure that the research was carried out ethically. Additionally, appropriate ethical approval was sought before conducting the research. Furthermore, the researcher strived to complete the research with integrity and commitment to the search for knowledge (144).

As this PhD study used Mixed methods, many ethical issues were raised during each phase of the research. During the qualitative interviews with stakeholders and patients in phases 1, 3 and 5, the researcher will maintain openness and respect towards the participants. The researcher will treat the participants' perceptions, values and beliefs with total respect and appreciation. Furthermore, during the design of the research, the interview schedule will be reviewed by the supervisory team to ensure that the questions did not cause any distress for the participants.

Another ethical issue that required consideration was the researcher accessing patient sensitive data in phase 2 of the PhD project; this phase was designed in compliance with the General Data Protection Regulation (GDPR) (170). To enable this, the researcher engaged in GDPR training from LJMU during the design of the research and before conducting phase 2. As well as this, all supervisors undertake regular GDPR training at LJMU.

Research that involves human participants should be conducted in a way that respects the decision-making capacities of the participants by asking for their informed consent (144). Additionally, confidentiality and participant anonymity should be maintained during the research and dissemination of the research results (144). Informed consent, confidentiality, anonymity and data protection are discussed below.

3.5.1 Informed consent

Informed consent will be required for all phases of the PhD study as it involve human participants. Participant information sheets will be provided for participants in each phase. It will include the

following information: background to the research and the researcher, what participating involved, benefits and possible disadvantages, why they had been chosen to participate, confidentiality and participant's rights. The participant information sheet also will highlight that the interviews will be audio-recorded to ensure that they were comfortable with this. The researcher's contact details will be provided so that participants could contact the researcher to ask for further information if required. In addition, for phase 2 (the case note review), the participant information sheet also will include information regarding the range of data to be extracted from their medical records. The participants will be asked to sign a consent form prior to participation. The method that will be used to provide the information and obtain informed consent will be discussed in detail for each phase in the corresponding chapters 4, 5, 6, 7 and 8.

3.5.2 Confidentiality, anonymity and data protection

Participants' confidentiality and anonymity will be maintained in all phases of the PhD study. Sensitive data will be collected during phase 2 of this PhD, only as part of the case note review. No 'special category' personal data will be collected. Special category personal data includes "*data which reveals racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership; and data concerning the physical or mental health of a person, sexual orientation and biometric data" (171).* Further details are presented below.

For all the phases, no individual participants will be identified in the write up of results. All the participants will consent for the researcher to publish the anonymised study results using anonymised quotes in papers and the PhD thesis. For the participants other than patients, hard copies of personal data and their consent forms will be stored in a locked cupboard at LJMU and any electronic data with personal information will only be stored on an LJMU, password-protected computer. Hard copies of patient consent forms will be stored in a locked cupboard in the GP practice. Any personal data will be securely destroyed once it was no longer needed at the end of the study.

3.6 Quality

Quality in Mixed methods research can be ensured by enhancing the quality of the methodologies used in the Mixed methods research, for example, the trustworthiness of the qualitative and validity and reliability of the quantitative data collection and analysis (145, 152, 165, 172). Furthermore, the researcher should discuss the mixing of those methodologies in a transparent way to allow the reader to understand the purposes, timing and way of mixing (145, 152, 165, 172). Therefore, in

this PhD study, the researcher will follow the Good Reporting of A Mixed Methods Study (GRAMMS) that was developed by Cathain and colleagues (172) to help researchers report the Mixed methods research and show the strengths and weaknesses of the mixing in the study. Table 3-1 below will present the GRAAM guidance (172) and how it will be addressed and reported in the PhD study by the researcher.

Table 3-1 GRAAM guidance on ensuring quality in reporting Mixed methods research and how the researcher followed the guidance

GRAAM guidance (172)	**How the researcher ensured quality and good reporting in the PhD study**
1. Describe the justification of using mixed methods research	Mixed methods research was selected to address the complexity of the research question. Further details on the rationale of conducting Mixed methods research were discussed in this chapter (section 3.3).
2. Describe the design in terms of purpose, priority and sequence	This PhD will use a sequential Mixed methods research design that utilise a multiphase approach. The researcher discussed the details of conducting the five phases of the PhD using a flow chart (see Figure 3-2) and described it verbally in this chapter (section 3.3.2). The rationale for each phase will be discussed in **chapters 4, 5, 6, 7 and 8**. Moreover, the weighing of the phases will be undertaken in phase 4 based on the strengths and limitations of the phases and the way the phases were conducted.
3. Describe each method in terms of sampling, data collection and analysis	The methods of phases 1, 2, 3, 4 and 5 will be discussed along with the findings in **chapters 4, 5, 6, 7 and 8**.
4. Describe where the integration occurred, when and who participated in it	The triangulation of the findings will be conducted in phase 4 after the researcher

	finish the data collection and analysis of the three first phases. The triangulation will be discussed in detail in **chapter 7**.
5. Describe any limitation of one method that is associated with the presence of another method	The strengths and limitations of each of the phases will be presented (in a separate section) after discussing each of the five phases. Additionally, the strength and limitations of each of the phases will be considered by the researcher when interpreting the findings of each of the phases and in triangulation. Finally, the overall strengths and limitations of the Mixed methods research and how the limitations of each of the phases affected the overall findings and interpretation of the findings will be discussed in **chapter 9.**
6. Insights gained from mixing or integrating methods	The method for triangulation and its limitations and strengths will be discussed in **chapter 7**.

This chapter has discussed the methodology of the PhD study and provided insights into the philosophical approach. Further, it explored Mixed methods research design and explained the rationale. Additionally, it provided an overview of the five phases of the PhD. Finally, it discussed the ethical issues and how the researcher ensured the quality of reporting in the PhD study, which were described in the last section.

The following chapters (4 to 8) will discuss the methods utilised in each of the five phases, findings and discussion.

4 Phase 1: Face-to-face or telephone interviews with stakeholders

The previous chapter discussed the Mixed methods research design that was utilised in the PhD study, which was selected to address the complexity of the research question about asthma care. The PhD involved five phases that utilised qualitative and quantitative methodologies. This chapter will discuss the first phase of the PhD.

This chapter includes an introduction, aim and objectives, methods, findings and discussion of phase 1. The chapter ends up with the implication of phase 1 to the thesis.

Conference poster developed from this phase:

A. Mahmoud, R. Mullen, P. Penson and C. Morecroft. (2019) Exploring the management and control of adult asthma patients: stakeholder perspectives in the North West of England. International Journal of Pharmacy Practice, 27, 27-60. (Poster at HSRPP 2019)

4.1 Introduction

The literature review (discussed in chapter 2) found that only one of the studies included in the review was conducted in England. Accordingly, there was not sufficient evidence to identify how community pharmacy can enhance asthma care in adult patients in England. Moreover, the evidence and the literature review (chapter 2) highlighted barriers for the implementation of asthma intervention in the community pharmacy setting. Some of these barriers are organisational and/or related to HCPs, while others are related to asthma patients but there is a lack of evidence on solutions that could be taken to overcome those barriers. Overall, there is a need to get better insights into the provision of further support for asthma patients in the community pharmacy setting in England.

Therefore, this first phase of the PhD aimed to explore HCPs and commissioners' perspectives on the management of asthma in adult patients. This first phase of the PhD was an exploratory study, using semi-structured, face-to-face or telephone interviews that were conducted with healthcare practitioners and a service commissioner in the North West of England.

Using a qualitative approach allowed the researcher to explore the issues concerning the management of asthma in adult patients and allowed an in-depth understanding of the participants' perspectives and views (152).

4.2 Aim and objectives

The aim of phase 1 was to explore healthcare practitioners and commissioners' perspectives on asthma management in adult patients.

The study objectives were to explore:

- The current challenges with the management of asthma.
- How asthma management could be improved.
- Further opportunities for community pharmacists to support adult asthma patients.

4.3 Methods and methodology

Ethical approval was granted by LJMU Research Ethics Committee (REC) (18/PBS/004) on 9th April 2018 for this first phase of the PhD (see Appendix 1).

4.3.1 Study design

This first phase of the PhD was an exploratory qualitative study that utilised semi-structured, face-to-face or telephone interviews.

In this phase, a qualitative methodology was considered relevant to achieve the aim of the phase to explore HCPs' perceptions of asthma management because it allows the researcher to get an in-depth understanding of asthma management in adult patients (173, 174). This phase aimed to explore the participants' experience, thoughts and expectations that are related to asthma management and their interaction with asthma patients (174). These are contextual issues that can be better studied by qualitative rather than quantitative methodologies (174). Although qualitative findings might not provide a definite answer, they might help the researcher to get better insights into asthma management (174). Finally, qualitative data collection was thought to contribute to a broader understanding of asthma care in combination with the other phases of the PhD (145, 146, 152, 173-175).

Qualitative methodology intends to collect views and opinions from the participants by different methods, for example, interviews or a focus group with a group of participants (145, 152).

In this phase, qualitative interviews were selected to gain a deeper understanding (152, 176) of participants' perspectives that cannot be gained by other methods that concentrate on consensus, for example, focus groups (145, 152).

This phase utilised semi-structured interviews. The researcher developed and used a semi-structured interview schedule that contains open-ended questions and encouraged the interviewee to talk openly. In-depth interviews were not selected because they usually use a few very open-ended questions to allow the participant to guide the interview and require more time (145). Whereas, semi-structured interviews were selected to enable the researcher to maintain consistency of the topics covered throughout each interview and probe for further detail where appropriate (144, 145).

Additionally, semi-structured interviews in this phase were selected to allow the participants to freely express their perspectives (145, 176) and provide flexibility for them to discuss further relevant issues not covered by the interview questions, which cannot be gained in structured interviews that utilise close-ended questions.

Interviews were conducted either face-to-face or over the telephone, based on participant preference and availability. Both methods of interviewing were chosen to adapt to the busy nature of the participants and to increase the study response rate. However, using both methods might cause bias, therefore the researcher aimed to build trust with the participants regardless of the interview method. Additionally, the strengths and limitations that might be caused by using both methods are discussed in the strengths and limitations in the final chapter.

4.3.2 Research sites

The study was carried out with participants from a range of primary and secondary care settings across the North West of England. This geographical area was chosen to enable the researcher to conduct interviews within the time frame and to reduce travel time and cost. In addition, extending the study across the whole of England or the UK was not considered feasible within the time frame and budget for the study.

4.3.3 Inclusion criteria

The inclusion criteria for this phase included stakeholders involved in the delivery of services to asthma patients or service commissioning in the North West of England.

4.3.4 Exclusion criteria

The exclusion criteria for this phase included stakeholders who were not involved in service delivery for adult asthma patients or service commissioning or those based outside the North West of England.

4.3.5 Participant recruitment

Participation in this phase was voluntary. Participants could withdraw from the interview at any time and could choose not to answer the questions. Participants could withdraw after the interview had been conducted up until the data had been anonymised.

A convenience sampling strategy was used in recruiting participants for this study, participants were interviewed as soon as they consented to participate to allow the researcher to conduct the interviews easily and within the limited time of the PhD study (177). Participants were HCPs and a service commissioner. HCPs were based in different healthcare settings including hospitals, community pharmacy and GP practices to allow for a wide range of perspectives (145) on asthma management in adult patients and to provide insights on the management of asthma in different cohorts of patients who are using different health care settings. For example, patients who attend

A&E with an asthma attack and might need further follow-up after being discharged. Overall, there was a diversity in the background, experience and knowledge of the participants regarding asthma management, however, convenience sampling might cause limitations. Those are discussed in the strengths and limitations section in chapter 9.

Relevant stakeholder organisations acting as gatekeepers were accessed to obtain the names and email addresses of potential participants. In the first instance, email addresses for the gatekeepers at GP practices and CCGs in the North West of England were obtained from the NHS website (178). An invitation email outlining the study (see Appendix 2) was sent to each gatekeeper with a gatekeeper information sheet (see Appendix 3) and a consent form (see Appendix 4) attached. The gatekeepers were invited to nominate potential pharmacists based in GP practices, practice nurses, nurse practitioners, GPs, consultants and service commissioners, accordingly.

The generic email addresses of the community pharmacies in North West England which were available online were used to invite community pharmacists to participate. An invitation email outlining the study (see Appendix 5) was sent to each potential participant with a participant information sheet (see Appendix 6) and a consent form (see Appendix 7) attached.

Non-responding potential participants were contacted again with a reminder email at least three working days after sending the invitation email. In the reminder email, the researcher contacted non-respondent potential participants to determine their willingness to participate and to either nominate the most appropriate person to be interviewed or decide whether to be interviewed face-to-face or by telephone. A mutually convenient time for the interview was then arranged with the participants who agreed to participate. This was considered sufficient time for the participants to review the study documents and make an informed decision regarding their participation. Each gatekeeper and participant was asked to sign a consent form prior to participation (see Appendix 4- gatekeeper consent form and Appendix 7- participant consent form).

4.3.6 Data collection

Interview schedule

A semi-structured interview schedule was developed by the researcher to achieve the aims and objectives of this phase and was guided by the existing literature that was reviewed by conducting a narrative review (179) (chapter 2) and Murray's review on the clinical role of community pharmacists in the UK (46). Non-leading questions and prompts were developed by the researcher.

The interview schedule was reviewed by the supervisory team prior to the pilot. The interview schedule and interviewing procedures were piloted by interviewing two community pharmacists. This was to verify the recruitment procedure, evaluate the interview schedule and develop the transcribing and data analysis skills of the researcher prior to commencing data collection. The transcripts of the two pilot interviews were reviewed and discussed with the supervisory team. Subsequently, some minor amendments, such as rephrasing some of the probing questions, was performed according to the outcome of the discussion. No major amendments were required. The interview schedule can be seen in Appendix 8.

The interview schedule covered a range of topics relating to asthma management in adult patients. The schedule contained a combination of open-ended and closed-ended questions. Closed-ended questions (collecting demographics) were asked initially to build rapport and then the participant was prompted to discuss challenges with asthma management and how it could be improved. This was followed by questions about further opportunities for community pharmacists to support asthma patients. The interview schedule also contained some prompts to facilitate the researcher to probe participants for more information about asthma management. All participants were asked if they would like to add anything else regarding each topic. This was to ensure that participants were given every opportunity to mention any issue they found important, not directly addressed by the interview questions. Any additional issues added by participants were further clarified by the researcher, to gain a better understanding.

Procedure

Having pre-arranged the interview at a mutually convenient time, each interview began with a verbatim introductory script, ensuring that each participant was given the same information about the study before the interview. For face-to-face interviews, a signed consent form was obtained before commencing the interview. For the telephone interviews, the researcher confirmed with participants that a signed consent form had been completed and returned as part of the introduction. If the researcher had not received this form from the participant, then the consent form was read out and verbal consent was obtained and recorded before the telephone interview commenced. The participants were then asked to complete the signed consent form and return it as soon as possible.

Individual demographic data collected included the participant's work setting and job title. The participants were then asked a range of open-ended questions to discuss issues concerning adult

asthma management in adult patients. In addition, the participants were prompted to express their experiences and concerns throughout the interview. No topics were discussed that any of the participants found distressing during the interview.

The interview schedule served as a guide, but the order and wording of the questions were modified based on the flow of each individual interview. All questions were asked at some point during each interview to ensure consistency of data collection. Any specific comments were further explored by the researcher. Care and attentiveness were maintained by the researcher throughout each interview to ensure that all interviews were conducted to a similarly high standard. The researcher aimed to minimise interviewer bias which could adversely affect results; for example, any questions or prompts were asked impartially and properly explained to all participants. Additionally, the researcher strived to conduct the interviews neutrally regardless of participants' responses in order to reduce bias. On the other hand, the researcher's background knowledge of the topic aided the discussion and helped participants add additional information to gain a more rounded and richer dataset.

The face-to-face interviews took place in a private room to minimise distractions or interruptions whilst the interview took place. All the face-to-face interviews were conducted on LJMU premises, except one, which was undertaken in the interviewee's office at the hospital. The telephone interviews were conducted in the participant's 'natural setting' by calling them at their workplace. The participants who were interviewed by telephone were advised to be in a quiet room. This allowed the participants to answer the questions freely without interruption. The same researcher conducted all the interviews in a quiet research office free from interruptions, to ensure the robustness of data collected. The interviewee was made aware that the interview would take up to 20 minutes, so they were able to make appropriate arrangements. Sufficient time was provided to ensure all questions were asked and answered thoroughly.

The interviews were audio-recorded, and the audio recording device was tested by the researcher before each interview. Handwritten notes were taken on a printed interview schedule for each participant during the interview.

Safety issues

The interview settings allowed both the interviewer and the interviewee to be in a safe environment during the interview; neither were put at risk. No obvious sensitive topics were discussed. If the

interviewee had found any topics distressing, this would have been handled tactfully by the interviewer. Every effort was taken to ensure that the interviewee was comfortable with the topics being discussed.

Sample size

As this study is qualitative, there is no fixed number of participants to be interviewed, however, the sample size can be determined inductively while collecting the data (180, 181). Therefore, when the researcher found that no more explanations were emerging from the new interviews (145), data saturation was thought to be achieved and the researcher stopped data collection. Data saturation is a term used in qualitative research to describe the point at which the researchers stop data collection because collecting more data will not lead to more findings related to the research question (145, 182). In qualitative research, the aim is to get a deeper understanding that can be reached by probing the interviewees to get a rounded data set with explanations rather than conducting more and more interviews (181).

4.3.7 Data analysis

This phase utilised qualitative data collection that required qualitative analysis. Qualitative analysis is iterative and is conducted concurrently with data collection, making interpretations and writing reports (152, 175, 183). It involves a continual reflection about the data, asking analytical questions and writing means throughout the data (152). According to Creswell, the generic qualitative analysis includes data collection, analysing data into themes and reporting the themes (152).

The differences in the qualitative enquiry and philosophical approach affect that the analysis approach used (152). In case studies and ethnographical research, the analysis starts by describing the setting and/or individuals and is followed by analysis for themes or issues (152). In phenomenology and narrative research, the analysis is concerned with meaning, language and experience (152). Moreover, in Grounded theory, the research aims to develop a theory that is grounded in the data (152). Corbin and Strauss defined systematic steps for conducting analysis in grounded theory

Corbin and Strauss's systematic approach for qualitative analysis is not the only one, there are other approaches for qualitative analysis that are flexible and suit a range of data collection approaches including framework analysis and thematic analysis (184, 185).

In this phase, the interview transcripts were analysed thematically by the researcher, as described below. Framework analysis is suitable for large data sets, has to be conducted by a multidisciplinary team and cannot be conducted by one researcher (186). Thematic analysis was chosen to allow the researcher to highlight similarities and differences in the perspectives of the participants (183). Thematic analysis is accessible for researchers and can be used for both deductive and inductive analysis (184). Additionally, thematic analysis can provide flexibility in the analysis that can be modified to suit the needs of the study (184, 185, 187). The following section will discuss thematic analysis in detail.

Thematic analysis

Thematic analysis is defined as:

> *"A method for identifying, analysing, and interpreting patterns of meaning (themes) within the qualitative data"* (184).

The essence of qualitative analysis is contrast and comparison. Thematic analysis is an iterative process that involves constant comparison of the codes and themes during data collection and analysis. The thematic analysis allows the researcher to highlight similarities and differences in the data set and generate unanticipated insights (183). Braun and Clarke described the thematic analysis method as a recursive, rather than a linear process, and identified six phases for the method (183, 184). The thematic analysis phases (184) and a description of the steps undertaken by the researcher to analyse the interview transcripts are detailed below in *Table 4-1*.

Table 4-1 Phases of the thematic analysis

Thematic analysis phases (184)	**Steps of the thematic analysis performed by the researcher**
1. Familiarising yourself with the data	All the interviews were transcribed verbatim by the researcher. The researcher then re-listened to the audio recordings and read the transcripts more than once to become familiar with the interviews. The full transcripts were utilised in the analysis. Notes and impressions were recorded in the margin of the interview transcripts to be used later for coding and interpretation. The notes were generated while keeping in mind the three ideas from the theoretical framework.

2. Generating initial codes	The interview transcripts were read line by line searching for ideas or thoughts and underlining the sentence, line or paragraph that describes them. Initial codes were generated by the researcher by searching for similar ideas or thoughts that can be categorised into a code.
3. Searching for themes	The transcripts were re-read and some codes were merged together while codes that were related to each other were grouped into potential themes and data (quotes) related to each theme were gathered. Consequently, the potential themes were discussed with the supervisory team.
4. Reviewing the themes	The theme and codes were reviewed continually during the analysis process. The interview transcripts were re-read by the researcher while having the codes and themes on hand to ensure that all the codes were applied to all the transcripts. Additionally, this allowed the researcher to ensure that ideas or thoughts from each transcript were coded under the right code. This was conducted to apply any emergent codes to the whole data set.
5. Defining and naming the themes	The final themes and sub-themes were identified by the researcher and discussed with the supervisory team.
6. Producing the report	The analysis findings were written as part of this chapter and reviewed by the supervisory team. Additionally, a poster was developed from this phase and presented at a conference by the researcher. The reporting was informed by the Standards for Reporting Qualitative Research (SRQR) checklist (188).

This section details the thematic analysis process undertaken by the researcher, including the interview transcription, coding, and generation of themes.

Interview transcription

Transcription of the recorded interviews was carried out by the researcher, and any participant identifiable data was removed at this stage. The interviews were transcribed verbatim in Microsoft Word directly after each interview to reduce the risk of transcription errors and memory recall. The

researcher's first language is not English; this was overcome by double-checking any expressions or uncommon phrases with one of the supervisory team.

The closed-ended questions for demographic data collection were not transcribed because necessary handwritten notes were taken during the interview. Full transcription was performed for the rest of the interview that included open-ended questions yielding qualitative data. The transcriptions included indications of long pauses to ensure that the context of the original discussion remained intact. Once transcribed, the transcriptions were checked against the audio recording to ensure the content and meaning was maintained. Additionally, some of the transcripts were reviewed by the supervisory team to ensure the quality of the transcripts.

Coding

According to Creswell, coding is the main analytic procedure in qualitative analysis (189). Coding is:

"*Categorising collected data, segment sentences or paragraphs into categories and label them with a term that is often based on the participant language"*.

Coding allows the qualitative researchers to conceptualise their data under multiple categories of coding that involves setting and context coding, perspectives held by participants and their way of thinking about people or objects, process, activity strategy or relationship codes and/or pre-assigned codes (152). Qualitative researchers should choose a coding scheme before conducting the analysis. There are three coding schemes (152, 190):

- **The inductive scheme**, in which the codes are only generated inductively from the data collected.
- **The deductive scheme**, in which the researcher uses predetermined codes and fit data to them.
- **Combination** of deductive and inductive schemes for coding.

In this phase, the inductive coding scheme was used, however, the theoretical framework of the study aided the grouping of the codes. This was considered a suitable approach to achieve the aim and objectives and to create a balance between the insights generated from the interview transcripts and theoretical framework.

The analysis began with a detailed exploration of the transcripts, involving reading the transcripts thoroughly and highlighting ideas and thoughts line by line in the data (sentence, line or paragraph). The related ideas and thoughts were categorised into codes. Each transcript was then imported into NVivo version 12.0 to facilitate the analysis. NVivo was used to double-check the codes and all the interview transcripts were searched for the codes manually and using NVivo.

Theme generation

The related codes were grouped into themes based on their differences and similarities. The themes were reviewed and compared continually throughout the analysis process because new themes arose during the analysis. Moreover, the themes were compared constantly during the analysis to decide if no more themes had emerged and if data saturation was achieved.

NVivo was used to facilitate the searching and reviewing for the themes and to build a tree diagram of the themes. The tree diagram helped to identify any relation between different themes and allowed for the highlighting of overarching themes, under which the other themes could be listed as sub-themes.

Grouping of the codes into themes was discussed with the supervisory team. Consequently, themes and sub-themes were reviewed. The transcripts were then checked again to ensure that all the themes were recognised and that all the codes were grouped under the correct theme.

4.3.8 Ethical issues

In phase 1, interviews were audio-recorded. Audio recordings using a digital voice recorder were downloaded onto a secure, password-protected LJMU computer, after which the file was securely deleted from the digital voice recorder. The electronic, password-protected file containing the audio recording was securely deleted after it was transcribed and checked for quality.

Confidentiality was maintained by allowing only the researcher and supervisory team to access the interview recordings and transcripts. All data was anonymised by the researcher by removing any participant identifiable information and coding the transcripts to enable participant identification only by the researcher.

Informed consent and other ethical issues were discussed in chapter 3.

4.3.9 Trustworthiness

The quality of qualitative research and analysis cannot be specified by methodological rules but can be enhanced by conducting systematic and rigorous data collection and analysis (145, 191). In this phase, the quality of the qualitative data collection and analysis was enhanced by several strategies that helped to ensure the trustworthiness of this phase (192). The criteria for trustworthiness in qualitative research that were introduced by Lincoln and Guba (193) were used to demonstrate how the researcher ensured the trustworthiness of the qualitative methodology. Those criteria will be presented in Table 4-2 below along with the steps taken by the researcher to ensure trustworthiness.

Table 4-2 Criteria for ensuring trustworthiness in qualitative research

Criteria for trustworthiness in qualitative research as introduced by Lincoln and Guba (193)	**Steps taken by the researcher to ensure trustworthiness**
Credibility	Triangulation, respondent validation and peer debriefing can enhance credibility in qualitative research (145, 191, 194, 195). The findings of this phase were triangulated in phase 4 along with the findings of phases 2 and 3. Triangulation helped to enhance the credibility of the findings by allowing richness and in-depth understanding of the data and by providing an additional way to generate evidence that supports the findings (191). Unfortunately, respondents' validation of the interview transcripts was not a viable option for this study, because of the busy nature of the participants' work commitments. However, the credibility of the data collected was aided by building rapport, trust, and openness with participants so that they were able to express their views and recruiting a range of participants of different perspectives to ensure a fair dealing of the research topic (145, 194). Several measures were conducted by the researcher and

	the supervisory team to ensure the quality of the transcripts, as mentioned above (see section 4.3.7). Quotations from the interview transcripts were outlined under the related themes and sub-themes to ensure credibility of the data collected (152, 194). Moreover, a pilot was conducted before the data collection commenced (see section 4.3.6) to review the interview schedule and to improve the researcher's skills (152, 195). Finally, the findings and interpretations were peer debriefed by the supervisory team and an external investigator to enhance credibility (185).
Transferability	The researcher was not able to judge the transferability of the findings to another setting but she provided a thick description of the participants and the settings they were based in (while maintaining anonymity) to allow the reader to judge the representativeness of the sample (145, 185).
Dependability	The researcher strived to undertake the data collection consistently (145), therefore she used a semi-structured interview schedule to collect the data, audio-recorded and transcribed all interviews and conducted all interviews consistently. Additionally, the methods for data collection, sampling and data analysis were all documented clearly to ensure auditability of the research conducted (194).
Confirmability	Confirmability was established by describing credibility, transferability and dependability (185). Moreover, the researcher highlighted the rationale for decisions that were undertaken during data collection and analysis in the methods section (see section 4.3) (185).
Auditability	To establish auditability, the rationale for the selection of qualitative methodology, semi-structured interviews for

	data collection and thematic analysis was discussed in the methods section (185). The interview schedule that was used in the interviews was appended to the thesis. Additionally, the procedure for data collection and details of data analysis were presented clearly. Finally, the study reporting followed the SRQR checklist (188) for qualitative research. Those strategies will help the reader to trace the decisions that have been made and be able to evaluate the trustworthiness and quality of the study (185).
Reflexivity	As a pharmacist, the researcher's background and preconceptions may affect the findings during the data collection and analysis (196). Being reflexive (145, 191, 194) in data collection and interpretation of the findings, allowed the researcher to enhance the trustworthiness of data collection and analysis by reducing the influence of the researcher and bias of her self-reflection as much as possible. The methods section discussed how the researcher aimed to reduce the bias that was related to the researcher's background and knowledge. Reflexivity was introduced in the qualitative data collection and interpretation of the findings. The researcher kept a research diary to decrease her influence on the findings, which is considered beneficial by other qualitative researchers (185, 196, 197). In the research diary, the researcher recorded her thoughts, ideas, and preconceptions to keep herself aware of her self-reflections during the research process. Regardless of all those measures, there could be a bias that was related to the researcher's background but those

	measures helped to reduce it as much as possible.

Table 4-2 above described the steps that the researcher took to establish trustworthiness in this phase.

To ensure the rigour of qualitative analysis, a systematic approach was followed to enhance its trustworthiness and credibility in this phase (152, 183, 185-187, 190, 198). Table 4-3 will present how the researcher established trustworthiness in thematic analysis using the means that were suggested by Nowell and Colleagues (185) in each phase of the Braun and Clarke thematic analysis process.

Table 4-3 Steps taken by the researcher to establish trustworthiness in data analysis

Thematic analysis phases (184)	**Steps that were undertaken by the researcher to establish trustworthiness in the analysis of phase 1 (influenced by Nowell (185))**
1. Familiarising yourself with the data	1. Prolong engagement with the data; the interviews were transcribed by the researcher and she listened to the recordings many times. 2. The handwritten notes, audio recordings, transcripts and printed transcripts with the researcher's codes in the margins were stored to be used during the analysis and interpretation. 3. The transcripts were copied to NVivo to aid the analysis process and to organise the data collected.
2. Generating initial codes	Peer de-briefing; the initial codes were discussed with the supervisory team before being applied to all of the transcripts.
3. Searching for themes	1. A record of the themes and the codes, which were grouped into each theme, was created by the researcher. 2. A tree diagram of the themes was built using NVivo by the researcher to understand correlations. 3. Initial themes were discussed with the supervisory team before being applied to all of the transcripts.
4. Reviewing the themes	1. The resultant codes and themes were reviewed continually by

	the researcher as new codes emerged during the analysis. 2. The themes and sub-themes were written on sticky note papers and reviewed by the supervisory team and their feedback was used in refining the themes and sub-themes.
5. Defining and naming the themes	The researcher documented the naming of the themes and this was reviewed by the supervisory team and an external advisor.
6. Producing the report	1. The steps for thematic analysis were described clearly by the researcher in the methods section. 2. The findings and interpretations of the results were all reviewed by the supervisory team. 3. The resultant themes were summarised in a table and a flow chart in the findings section to allow the reader to understand how the researcher interpreted the findings. 4. Detailed description of the themes and sub-themes and anonymised quotes were included in the findings section to provide a thick description of the findings. 5. The interpretation of the findings included evidence from previous research and this was presented in the discussion section.

Besides the steps that were undertaken by the researcher to establish trustworthiness in data analysis, which were listed in Table 4-3 above, the findings of this phase were triangulated with those from phases 2 and 3. Triangulation enhances the trustworthiness of qualitative data analysis (185). Additionally, being reflexive in the analysis aided the establishment of trustworthiness across all the phases of thematic analysis that was conducted in phase 1 (185). Reflexivity was discussed earlier in Table 4-2 and will be discussed in detail in chapter 9.

4.4 Findings

4.4.1 Participant demographics

Sixteen HCPs and a service commissioner participated in the study, giving a response rate of 51.5%. Demographic data was collected only to contextualise the qualitative data and was not analysed. A full list of the participants and their occupations can be seen in Table 4-4.

Table 4-4 Participants' demographics for phase 1

Job title	Number of participants	Setting
Community Pharmacist	7	Community pharmacy
Practice Pharmacist	4	GP practice
Independent Prescribing Pharmacist	1	GP practice
Hospital Pharmacist	1	Hospital
Respiratory Pharmacist	1	Hospital
Severe Asthma and Respiratory Pharmacist	1	Hospital
Respiratory Consultant	1	Hospital
Long Term Conditions Program Manager	1	CCG

As shown in Table 4-4, a range of stakeholders participated in the study. There was diversity in the backgrounds, experiences and knowledge of the participants regarding asthma management in adult patients.

Community pharmacists who participated were involved in the delivery of adult asthma patient services by dispensing their inhalers monthly, checking their inhaler technique, providing services such as the NMS or MUR to adult asthma patients or asthma referrals. While hospital pharmacists, pharmacists based in GP practices and independent prescriber pharmacists who participated in the study were involved in providing clinical services to adult asthma patients, including prescribing and deprescribing asthma medications. The respiratory consultant was involved in both hospital-based services and an integrated asthma clinic in the GP practice. Administrative and cost-related issues were covered by the care commissioning group member.

These different perspectives ensured a rich dataset and provided a holistic overview (145, 152) of the issues concerning asthma management.

4.4.2 Themes

Three themes resulted from the data analysis, all of which were based around asthma management in adult patients. The key themes were subdivided into sub-themes as shown in Table 4-5 below.

Table 4-5 Summary of the themes and sub-themes

Theme	Description and sub-themes	Sub-themes
Asthma management and opportunities for improvements	This theme described different perspectives on asthma management in adult patients and opportunities for improvement.	▪ Regular asthma reviews ▪ Patient education ▪ Diagnosis improvement ▪ Training provision for HCPs
Patients	This theme described issues (that were perceived by the participants) regarding asthma management that are related to patients.	▪ Asthma patients' satisfaction with the service ▪ Asthma patients' engagement with their asthma reviews
Proposed solutions	This theme discussed suggested solutions that could be implemented to improve the management of asthma in adult patients.	▪ Co-ordinated care ▪ Health coaching ▪ Community pharmacy utilisation ▪ Using technology in asthma management

The themes and sub-themes will be described below including anonymised quotes that are related to themes and sub-themes. Additionally, interpretations, thoughts and relations between the sub-themes will be presented in separate boxes throughout the findings. The boxes were used to distinguish the researcher's thoughts and observations during the interviews from the data.

Theme 1: Asthma management and opportunities for improvement

The participants' opinions regarding management and symptom control in asthma patients were varied. HCPs in different settings see different cohorts of asthma patients with different asthma symptom control levels and care needs. For example, HCPs in secondary care might be in contact mainly with patients with severe conditions or poorly controlled asthma. Most of the participants agreed that many asthma patients are with poorly controlled symptoms. However, some participants who were practice and community pharmacists felt that asthma patients are with controlled symptoms:

"My view on how well-controlled asthma patients are, probably is impacted by demographic of patients that I would see in my practice as a hospital pharmacist. I would see those who were not very well controlled. And I think, based on the available data, that most of the population is not well controlled and improvements need to be made to asthma control in the country, in terms of bad patient outcomes," Respiratory pharmacist.

"I do not think they [asthma patients] are well managed," Community pharmacist.

"Generally, they [asthma patients] are well controlled to an extent. They could be a lot better but with the pressures [on the GP practices] and real-life situations, yeah [asthma] is managed okay", Practice pharmacist.

"I think [asthma control] varied [among patients]; we can see some patients who do not follow the stepwise treatment for asthma, but for the majority of patients they are fairly well controlled," Community pharmacist.

According to the participants, poor control could be related to poor inhaler technique and poor medication adherence (especially with the preventer inhaler) among asthma patients:

"Overuse of reliever [inhalers] and poor inhaler technique. They are the main things that need to be addressed to improve asthma management in patients," Hospital pharmacist.

Although there was variability in the participants' opinions regarding how well asthma is managed in adult patients, the participants suggested that asthma management can be improved and highlighted opportunities to improve asthma management. Those opportunities will be discussed in the following sub-themes.

Sub-theme 1: Regular asthma reviews

Most of the participants expressed the view that more frequent reviews of patients' medication and inhaler technique are needed. The participants perceived that conducting an annual review for patients with asthma might not be enough for all patients.

The participants felt that more frequent reviews will help patients to:

- **Enhance their inhaler technique**

"The main problems with asthma patients are [their] understanding of their asthma and the inhaler technique. It is always quite difficult to [teach patients] doing it correctly unless you got them in front of you," Practice pharmacist.

The participants (who were community pharmacists) described individual efforts that were undertaken by community pharmacists to coach patients to use their inhalers properly. Despite the participants' perception of the effectiveness of the inhaler technique check using the inhaler In-Check devices in community pharmacy, it is not included in any nationally commissioned NHS service and not included the PQS:

"Whenever I've used the inhaler In-Check device, the patients found it useful, because they have never been told how to inhale or how long to inhale," Community pharmacist.

"I teach asthma patients how to use their inhaler or send them videos, so they can see a person who uses the medication online. It is an ongoing thing we do with everybody," Community pharmacist.

Those efforts that were undertaken by community pharmacists showed that some community pharmacists are aware of asthma patients' need to enhance their inhaler technique and their willingness to do so.

- **Enhance medication adherence in asthma patients**

A finding from the analysis of the interviews was that asthma patients tend to be overtreated or undertreated. The participants felt that more frequent reviews of the patient's medication, followed by stepping down or stepping up the patient's medication as appropriate to ensure that patients are treated according to the recent guidelines for asthma management:

"Patients should be seen by the nurses or doctors more often and step up or step down [their asthma medication]," Community pharmacist.

- **Finally, some participants thought that more frequent reviews can help asthma patients by providing them with an opportunity to be educated more regarding their asthma.**

The findings on patient education were presented in the following sub-theme that included participants' thoughts on the content of patient education and not the frequency only.

Sub-theme 2: Patient education

The participants appreciated the current education provided to asthma patients but some participants felt that patient education should be enhanced to cover all issues regarding asthma disease and medication use including asthma symptoms control, asthma attacks, the rationale for their asthma medication and non-pharmacological management of asthma including trigger factors and physical exercises:

"New patients that come to our clinic [specialist clinic], tell us that they never had any information about what asthma is. I think as health care professionals, we are guilty of thinking that somebody else has already done that or assuming that patients know certain things when they might not," Severe asthma and respiratory pharmacist.

"[Asthma] patients just need to understand [that] they need to use these [preventer] inhalers every day to prevent exacerbations [of asthma symptoms]," Community pharmacist.

"Some of them [asthma patients] do not have some skills to understand how to use their inhaler properly, how to plan their daily routine, to avoid trigger factors and avoid other things. In general, asthma patients do not fully understand their asthma. They can control their asthma, but they need skills. Maybe, education on how to control [their asthma] is what they need," Community pharmacist.

"You can do like an asthma rehabilitation [program] to improve their exercise tolerance, it is in place already [in other cities] but it will be very useful if it is in [city]," Independent prescribing pharmacist.

Only two of the participants focused on supporting self-management in asthma patients. Those two participants felt that asthma patients should be motivated, engaged in shared decision making with their HCPs and supported in self-managing of their condition. The participants felt that there is a role for nurses and other HCPs in the provision of preventive care to asthma patients by helping them to self-manage their condition:

"Maybe, a preventative intervention by nurses is a better value intervention than just treating an asthma attack. We could prevent patients [from having] an attack. Most of the problem is probably

how patients think. Anybody skilled in influencing people, they could deliver that sort of intervention," Community pharmacist

"I think with asthma there should be a much greater onus on self-ownership and the patients should be more involved in the management of their care and monitoring of their asthma control," Severe asthma and respiratory pharmacist.

Another issue that participants raised about patient education was that asthma patients should be more aware of their condition and its impact on their health. Interestingly, one of those participants used a strong expression to highlight this, however, this might be related to the nature of the job of this participant as an LTCs program manager that does not involve direct contact with patients:

"I think we should scare them [patients who do not attend their AAR]. [We should] tell them that so many people a year die [because] of asthma. I think it is an education thing," Long term conditions program manager.

In this sub-theme, there was limited focus on enabling self management. One of the two participants who mentioned this was a community pharmacist who has another job in teaching in a university and this might affected the participant's views and/or background. The other participant was a severe asthma and respiratory pharmacist who was based in a hospital and this might provided the participant with the opportunity to interact with asthma patients in a different way than other participants who were based in community pharmacy and the GP practice, which affected his/her views. Another issue might be that those participants were updating their information more frequently than the other participants.

Sub-theme 3: Diagnosis improvement

The findings concluded that asthmatic patients are not currently well diagnosed and suggested using Fractional Exhaled Nitric Oxide [FeNO] testing for diagnosis, as well as for the monitoring of asthma patients. The participants perceived that there is a need to decrease false diagnosis with asthma:

"There are patients who don't have asthma but have anxiety or other conditions. [There is a problem of] false diagnosis [with asthma]," Practice pharmacist.

"Once the diagnosis is made [once it is suspected], that seem quite quickly with spirometry. Use of respiratory FeNO [will ensure] that a correct diagnosis is made and those who had asthma they [could] have some immediate education from a specialist," Respiratory consultant.

"We [CCG] are looking forward to specialist-led diagnostic hubs in the community and we kind of wrote a business case of a diagnostic hub, where patients will have a diagnosis by a specialist and follow-up by a nurse with education, but there is no money at the moment to invest. The business case says that we will reduce ambulance use and deaths and savings will come from the specialist

diagnostic hub. The diagnostic hubs will diagnose almost 30% less asthma than in the GP. So, in the GP almost 30% of those people [diagnosed with asthma] don't have asthma or need to be managed differently," Long term conditions manager.

The findings on this sub-theme were limited because not all of the participants are involved in asthma diagnosis, for example, community pharmacists do not diagnose asthma and do not have access to records of the patients to know about issues with asthma diagnosis.

Sub-theme 4: Training provision to HCPs

The participants perceived that there is a need to enhance the training provided to the HCPs regarding asthma management:

"Probably a lot more training to be provided across the board, some asthma nurses are great in asthma but I think there is a lot of gaps out there and the same for the GPs," Long term conditions manager.

Other participants felt that there is a need to provide training to community pharmacists to be able to provide further support for asthma patients. However, some participants thought that community pharmacists are well-qualified to provide support for asthma patients:

"Not all the time the community pharmacist has the prescribing qualification, so they could highlight poor control but might not necessarily be equipped or able to prescribe alternative treatment to the patients," Hospital pharmacist.

Theme 2: Patients

This theme covers the issues regarding asthma management that are directly related to the patients as perceived by the participants in this phase.

Sub-theme 1: Asthma patient satisfaction with the services

When the participants were asked about patient feedback regarding the current services provided to them, some of the participants were aware of patient perceptions, whereas, others did not have a sense of the patient's perspective and were unable to comment:

"We mainly get the feedback on the national in-patient survey, which is quite general. You know when you focus specifically on asthma, no sort of any feedback about asthma management," Hospital pharmacist.

The researcher noticed that some participants were surprised by the question and gave the feeling that they have never thought about what patients think before.

Other participants who were aware of patients' feedback perceived that:

- Some asthma patients appreciate support provided to them in the GP practice and community pharmacy.

Asthma patients who are attending their GP appointments appreciate the AARs provided to them by the practice nurse and are receptive to the information given to them by the practice nurse or pharmacist, or community pharmacist:

"We [CCG] got very good feedback on all our GP services. About the practice nurse services, they [asthma patients] like the practice nurse. When we did some consultations with some asthma patients about some changes that we were planning to do about the diagnosis and to provide education, we had a group of patients who love that practice nurse thought she was fantastic, really happy with what they've got, they all had asthma plans and they were well-managed," Long term conditions manager.

"When I have done medicine reviews for patients with asthma, they have come back and said that their condition seems better controlled because they knew how to use their [inhaler] device properly," Community pharmacist.

- Asthma patients are happy with their asthma services.

One participant mentioned that some asthma patients are happy with services because they could be seen by more than one HCP:

"Generally, people with asthma seem to be happier than [people with] other conditions because they are engaging quite a lot with doctors, engaging with pharmacists regularly when picking up their prescriptions, that just my experience," Community pharmacist.

- Asthma patients have low expectations

The participant highlighted that some asthma patients might have low or no expectations in the management of their asthma, such patients are happy with what is being encountered in their asthma appointments:

"They [asthma patients] think it [asthma service] is good, but I think the problem is that they have not seen how it could be better," Practice pharmacist.

- There is inequity in access and quality of asthma care.

However, according to the participants, there is variability in the access to services and quality of care provided to asthma patients among different GP practices and HCPs:

"I think there is a bit of a variation, we've got some good practice nurses and some that are not so great," Long term conditions manager.

The findings on this sub-theme showed some of the participants highlighted issues that are more related to the bigger picture on asthma care rather than their personal experience. Among those is a LTCs manager and a practice pharmacist and both of them were involved in research projects or studies that based around health services, this might have provided them with additional or different knowledge and views.

Sub-theme 2: Asthma patients' engagement with their AAR appointments.

Some of the participants suggested that one of the main issues regarding adult asthma patients' management is patient engagement:

"There is a cohort of patients who don't come in [to the GP practice] for a review. We cannot reach them because they don't engage with the practice," Practice pharmacist.

According to the participants, those patients who do not attend their asthma reviews are not fully aware of their condition or because of the poor quality of the AARs provided in some GPs due to the short time provided for the review. Additionally, some asthma patients might have issues with the appointments system and the flexibility in the delivery method of asthma reviews in the GP practice:

"There is a cohort of patients that are very difficult to see for reviews and it is a challenge improving their engagement to it. …They think they are managing their condition and that they don't need help or support," Practice pharmacist.

"I know some of the nurses who do a proper [annual asthma] review, whereas others recorded that the patients' asthma is not interfering with any of their activity, but they are using their salbutamol [reliever] inhaler about 5 times a day. I think this is because of the time pressure in those reviews. I think they need a little bit more time," Independent prescribing pharmacist.

"[Asthma] patients complain that it is really difficult to get an appointment with GPs", Community pharmacist.

The participants suggested that delivery methods other than face-to-face appointments could be used to enhance patients' engagement with their AARs. However, the participants highlighted that using other delivery methods might affect the effectiveness of the appointment. For example, one of the participants felt that telephone reviews are not as effective as face-to-face review appointments because lung function cannot be assessed:

"Maybe we need to offer [asthma patients] appointments over Skype," Long term conditions program manager.

"We [GP practice] have started this year to do telephone reviews for [asthma] patients but you cannot do so much of a review over the phone. You can find out about the symptoms, you can talk to them about the RCPs' 3 questions, you can ask if they are having any night-time symptoms and talk about their normal activities over the phone. So, we can do things like that over the phone, which can be quite beneficial for patients who would not come in and over the phone we can convince them to come in, but it is difficult," Practice pharmacist.

These two sub-themes were related to each other because enhancement in the satisfaction of patients with services might help them to engage more with them. The patient engagement was related with community pharmacy utilisation because the participants thought that community pharmacy can enhance patients' engagement as discussed later in theme 3. On the other hand, direct relation can be built between patient engagement and more frequent reviews because patient's engagement is essential to get the benefit of providing more frequent reviews.

Theme 3: Proposed solutions

The participants suggested solutions and approaches to enhance the management of asthma in adult patients and improve asthma patients' engagement with the services. Those proposed solutions are discussed in the following sub-themes.

Sub-theme 1: Co-ordinated care

The participants perceived that an improvement in asthma management could be achieved through the delivery of co-ordinated care to patients with asthma:

"If we could have all the parts of the [healthcare] system working together better, [asthma management] will be improved," Long term conditions program manager.

Many participants agreed on the importance of information sharing between different healthcare settings; suggesting the need for better communication between community pharmacy and GPs:

"I think it is about the inclusion of information and thinking about how we ensure that pharmacists are aware that patients have been in hospital. So, we may have the best post-discharge services in pharmacies but we are not able to offer, because it is meaningless if we don't know the patient has been in hospital. I think that is pharmacists are uniquely equipped to deliver certain services but if you don't know who you can deliver those services to, it makes things very difficult," Respiratory pharmacist.

"[GPs] do not know if [community pharmacy] did an emergency supply for asthma patients over the weekend. We won't know about that until we issue the next prescription," Practice pharmacist.

Many suggestions were made by the participants regarding asthma services that utilise different HCPs' expertise and resources, including community pharmacists, pharmacy support staff, GPs, consultants, nurses, practice nurses, respiratory specialist nurses and independent prescribers:

"I can see a real role for pharmacists and nurses in community practice, in GP surgeries, primary care and community pharmacies for a day-to-day management of asthma," Respiratory pharmacist.

One of the participants [who is a service commissioner] mentioned examples of utilisation of multidisciplinary work to improve asthma management. Looking globally, the participant mentioned the 10-year asthma program that was undertaken in Finland between 1994 and 2004. According to the participant, it might be useful to develop and provide such programs for asthma patients in the UK.

Overall, the participants thought that Better communication between the different health settings, information sharing, and multidisciplinary teamwork could facilitate the provision of co-ordinated care.

This sub-theme was not connected to any other sub-theme and this is because it is the only sub-theme that were based on organisational issues.

Sub-theme2: Health coaching

One participant perceived that asthma patients might need support to empower them and enable them to manage their condition through the provision of health coaching interventions. However, the current financial and resource limitations might restrict the provision of such services for asthma, according to the participant:

"[I suggest] some health coaching interventions on asthma [that provide] more talking and listening to the patients rather than passing health care messages into the patients. I have seen patient

groups and things like that, [health coaching and patient groups] are very helpful but [there] seem to be [more] focusing on the more effective and cost limited [interventions]. Certainly, healthcare coaching conversation would be quite useful," Community pharmacist.

This sub-theme was based on a view from one participant only and surprisingly, this participant was a community pharmacist who suggested the need for patients' motivation and enabling patients to self-manage their condition. This might be an area of interest for the participant.

Sub-theme 3: Community pharmacy utilisation

The participants felt that community pharmacy could support asthma patients. The participants appreciated the regular contact between community pharmacists and patients:

"In community pharmacy, every single month they [community pharmacists] see the patient, so they can check that everything is okay, and I don't think any other professional role has that sort of regular contact with the patients," Practice pharmacist.

Some of the participants expressed that currently, community pharmacists are having a role in enhancing medication adherence in asthma patients as part of the asthma referrals scheme:

"We [community pharmacy] had a [referral] scheme, a few months ago, where we will highlight patients who just had a salbutamol inhaler for the previous 6 months. We would highlight those patients, speak to them and send them to the surgery for review. Because they are not very well controlled, they are just using a salbutamol inhaler," Community pharmacist.

One of the participants expressed that the asthma referrals service is not as useful as expected. However, this was based on the participant's experience in the community pharmacy that he/she was based in:

"There is a current service about referring patients who prescribed 6 reliever inhalers and no corticosteroids. Where I work, I have not found any patient in twelve months or more doing it," Community pharmacist.

Suggestions were made by the participants regarding a potential role that community pharmacists could play to support asthma patients, and those suggestions included:

- Increase the provision of NMS and MURs (the MURs was not decommissioned when the study was conducted).

A participant who was a community pharmacist appreciated the MURs and NMS and thought that they can provide further help to asthma patients by reinforcing the provision of those services:

"Again it is just around the multidisciplinary, so the pharmacist can be more involved, with checking the inhaler technique on the regular basis, making sure that they are reviewing the patient through an MUR or making sure that [patients] know how to use all new medicines they have by offering an NMS," Community pharmacist.

However, other participants including a community pharmacist showed a negative response to enhance the use of MURs and NMS to improve asthma management due to the time restrictions and the high current workload. The participants perceived that these services only identify the problem and refer the patient again to the GP practice for intervention:

"I have never seen a good one [MUR], so it is a waste of the money they [community pharmacist] get paid to do MURs. It [MUR] is not useful for the patient and can cause more issues really for the GP practice," Practice pharmacist.

"I think it will be difficult to integrate [another service] into NMS or MUR because [community pharmacists] already have limited time to do a lot of jobs but maybe sometime a second service might be the way [to support asthma patients]," Community Pharmacist.

- Supporting GPs with asthma management.

According to a participant who was a community pharmacist, community pharmacy and GPs could work together to organise asthma management in patients:

"I suppose asthma patients should be reviewed more frequently. Some of them get reviewed once a year, but when you check [their inhaler] technique people [asthma patients] forget it, after a certain period. So, maybe a more joined-up service with the GP. So, you know maybe the surgery review patients yearly and we [community pharmacists] could do a review halfway through the year." Community pharmacist.

The community pharmacists thought that providing further support for asthma patients in the community pharmacy setting can help to manage the workload between different HCPs if patients were referred from the GP to the community pharmacy:

"Maybe we [community pharmacy] could take the onus off the GPs. If we got a list once a month of patients from GP practices for us to go through that patients' inhalers technique, but paying us for the service and recognising the people to do that. We can do that in the pharmacy," Community pharmacist.

Community pharmacists suggested a new service and more asthma reviews that could be conducted by community pharmacists. This might show that pharmacists are keen to support asthma patients or enhance their role. However, this was contradicted by another participant who

was an LTCs program manager. The participant mentioned that in the UK, the Isle of Wight respiratory inhaler project (199) was mentioned by the participant as a successful example of an intervention that involved multidisciplinary work, however, the project implementation in the North West was not successful due to the lack of engagement by the community pharmacists:

"We [CCG] tried it [respiratory inhaler project] here [North West] but we didn't get very good engagement from the community pharmacists. I don't know what we did wrong, but we tried and we provided some education for them [community pharmacists]. They had to fill out many forms about what they have done, I don't know whether the forms were too hard or took too much time," Long term conditions manager.

- Community pharmacy-based clinic

When participants were asked what a new asthma intervention or any kind of support could be, they suggested a community pharmacy-based clinic for adult asthma patients, in which the community pharmacist could review medication, inhaler technique, provide an AAP, and adjust their medication instead of referring them to the GP:

"I think it should not just be nurse-led asthma clinics; community pharmacy should be able to tweak the therapy, may be able to do it as part of the MUR and then sending the changes to the doctor. Rather than sending them after MUR to the asthma clinic who just do what we said should be done in the first place," Community pharmacist.

- The provision of an intervention that focuses on inhaler technique improvement.

The participants thought that community pharmacist can help asthma patients to improve their inhaler technique, switching inhaler devices if their technique is poor and enhance their adherence to asthma medication:

"I think inhaler review every 3 months in community pharmacy would be appropriate, that could be funded from the CCGs," Independent prescribing pharmacist.

"I think from my point of view, there should be a core service in community pharmacy for asthma patients. That would involve checking their inhaler technique and providing patients with active support and education on their asthma," Community pharmacist.

- The provision of an AAP.

Some of the participants perceived that community pharmacists are well qualified to optimise to develop and deliver an AAP:

"[Community pharmacists can] use the opportunity, when people pick up their inhalers, to make sure they know how to use them. Trying to encourage people to get an AAP, if they haven't got already an action plan. I don't see why a pharmacist couldn't complete an action plan for patients if they know what inhalers they are on," Respiratory specialist.

- Medication adjustment in community pharmacy.

Additionally, some of the participants suggested providing medication adjustment service in community pharmacy, but by an independent prescriber pharmacist, rather than a community pharmacist:

"I see patients chosen devices or medicines, some devices that they are not happy with. And it might be good in a pharmacy if we had a clinic where we could change the device. So, I think there will be a place for independent prescribing in a pharmacy. An independent prescribing service in a pharmacy might be helpful. This is because patients do complain that it is really difficult to get an appointment with GPs, I think that something that we could do," Community pharmacist.

The participants highlighted that to deliver community pharmacy-based asthma intervention effectively and safely, community pharmacy should be provided with additional funding, necessary equipment, professional training, communication with the GP practice, access to patient's information and a clear service protocol to follow:

"I have no issues about community pharmacists to be much more integrated into primary care practices, but I think they should set within the practice and be able to get a full access to know what is going on," Practice pharmacist.

"If we [community pharmacy] got a list once a month of asthma patients from the GP to review' those patients' inhalers techniques and medication. We [community pharmacy] should be provided strict criteria to know when patients should be referred back to the GP or giving us the potential to be able to prescribe," Community pharmacist.

When participants were asked which asthma patients could benefit the most from support in community pharmacy based on their experience and views, there was a variability in their opinions.

One of the participants perceived that when developing a new service for asthma patients, one should focus on equity and ease of access to the service by all asthma patients. However, the participant felt that it might be beneficial to target the support to newly diagnosed asthma patients:

"I would say in general we should think about all groups because we need to offer a service that is accessible to everyone, easily accessible, so I don't think we should focus on a particular group. But probably the group that I mentioned is newly diagnosed asthmatics that might be an area where we can focus. The other is people that have been asthmatic for years and years and are still

not controlled. That might be an area to focus on as well because you could improve minimal intervention [for this group of patients]," Community pharmacist.

It was suggested by other participants too, that the newly diagnosed patient group would benefit from the provision of a correct diagnosis, as well as a full education regarding the disease and the inhaler technique:

"[I suggest] a structured education program and management program for [asthma patients] on the early diagnosis," Community pharmacist.

Among those participants who thought that newly diagnosed asthma patients were community pharmacists. This suggestion complement the other participants suggestion of enhancing the current NMS. Additionally, it raised the question (Is NMS a tick box exercise as described by some participants and it is not enough for asthma patients?). However, this suggestion is from HCPs' point of view and not patients. Asthma patients might have different perceptions on the NMS.

Other participants felt that patients with poorly controlled asthma symptoms can be supported in community pharmacy. According to the participants those patients could be identified by reviewing the number of preventive and reliever inhalers collected by the patient in the community pharmacy and/or by reviewing patients' symptoms by an HCP:

"[Community pharmacists could] pick up patients who are not well controlled or do not have ICS or preventer, picking up patients that have a diagnosis of asthma but not on a steroid inhaler, pick up patients who are using less than 6 inhalers a year. [Those patients could be targeted by community pharmacy]," Respiratory specialist.

This suggestion might be complementary to the asthma referrals scheme, but the participants felt that community pharmacists can support those patients themselves rather than referring them to the GP practice. However, as discussed earlier, one community pharmacist mentioned that he/she has not identified any such patient for over a year.

Other, participants perceived that patients with controlled asthma symptoms need a regular follow-up and medication review to step down their medication, which could decrease the cost of unnecessary treatment:

"We got a cohort of patients who do speak to us, however when they are reviewed in the GP it doesn't seem to be noticed that they are not using salbutamol [reliever], but they don't get stepped down," Independent prescribing pharmacist.

Many of the participants agreed that young adult asthma patients have less control over their symptoms compared to older patients. When the participants were asked why young adults have less controlled asthma symptoms, they thought that this age group usually pay for their prescriptions and this might affect their medication adherence:

"[Patients with] uncontrolled [asthma], especially people in their twenties and thirties and it could be a lot of different issues. Sometimes they cannot afford to pay for their medication, so they do not get their medication prescribed. So, their asthma is not very well controlled. So that could be an issue and tends to be in the younger age group more of the older age group," Community pharmacist.

"In terms of young adults, I think asthma should be one of the groups that are qualified for free prescriptions. I think asthmatics should get free inhalers," Community pharmacist.

The participants also related poor asthma control in young adults to the busy nature of their lives so they do not engage with services. Based on this, this age group could benefit from a service in community pharmacy that adapts to their busy schedule to increase their engagement.

Furthermore, asthma patients who do not engage with their GP appointments could also be targeted by community pharmacy to increase their engagement with asthma reviews. The participants suggested that the provision of asthma reviews in community pharmacy could improve the engagement of asthma patients because community pharmacy can provide more flexible appointments than the GP practice. Such a service can enhance engagement and be beneficial for patients if community pharmacists provide them with a review along with medication adjustment if needed:

"Maybe doing service in community pharmacy to reach those patients [hard to reach], they still pick up prescriptions from the pharmacy. They are not attending the GP practice for review but they could potentially be at their local community pharmacy. You know community pharmacy can be involved in [asthma review] and they can send the patient information back to us [GP practice]. Something like that might work, it is a little bit more practical for patients," Practice pharmacist.

Some of the participants suggested targeting post-discharge patients. Participants suggested that adequate follow-up of post-discharge asthma patients will lower their readmission into the hospital and improve their asthma control. However, other participants were hesitant to support post-discharge asthma patients in community pharmacy because their condition may be complicated and require specialist intervention:

"I believe that community pharmacists are ideally placed alongside the nurses and other allied health care professionals for delivering asthma services. Not necessarily for too complex patients, not necessarily for those with brittle asthma or who had life-threatening exacerbations resulted in them being in intensive care. But for the average asthmatic patients," Respiratory pharmacist.

Additionally, one participant thought that further support could be provided to smokers with asthma to improve their asthma control through a smoking cessation service in community pharmacy:

"I think smoking cessation would improve asthma control, I think community pharmacy is the ideal place to help with that," Hospital pharmacist.

There was variability in the participants' suggestion on which asthma patients could benefit the most from support in community pharmacy. Although this might be related to the different cohort of patients that the participants contact with across the different healthcare settings, it might be related to different views on the ability of community pharmacists to provide further support to asthma patients.

Sub-theme 4: Using technology in asthma management

Four of the participants were keen to introduce technology into the monitoring and follow-up of asthma patients, in terms of inhaler technique and medication adherence:

"I think there is a massive role for technology in the monitoring of asthma [patients]," Respiratory pharmacist.

- Technology to assess medication adherence and inhaler technique.

One of the interesting suggestions was to use smart inhalers, which can record when the patients inhale their medication to improve their medication adherence and allow the development of individualised treatment plans. However, these inhalers are not currently available in the UK. Another participant mentioned a technology-based project called Inhaler Compliance Assessment (INCA), the Inhaler Compliance Assessment device (200, 201). The INCA device was designed to assess patients' inhaler technique (201). This device along with the smart inhaler could allow improved monitoring of patients' medication adherence and inhaler technique:

"Smart inhalers, which tells about how often asthma patients use their inhaler at home. They have electronic chips in them, which can be linked to an app. The app tells how often the patient is using inhalers. I think part of it is for the patient who self-monitor [their asthma] at home and for us [HCP] to be able to check how often the patient is using their treatments at home. I think that would be a big change that these smart inhalers are coming to the market in the next two years," Respiratory and severe asthma pharmacist.

- Smart cards

Two of the participants thought that there is a need to identify the exact number of inhalers that the patient picked up from the community pharmacy, to ensure that patients are adherent to their preventive medication:

"If there is a patient with asthma that is on a brown [preventer] inhaler and they are picking it up. If they had some kind of a swipe card to say that they picked it up from any pharmacy. It will be very useful if the pharmacist knew how often they have been using their preventer inhaler, then they [community pharmacists] could increase the brown to blue [reliever] ratio. I am not sure how that could be done, but I think something that pharmacy could set into really well," Respiratory specialist, hospital.

According to the participants, using technology will allow day-to-day monitoring of asthma rather than waiting for an appointment to review their medication or inhaler technique. Daily monitoring could improve medication adherence, inhaler technique, self-management in asthma patients and prevent asthma exacerbations. Accordingly, this will improve asthma management:

"The use of technology must be more interactive than just keeping a peak flow diary where you are writing down a number every day," Respiratory pharmacist.

"Maybe, an application that would allow patients to answer the Royal College Physician's three questions and to track that data over time. I think this will build up that historical data because what tends to happen is when you ask patients how well controlled their asthma is and they [patients] tell you how they feel on that day and not how they [patients] felt two weeks ago because they cannot remember," Respiratory pharmacist.

In this sub-theme, only three participants provided the suggestions on using technology. Interestingly, two of them were working in the same asthma clinic, therefore, they might have similar access to information and training. The third one has another job in a university and this might provide the participant with the opportunity for updating his/her knowledge and information more frequently than other participants.

4.5 Discussion

This phase explored stakeholders' perspectives on asthma management in the North West of England. There was limited representativeness in the sample, however, the researcher strived to represent all the participants' views to ensure fair dealing of the topic of the study. Additionally, contradictory opinions were taken into consideration during analysis and in the interpretation of the findings. Moreover, how the participants' role or healthcare setting might have affected their opinion were presented in the findings and will be discussed in this section.

4.5.1 What did the participants think about the improvement of asthma management in adult patients?

Every asthma consultation is an opportunity to assess asthma management and to review and extend patient knowledge and skills (22, 23). Therefore, the participants in this study highlighted the importance of the enhancement of asthma patient education regarding their condition, symptoms control, asthma medication and non-pharmacological management (including trigger factors, physical exercise and smoking cessation) to improve patients' outcomes.

Only some participants mentioned other aspects to improve asthma management that were based around the provision of an AAP to support patients in self-managing their asthma, shared decision making and motivation. Similar findings were highlighted in a qualitative study in America (202) that involved conducting six focus groups with 46 adult asthma patients (average age was 72.6 years) and found that asthma patients are interested in getting asthma education and that many of them have not received an AAP. Another Australian study that was included in the literature review (chapter 2) found that less than 20% of the 248 patients in a cross-sectional study had an AAP (101). In the UK, the annual asthma survey conducted by Asthma UK in 2017 found that only 44% of patients who participated in the survey had an AAP (15). Furthermore, according to the participants, health coaching could help asthma patients to self-manage their asthma.

Some participants highlighted the need to improve asthma patients' access to services and engagement with their AARs and mentioned a cohort of asthma patients who do not attend their AAR, despite efforts to engage them, they are still hard to reach patients (28, 29, 203). According to the participants, some of those patients are not engaging with their AARs because they are not aware of the importance of follow-up and monitoring their condition.

The findings suggested that the provision of preventive and co-ordinated care to asthma patients across different healthcare settings could improve asthma outcomes in adult patients. Co-ordinated care is an essential element of care in patients with LTCs because they might be seen by a variety of HCPs who have not shared information about their condition (38, 39). The findings suggested that better information sharing could allow the provision of co-ordinated care to asthma patients and improve the follow-up of their asthma.

For example, the participants suggested the enhancement of the use of compatible IT systems that support information sharing between community pharmacy and GP. This finding agrees with the CPCF (65) and findings of Smith's review that was conducted in 2018 (56).

Moreover, the participants suggested the provision of services that adopt a preventive care approach and utilise the expertise of many HCPs, including asthma specialists and nurses, to improve asthma diagnosis and follow-up.

Finally, smart inhalers, smartphone apps, smart chip cards and virtual appointments were suggested by the participants in this study as technological approaches to enhance the monitoring of asthma symptoms, medication adherence and self-management and by offering flexible appointments to fit around patients' schedules to increase their engagement. This finding is consistent with the findings of the Connected Asthma report that was published by Asthma UK (204). In response to the COVID-19 pandemic, the use of telephone and video appointments were enhanced enormously in the UK for patients with LTCs including asthma patients (18, 205). However, the most recent annual asthma report showed that 3.53 million patients in the UK have not received asthma management in 2020 regardless of the availability of remote appointments (18). Additionally, organisational and structural changes in the healthcare system in response to the pandemic might be utilised to expand the role of community pharmacy within the wider primary care team (133).

4.5.2 Different responses of the participants might be related to different specialities, healthcare settings or background

The absence of many of the person-centred care elements in the interviews of many of the participants might be related to the differences in knowledge, skills and training among different HCPs (46). This was shown through the findings, where participants who have another role in a university showed some different views or thoughts. As well as those who were based in secondary care and showed interest in technology solutions. On the other hand, this might be caused by the questions asked during the interview.

Moreover, not all of the participants were aware if asthma patients were satisfied with the services provided to them or not, or about their perceptions of the services. This might be related to the nature of the sample, could be related to the presence of some paternalism in care delivery by those participants or because of the nature of participants' current role that does not allow much

interaction with patients. For example, community pharmacists are mostly dispensing patients' prescriptions that do not require much interaction.

Some of the participants felt that sometimes HCPs might assume that the patients were fully educated regarding their asthma or inhaler use in another setting, or they were using the inhaler for long period. Additionally, the participants focused on delivering information to patients regarding asthma with less focus on sharing, interacting and enabling patients to manage their asthma. Although those might be caused by the limited representativeness of the sample, they could highlight paternalism in the approach for care provision. HCPs should measure what is important to the patients without assumptions and should be aware of patients' preferences to be able to work collaboratively with them (38, 39).

For HCPs (including pharmacists) to be able to support self-management is one of the approaches for person-centred care and they should be provided with training to improve their communication skills, collaborative care planning and motivational interviewing skills and not solely rely on their clinical knowledge (38, 39, 206). This might help to shift the care more towards person-centred approaches and less paternalistic approaches.

4.5.3 What did the participants think regarding further opportunities for community pharmacy to support asthma patients?

Some of the participants perceived that community pharmacy could further support the GP in managing adult asthma patients by providing frequent or additional reviews of their medication, inhaler technique, medication adjustment and/or the provision of an AAP. This finding supports the findings from two RCTs in Spain (106) and in the UK (110). Both studies involved regular follow-up of asthma patients in community pharmacy over the study period, which resulted in improvement in asthma symptom control in the participants.

Some of the participants felt that further opportunity for community pharmacy to support asthma patients is limited to inhaler technique check and training and suggested the use of inhaler In-Check devices to train the patients. Whereas, other participants were keen on the development and provision of AAPs in community pharmacy. One of the participants who was a specialist thought that community pharmacists can provide an AAP.

Another opportunity that was suggested by the participants was to allow community pharmacists to adjust asthma medications in community pharmacy. However, there was variability in the

participants' opinions regarding medication change in community pharmacy. Nevertheless, the participants felt that conducting a medication change might need training. Other participants were worried regarding the ability of community pharmacists to change patients' medication because of their limited access to patients' data.

Enablers for the provision of further support for asthma patients in community pharmacy

While the participants were discussing their opinions on the opportunity for community pharmacy to provide further support to asthma patients, they mentioned many enablers for the provision of further support for asthma patients in community pharmacy. Those enablers included: the need for referring patients from the GP to community pharmacy because it might be hard to identify patients in community pharmacy, additional funding, training and written guidelines or protocols to provide the services effectively and information sharing pathways to share feedback with the GP practice.

In the Australian cross-sectional survey (101), which was conducted with 248 asthma patients, the findings identified barriers to the improvement of the role of community pharmacy in the management of asthma in adult patients, including patient acceptance and the lack of cooperation between community pharmacists and other healthcare practitioners (101). In contrast, this phase showed that HCPs perceive that asthma patients were receptive to the interventions provided to them in community pharmacy; however, the results are from the community pharmacists' perspectives only.

Although this phase has not aimed to explore barriers or tension between different HCPs and the thoughts and views of the participants highlighted those barriers, the findings showed that practice pharmacists who were based in the GP practice were less receptive to providing further support to asthma patients in community pharmacy than other participants. On the other hand, those who were based in secondary care showed more positive responses. This might be related to the previous experience of practice pharmacists with MURs and NMS that could increase the workload in the GP practice as the participants perceived. This finding showed that HCPs who are based in the GP practice might be hesitant to support the provision of intervention in community pharmacy because they might think it is a loss of opportunity for them to provide the intervention to the patients (207). Although the findings of this study might be limited to the region where the study was conducted, this finding was discussed before by Latif and colleagues (207).

Regardless of the barriers and limitations mentioned above, the provision of asthma services in community pharmacy can help to release the GP's appointments to patients with more severe cases and enhance patients' engagement by offering flexible appointments, which agree with the findings of other studies (42, 80, 208). However, the current workload on the community pharmacists and time restrictions could limit the uptake of new services in community pharmacy as perceived by some participants in this phase. Although some community pharmacists who were interviewed in this phase were keen to support asthma patients, one of the participants who was involved in service commissioning thought that community pharmacists might not be receptive to supporting asthma patients. This barrier could be addressed if pharmacy support staff were more involved in the provision of those services and help the community pharmacy to re-organise the workload (46).

Which patients can be supported in community pharmacy?

There was variability in the participants' suggestions, this was not surprising because the studies in the literature review (see Chapter 2) showed variability in the patients who were targeted by the interventions.

Some participants thought that community pharmacists could support patients with well-controlled asthma through regular reviews and stepping down their medication if required. Such an intervention could decrease the cost of asthma treatment by cutting unnecessary treatment, increasing the safety of treatment in asthma patients.

Other participants thought that an improved NMS could be provided to newly diagnosed asthma patients that includes a diagnosis check using FeNO testing and/or patient education. Accurate diagnosis of asthma and early assessment of severity could reduce the risks of asthma and allow HCPs to deliver effective asthma management at the right time (9, 10, 209). However, providing FeNO testing in community pharmacy might not be an easy option to do.

Some participants felt that patients with poorly controlled asthma symptoms can be supported in community pharmacy by improving their inhaler technique and medication adherence. This finding agrees with the results from other studies (100, 103-105, 113) that were conducted to evaluate community pharmacy-based asthma interventions, targeted at patients with poorly controlled asthma.

The participants in this study were hesitant to provide support to post-discharge asthma patients in community pharmacy because patients with severe asthma are followed up in secondary care (26). However, the evidence showed a gap in the follow-up and management of asthma patients after discharge from the hospital and is considered a preventable cause of asthma deaths in the UK (1, 11, 15).

Another participant thought that community pharmacy can provide smoking cessation support to patients with asthma. In England, a support service for patients with COPD in community pharmacy involved referring the patient to a smoking cessation service in community pharmacy and saw a 4.1% decrease in the percentage of patients who were smoking over the study period (73).

Interestingly, many of the participants in this study felt that young adult asthma patients' condition is not well controlled and they might be supported in community pharmacy. In Italy, a questionnaire (210) that was conducted on asthma patients aged 20-44 years showed that only 10% (63/649) of the participants were classified as having controlled asthma. The findings of this study highlighted that poor asthma control could be related to treatment costs, as revealed by the findings of Urbstonaitis et al. (211). As suggested by the participants the cost barrier requires policy changes, which is outside the scope of this study. However, the participants felt that this group of asthma patients could be further supported in community pharmacy if they are not engaging with their appointments due to time limitations so they could be supported along with patients who do not attend their AAR to increase their engagement.

4.6 Implications for thesis

The findings of this phase support the presence of problems with the current management of asthma in adult patients and the opportunity for community pharmacy to enhance asthma care in the North West of England.

The participants highlighted possible opportunities to enhance asthma management in adult patients. Those opportunities included:

1. According to the participants, further education, enabling patients to self-manage their conditions and health coaching might enhance asthma management in adult patients.

2. The participants perceived that there is a need to enhance access to care to increase asthma patients' satisfaction and engagement. Additionally, the findings support the need to enhance

engagement with AARs in adult patients, quality of AARs, access to asthma reviews and asthma patients' awareness of their condition and importance of follow-up.

3. The participants mentioned smart inhalers, smart chip cards and INCA devices. Moreover, some participants highlighted the need for virtual appointments to engage patients.

4. The participants highlighted that new interventions for asthma patients need to focus more on preventive and co-ordinated care.

5. The provision of frequent asthma reviews in community pharmacy could be a solution to enhance adult asthma patients' management of their condition and highlighted enablers for the provision of asthma interventions in the community pharmacy setting. Although asthma patients are currently supported in primary care by the GP and nurse and practice pharmacists, such an approach allows community pharmacy to support the GPs with their workload, as well as, to support patients in managing their asthma.

6. Further support in community pharmacy could be provided to asthma patients who might benefit the most from further support in community pharmacy. The participants suggested patients with poorly controlled asthma symptoms and those who do not attend their AARs and this agrees with previous studies.

On the other hand, participants in this phase suggested that patients with controlled asthma symptoms and thought that they could be targeted by stepping down their medication if appropriate. Targeting patients with controlled asthma symptoms is a new approach that was not conducted before to the best of the researcher's knowledge.

There were contradictions in the participants' opinions regarding supporting post-hospital discharged patients in community pharmacy due to the complexity of their condition.

Although the participants agreed on the provision of further support for newly-diagnosed asthma patients, they showed variation in the suggestions to support them. While some thought of new intervention, others thought that enhancement of the current NMS might help.

This phase explored asthma management and what HCPs thought about what further support could be provided to adult asthma patients. Phase 1 allowed exploration of the challenges with asthma management and opportunities for community pharmacy to support adult asthma patients but from HCPs' perspectives only. Additionally, this phase showed variation in the opinions of

HCPs regarding which asthma patients could benefit the most from support and how they could be supported in community pharmacy. The following phases will investigate asthma management in adult patients using different methodologies and with different participants.

The next phases of the PhD study utilised asthma patients' data in phase 2 and involved asthma patients in phase 3 to get insights from multiple stakeholders' perspectives. The findings of this phase influenced the development of the interview schedule in phase 3 (interviews with asthma patients). For example, the patients' expectations and what they need from support in community pharmacy.

Moreover, the findings of this phase will be triangulated with the findings from phases 2 and 3 in phase 4. This will allow the researcher to identify what support could be provided to patients in community pharmacy, and to which patients, taking into accounts the enablers suggested in this phase.

The following chapter will discuss the findings of phase 2 (case note review) of the study, which aimed to assess asthma management in adult patients by reviewing asthma patients' medical records held in a GP practice.

5 Phase 2: Case note review of patients' medical records

The first phase (discussed in chapter 4) provided better insights into asthma management and opportunities to enhance adult patients' management of their asthma, however, it involved HCPs and a service commissioner and has not involved asthma patients.

The following phases 2 and 3 involved asthma patients and their data. This second phase (of four phases in total) was a retrospective case note review of patients' medical records held in the GP practice.

This chapter will start with an introduction to phase 2 then it will discuss the aim and objectives, methods, findings, discussion and implications for the thesis of phase 2.

5.1 Introduction

In England, asthma care is provided to patients across different healthcare settings, however, the GP is responsible for co-ordinating patient care (26). As 85% of asthma patients are managed in primary care (15), asthma patients' medical records held in the general practice are a source for clinical information about a patient; for example, medical history, consultation and hospital letters (212, 213). Patients' medical records are also used as a source of data to evaluate and improve the quality of care provided by the GP practice (212, 213). Therefore, patients' medical records held in the GP practice were utilised in this phase to collect quantitative data.

This phase involved a case note review of asthma patients' medical records held in the GP practice that aimed to assess asthma management in adult patients in a general practice in England. During the review, the researcher developed a data extraction tool to aid the data collection and ensure the reliability of the data collected. The tool development was informed by the validated Asthma Care Quality Improvement tool that was developed to report the level of care provided to asthma patients in the GP practice (214).

5.2 Aim and objectives

This phase aimed to assess asthma management in a sample of adult patients in a general practice in England using a validated tool.

The objectives were to:

- Identify asthma medication history and associated comorbidities in the sample of adult patients.
- Identify secondary care engagement related to asthma in the sample of adult patients.
- Identify asthma symptoms control in the sample of adult patients.
- Highlight patients from the sample who may require a review of their asthma management.

5.3 Methods and methodology

This phase of the PhD involved accessing patient information and was carried out on NHS premises, therefore, GP practice authorisation was obtained along with ethical approval for this phase by the HRA (see Appendix 9) and REC (see Appendix 10) on 29th August 2019.

5.3.1 Study design

This phase was an explanatory phase that involved quantitative data collection to assess asthma management in a sample of adult patients in a general practice in England. This phase is the first part of a case series study that involved a case note review of asthma patients' medical records (phase 2) and the interviewing of a sample of participants (phase 3).

Many methods can be used to assess the quality of care provided to patients including prospective data collection by staff, use of simulated patients or evaluation videotapes of an episode of care (215, 216). However, case notes are the most widely used source of information that is used in the assessment and improvement of the quality of care and research (215, 216).

A case note review was chosen in this phase because it is considered a feasible method that allows for easy collection of information from a large sample at a limited cost and without involving the patients directly for assessment (217). Unlike other methods, case note reviews can be conducted by the researcher without disturbing the usual care process provided to the patients (215). This method also minimises the recall bias that may occur when data is collected directly from patients and observer or HCP bias because it can be conducted independently of HCPs (215, 217).

As with any other method, case note review has limitations. It is time-consuming and requires training before conducting the review. Additionally, it requires knowledge of administrative issues and the use of the clinical database in the healthcare setting where the review will be conducted. One more limitation is that it might be less reliable than other methods because it uses the patients' medical records as a data source and those might not be as reliable as expected. Those limitations were taken into consideration while developing the method for the case note review, collecting the data and reporting the phase. The measures that the researcher undertook to address those limitations will be discussed in this chapter.

Many researchers have utilised case note review in their research to answer a clinical question or to assess the quality of care. For example, case note review is the main method to study the prevalence of adverse events and it has been used to determine the prevalence of adverse events in primary and secondary care globally and in the UK (218, 219). Moreover, primary and secondary care-based medical records were reviewed retrospectively to identify transitional safety incidents in patients transferred between the two settings (220). Using this method, Avery and colleagues

determined the prevalence of prescribing and monitoring errors in general practices in England (221). In their study, Avery et al. identified the most common errors and factors associated with those errors to be addressed by appropriate strategies to decrease the incidence of errors in the future (221).

Case note review use in England was not limited to patients' safety issues but it was used to assess clinical practice. For example, in 2019, the medical records held in secondary care for patients with advanced cancer were reviewed to examine the assessment and management of constipation in those patients (222). In this study, the researchers intended to examine to which extent the assessment and management of constipation in those patients align with the clinical guidelines (222).

Case note reviews have been used in research based around asthma. For example, in 2015, Xi and colleagues (223) reviewed the medical record of asthma patients held in general practices in Canada to develop and test electronic medical records search algorithms for the identification of asthma patients. Such search algorithms could help to assess and enhance the quality of asthma care (223).

More recently, in 2017, Blakey et al. (224) conducted a review of medical records of asthma patients that were held in general practices in the UK to investigate if the routinely collected data in asthma patients' records could be used to identify asthma patients with future risk for an asthma attack. According to Blakey et al. study (224), the case notes of asthma patients could be used to identify patients with risk for an asthma attack and to highlight their characteristics. However, none of the two studies assessed asthma management in adult patients.

Based on these previous studies (223, 224), reviewing asthma patients' medical records that are held in the GP can help to assess asthma management and identify asthma patients who might have a risk for an asthma attack. Overall, the evidence showed that the medical records of patients could be utilised to answer clinical research questions regarding the prevalence of clinical conditions, investigate whether the usual care provided to patients aligns with clinical guidelines or not, assess and highlight risk factors in patients and/or to assess and improve the care provided to patients (215, 217, 220-225).

In this phase, a retrospective case note review of patients' medical records held in the general practice research site was undertaken by the researcher using a validated tool. The researcher

followed a process that was developed by Sarkar and Seshadri (217) to conduct the case note review. Moreover, the researcher used a published, validated tool to extract data from patients' medical records to enhance the quality of the case note review and ensure correct identification of patients, prevalence and risk factors (215, 223, 226). The process used to conduct the case note review and the tool that was used in this phase will be discussed in the next sections.

Retrospective case note review process

Phase 2 was conducted according to the case note review process that was developed by Sarkar and Seshadri (217). The detailed steps of Sarkar and Seshadri's process for carrying out a case note review and the application to this research are described in *Table 5-1*.

Table 5-1 Case note review process and application to phase 2 method

Steps for conducting a case note review (217)	**Application to phase 2 method**
1. Identifying the research question(s) to be answered through the case note review.	The case note review aimed to assess asthma management in a sample of adult patients in a GP practice in England.
2. Identifying the appropriate data source to be used, assessing the accuracy and completion of the data and identifying the ethical approvals needed to handle the data.	GP patients' medical records were used as the data source. For this purpose, HRA and REC approvals were sought before the data collection.
3. Developing a data collection tool including a coding scheme for the variables.	The data collection tool was developed based on the Asthma Quality Improvement Tool (41). The data collection tool is fully described in section 5.3.4 below.
4. Extracting the data from	The data was extracted by the researcher from the

the medical records using the developed tool.	medical records using the developed tool.
5. Analysing the data.	The data was entered into Statistical Package for Social Sciences (SPSS), coded and quantitatively analysed.
6. Disseminating the results.	The results were triangulated along with the results of phases 1, 3 and 4. The results were reported back to the GP practice, submitted for publication in a peer-reviewed journal and included in the overall PhD thesis.

The first step of the case note review process displayed in Table 5-1, involved identifying the aim of the review (217), relating to asthma management in adult patients. Steps 2, 3, 4 and 5 of the case note review process are detailed below in the following sections.

5.3.2 Research site

The second step of the case note review process involved identifying an appropriate data source (217).

Regardless of the continuous changes and improvements in the NHS, patient care is provided in primary and secondary care settings (30). Information about a patient's health and care is stored as electronic and paper records across different healthcare settings and on different electronic systems (212). This is despite efforts to create a single integrated, person-centred medical record, accessible to all those involved in the patient's care (227). However, the GP practice is the gatekeeper to accessing care and is responsible for co-ordinating patient care (26).

To standardise improvements in the delivery of care to patients (including asthma patients) (33), the QOF was introduced on 1st April 2004 as part of the General Medical Services contract (34). The QOF is a voluntary reward and incentive program for all GP practices in England which details a points system where GP practices score points according to their level of achievement (33). Additionally, the QOF allowed for the establishment of disease registers in individual GP practices, which are lists of registered patients with a particular condition or risk factor, for example, asthma.

Therefore, patients' medical records held in the general practice provide clinical information about a patient; for example, medical history, drug history, consultation and hospital letters (212, 213). In this case note review, patients' medical records held in the general practice setting were considered the most appropriate data source to be used.

The case note review was carried out in a training GP practice that is located in the North West of England and has more than 11,000 registered patients. The GP is located in one of the most deprived areas in England with 50% of residents living in the 10% of most deprived areas. Conducting research in such an area provided the opportunity to highlight issues in quality of care provided to asthma patients in primary care; because people in these areas are usually living with poorer health outcomes due to many reasons, for example, quality and behavioural issues (228).

The GP practice location also allowed the researcher to carry out data collection within a limited time frame and budget. Moreover, GPs and practice nurses and pharmacists were involved in the delivery of care in the GP practice, therefore, the approach for asthma care delivery in the GP practice was considered representative of asthma care delivery in general. The review was conducted in one GP practice and this might cause bias, however, it was considered feasible for the PhD study because the study was conducted by one researcher only.

The data collected in a case note review may be affected by the recording system in the GP practice (217, 226). This was overcome by selecting a GP practice with a relatively high QOF achievement in asthma (229) to ensure the usefulness of collected data (217, 226). The QOF system measures the practice's achievements by a group of indicators for each domain (230). The total QOF achievement for the GP practice in 2018-2019 was 96% compared to a 96.19% average of QOF percentage achievement in England for the same year. Additionally, the GP practice QOF achievement percentage per asthma indicator was 100% in 2018-2019 compared to a 98.1% average of QOF achievement percentage per asthma indicator in England for the same year (229). The practice achieved 100% per asthma indicator for the years 2016/2017 and 2017/2018 too.

The prevalence of asthma in the GP practice in 2018-2019 was 7.04% compared to an average of 6.05% in England for the same year. This difference might be related to the GP population or false diagnosis with asthma or false recording. Moreover, it might be related to better screening and identification of asthma patients in the GP practice compared to other GP practices. The study involved patients who were coded with asthma and who have been issued with a prescription(s) for

asthma medication within the previous 12 months, patients who have received asthma monitoring or patients who have positive asthma spirometry recorded at any time in their medical history. Additionally, patients with possible asthma were identified using the case finder tool.

Research site setup

As this study was considered a clinical study involving patients' data and was conducted at a GP practice, the researcher conducted the study in compliance with the Good Clinical Practice standards. The study site setup was undertaken by the researcher and the practice manager. Firstly, the researcher received induction training provided by the practice manager. This included training on the use of the practice's EMIS Web system (this is one of the clinical recording systems that allows healthcare professionals in the primary care setting to record, access and share patient information (231)). A study initiation meeting was held in the GP practice to introduce the study, explain the inclusion and exclusion criteria and arrange the recruitment process for potential participants. The meeting involved the researcher, a member of the supervisory team, the practice manager, and a member of administration staff. The practice manager read the gatekeeper participant information sheet and signed a copy of the gatekeeper consent form for the case note review and interviews with patients (see chapter 5) to enable the researcher to conduct the study.

A study site file was prepared by the researcher and was held securely in the GP practice. This file contained the following documents: ethical approvals, Curricula Vitae of the chief and principal investigators, a delegation log of research responsibilities, a copy of the signed gatekeeper consent form, a participant invitation letter, a participant information sheet, participant consent forms and a data collection sheet.

A study master file was also prepared by the researcher and was held securely in a locked cupboard in a private research office at LJMU. The study master file contained the following: the study protocol; ethical approvals; research and development related documents; research team Curricula Vitae and training; supplementary documents; and data collection. Both the study site file and the study master file were prepared in compliance with the Good Clinical Practice standards.

5.3.3 Participants

Adult patients diagnosed with asthma or with possible asthma were identified from the electronic medical records stored on the GP practice's clinical system. Adult patients were identified as patients as over 17 years of age based on the NICE guidelines for asthma management (12). Older

adults over 65 years of age (232) were excluded because they usually have many comorbidities and use many medications that may complicate their asthma management (22, 233), which could have affected the quality of the data collected. Moreover, asthma and COPD overlap and converge in patients over 65 due to the similar pattern of the two diseases in terms of airways obstruction and the presence of other comorbidities (233, 234). Additionally, older patients are more susceptible to allergic reactions that might increase the risk of having asthma attacks (224, 234). Overall, the evidence showed that asthma in elderly patients could be underdiagnosed, overdiagnosed or mistreated (233, 234).

The practice manager acted as the gatekeeper to the GP practice, identified potential participants according to the inclusion criteria that are presented below and invited them to participate in the study based on the inclusion and exclusion criteria listed below.

Inclusion criteria

All patients aged 17 to 65 years of age with active asthma were eligible to take part. This includes patients who have been issued with a prescription(s) for asthma medication within the previous 12 months, patients who have received asthma monitoring or patients who have positive asthma spirometry recorded at any time in their medical history.

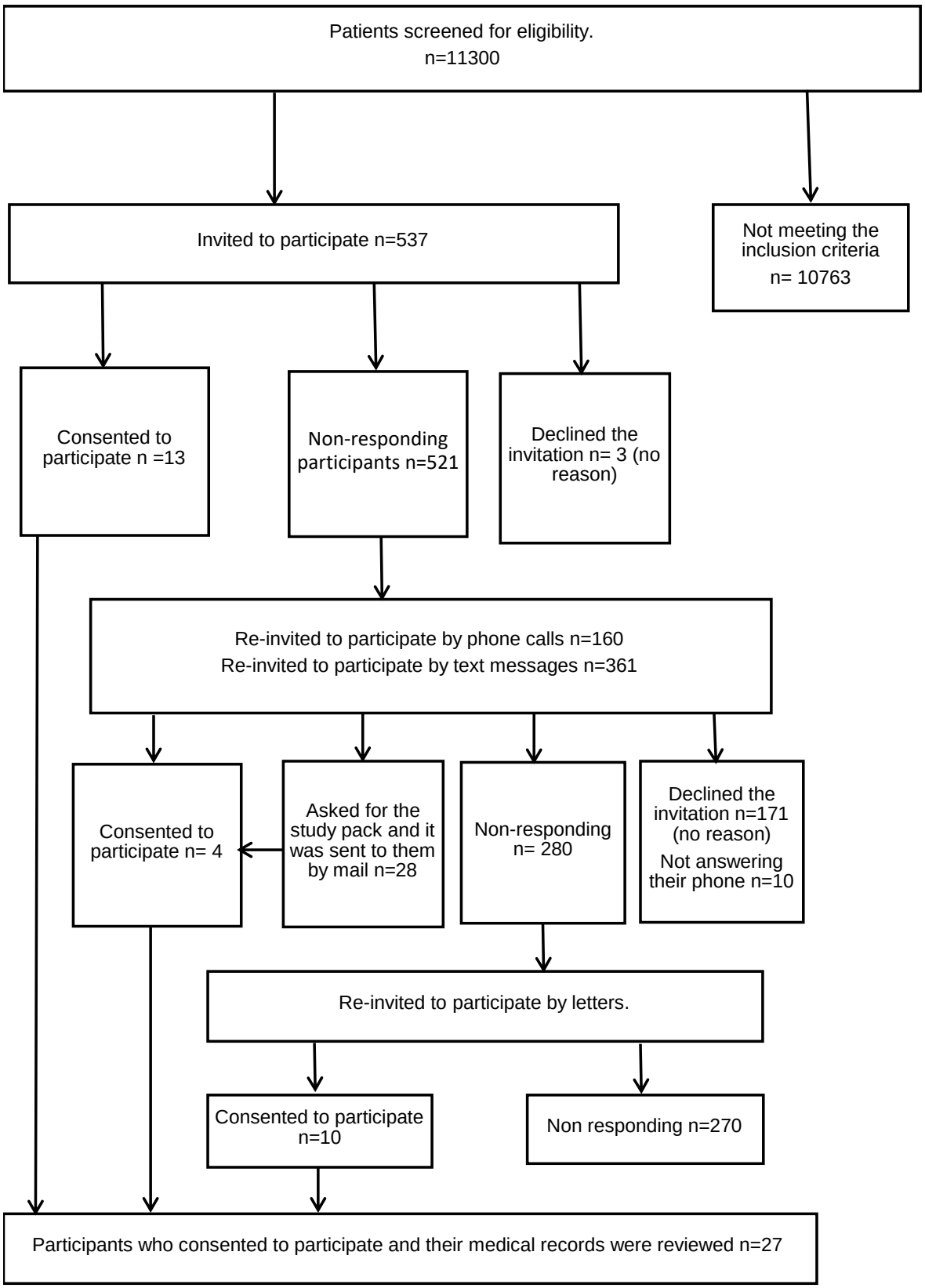
Exclusion criteria

Medical records of any asthma patients aged less than 17 or over 66 years of age were excluded from the study. Patients who did not have asthma had acute cancer, severe mental illness or those who were not registered at the GP practice research site were also excluded from the case note review.

Participants recruitment

Potential participants for the case note review and the interviews with patients (see chapter 5) were recruited simultaneously. A list of all eligible patients with active asthma was identified by the practice manager from the asthma register, by searching for patients whose medical records were coded with any Read code (a coded thesaurus of clinical terms, which provide a standard vocabulary for clinicians to record patient findings (235)) for asthma, prescribed asthma medication in the last 12 months and aged 17-65 year old. The recruitment process is detailed in Figure 5-1 below.

Figure 5-1 Flow chart of participants' recruitment for phase 2



All potential participants (n=537) with active asthma were invited to participate in the study. An invitation letter outlining the study (see Appendix 11) was sent out by the practice manager to each potential participant with a participant information sheet (see Appendix 12) and two consent forms,

one for the case note review (see Appendix 13) and another for the patient interview (see Appendix 14).

The participant information sheet included the following information: background to the research and the researcher, what participating involved, benefits and possible disadvantages, why they were chosen to participate, confidentiality and participant's rights. For the case note review, the participant information sheet also described the range of data that would be extracted from their medical records. For the patient interviews, the participant information sheet highlighted that the interviews were audio-recorded to ensure that they were comfortable with this. The participants were asked to sign a consent form and return it by post prior to participation (see Appendix 13 and Appendix 14).

All non-responding participants were sent text messages by a member of the GP practice's administration staff two weeks after receiving the invitation letter (see Appendix 11), to check that they had received the letter. Not all the potential participants responded to the text messages, therefore 160 non-responding participants were contacted over the phone. The rest of the non-respondents (n=280) were sent another recruitment letter by a member of the GP practice's administration staff. Potential participants were offered the opportunity to speak to the researcher if they required further information about the study. The researcher's contact details were also provided so potential participants could contact the researcher directly for further information if required.

Although the researcher strived to recruit more participants, only 27 asthma patients consented to participate. Accordingly, the researcher obtained an ethical approval to recruit participants from other GP practices but this was limited due to the COVID-19 lockdown restrictions.

A list of patients who provided written consent for the researcher to access their medical records for the case note review and the interviews was provided by a member of the GP practice administration staff.

5.3.4 Data collection

As described in Table 5-1, the third step of Sarkar and Seshadri's (217) process for carrying out a case note review is developing a data collection tool including a coding scheme for the variables. The development of the data collection was informed by the Asthma Quality Improvement Tool (the version that was launched in April 2018 (214)).

Asthma Quality Improvement Tool

The tool used was designed by PRIMIS, which is an organisation that was formed in 2000 to produce effective solutions to access and use patient data held in GP practices (236). The Asthma Quality Improvement Tool was designed to help GP practices audit their clinical data and contribute to the delivery of both the QOF and the NICE Quality Standards for asthma (214). Although not implemented in all GP practices, this tool allows practices to track improvement in the care provided to asthma patients; consequently, the CCGs can monitor care provision locally (214, 236).

This tool contains case finder and care management elements (214). The case finder element provides a list of patients who present symptoms of asthma but are not diagnosed, and therefore are not listed on the asthma register (214). Consequently, the list can be reviewed and patients with asthma can be added to the register (214). The case finder helps GP practices to improve the asthma register's quality, increase the accuracy of the prevalence and ensure appropriate monitoring and management of patients with asthma (214).

The care management element allows GP practices to identify the enablers to improve the quality of care they are providing to asthma patients and to reduce the risk of exacerbations (214). This, and similar tools, could be used not only to improve the quality of patients' medical records but to also identify patients and enable referral to services in other healthcare settings.

Data collection tool

The prevalence of asthma in the GP practice was identified by obtaining the number of active asthma patients, who were either prescribed medication over the last year or diagnosed with asthma. Additionally, the asthma case finder tool was used to identify patients who were not registered on the asthma register but were coded with entries suggesting possible asthma, including patients who have been issued with a prescription(s) for asthma medication within the previous 12 months, patients who have received asthma monitoring or patients who had been recorded with positive asthma spirometry at any time (214).

A data collection tool (see Appendix 15 and Appendix 16) was developed by the researcher, reviewed by the supervisory team and piloted before the data collection commenced. The data collection tool was designed to capture outcomes that were patients demographics (age and gender), medical history (BTS/SIGN treatment step (11), presence of comorbidity, the RCP '3 questions' (27), short-acting beta 2 agonist (SABA) inhaler use, ICS use), secondary care

engagement and asthma management. A detailed description of each outcome can be seen in *Table 5-2* below.

Table 5-2 Outcomes of the case note review

Outcome	Description
Patient demographic	Patient's age and gender.
BTS/SIGN treatment step	The patients' current treatment step was identified by reviewing prescription data for short-acting beta-agonist (SABA) inhaler use over the last 12 months and for other asthma medications over the last six months.
Presence of a comorbidity	Data regarding the patients' comorbidities including chronic obstructive pulmonary disease (COPD), anxiety, obesity or depression, was obtained.
Royal College of Physicians (RCP) '3 questions': (Q1 Have you had difficulty sleeping because of your asthma symptoms?; Q2 Have you had your usual asthma symptoms during the day?; Q3 Has your asthma interfered with your usual activities?) (27).	The researcher identified if the patient had been asked the RCP '3 questions' within the last 12 months. The RCP score was obtained from the medical records if available.
Short-acting beta 2-agonist (SABA) inhaler use	The number of SABA inhalers prescribed for the patient over the previous 12 months was recorded. This information helped to identify medicine adherence issues related to patients overusing SABA inhalers as a reliever therapy.

Inhaled corticosteroids (ICS) use	The number of ICS inhalers prescribed for the patient over the previous 12 months was recorded. This information helped to identify medicine adherence issues related to patients underusing ICS preventive therapy.
Secondary care engagement	Data regarding the patient's secondary care engagement was obtained from patients' medical records, including asthma-related hospital admissions, accident and emergency admissions and frequent use of oral corticosteroids (CS).
Asthma management	Patient data related to asthma management was collected by the researcher including attendance at their annual asthma review, smoking status, asthma exacerbations, self-management plan and inhaler technique.

The outcomes in the data collection tool were used to allow the assessment of asthma care provided to asthma patients in the GP practice against the current BTS/SIGN guidance. Patients' demographics allowed the researcher to describe the participants involved in the study. Additionally, other variables were collected to assess the medical history of the participants and to relate these variables to their asthma control and future risk for an asthma attack.

Data regarding the BTS/SIGN (11) treatment step was collected to investigate any uncategorised patients, identify patients on treatment steps 4 and 5 who uses high dose therapies and highlight patients who might need a review or referral to secondary care.

Data regarding the patients' comorbidities including COPD, anxiety, obesity, depression or allergic rhinitis and smoking status, was obtained in this phase to assess the future risk for an asthma attack. The presence of comorbidities can complicate asthma management and might increase the risk for a future asthma attack (11, 22). For example, in asthma patients with COPD, it is hard to identify their BTS/SIGN treatment step (214). As well as this, in asthma patients with allergic

rhinitis, allergic symptoms could be misdiagnosed as an asthma attack (11, 237). Those comorbidities along with age, gender and smoking were identified in the current BTS/SIGN guidance as factors that might increase the risk for a future asthma attack (11).

To build a picture of asthma control assessment in the participants, data was collected regarding the RCP 3 questions, the use of SABA and ICS inhalers. The number of SABA inhalers used by asthma patients is an indicator of asthma control and their future risk of developing an asthma attack (1). Based on the BTS/SIGN guideline (11) for asthma management and diagnosis, low or no use of the SABA inhaler indicates good asthma symptoms control. Inappropriate or excessive use of SABA inhalers indicates poorly controlled asthma symptoms and these patients should be reviewed urgently (1, 11). In this phase, the number of SABA inhalers were used alongside the RCP score to estimate asthma control level.

Asthma patients need at least 12 preventer inhalers per year (1, 11). Underuse (less than 12 inhalers) of the preventer inhaler is associated with poor asthma symptoms control and a high risk of a future asthma attack in patients, and their condition and medication should be reviewed (1, 214). In addition, inappropriate prescribing of long-acting beta-agonist (LABA) inhalers as a single inhaler, without an ICS inhaler was identified as a cause of asthma deaths by the NRAD in their confidential enquiry report in 2014 (1). Therefore, the number of ICS inhalers used by patients were counted during the case note review.

Although asthma patients are usually managed in primary care settings, some patients may be referred to secondary care by their GP for asthma diagnosis or management (11). Moreover, some asthma patients may attend A&E or be hospitalised due to an asthma attack (11). Therefore, data regarding the secondary care engagement was collected including A&E attendance, hospital admissions and frequent oral CS use. This data facilitated the assessment of a future risk of an asthma attack and the identification of participants who needed a review or referral to secondary care. According to the BTS/SIGN guideline, asthma patients who are prescribed more than two oral CS prescriptions should be referred to a specialist for an assessment or managed using the BTS/SIGN stepwise treatment steps 4 or 5 to achieve asthma symptoms control (1, 11).

In this case note review, to assess the AAR provided in the GP practice, data was collected regarding each element of the AAR that was discussed above if it was conducted or not and if appropriate action was undertaken. The researcher checked for all of the participants if the AAR

was provided or not, if all the RCP questions were asked to assess symptom control during the AAR or not and if the smoking status was checked or not, if smoking advice was given or not and if an asthma attack occurred in any of the participants (if they were prescribed an oral CS). Finally, the researcher checked if a self-management plan was updated and documented and if the inhaler technique was checked and recorded for the participants.

The data collection tool identified the variables to be collected, designed the data collection sheet (see Appendix 15) and identified the coding scheme for data entry (see Appendix 16).

Procedure

The fourth step of a case note review (see *Table 5-1*) is extracting the data from the medical records using the developed tool (217). In this phase, the medical records of patients who consented to participate were reviewed by the researcher and anonymised data was collected using the data collection tool (see the previous section). Field notes were also recorded on the data collection sheet where relevant to explain and illuminate the findings.

Safety issues

The case note review was performed by the researcher at the GP practice in a safe environment. If any issues or concerns relating to patient care were identified during the study, for example, poor practice, the researcher would discuss these with the GP practice's manager and PhD supervisory team as soon as possible.

Sample size

The convenience sampling strategy was used (238), at which the records of the participants were reviewed as soon as the participant consented to the participation in the phase. This strategy is considered practical in the small sample size and the limited time frame of the study (238).

Medical records were reviewed for 27 adult asthma patients only, who agreed to participate by written consent, although the researcher strived to recruit more participants. This caused a limitation in the generalisability of the findings and affected the analysis of the data.

Data entry and analysis

The fifth step of a case note review as described in *Table 5-1* is analysing the collected data. A coding scheme (see Appendix 15) was developed for each of the identified outcomes to facilitate data entry into Statistical Package for Social Sciences (SPSS). Coding was performed by assigning a number to each variable value, for example, the gender variable is coded using the numbers one

for female, two for male and three if the data was not available. The coding for the rest of the variables was detailed in Appendix 15. The collected data was entered by the researcher into the SPSS data sheet directly.

The quantitative data extracted was analysed statistically by the researcher, using SPSS descriptive statistics tool. The field notes were entered as a string variable. The data was analysed using frequencies testing.

5.3.5 Pilot

The first three patients' (out of eight patients who had consented up to this point and out of 27 patients participated in this phase) reviewed case notes were used as a pilot to determine if the methods of recruitment, data collection and data entry were suitable and yielded appropriate data for analysis. The data was collected twice for the pilot; by the researcher and a practice pharmacist in the GP practice.

The variables collected by the researcher and the practice pharmacist for each participant's medical record were compared one by one. The results showed that out of the 20 variables that were collected, there were only two occasions of disagreement between the data collected by the researcher and a practice pharmacist among the whole sub-sample. The disagreement occurred in the BTS/SIGN treatment step and the presence of comorbidities.

Further discussion was undertaken with the practice pharmacist to identify the reasons for the disagreement. For the BTS/SIGN treatment step, estimated treatment step depends on using the availability of dosage information (214). The BTS/SIGN treatment step variable description on the data collection sheet was amended to enhance the reliability of the collected data.

The other variable was the presence of comorbid allergic rhinitis. Further, the disagreement causes were identified. Then, the variable description of comorbid allergic rhinitis was updated to include patients with allergic rhinitis and/or hay fever. This decision was made based on the NICE clinical knowledge summaries that classify hay fever as seasonal allergic rhinitis (239). The data extracted for the sub-sample was amended as appropriate and was included in the overall data collected.

Overall, the pilot demonstrated that the recruitment and data extraction process was successful. Moreover, it revealed that the data collection tool yielded suitable data and no major amendments were made to the data collection tool.

5.3.6 Ethical issues

Printed lists of patients (including patient identification numbers from the GP practice's clinical system) were shared with the researcher by the administrative staff at the GP practice and were stored securely in a locked filing cabinet in the practice manager's office.

During the case note review the researcher accessed the patients' medical records at the GP practice to extract anonymised data only. No personal data was extracted from the patients' medical records. Hard copies of pseudo-anonymised data were stored in a locked cupboard and any electronic data was stored on an LJMU password-protected computer.

The researcher's induction at the GP practice involved reading and signing a confidentiality statement and declaration to ensure that confidential patient information would not be disclosed. Confidentiality was maintained by allowing only the researcher to access the patients' medical records. The supervisory team only had access to anonymised case note review reports for review purposes.

5.3.7 Reliability and validity

Following a published process for conducting the case note review and using a validated tool for the data extraction helped to enhance the quality of the case note review and ensure correct identification of patients, prevalence and risk factors (215, 223, 226).

Reliability was ensured by developing a coding scheme for each variable for entry into the SPSS data collection sheet and conducting a pilot study (detailed in section 5.3.5) to review the data collection sheet. Extracting the data by one researcher using predefined variables in accordance with a validated tool enhanced the reliability and validity of the data (217, 226, 238). Additionally, conducting a pilot and providing training to the researcher on the EMIS system helped to enhance the reliability of the data collected.

Using routinely recorded data as a source of data may not be reliable (217, 226), this was overcome by selecting a GP with a relatively high QOF in asthma to ensure the completeness of patients' records and therefore the usefulness of collected data (217, 226). The QOF achievements of the GP practice was discussed earlier in the research site section.

The development of a data collection tool and abstraction method allowed the researcher to extract the data accurately from the records (217, 238). As well as this, the abstraction of the data using the developed data collection tool and according to the definitions of the variables in the tool

enhanced the reliability of the data collected (217, 238). Conducting a pilot to detect any inaccuracies before completing the data collection and reviewing the records by one researcher only, enhanced the reliability of the case note review (217, 238). The data and variables collected were influenced by the PRIMIS Asthma Quality Improvement Tool, which allowed the presentation of the variables in the form of categorical variables rather than numerical variables. The categorical variables allowed assessment of the variables to decide whether the targets for an asthma review, medication use and other variables were met or not, but some information was lost. However, it is a suggested approach to enhance the reliability of the data collected in case note reviews (226).

5.4 Quality in reporting the case note review

The quality in the reporting of the case note review was ensured by following a published checklist that was developed by Jeroan and colleagues in 2000 (226). The checklist is listed in Table 5-3 below along with the steps taken by the researcher to ensure quality in the reporting of the case note review in this phase.

Table 5-3 Ensuring quality in reporting the case note review in phase 2

Checklist for the description of case note review (226)	**Steps that were taken by the researcher to ensure quality in reporting the case note review**
Was the case note review protocol documented?	The researcher described the detailed methodology for the case note review in section 5.3.
Was the method refined during the pilot?	The researcher conducted a pilot and the findings informed changes in the data collection tool, which was discussed in section 5.3.
Was the training described?	The researcher undertook training on the EMIS system before conducting the case note review, which was described in the methods.
Was the data quality monitored?	The researcher ensured the quality of the data by many strategies (225): 1. Use of published protocol and forms:

	A published method was used for conducting the case note review and a validated tool was used to inform the data collection tool. The data collection tool, variables and codes were all appended to the thesis. 2. Training: The researcher undertook training before the data collection commenced as discussed earlier. 3. Continuous monitoring: The pilot study ensured the quality of the data collection sheet and the reliability in extracting the data from patients' records by the researcher. The researcher planned to conduct three quality checks during the case note review but this was not needed because of the small sample size. 4. Quality improvement, retraining and editing: As discussed earlier the description of two of the variables was amended after the pilot. Retraining was not necessary.
Were the reliability and validity reported?	Reliability and validity were described in the section above. Inter-rater reliability was not measured because the study was conducted by one researcher

5.5 Findings

This section presents the findings of phase 2, including the pilot, asthma prevalence, demographics, BTS/SIGN treatment step, associated features, RCP questions, medication use, secondary care engagement and asthma management and monitoring. The findings of the statistical tests that were performed are displayed in the tables throughout the findings section.

5.5.1 Population and asthma prevalence

The GP practice population was 11,303 patients. In the first visit to the GP practice, the researcher and the local investigator ran a search to identify eligible participants for recruitment in this phase. The search identified 815 patients aged 17-65 who had been coded with asthma, these patients were referred to as patients with asthma ever recorded. Furthermore, it identified 537 patients aged 17-65, coded with asthma, prescribed asthma medication and/or were provided with any asthma monitoring in the last 12 months, who were considered as active asthma patients. Finally, the case finder tool was used to search for patients with possible asthma who were not on the asthma register but had received asthma monitoring, asthma medication or spirometry testing within the last 12 months. The search results are shown in Table 5-4 below.

Table 5-4 Asthma prevalence in the GP practice

Parameter	Number
Practice population	11,303
Patients aged 17-65	7257
Patients aged 17-65 with asthma ever recorded	815 (11.23%)
Patients aged 17-65 with active asthma	537 (7.39%)
Patients with possible asthma	125 (1.72%)

The results showed that the prevalence of adult patients with asthma ever recorded was 11.23% in the GP practice. Additionally, the prevalence of adult patients with active asthma was 7.39%. Using the case finder tool, 125 patients were identified as patients with possible asthma. These patients had an item that was related to asthma in their medical record but were not diagnosed with asthma. The search results were shared with a practice pharmacist in the GP practice to assess the clinical status of the 125 patients with possible asthma, to code them with asthma or confirm their diagnosis with asthma or other respiratory diseases.

5.5.2 Participant demographic data

In total, 537 participants were identified in the GP practice and invited to participate in phase 2. Of these, only 27 patients consented to participate who represented 5.02% of adult patients with active asthma in the GP practice.

Full data regarding asthma management and control were extracted from a total of 27 asthma patients' medical records between 26th September 2019 and 14th January 2020. Demographic characteristics of the participants are shown in Table 5-5.

Table 5-5 Demographic characteristics of participants in phase 2.

Parameter		**Participants**
Age	Mean (SD)	49.7 (11.2) years
	Range	25-65 years
Gender n, (%)	Male	12 (44.4%)
	Female	15 (55.6%)

The mean age of the participants was 49.7 (SD=11.23) years with a range of 25-65 years and 55.6% were female. More females (15, 55.6%) participated in phase 2 than men (12, 44.4%).

5.5.3 BTS/SIGN asthma treatment steps

The participants' prescribing data during the last 12 months, including the inhaler used and the dosage, were extracted from the EMIS clinical system. Consequently, the researcher classified the inhalers by dose as low, medium and high, using the BTS/SIGN guidelines ranking table for adult dosage. Finally, the BTS/SIGN asthma treatment step was estimated for each patient based on the inhaler prescribed and the daily dose using the BTS/SIGN step diagram. The number and percentages of patients within each treatment step are detailed in Table 5-6.

Table 5-6 BTS/SIGN treatment step categories.

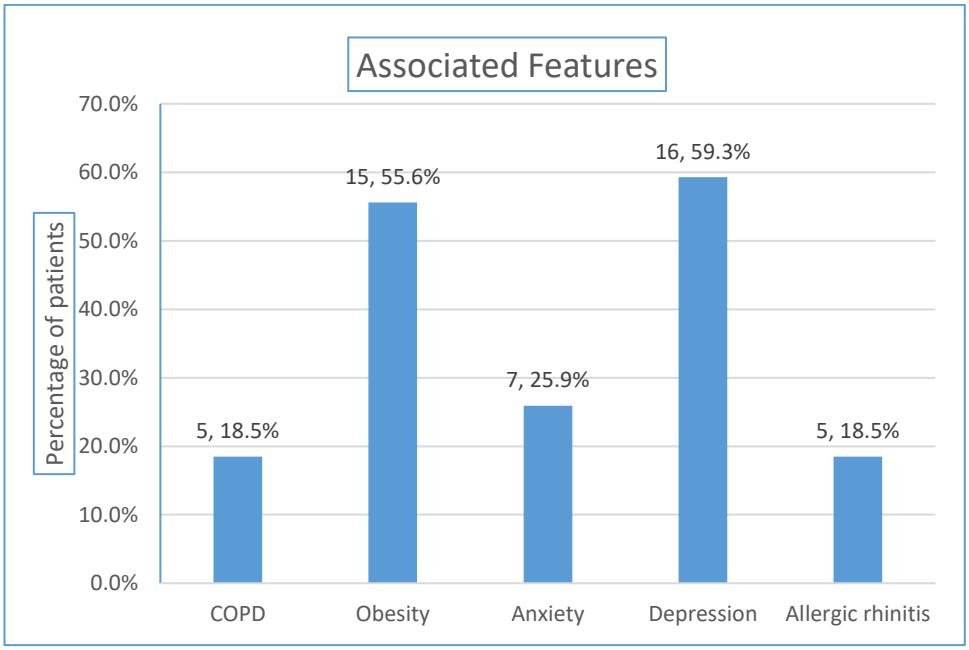
BTS/SIGN treatment step	Number of participants (n)	Percentage of participants (%)
SABA	3	11.1%
Step 1	10	37.0%
Step 2	2	7.4%
Step 3	6	22.2%
Step 4	1	3.7%
Step 5	2	7.4%
Uncategorised	3	11.1%
Total	27	100%

Of the participants, 13 (48.1%) were on SABA and step 1 (low dose ICS), followed by 22.2% (n=6) of participants on step 3 (medium dose ICS combined with another drug). Only three participants were on step 4 (high dose therapies) and step 5 (oral CS). As shown in *Table 5-6*, three participants had comorbid COPD, which made it difficult to determine the treatment step. This was due to the similarities in the inhalers used for the treatment of asthma and COPD, and the modification in the asthma treatment that was usually implemented by the HCPs for asthma patients with comorbid COPD.

5.5.4 Associated features

The participants' medical records were reviewed to extract information about other comorbidities that the participants might have. These comorbidities included COPD, obesity, anxiety, depression, and allergic rhinitis. The numbers and percentages of participants with comorbidities are detailed in Figure 5-2 below.

Figure 5-2 Associated features



The majority of the participants (n=16, 59.3%) had depression and 15 participants (55.6%) were classed as obese. The high number of asthma patients with depression in the sample might be related to the limited representativeness in the sample. The associated features were analysed and used to build a picture of the patient's asthma symptoms controls.

5.5.5 RCP questions

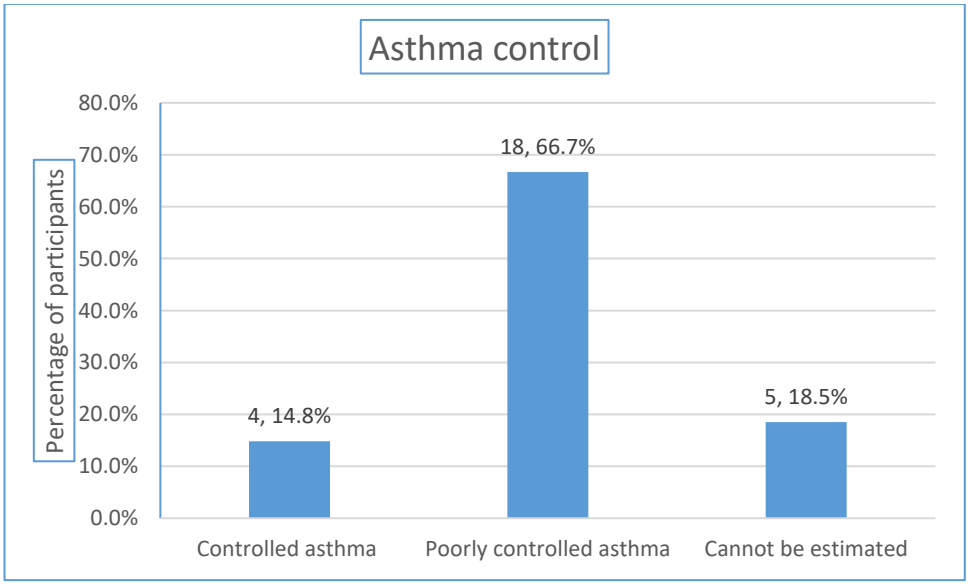
During the case note review, the participants' records were reviewed to extract data regarding the RCP questions during the last 12 months. The researcher checked if the participants were asked all three RCP questions and used their answers to the questions to estimate the participants' asthma control level. The results are detailed in *Table 5-7*.

Table 5-7 RCP questions and score

RCP questions		Number of participants (n)	Percentage of participants (%)
Asked the questions or not	Asked all the three questions	20	74.1%
	Asked one or two questions	2	7.4%
	Not asked any	5	18.5%
RCP score	No to all of the questions (RCP=0)	2	7.4%%
	Yes to one question (RCP=1)	5	18.5%
	Yes to two or three questions (RCP=2 or 3)	15	55.6%
	Not recorded	5	18.5%

Almost three-quarters of the participants (20, 74.1%) had their asthma symptoms control reviewed during the last 12 months using the RCP 3 questions. The RCP score was used to identify patients with controlled asthma symptoms and those with poorly controlled asthma symptoms. The results regarding asthma control are displayed below in *Figure 5-3*.

Figure 5-3 Asthma control



Only two of these participants had an RCP score of zero, which indicates controlled asthma symptoms. Most of the participants (15, 55.6%) scored two or three which indicates poorly controlled asthma symptoms. The RCP score was one for five participants (18.5%), indicating poor symptoms control, suggesting further analysis should be undertaken to assess their asthma symptoms control.

The participants who scored one were considered poorly controlled if they were prescribed more than four SABA inhalers, or had one or more asthma exacerbations within the last 12 months. Further analysis showed that out of the five participants who scored one, only two were considered to have controlled asthma, while three were considered to have poorly controlled asthma. Five of the participants (18.5%) were not asked any of the RCP questions; therefore, their RCP score was not calculated, and it was impossible to estimate their asthma control level. Overall, only four participants (14.8%) had controlled asthma, while 18 participants (66.7%) had poorly controlled asthma. Further analysis of those with poorly controlled asthma symptoms will be discussed throughout this chapter.

The RCP score was not recorded in the patients' medical records. The researcher had to calculate the score from the recorded patients' answers to the RCP questions. Then the researcher used the RCP score along with the patient's medication use to assess asthma symptoms control. This was a time-consuming process.

5.5.6 Medication use

The participants' medical records were reviewed to extract data regarding the asthma medication prescribed to the participants in the last 12 months. The results of the participants' use of SABA and ICS are detailed in *Table 5-8*.

Table 5-8 Medication use

Medication use		**Number of participants (n)**	**Percentage of participants (%)**
SABA	Over 12 inhalers	4	14.8%
	9-12 inhalers	3	11.1%
	5-8 inhalers	2	7.4%
	1-4 inhalers	12	44.4%

	None	6	22.2%
ICS	Over 12 inhalers	3	11.1%
	9-12 inhalers	5	18.5 %
	5-8 inhalers	7	25.9%
	1-4 inhalers	9	33.3%
	None	3	11.1%

SABA use

Of the participants, 12 (44.4%) were prescribed one to four SABA inhalers during the last 12 months; whilst six participants had not used any SABA inhalers in the same period. Five of the participants (18.5%) were prescribed 5-12 inhalers during the last 12 months, although those participants were reviewed within the last 12 months. The rest of the participants (four, 14.8%) were prescribed 12 SABA inhalers during the last 12 months despite being reviewed in the last 12 months. Those participants may have poorly controlled asthma symptoms and should be reviewed to improve their asthma symptoms control, however, those patients may have been reviewed recently (before the case note review was conducted) and patients were educated regarding the use of their SABA inhaler.

ICS use

Only three of the participants (11.1%) were prescribed 12 or more ICS inhalers. The majority of the participants (21, 77.8%) were prescribed less than 12 ICS inhalers during the last 12 months. Among these 21 participants who were underusing their preventer inhalers, nine were prescribed 1-4 ICS inhalers during the last 12 months. The analysis showed that 17 (80%) of those 21 participants were reviewed in the last 12 months while the other four (20%) were not. The field notes that were taken during the review showed that three participants out of those were contacted on more than one occasion and re-invited to their appointments, but they still had not attended their AAR.

On the other hand, three participants were not prescribed any ICS inhalers during the last 12 months. Further review of the three participants' medical records showed that they were referred to a specialist to confirm or check their asthma diagnosis, but two of them missed their appointments and the third one was referred recently. This could be the reason why they were not prescribed any

ICS inhalers. None of the participants were prescribed a LABA without ICS. Based on the participants' medication use, four out of 27 needed a review of their asthma medication to reduce the risk of a future asthma attack and to improve their asthma control, and three of them were approached many times to be reviewed.

The findings showed that some patients in the sample study were non-adherent with their asthma medications. The participants' medication use, including overuse of their reliever inhaler and underuse of their preventer inhaler, will be further discussed in this chapter and correlated to other variables based around asthma control, asthma management and secondary care engagement.

5.5.7 Secondary care engagement

The participants' medical records were reviewed to extract data regarding contact with secondary care services. The data extracted included hospital admission, A&E attendance, referral to secondary care and frequent oral steroid use. The results for the participants' secondary care engagement are detailed in *Table 5-9.*

Table 5-9 Secondary care engagement

Secondary care engagement		Number of participants (n)	Percentage of participants
Hospital admission	Admitted to hospital related to asthma during the last 12 months	0	0
A&E attendance related to asthma	Seen in A&E related to asthma	4	14.8%
	Not seen in A&E related to asthma	23	85.2%
Referral to secondary care	Referred to specialist	15	55.6%
	Not referred to a specialist	12	44.4%
Frequent oral steroid use	Six or more prescriptions	1	3.7%
	Less than six	9	33.3%
	None	17	63.0%

The results showed that none of the participants were admitted in the last 12 months to the hospital due to their asthma. However, the participants used secondary care services including A&E

attendance and/or referral to a specialist. Four of the participants were seen in A&E in relation to their asthma. Although the other 23 participants were not seen in A&E, they were seen by the GP for urgent appointments for their asthma. The majority of the participants (15, 55.6%) were referred to secondary care by the GP. Referrals to secondary care included six referrals for management advice, four referrals for diagnosis, one referral for spirometry measurement and one referral was for regular care and pulmonary rehabilitation (for a patient with asthma, COPD and mobility problems).

The analysis of the findings showed that only one of the participants received more than six oral CS prescriptions in the last 12 months and was referred to a specialist for a self-management plan. Nine participants (33.7%) were prescribed less than six oral CS in the last 12 months. Eight of these participants were referred to a specialist, whilst one of them was neither referred to a specialist nor treated with BTS/SIGN treatment step four or five. The majority of the participants (17, 63.0%) were not prescribed any oral CS in the last 12 months. Although these participants were not prescribed any oral CS, some were categorised as having poorly controlled asthma, according to their RCP score.

Extracting data regarding hospital admissions, A&E and referral to secondary care was time-consuming. The researcher needed to open all the letters between the GP practice and secondary care (that were saved in another database) to search for any incident of a visit or admission that were related to asthma.

5.5.8 Asthma management and monitoring

In this case note review, data regarding asthma monitoring and management were extracted and analysed. The data included: AARs, smoking status, asthma attack(s), self-management plan and inhaler technique check. The findings of asthma management and monitoring are detailed in *Table 5-10*.

Table 5-10 Asthma management and monitoring

Asthma management and monitoring		Number of participants (n)	Percentage of participants (%)
Annual Asthma Review (AAR)	Reviewed in the last 12 months	21	77.8%
	Not reviewed in the last 12 months	6	22.2%

Smoking status	Non-smoker	20	74.1%
	Current smoker	7	25.9%
Asthma attack	Had an asthma attack(s) during the last 12 months	7	25.9%
	None	20	74.1%
Asthma self-management plan	Recorded or updated during the last 12 months	12	44.4%
	Not recorded or updated during the last 12 months	15	55.6%
Inhaler technique	Inhaler technique reviewed	10	37%
	Inhaler technique not reviewed	17	63%

Annual asthma review

The AARs were conducted by the practice nurse or pharmacist in the GP practice. The majority of the participants (21, 77.8%) were reviewed by their HCP within the last 12 months and six participants (22.2%) were not reviewed within the last 12 months. The review of these six participants' medical records showed that five of them were contacted on more than one occasion regarding their AAR appointment but they had not responded or attended. Of these, one participant was not invited for an AAR and this information was shared with the practice pharmacist to follow-up. Amongst these six participants, five had comorbid depression and/or anxiety. One of these participants had not attended any AAR appointments since 2016 and another participant had not attended an AAR during the last 12 months and had declined a general NHS health check appointment.

No relationship was identified between the participants' asthma symptoms control and their AAR engagement because the RCP scores were not recorded for the participants who did not attend their AAR appointment.

Smoking status

In this case note review, the smoking status was recorded in the medical records of all the participants. The smoking status was checked as part of the participants' health check and recorded as smokers, non-smokers or pre-smokers. Seven participants were current smokers (25.9%) and only three of them were referred to a smoking cessation service in the last 12 months.

Asthma attack

In this case note review, the participants who had been prescribed an oral CS within the last 12 months, were counted as patients who had an asthma attack based on the PRIMIS tool. The analysis showed that seven participants (25.9%) had an asthma attack in the last 12 months and all of them were referred to secondary care.

Further analysis of the extracted data was undertaken to identify characteristics of patients who had an asthma attack among the study sample. These characteristics included: poor asthma control, SABA inhalers prescribed, gender, obesity, smoking status, and depression. Age was not included because those over the age of 65 were excluded from the study. The results are detailed in *Table 5-11.*

Table 5-11 Characteristics of patients who had an asthma attack among the study sample

Participant Number	Poor asthma Control	Over-used SABA inhaler	Depression	Current smoker	Obesity	Gender
1			✓		✓	Female
2	✓	✓			✓	Male
3	✓				✓	Female
4	✓	✓				Female
5	✓			✓		Female
6	✓	✓	✓		✓	Male
7			✓		✓	Male

Among the seven participants who had experienced an asthma attack, five had poorly controlled asthma and/or overused their SABA inhaler. Although the other two participants had controlled asthma and had not overused their SABA inhaler, they had other risk factors that resulted in an asthma attack, including obesity, female gender and/or depression.

Self-management plan

The analysis of the data extracted from this review showed that 12 participants (44.4%) had a recorded and/or updated AAP within the last 12 months. Although the AAP was not recorded or updated for the other 15 participants, six of these were followed up by secondary care where their

asthma AAP might have been updated and recorded. Additionally, four out of those 15 participants had not attended their AAR appointment within the last 12 months, so their AAP was not updated or recorded. Based on this, AAP for five of the participants had not been recorded within the last 12 months, although they had attended their AAR and they were not followed up by secondary care.

Inhaler technique

Inhaler technique was checked for 10 participants (37%) and recorded as good, moderate or poor. The inhaler technique was not checked or recorded for the other 17 participants (63%). Among these 17 participants, six had not attended their AAR and were not reviewed during the last 12 months. This may explain why these participants' inhaler technique was not checked or recorded. On the other hand, 11 participants attended their AAR appointment and were reviewed, but their inhaler technique was not checked or recorded.

5.5.9 Summary of all the participants who needed a review based on the case note review findings

Further analysis of the extracted data was undertaken to identify the main reasons that asthma patients might need a review for. A list of these patients was shared with the practice pharmacist in the general practice. *Table 5-12* represents a summary of the number and percentages of participants who needed a review.

Table 5-12 Participants who needed review

Reason for review	Participants (number, %)	Review in the last 12 months
Participants used over 12 SABA inhalers	4, 14.8%	All were reviewed in the last 12 months
Participants used 5-12 SABA inhalers	5, 18.5%	All were reviewed in the last 12 months
Participants used no ICS inhalers	3, 11.1%	One participant was reviewed in the last 12 months and two were contacted but did not attend their AAR
Participants used less than 12 ICS inhalers	21, 77.8%	17 participants were reviewed, three were contacted to attend their review but had not responded and one was not reviewed

Participants used more than six oral CS	1, 3.7%	Referred to secondary care

5.6 Discussion

This phase assessed asthma management in adult patients by conducting a retrospective case note review of patients 'medical records held in a GP practice. The review was conducted in 5% of the adult asthma patients in the GP practice. Therefore, the findings of this phase cannot be generalised even to asthma patients in the GP practice. However, the findings were utilised to support findings from phase 1 and identify some issues in the provision and/or recording of elements of the AAR that will be discussed in this section.

The review began by examining the population of asthma patients in the GP practice for the prevalence of asthma; the number of adult patients with active asthma and the number of adult patients with possible asthma. The prevalence of asthma in adult patients in the GP was 7.39% compared to a 7.04% prevalence of asthma in the practice population and this difference might be because 64.2% of the practice population were aged from 17-65. The prevalence of asthma in adults in England is 8.33% as reported by Asthma UK (5).

The findings showed that 77.8% of the participants were reviewed in the last 12 months regardless of the efforts to engage asthma patients with their AARs. This finding supports evidence from other studies that highlighted that around 30% of asthma patients do not attend their asthma reviews (29, 203). During their AARs, 20 participants (74.1%) were asked all three RCPs' questions and their answers were recorded, compared to 81% in another study in the UK that reviewed medical records of asthma patients in the GP (240). This difference can be related to the small sample number in this phase.

In the study sample, 66.7% had poorly controlled asthma symptoms. This finding was not surprising because poor asthma symptoms control was reported in asthma patients in the UK by Asthma UK (8, 15, 17). Although 66.7% of the participants in this phase had poorly controlled asthma symptoms, none of them had an asthma-related hospital admission in 12 months. One participant visited the A&E and, based on the HCP's assessment, the patient needed hospitalisation but refused, which is common among asthma patients (241). Although the referrals of participants to secondary care were in accordance with the current guidance (11, 22, 242),

referring 55.6% of the participants to secondary care highlighted the limited representativeness of the study sample.

The case note review identified factors that are associated with poor asthma management in the study sample. Moreover, it identified participants who needed a review because of having poor-asthma symptoms control, overusing their SABA-inhaler, underusing their preventer-inhaler or receiving a prescription for more than six oral-CS in the last 12 months. This highlighted the importance of regular quality checks of asthma patients' medical records to improve asthma management (214). Reviewing medical records of patients to assess and develop care provided to patients with LTCs was conducted by other researchers and allowed the highlighting of issues with care to be developed (222, 243-245). Overuse of the reliever inhaler and non-adherence to the preventer inhaler were related to poor-asthma control and were highlighted as preventable causes for asthma deaths (1, 6). Currently, asthma patients who were prescribed more than six SABA-inhalers within six months without any ICS are referred by community pharmacists to the general practice for a review as part of the PQS (70).

The participants' smoking status was checked and recorded for all the participants within the last 12 months. However, not all the current smokers were given advice and/or referred to a smoking cessation programme during their AAR. The national standards for asthma management recommended checking and recording smoking status for asthma patients regularly because it is considered a factor that slightly increases the future risk of an asthma attack and asthma deaths (1, 11, 246).

Associated comorbidities for participants were reviewed to assess the risk for a future asthma attack (214). Among the seven participants who had experienced one previously some of them were overusing SABA-inhalers, having poorly controlled asthma, having comorbid obesity and/or depression and female. It is suggested that these characteristics might increase the risk of having an asthma attack in patients and should be taken into account in asthma care in adult patients (224).

The findings suggest a gap in the provision and/or documenting of some elements of the AARs that might affect the care provided to the patients. The findings highlighted that 15 out of 27 patients were not provided with an AAP in the study sample. This finding supported the findings of phase 1 and findings from a cross-sectional survey that was conducted in Australia and found that less than

20% of the 248 adult asthma patients in the study had an AAP (101). The review highlighted a lack of a standardised process for inhaler-technique recording in the study sample. This might support the findings of phase 1 on the need to improve inhaler technique training provision for asthma patients.

The case note review highlighted that assessment of asthma symptoms control in the study sample was time-consuming. This might indicate the difficulty in identifying patients with poorly controlled asthma symptoms using their medical records. Additionally, the information regarding using secondary care was not easy to obtain because it was kept in a different clinical database and required reading all the letters sent from secondary care to the GP practice.

5.7 Implications for thesis

The findings of this phase support the suggestions from phase 1 that there are some issues with asthma management in adult patients. This phase highlighted issues with asthma management in the study sample including asthma medication use (overusing their reliever inhaler or underusing their ICS inhaler), engagement with AARs, inhaler technique check, AAPs and referral to secondary care for follow-up.

Additionally, the findings support the presence of some asthma patients who are not attending their AARs, having poorly controlled asthma and overusing their reliever inhaler or underusing their ICS inhaler, who needed further follow-up.

The findings of this phase highlighted that, regardless of the efforts of the GP practice to engage asthma patients with their AARs (by sending text messages, letters and calling the patients over the phone), there is still a need to improve patients' engagement with their AARs.

Furthermore, the findings of the case note review revealed issues with the provision or documenting of asthma care in the study sample. Those included:

1. The provision of AAPs to adult patients.

2. Documenting of inhaler technique check.

3. Documenting of the RCP score.

4. Identification of patients with poorly controlled asthma symptoms.

5. Identification of secondary care use.

Those issues might be related to the nature of the AARs, QOF requirements and/or the clinical databases used in the GP practice where this phase was conducted.

The findings of this phase and phase 1 provided insights into asthma management in adult patients and highlighted some issues with the provision and recording of some elements of the AARs, as recommended by the MRC framework (82). Consequently, the next step was to get an in-depth understanding of asthma care provided to adult patients from patients' perspectives.

Therefore, phase 3 of the PhD involved qualitative interviews with adult asthma patients to explore their perception of the management of their asthma. A purposive sample was selected from patients who participated in this phase to participate in phase 3. Qualitative interviews were considered appropriate to allow the patients to express their feeling and allow the researcher to get insights into the experience of asthma patients with different comorbidities. Additionally, qualitative interviews were considered suitable to provide explanations of some of the findings in phase 2. For example, how to increase patients' engagements with their AARs. Moreover, patients could suggest solutions to enhance their asthma care. The following chapter will discuss phase 3.

6 Phase 3: Face-to-face or telephone interviews with adult asthma patients

In phase 2, the medical records of adult asthma patients in a GP practice were reviewed to assess asthma management. A sample of those patients was selected and interviewed in this phase to explore patients' perceptions on the management of their asthma.

This chapter will start with an introduction then it will discuss the aim and objectives, methods, findings and discussion of this third phase of the PhD study. Finally, it will end up with implications for the thesis.

6.1 Introduction

The evidence showed a need for the provision of effective asthma care that addresses patients' needs and improves patients' engagement with their asthma care. Being easily accessible, with 89% of the population in England having access within a 20 minute walk and having a less formal and convenient environment (55), community pharmacy might enhance asthma care by providing further support to asthma patients and/or facilitating their engagement with asthma care, as was shown in phase 1. Therefore, this study involved an exploration of adult patients' perception of the management of their asthma in England and opportunities for community pharmacy to support patients managing their asthma.

HCPs and a service commissioner were interviewed in phase 1 and patients' data was used in phase 2. In this phase, the researcher tried to invite participants of different ages, gender, comorbidities, asthma symptom control and those who do not attend their asthma reviews. Inclusion of asthma patients in this phase helped to get insights into asthma patients' thoughts and preferences in relation to their asthma management.

6.2 Aim and objectives

The aim of phase 3 was to explore patients' perceptions on the management of their asthma.

The study objectives were to explore:

- Patient's experiences of their asthma management.
- Patients' perceptions on how community pharmacists are supporting them to manage their asthma.
- Further opportunities for community pharmacy to enhance asthma management in adult patients.

6.3 Methods and methodology

This phase of the PhD was undertaken on NHS premises and included contact with patients; therefore, HRA and REC approval was obtained on 29th August 2019 before data collection commenced.

6.3.1 Study design

This phase of the PhD was exploratory, using a qualitative methodology to explore patient perceptions of asthma management. Semi-structured interviews (face to face or via the telephone) were conducted with adult asthma patients identified from the case note review (see section 3.5).

Collecting qualitative data from patients with asthma was considered suitable to allow the researcher to understand patients' experience of how their condition is being managed (247). This phase allowed the capturing of data from patients' perspectives regarding asthma management. Additionally, qualitative interviews allowed for interpretative data collection and analysis and detailed exploration of patients' experience regarding their asthma management, as described by the patients themselves (145, 152, 176).

Semi-structured interviews were selected to allow the participants to freely express their perspectives (145, 176), in order to gain an in-depth understanding of patients' experiences of asthma management. Semi-structured interviews provided the flexibility for discussion of further relevant issues not covered by the interview questions, which cannot be gained in structured interviews with closed-ended questions (145). Additionally, semi-structured interviews enabled the researcher to maintain consistency of the topics covered throughout each interview, whilst encouraging the patients to talk openly by probing for further detail where appropriate (144, 145, 152).

Interviews were conducted either face-to-face or over the telephone, based on participant preference and availability. Both methods of interviewing were offered to participants to increase the study response rate, however, using both methods might cause bias (248) and this was taken into consideration while conducting the interviews and will be discussed in the strengths and limitations of this phase in chapter 9.

6.3.2 Research site

This phase was carried out with patients from the GP practice where the case note review was undertaken. Details of the site were outlined in section 4.3.2.

Participants

Potential participants were adult asthma patients registered with the GP practice whose medical records were reviewed in phase 2 and consented to be interviewed in this phase. There was a diversity in the age, gender and asthma symptoms control of the participants recruited in this

phase. This ensured a rich dataset and allowed the researcher to capture more data regarding asthma care from the perspectives of patients of different ages and with different associated comorbidities. Additionally, participants in this phase were with different comorbidities that might affect their asthma management.

Inclusion Criteria

The inclusion criteria for this phase were adult patients aged 17 to 65 years of age, diagnosed with asthma and identified earlier in the case note review.

Exclusion Criteria

The exclusion criteria for this phase were patients aged 66 or more or less than 17 years of age; patients with no asthma diagnosis; patients with acute cancer; severe mental illness; those with cognitive impairment or those who would be unable to consent; and individuals who did not give consent. Patients who met any of the exclusion criteria were not contacted to participate.

Participants recruitment

All participation was voluntary. Participants were allowed to withdraw from the interview at any time or after the interview had been conducted up until the data had been anonymised without affecting their rights, any future treatment, or service they receive and could choose not to answer the questions. Participants could withdraw at any time before anonymisation of data. The recruitment for phases 2 and 3 was undertaken simultaneously.

A list of patients who provided written consent for the researcher to access their medical records for the case note review and the interviews was provided by a member of the GP practice administration staff. All patients from this list were invited to take part in the interviews and 21 participants consented to participate in the interviews. The participants were contacted as soon as their medical records were reviewed. Out of the 21 participants, 17 were contacted by the researcher over the telephone to arrange an interview; four of them withdrew from the interview and the other 13 were interviewed. The remaining four were not contacted because data saturation was thought to be achieved after conducting 13 interviews.

6.3.3 Data collection

Interview Schedule

A semi-structured interview schedule was developed by the researcher to achieve the aims and objectives of this phase of the study, guided by the literature review, Murray's review (46, 179) and

the results of phases 1 and 2. For example, in phase 1 the participants thought that asthma patients have low expectations regarding their asthma management. Therefore, in this phase, patients were asked if anything could be done to enhance the management of their asthma to be able to explore their expectations from new intervention, service or support.

Additionally, in phase 2, the researcher identified patients who do not attend their AARs in the study sample. In this phase, the researcher probed the participants to explore opportunities to enhance asthma patients' engagement with their AARs from patients' perceptions.

The interview schedule covered a range of topics relating to asthma management in adult patients. The schedule contained open-ended questions. Participants were prompted to discuss issues regarding their experience of the management of their asthma, their perceptions on how community pharmacists are supporting them to manage their asthma and opportunities to enhance their asthma management (see the interview schedule in Appendix 17 for more details). The interview schedule also contained a number of prompts to facilitate the probing of participants for more information about asthma management.

All participants were asked if they would like to add anything else regarding each topic. This was to ensure that participants were given every opportunity to discuss any relevant issues not directly addressed in the interview questions. Any issues discussed by participants were further clarified by the researcher, for a better understanding.

The researcher strived to use non-leading questions and prompts. The interview schedule was reviewed by the supervisory team prior to the pilot. The language used and the clarity of the questions was checked during the pilot interviews.

The interview schedule and the interviewing process was piloted by interviewing two adult asthma patients. A review of the transcript of the pilot interviews was undertaken by the supervisory team, to ensure the trustworthiness of the data. Some minor amendments identified in the pilot were incorporated into the method before the study commenced. These amendments included the addition of more prompts to allow the researcher to accomplish the aim and objectives of the study. No major amendments were required. The pilot ensured that the content and meaning of the interviews were maintained in the transcripts. Subsequently, the pilot interviews were included in this phase.

Procedure

Interviews were pre-arranged for a mutually convenient time. Each interview began with a verbatim introductory script, ensuring that each participant was given the same information about the study before the interview. A signed consent form was obtained before commencing the interview.

The participants were asked a range of open-ended questions to discuss issues concerning the management of their asthma. Participants were prompted to express their experiences and concerns throughout the interview. No topics were discussed that any of the participants found distressing.

The interview schedule served as a guide, but the order and wording of the questions were modified based on the flow of each interview. All questions were asked at some point during each interview to ensure consistency in data collection. Any specific comments were further explored by the researcher. Care and attentiveness were maintained by the researcher during questioning and listening to responses in each interview, to ensure that all interviews were conducted to a similarly high standard. The interviews were led by the participants' experience and responses to the questions asked. However, the researcher's background knowledge of the topic aided the discussion and helped participants add additional information to gain a more rounded and richer dataset.

The face-to-face interviews took place in a private room in the GP practice to minimise distractions or interruptions whilst the interview took place. The telephone interviews were conducted in the participant's 'natural setting' by calling them. Participants interviewed by telephone were advised to be in a quiet room to enable them to answer the questions freely without interruption. The same researcher conducted all the interviews in a quiet room free from interruptions. The interviewee was made aware that the interview would take a maximum of 40 minutes, so they were able to make appropriate arrangements. Sufficient time was allocated to ensure all questions were asked and answered thoroughly.

The interviews were audio-recorded, and the recording device was tested by the researcher before each interview. Handwritten notes were taken by the researcher on the interview schedule for each participant during the interview to highlight the ideas or points that the participant had emphasised during the interview. The handwritten notes allowed the researcher to highlight the new issues that

were mentioned by the participants and were not included in the interview schedule, in order to use them in analysis and interpretation of the findings.

Safety Issues

Interviews allowed both the interviewer and the interviewee to be in a safe environment during the interview; neither were put at risk. No obvious sensitive topics were discussed. If the interviewee had found any topics distressing, this would have been handled tactfully by the interviewer. Every effort was taken to ensure that the interviewee was comfortable with the topics being discussed.

Sample size

A purposive sampling strategy was followed in this phase to allow for variation in the sample to enrich the data set (145). The researcher aimed to include asthma patients with different demographics, comorbidities, asthma symptoms control and attendance to their asthma appointments. However, the limited sample size in phase 2 limited the sample in phase 3. Further discussion of the limitations and bias in the sample will be discussed in the strengths and limitations in chapter 9.

As this study is qualitative, there is no fixed number of participants to be interviewed (180, 181). Therefore, when the researcher found that no more explanations were emerging from the new interviews (145), data saturation was thought to be achieved and the researcher stopped data collection. The researcher probed the interviewees and encouraged them to answer the questions to get a rounded data set with explanations (181).

6.3.4 Data analysis

The interview transcripts were analysed thematically by the researcher. The thematic analysis process adopted by the researcher was the same as that used in phase 1 and is detailed in section 4.3.7.

Interview Transcription

The interviews were transcribed verbatim by an independent transcriber. Verbatim transcription was undertaken to reduce the risk of transcription errors and memory recall. The transcriptions included indications of long pauses to ensure that the context of the original discussion remained intact. Once transcribed, the transcriptions were checked against the audio-recording by the researcher to ensure the content and meaning was maintained.

Coding

After the interviews were transcribed, the researcher re-listened to the audio recordings and read the transcripts several times to become familiar with the data. The coding of the interview transcripts was undertaken using the same process in phase one (for details, see section 4.3.7).

Theme Generation

The resultant codes were grouped into themes based on their differences and similarities. The detailed process of the theme generation was discussed in phase 1 data analysis (see section 4.3.7).

6.4 Ethical issues

Interviews were audio-recorded. Audio recordings using a digital voice recorder were downloaded onto a secure, password-protected LJMU computer, after which the file was securely deleted from the digital voice recorder. The electronic, password-protected file containing the audio recording was securely deleted after it was transcribed and checked for quality.

Confidentiality was maintained by allowing only the independent transcriber, researcher, and supervisory team to access the interview recordings and transcripts. Furthermore, a transcriber confidentiality agreement (see Appendix 18) was signed by the independent transcriber to ensure confidentiality. The transcriber agreed to keep the audio recordings and the transcripts secure as password-protected files and to securely delete all files related to the research after the transcription task was completed.

6.5 Quality and trustworthiness

In this phase and the other qualitative phases, the quality of the qualitative data collection and analysis was enhanced by several strategies that helped to ensure the trustworthiness of data collection and analysis (192). Those strategies were discussed in chapter 4 in detail, see section 4.3.9. This section will summarise those strategies.

These strategies included undertaking the data collection procedures consistently (145); the researcher used a semi-structured interview schedule to collect the data, audio-recorded and transcribed all interviews and conducted all interviews consistently. An introductory section for the interviews was included in the interview schedule and was read at the beginning of all of the interviews by the researcher, to enhance consistency through the interviews. Additionally, the

methods for data collection, sampling and data analysis were all documented clearly to ensure auditability of the research conducted (194, 195).

Moreover, the quality of the transcripts was enhanced by checking the transcripts against the audio recordings. Quotations from the interview transcripts were outlined under the related themes and sub-themes to ensure the credibility and trustworthiness of the data collected (152, 194).

Although conducting the interviews by one researcher increased the consistency in data collection, however, it might cause bias in the interpretations (145). The findings were discussed with the supervisory team to decrease the risk of this bias. Moreover, the methods and findings were reviewed by an external investigator to enhance trustworthiness. The researcher aimed to minimise interviewer bias which could adversely affect results by introducing reflexivity. Additionally, any questions or prompts were asked impartially and properly explained to all participants.

The researcher strived to conduct the interviews in a neutral manner regardless of participants' responses in order to reduce social desirability bias. Moreover, social desirability bias was decreased by building trust and rapport with the interviewees at the beginning of the interview, encouraging the participants to express their thoughts and perceptions freely without judgment and confirming that their opinions will not affect the services provided to them in the GP practice (145, 194).

Respondents' validation of the interview transcripts was not a viable option for this study, because of the time frame of the PhD study and the COVID restrictions (191, 195). However, the findings of this phase were triangulated along with the other two phases. Triangulation helped to enhance the trustworthiness and rigour of the research findings (152, 191, 195).

6.6 Findings

6.6.1 Participant demographic data

Data collection took place between 9th October 2019 and 21st November 2019. Patients who consented to be contacted by the researcher were invited to participate. See section 5.3.3 for recruitment details. A total of 13 participants were involved in the study. The average duration of the interviews was 19 minutes (ranging from 6-54 minutes). Of the interviews, 10 were conducted face-to-face and three were conducted over the phone.

A range of adult asthma patients participated in the study. All participants were registered in the same GP practice. The demographic data of the participants in phase 3 is shown in Table 6-1.

Table 6-1 Participants' demographics in phase 3

Participant number	Age	Gender	Comorbidities
1	53	Female	Anxiety and depression
2	47	Female	Obesity and depression
3	49	Female	None
4	59	Male	COPD
5	35	Male	None
6	53	Female	Obesity, depression and allergic rhinitis
7	32	Male	Depression
8	61	Female	Depression
9	64	Male	Obesity and depression
10	50	Female	Depression
11	49	Male	Depression and allergic rhinitis
12	49	Male	Obesity and depression
13	32	Male	Depression

The average age of the participants was 48.8 years with an age range of 32 to 64 years. More males (53.8%) than females (46.2%) participated in phase 3. Most of the patients had other comorbidities alongside their asthma. These comorbidities included: COPD (one participant), depression (nine participants), anxiety (one participant), obesity (four participants) and allergic rhinitis (two participants). Furthermore, participants in phase three included asthma patients with controlled asthma and poorly controlled asthma (based on their RCP score) and eight of the participants had poorly controlled asthma symptoms.

Demographic data was collected during the case note review and used during the data collection and analysis to contextualise the qualitative data.

6.6.2 Themes

The themes, their description and sub-themes are presented in Table 6-2 below and discussed in detail in this section.

Table 6-2 Summary of themes and sub-themes

Theme	Description	Sub-themes
Patients' experiences of asthma management in	This theme described different perspectives on	▪ Annual asthma reviews ▪ Patient's engagement with

the GP	asthma management in adult patients in the GP.	AAR appointments. ▪ Continuity and quality of care
Patients' experiences of asthma management in community pharmacy	This theme described different perspectives on asthma management in adult patients in community pharmacy.	▪ Patients' perceptions of community pharmacy-based services. ▪ Patients' acceptance of getting asthma support in community pharmacy.
What do patients want to improve their asthma management?	This theme described different perspectives on opportunities to enhance asthma management.	▪ More frequent reviews ▪ More patient education and information sharing. ▪ Improvement in access to urgent care services. ▪ Non-pharmacological treatment and preventative actions.

The themes and sub-themes will be discussed below. Each theme represents an overview and description of the sub-themes. Anonymised quotes from the original transcripts have been used to help understand the theme. Additionally, interpretations from the researcher and the rationale for the relationships between different sub-themes will be presented in boxes throughout the findings.

Theme 1: Patients' experiences of asthma management in the GP

All the participants were asked about their experiences and how their asthma is being managed. The participants responded by describing the care provided to them in the GP practice. This sub-theme was divided into two sub-themes that will be discussed below.

Sub-theme 1: Annual asthma reviews

Most of the participants confirmed that they were provided with an AAR by a practice nurse or pharmacist in the GP practice and highlighted positive aspects regarding it:

"[AAR] has been brilliant, she's [the nurse] dead sympathetic, she knows her job, and she tells me what to do," Participant-9.

"It [AAR] is actually quite good, I've never had a problem, and they're always regularly inviting me back in," Participant-1.

On the contrary, some of the participants felt that the AAR was not useful for their asthma management and others were not satisfied by the way the nurse checked their inhaler technique:

"Basically they [HCPs] just say, "Are you using it all right?" or, "Is everything all right?" Participant-12.

More than one participant mentioned that his/her inhaler technique was checked verbally during the AAR and patients were not happy and confused about how their inhaler technique was checked.

Sub-theme 2: Patients' engagement with their AARs

Patients were facing difficulties with their appointments in the GP that is affecting their engagement with their AARs. Some participants mentioned difficulties in booking appointments:

"It's like every doctor basically, if you need an appointment you've got to wait," Participant-12.

While others felt that the duration of the appointments is too short and affecting the care provided to them:

"I think if things are wrong at the moment it's because you only get 15 minutes with the GP," Participant-8.

When the participants were describing their feeling regarding the difficulties in getting appointments in the GP practice, they showed very negative feelings and described that this issue is affecting their engagement with their asthma management.

On the other hand, some participants found difficulties in engaging with their AARs appointments because of mood changes related to comorbid depression:

"This is me normally, any other time I can't get out the house because I feel low with the depression. Otherwise, I wouldn't have come if I was low, I wouldn't have been able to come," Participant-10.

Finally, some participants were not engaged with their AARs because they thought that other LTCs they have is much more important than asthma.

"I need follow-up for my back and nerves, not for asthma," Participant-1.

This sub-theme showed that some asthma patients are not engaging with their AARs because they were not happy with the AARs provided to them or found difficulties in booking an appointment. Asthma patients with comorbidities were not aware of the importance of managing their asthma.

Sub-theme 3: Continuity and quality of care

Although all the participants were almost satisfied by the GP practice services and appreciated the healthcare practitioners, some felt that their appointments and visits to the GP practice could be utilised better. The participants were dissatisfied because they often could not see the same healthcare practitioner each time they visited the GP. Other participants felt that they could not build rapport and trust as the healthcare practitioners changed in each appointment:

"They're [GPs] all locums, it's like in a hospital when you have a locum consultant, they haven't got a vested interest because they're not going to be there that long, so they'll throw a drug at you, and they know they're not going to be there next week," Participant-2.

"I don't think I've had the same nurse every time I've come," Participant-2.

Two of the participants who changed their living area found differences in the quality of asthma care and access to AARs in different regions:

"When I was in [name] GP, I didn't have an asthma review. But now since moving to [name] GP, I had a review to start me off, to ensure that they could give me the prescriptions in there," Participant-13.

Those participants were so happy with the change in the AARs provided to them and the way their asthma is being managed in their current GP practice compared to the GP practice that they were registered with before:

"I think, well I know when I moved back to the area because I lived in [area] for a while, I was never contacted once by the surgery I was registered with there to come and have an asthma check, and to check that everything was okay with the inhaler. So, I think I've experienced different service in different NHS areas, but I certainly think it's improved here to what I've experienced elsewhere," Participant-3.

This sub-theme was connected to patients' engagement to their AARs because enhancement of quality and access might encourage patients to engage with their AARs.

Theme 2: Patients' experiences of asthma management in the community pharmacy

In this phase, patients were asked about their experience with services provided to them in community pharmacy. Based on their responses this theme was sub-divided into two sub-themes.

Sub-theme 1: Patients' perceptions of community pharmacy-based services

It was evident in the interview transcripts that the participants were not aware that community pharmacists could support them with services other than dispensing their prescribed medications:

"Only picking up my prescriptions, I haven't received any other services in [community pharmacy]," Participant-7.

"Normally the nurse or doctor that would give me advice on [asthma] or make sure that I'm using the inhalers correctly," Participant-4.

However, some of them mentioned the emergency supply service and described their personal experience when they needed the community pharmacist's advice:

"I remember one time I felt bad with my chest, and I'd used much Ventolin that day, I didn't have much and I was worried about the night. I didn't know you can get it [emergency supply] through your pharmacist, so I waited until the next day for the GP. I only knew that you can go to the pharmacy just recently because it's on the GP website. Only very recently as well, I'm not talking about a few months, I mean the last few weeks," Participant-1.

"I've been over there [community pharmacy] a few times to see the pharmacist and asked him for his advice when I'm a bit wheezy. He's there for you, you can talk to him," Participant-13.

Some of the participants were surprised that community pharmacists could support them with their medication use by enhanced services like MURs or NMS, while others highlighted that it was not regular:

"I think I've been asked once to do a peak flow test in a pharmacy, but it's a long time ago. It's certainly not the last couple of checks that I've had," Participant-3.

"I have [MUR], but not specifically for asthma. Because I've got other medical conditions as well, and I'm on other medication, it formed part of the questionnaire that I get. I think that's about once a year in the pharmacy. But it's not specific to my asthma, it tends to get wrapped up with other medication that I pick up as well," Participant-3.

"I have not used these services [MUR and NMS] and I never heard about them," Participant-2.

Prompts were used to help the participants to remember if they had any medication reviews in community pharmacy, however, these participants were unable to comment on these services. This highlighted that asthma patients may not be fully aware of the services that could be provided to them in community pharmacy.

The participants' feelings regarding the MUR were varied among those who had one before and only one of the participants was provided with the NMS.

Some participants thought that the MURs was useful for them:

"I think it [MUR] can be useful because, again, it's just seeing where you're – how you are. Again, it's another thing of seeing where you're, whether your medication is working and that sort of things", Participant 11.

"[MUR] is very useful because it's trying to keep you in control of your medication in case something goes wrong with your medication. One of the medications, I got an allergic reaction to, so I have to keep an eye on my medication," Participant-6.

A participant thought that MURs are not useful:

"I don't think [MUR is] useful for me specifically," Participant-3.

However, the same participant thought that NMS is useful:

"I think it [the NMS] is useful. I think anything that takes away the pressure on surgery is probably worthwhile," Participant-3.

Sub-theme 2: Patients' acceptance of getting asthma support in community pharmacy

Most of the participants felt that the community pharmacists were trustworthy, helpful and are well-qualified to support asthma patients to better manage their condition:

"See the pharmacists, they're looking after you, they've only got your best interests at heart," Participant-9.

The participants felt that community pharmacists were qualified to review asthma patients, perform peak flow measurements, and check their inhaler technique and medication use. In addition, some of the participants appreciated community pharmacists as a source of reliable medical information:

"I think a pharmacist is as knowledgeable as a doctor, and I'm sure they can take peak flows as well, and they will know that the patient is struggling. I don't think you need to see a doctor if you've got someone who knows the symptoms of asthma, and how to treat it," Participant-8.

"I might think I'm not that bad, and then all of a sudden there's something wrong. So they [community pharmacists] can pinpoint [any problem], whereas you might not see it," Participant-11.

Additionally, participants appreciated community pharmacists' knowledge about medication and disease interactions and mentioned how they had been told by community pharmacists that ibuprofen might increase their asthma symptoms:

"I was taking Ibuprofen for inflammation because I've got arthritis, and I didn't know I wasn't allowed to take them until the pharmacist told me," Participant-10.

"When I've gone to the hospital, because I have back problems and they always go to give me ibuprofen, and the nurse goes, "you can't give asthma patients ibuprofen." And I never knew that, because I was taking ibuprofen and not realising that I shouldn't be taking the ibuprofen," Participant-8.

Another participant mentioned that the community pharmacist helped him to get a spacer that helped him to inhale the medication appropriately:

"[The community pharmacist] phoned the doctor and they got me a spacer, which I find brilliant because that's going right over your mouth, you can breathe it into your lungs,", Participant-9.

Some participants appreciated the high workload on the GP practices and thought that community pharmacy can support them with their asthma management to support the GP practice. However, participants were aware of the community pharmacists' limited access to their information and that this might limit the community pharmacists' ability to support patients to manage their asthma:

"The doctors are happy to use nurse practitioners to issue certain medications and that takes the strain off them. I think if they were to use pharmacists a little bit more that would take an additional strain off them. Pharmacists are well-qualified people when it comes to medication, and I think as long as the pharmacist has access to the medical notes, then there could be a time when a pharmacist could step in quicker than a GP could," Participant-8.

The participants appreciated the availability of the community pharmacists due to the easy access, and their availability to support them with follow-up of their asthma or urgent care:

"It puts your mind at ease, knowing that the shop's [community pharmacy] only across the road from where I live. If I have got a problem I don't have to wait until I get a doctor's appointment. I can go over there [community pharmacy] and have a word, it's like frontline for me," Participant-9.

The participants thought that having support in community pharmacy will overcome the difficulties that they were having in booking appointments in the GP practice:

"If the chemist can offer that service [asthma-review], then that would be brilliant, it will free up time. It's more of a casual approach, rather than trying to book an appointment, which can be hard to fit into your schedule," Participant-13.

"They [community pharmacists] could check-up on what I'm being prescribed. Maybe do a similar thing as to what the nurse does on an annual basis. Maybe it will take us away from getting an appointment with the doctor, you could have it at your local pharmacy," Participant-5.

According to those participants, asthma patients might benefit from an easy access support for their asthma management and they thought that this is can be achieved in community pharmacy.

In contrast, some participants suggested that community pharmacists were not well qualified and educated to provide any services for asthma patients other than medication dispensing. However, the participant felt that they could help patients with other LTCs like hypertension or diabetes, but not with asthma because its monitoring is different. According to those participants, it is easier for pharmacists to interpret laboratory findings for such LTCs rather than a clinical assessment of symptoms in the case of asthma:

"If I went into a pharmacist and they said, "Let's take your blood pressure", and the blood pressure comes up and they went …., "I don't like that blood pressure, let's start doing something about it, let's send you for this test", that would be fantastic, but some conditions [like asthma] aren't the same," Participant-2.

"If I wanted something over the counter and I wasn't sure what I wanted then that would be one thing [that community pharmacists could help me with], but not to start messing with medications that were prescribed by a specialist," Participant-2.

Interestingly, one of the participants who was a nurse and an asthma patient had a negative experience with community pharmacy on more than one occasion. This participant thought that pharmacists are not qualified to provide any support for asthma patients and that it is difficult to provide them with sufficient training to support asthma patients.

Another participant (who had both asthma and COPD) preferred the secondary care-based services and to be treated and managed by a specialist. This might be related to the complexity of this patients' condition as the participant mentioned that he is currently using an oxygen supply:

"I like to be managed by the specialist and the nurse in the clinic", Participant-4.

Overall, some of the participants had relatively limited information regarding the community pharmacists' qualifications that affected their views.

This sub-theme was connected in Figure 6-1 to two sub-themes that involved education and more frequent reviews because the participants thought that community pharmacy can have a role in asthma patient education and can provide asthma reviews.

Theme 3: What did patients think about improving their asthma management?

Only one of the participants felt that there is no need to improve asthma management:

"Unless they can find a way to replace my throat and make it easier for me, there's nothing else to do for me," Participant-7.

On the other hand, other participants suggested many potential opportunities to improve asthma management based on their experiences and preferences.

Sub-theme 1: Asthma patients wanted more information regarding their asthma management

Most of the participants expressed that they had not been provided with adequate education and motivation regarding self-management of their condition:

"I think they need to take more control and more responsibility for their conditions, and that only comes with understanding," Participant-2.

"I think a better explanation of asthma itself, and also guidelines on what to avoid. What exercise you can do, how far to push yourself," Participant-8.

Some of the participants were keen to know more regarding the rationale of their management plan in terms of any changes in their asthma management:

"I know why I'm having a peak flow test, but I don't know why specifically at that point [I had it in community pharmacy]," Participant-3.

"Sometimes it's changing medication, which becomes a pain. It's like they say…, "Oh that inhaler is not available anymore, you can't have that one, we have to find you something suitable". I'm used to that inhaler, why all of a sudden have things changed?" Participant-11.

Some participants mentioned that sometimes HCPs make assumptions or judgements without any further clarification. Additionally, the participants thought that there is a need for better communication and information sharing between asthma patients and their HCPs:

"I was referred to the Community Scheme, and the doctor there said he doesn't think I've got asthma, that's quite confusing," Participant-1.

"To get a bit of comfort by speaking to a professional, who understands the condition," Participant-8.

"They [nurse] will often have an assumption of a patient's ability, and what they know and they don't know." Participant-1

Other participants felt that the GP should regularly provide them with information regarding the available asthma services across different healthcare settings including community pharmacy:

"I think in order to do it [community pharmacy-based asthma service], market it. You have got to market things in order for people to know it," Participant-1.

Overall, this sub-theme showed that patients were left confused by some situations and had not been given the information they wanted to better understand their asthma management. Additionally, some of them were keen to know about all the services and any kind of support that they are eligible to have to engage it if they wanted. However, this might be limited to the sample of patients in this phase who accepted to participate compared to the high number of non-respondent potential participants.

This sub-theme was connected to other five sub-themes as shown in Figure 6-1 because enhancement in education and information sharing might encourage patients to engage with their AARs and community pharmacy services. Additionally, it will help patients to enhance their knowledge regarding non-pharmacological management and preventive care. Finally, it was related to more frequent reviews because more reviews might help to share more information between patients and their HCPs.

Sub-theme 2: More frequent reviews

Some participants suggested that they might benefit from being reviewed more than once a year to decrease the risk of asthma attacks especially in patients whose symptoms are affected by seasonal changes or have allergies:

"I'd prefer to be seen two or three times a year because you've got the change in the weather. Now with this cold weather, I can't breathe, now come spring, my chest will change again, and come

summer it will change again. So, I think once every three months, four months would do it, just to keep an eye on things," Participant-12.

One of the participants suggested that the inhaler technique should be reviewed more than once a year to improve asthma symptoms control:

"Patients get into bad habits with techniques or compliance and everything else, so it's never a bad idea for a recap," Participant-2.

On the contrary, some asthma patients might not engage with more asthma reviews than once a year:

"I think once every year is fine, no need for twice a year," Participant-7.

Additionally, some participants thought that they know how to manage their asthma and do not need further support or reviews, other than their usual asthma care:

"I'm quite lucky because I've got a background many years ago, I understand asthma and I understand what my inhalers are for," Participant-1.

Therefore, participants thought that asthma education and frequent reviews should be provided to patients who need them and those who might benefit from more information or reviews. For example, newly diagnosed asthma patients:

"When you get told you have asthma it's a daunting thing, you're getting told that straightaway. Just let me know what I can do and how to manage this, it's easy, and what steps to take, that would have helped me so much more at the very beginning, so I know how to handle it going forward," Participant-13.

The participants felt that asthma reviews should be provided in different methods and in different healthcare settings to adapt to patients' needs, lifestyle and age:

"You've two points of access, if you're not going to your doctor but you're going for your medication, they [community pharmacists] will catch you" Participant-11.

Sub-theme 3: Improvement in access to urgent care services

According to the participants, asthma patients might not visit the A&E when they needed it to avoid the long waiting periods and hospital admissions:

"A lot of people get anxious about going to the hospital and taking up space. I'm one of them, I think there's someone more deserving than me, I don't want to go and take up a bed," Participant-8.

"It's two hours at least [in the walk-in centre], and it doesn't make you feel any better. Because you can be in and out of the doctor's in five minutes can't you, and they've got everything on the screen," Participant-9.

One of the participants perceived that if a special asthma urgent care unit were introduced into the A&E department, their visit to the A&E department could become more effective:

"If there was a clinic where you could just ring up and say, "I'm having a bad time, would there be a possibility of prescribing something. It's always a steroid, isn't it? If someone could see me and give me some steroids," Participant-8.

Sub-theme 4: Non-pharmacological treatment and preventative actions

Some of the participants perceived the risk of asthma attacks and exacerbations could be reduced and/or prevented:

"One thing I would like to see happen is that there is a preventative stage when you have asthma to stop it from going further," Participant-8.

Other participants thought that better knowledge of non-pharmacological management including exercise, weight management and management of triggers of their asthma symptoms can help to enhance their asthma care:

"More breathing exercises, because you don't get taught something like that, you don't get told that," Participant-11.

"I have a problem with my weight. If I lose the weight then I can control my asthma," Participant-6.

"I've noticed certain things like lime juice things like that, I've realised that triggers, the acidity in the lime sort of irritates my chest, and I end up wheezing," Participant-8.

A participant (who has anxiety) felt that more support and follow-up should be provided to asthma patients with future risk for an asthma attack:

"When you have asthma and you start to struggle with your breathing, you tend to start to panic a little bit, because it's not a pleasant thing not to be able to get a good breath of air," Participant-8.

6.7 Discussion

This phase explored asthma management from patients' perspectives. Although in this phase the sample showed variation in age, gender and the presence of different comorbidities, the representativeness of the sample was limited because it was chosen from the small sample in phase 2 that presented 5% of the adult asthma patients in the GP practice. Additionally, all the

patients in this phase were registered with the same GP practice. However, asthma care in the GP practice involved GPs, practice nurses and pharmacists and therefore it was considered suitable to represent the usual asthma care that is provided to patients. Additionally, those patients who accepted the interview might have very different views to those who had not responded and this might cause bias in the findings. Further discussion of bias will be presented in the strengths and limitations section in chapter 9.

In this phase, asthma patients showed positive feelings with their AARs and appreciate the nurses' efforts. Whereas other patients showed negative perceptions toward their AARs. A similar finding was highlighted in another qualitative study that involved semi-structured interviews with 24 asthma patients in London in 2018 (249). The study highlighted that negative perceptions toward AARs in the GP practice were dominant among the study sample and patients thought that AARs were a waste of time (249). However, in this phase more patients had positive perceptions toward their AARs. This could be related to the different areas in which the two studies were conducted, it can also highlight social desirability bias in the sample in this phase because the interviews were conducted in the GP practice. Additionally, this could be related to the limitations in the representativeness of the sample in this phase that were discussed earlier. Finally, the findings of phase 1 suggested that patients might have low expectations of their asthma care and cannot see how it could be improved. This might explain why more patients in this phase showed positive perceptions toward their asthma management.

Consistent with the literature (39, 41, 44), the findings of this phase suggested that continuity of care could provide patients with an opportunity to get the most out of their asthma appointments and build a relationship with the HCP. Continuity in care provision involves relational continuity: "*continual caring relationship between patients and the HCP*" (250) and the provision of "*smooth co-ordinated care*" (251). Some patients mentioned that they prefer to be seen by the same HCP on each appointment because they thought it would facilitate building trust and rapport with their HCPs. Patients in this phase were asking for relational continuity of care. This finding supports the findings of another qualitative study that involved 33 semi-structured interviews with patients with different LTCs in London in 2019 (252). The study showed positive experiences of relational continual care provision in primary care among the study sample (252). Although the study was conducted in patients with LTCs other than asthma, the findings showed that the patients' perceptions were not related to a specific LTC (252). Additionally, all patients with LTCs should be

assigned a named co-ordinator to contact for advice and support and to help them manage their conditions and face the fragmented healthcare system (39, 41, 44).

Some patients thought that one review per year was not enough for them. Among those patients were those who have an allergy, those who felt that they need help with their inhaler technique and patients with high risk for an asthma attack. The provision of more frequent reviews for asthma patients was highlighted by other studies in the literature review (chapter 2), however, there was no sufficient evidence on the sustainability in improvement in patients' outcomes or the frequency of those reviews.

On the other hand, this phase showed that some asthma patients might not prefer to be reviewed more than once a year and others felt that they do not need further education or reviews other than the usual asthma care. Those patients might involve those who do not attend their AARs or those who had negative perceptions toward their AARs as shown in this phase and another study (249) that was discussed earlier in this section. Additionally, they might involve more patients who have not been represented by the sample in this phase.

Although many of the asthma patients in this phase were happy with their AARs, they highlighted some issues and expressed what they might need to enhance the management of their asthma.

6.7.1 Inhaler technique

Consistent with the literature (1, 6, 15), the findings suggested a need to improve inhaler technique check and training in some asthma patients to improve their asthma management. The current limitation of the process of checking the inhaler technique is that it is subjective and it depends on the HCPs experience (253). Some of the patients in this phase mentioned that their inhaler technique was checked verbally and felt that they were not satisfied with it.

Additionally, the participants felt that more reviews of patients' inhaler techniques might help asthma patients to enhance the control of their asthma symptoms. Physical demonstration of the inhaler technique aided by inhaler technique checking devices or videos might be solutions to improve inhaler technique checks and training (179, 253).

6.7.2 More patient education and information sharing

According to the participants, there is a need for better communication between patients and their HCPs. The participants felt that they wanted, on many occasions, more information regarding their asthma management, tests and to be able to discuss their management options better. The

participants were asked for explanations of the rationale for the changes and contradictions between HCPs in different healthcare settings in the diagnosis and treatment decisions. This finding agrees with the finding from another qualitative study that was conducted with 54 HCPs in Scotland (254). The study suggested that poor communication between asthma patients and their HCPs could result in poor asthma care (254).

Communication and information sharing might be enhanced by establishing a collaborative relationship between HCPs and patients and enhancing the patients' involvement in their treatment decisions (22, 37, 38). However, according to the study that was conducted in Scotland, HCPs "*might know why to communicate with patients and support self-management but need to improve their skills on what and how to communicate with their asthma patients"* (254).

Additionally, some patients in this phase did not know anything about other services that could be provided to patients with asthma in the community. The participants thought that HCPs can share information with asthma patients regarding asthma services and any kind of support they can get to be able to engage with any support or service they think they need. Some participants were not aware of the services that could be provided to them in community pharmacy, for example, NMS and MURs. This finding supports evidence that highlighted inequity in access to the MURs among patients as one of the limitations that might be attributed to its recent decommissioning in England (57, 255). Providing more information to asthma patients regarding services in community pharmacy might improve their engagement.

Additionally, patients felt that HCPs sometimes, make assumptions about patients' conditions and knowledge and they did not like this and prefer to share information with HCPs and be able to get the support based on their knowledge and preferences and not based on the HCPs' assumptions. Comparison of the findings with evidence, (37, 38, 98) confirms that asthma education should be targeted to patients' needs and preferences and not based on the HCPs' assumptions regarding patients' knowledge.

Many of the participants in this phase highlighted that they need more support with non-pharmacological management and preventive actions. This finding supports the findings from the study that was conducted on asthma patients in London (249). Some patients in that study showed a need to be supported to self-manage their condition and change their behaviour in managing their asthma (249). The study suggested that HCPs are focusing on pharmacological management

heavily rather than enabling asthma patients to self-manage their condition (249). This agrees with the Scotland study that suggested that poor communication between patients and their HCP led to poor uptake of self-management plans in the GP practices (254). Finally, the need for supported self-management and increasing the provision of AAPs were identified by Asthma UK (8)

6.7.3 Access to asthma care

Patients in this phase mentioned two issues regarding appointments in the GP practice. Asthma patients mentioned that they might fail to attend their AARs due to inability to book an appointment; therefore, there is a need to improve the GP-appointments system, which was identified as one of the priorities to improve the quality of care provided to patients in the GP practices (256).

Additionally, the participants thought that asthma patients might benefit from better access to urgent care. Most asthma deaths occurred before hospital admission (11); therefore, asthma patients with high risk for asthma attacks might benefit from further support and better access to urgent care. For example, patients in this phase highlighted that they were avoiding visiting A&E because of the long waiting hours. Additionally, one of the patients appreciated the high workload on the secondary care and this is why she tried not to be hospitalised so other patients can be served. This supports the evidence from the NRAD report, which showed that asthma patients are not seeking help at the right time and they require education to know when to seek help for their asthma (11).

6.7.4 Quality of asthma care

In this phase, two patients were registered with different GP practices before they moved to the GP practice at which the study was conducted. Those two participants experienced differences in the quality of asthma care provided to them and/or access to AARs. Inequality in asthma care was highlighted by Asthma UK in their annual asthma survey in 2019 (8). The results of the survey related the poor quality in asthma outcomes to the poor care provided to asthma patients in some areas in the UK compared to others (8). Although access to asthma care was enhanced in 2014 in response to NRAD reports, the quality of asthma care need to be improved too (8).

6.7.5 Presence of other comorbidities in asthma patients

In this phase, the findings showed that asthma patients who have other comorbidities might not engage with their asthma appointments. For example, asthma patients with comorbid depression might be affected by their mood changes. Depression is classed as a psychosocial factor that can

contribute to the risk of asthma deaths (1). Emotional changes may exacerbate asthma symptoms and patients may develop poor symptoms control due to their poor attendance at appointments (257, 258), as demonstrated in this study. Additionally, poor medication adherence and poor self-management were suggested to be related to poor asthma symptoms control in patients with comorbid depression (257, 258). On the other hand, some asthma patients with depression might overuse secondary care due to overestimation of their asthma severity (258) but this was not identified in this phase.

According to the participants in this phase, asthma patients might not engage with their appointments because of having other comorbidities that they perceive are more important to monitor and follow-up. This finding supports the findings from another study that was conducted on 41 patients with more than one LTC (259). The study found that patients were prioritising the condition that was affecting their daily activity the most (259). According to the participants in this phase, asthma patients are prioritising other LTCs but not their asthma.

Participants with anxiety might be over worrying about having an asthma attack and this is affecting their asthma symptoms. Anxiety is one of the psychosocial factors that is known to affect asthma symptoms control (258, 260). Additionally, patients might find it difficult to distinguish between asthma attacks and panic attacks (258, 260).

Patients in this phase were keen to be supported with their allergy, asthma triggers and allergic reactions to prevent deterioration of their asthma symptoms. In asthma patients with allergic rhinitis, allergic symptoms could be misdiagnosed as an asthma attack (11, 237). Additionally, a study that analysed the data collected from a previously conducted clinical trial in 1490 asthma patients in Finland found that asthma patients with comorbid allergic rhinitis are had more asthma attacks and visited the A&E more frequently than those without allergic rhinitis (237). This might explain why those participants were keen to be further supported with their asthma.

6.7.6 Community pharmacy

Patients in this phase thought that community pharmacy can support them in managing their asthma because they trust community pharmacists. Most of the participants perceived that community pharmacists are well-qualified to further support asthma patients, this agrees with another study (98) that involved the provision of a community pharmacy-based intervention to asthma patients who were receptive to the intervention (98). On the contrary, phase 3 revealed that

some asthma patients might not prefer to engage with community pharmacy-based services other than medication dispensing. Another study highlighted that some patients have not engaged with asthma reviews in community pharmacy because they were distressed about using the consultation room that is usually used for discussing personal issues (80).

Additionally, patients thought that it is easier to go to a community pharmacy rather than book an appointment with the GP practice. Additionally, some participants thought that community pharmacists can support the GP practices with their current increasing workload. This agrees with Murray's review (46) that the clinical expertise and skills of the community pharmacy team could be better utilised to improve patient care and decrease pressure on other healthcare settings (46).

Patients thought that community pharmacists can help them to enhance their inhaler technique and/or identify medication-disease interaction. Inappropriate prescription of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) caused worsening in asthma symptoms in two of the patients in this phase. Asthma patients' previous reactions to the NSAIDs should be reviewed before prescribing them to decrease the risk of future asthma attacks and asthma deaths (1, 11, 261).

Prescribing NSAIDs in patients with asthma might have been made by an HCP trying to balance the various health needs of the patient, the appropriateness of such prescription cannot be judged unless the HCPs (including community pharmacists) can consider the patient's condition holistically. Therefore, for community pharmacists to be able to further support asthma patients they might need better access to the patients' records and this was mentioned by patients in this phase.

Additionally, according to asthma patients in this phase, community pharmacists might support them to prevent asthma attacks. This is could be achieved by providing an asthma review or non-pharmacological support specifically supporting them to manage their asthma triggers. In the literature review (179), community pharmacy-based educational interventions were provided in most of the studies to adult asthma patients and resulted in improvements in asthma patients' knowledge and behaviour toward their condition and medications. For example, one study (110) suggested a role for community pharmacy in providing a self-management education intervention to adult asthma patients.

6.8 Implications for thesis

The findings of this phase revealed opportunities to improve asthma management in adult patients from the patient's perspective. The findings support the findings of phases 1 and 2 that highlighted a need for improvements in patient education, inhaler technique and non-pharmacological management and preventive care. Additionally, the findings showed a need to improve the inhaler technique check during the AAR, as perceived by patients in this phase.

Moreover, in this phase, the patients highlighted issues in asthma management related to quality and continuity of care and communication with HCPs. Continuity of care and communication with HCPs were not highlighted in phase 1, which emphasise the importance of involving patients in research to be able to address their preferences and satisfy them.

The findings of this phase, literature review and phase 1 agreed that more frequent reviews could help to enhance asthma patients' management of their condition and improve asthma care. However, the findings of this phase showed that not all asthma patients would like to be reviewed more than once a year and more frequent reviews might be utilised as a solution to enhance asthma care in asthma patients who need further support including newly-diagnosed patients and patients with high risk for future asthma attacks. Additionally, the findings highlighted that asthma patients with anxiety and/or depression might benefit from better from support for their asthma. Moreover, asthma patients with allergic rhinitis might be receptive to more frequent reviews to manage their symptoms.

Finally, the findings of this phase agreed with the findings of phase 1 that community pharmacy could work alongside the GP to support asthma patients. In this phase, asthma patients showed trust in community pharmacists to support them in regular and preventive care for their asthma.

The findings of phases 1, 2 and 3 are triangulated in the next and fourth phases of the PhD study to connect the findings and answer the research question. The next chapter will discuss phase 4.

7 Phase 4: Triangulation

The previous three chapters discussed phases 1, 2 and 3. This chapter will discuss phase 4 that involves triangulation of the findings from phases 1, 2 and 3. This chapter includes the aim and objectives of phase 4, methods, findings, discussion and implications for the thesis.

7.1 Introduction

The PhD study started with a qualitative phase that explored stakeholder perceptions of the management of asthma in adult patients (see chapter 4). Consequently, phase 2 included quantitative data collected from patients' medical records (see chapter 5), then a sample of asthma patients were selected from phase 2 to be interviewed in phase 3 (chapter 6). Phase 3 helped to explore issues with asthma management from the patient's perspective and more potential solutions and suggestions were identified.

In this phase, the findings of the qualitative methodology used in phases 1 and 3, and the quantitative methodology used in phase 2 were triangulated. Triangulation was conducted to connect the data collected from HCPs in phase 1 and patients in phase 3, along with data collected retrospectively from patients' medical records. Finally, triangulation resulted in multi-perspective suggestions to enhance asthma management in adult patients.

The triangulation findings were summarised and shared with HCPs in phase 5 (see Chapter 8) to get their feedback.

7.2 Aim and objectives

This fourth phase aimed to compare and connect the findings from the interviews with HCPs and commissioner (phase 1) and patients (phase 3) and case note review (phase 2) to increase understanding of the findings.

The objectives were to:

- Compare the findings from phases 1, 2 and 3.
- Assess convergence of the findings from phases 1, 2 and 3.
- Assess the complementarity of the findings of phases 1, 2 and 3.
- Create a summary of the findings from this phase.

7.3 Methods and methodology

7.3.1 Study design

The PhD study utilised Mixed methods research that included qualitative and quantitative data collection and involved stakeholders from different settings and experiences. This fourth phase of the PhD involved triangulation that was used to connect the findings from the three previous

phases. Consequently, the findings were summarised and shared with HCPs in phase 5 to get their feedback.

Triangulation

"*Triangulation is a means of connecting or integrating qualitative and quantitative methods*", it aims to examine the same research problem from different perspectives and provide a better understanding of the research problem (262).

In 1959, Campbell and Fiske (158) introduced triangulation as a method to enhance validity in quantitative research. The triangulation was later used in combining qualitative and quantitative methodologies by Denzin (159) and his expanded vision was further popularised by Jick in 1979 (262).

More recently, more qualitative researchers discussed the combination of qualitative and quantitative methodologies, the use of triangulation and Mixed methods research design (152, 164, 166, 168). Triangulation allows for the convergence of the results to increase its validity (165, 262, 263) for assessment of the completeness of the data collected and allows for better understanding (263). Although triangulation is seeking convergence, divergent results could be used to further explain the research problem and stimulate further assessment and research (262).

In this PhD study, triangulation was used to connect the data collected from different resources and by different methods for further interpretation of the data collected in phases 1, 2 and 3 (198, 263, 264). Using triangulation allowed the researcher to strengthen the Mixed methods, enhance the quality, rigour and credibility of the findings and add richness and depth to the collected data (159, 165, 262, 263). Highlighting convergence in the results provided an enriched explanation of issues with current asthma care (264). Additionally, triangulation was selected to help the researcher to tap into different elements of asthma care, which were utilised to build a full picture of asthma care in adult patients (165, 264). Finally, triangulation was used to identify and describe asthma patients who might benefit the most from further support with their asthma management in community pharmacy.

There is limited literature on the technique or steps that could be used to triangulate the data (168, 264). Three triangulation techniques were discussed by O'Cathain and colleagues (168). These triangulation techniques differ in the process of triangulation and each of them could be undertaken

in different stages of the research (168). The three techniques will be discussed below to clarify the rationale for the triangulation technique that was used in this phase.

Following a thread

This triangulation technique takes place during the analysis stage, the researcher starts identifying key themes in the early beginning of the analysis of data collected from each source (168). Consequently, the researcher defines a theme (thread) that requires further exploration and follows it using another method (168). In this PhD, the researcher aimed to connect the phases in the interpretation phase and not during the analysis, therefore, this technique was not considered suitable for use in this phase.

Mixed methods matrix

This technique involves the integration of quantitative and qualitative data in the analysis stage (168). In this technique, themes from qualitative data could be coded into quantitative codes to allow the analysis of qualitative data with quantitative data collected (168). Moreover, cases from the data could be defined instead of themes and all the data collected on a case could be further examined (168). This technique for triangulation was not selected because it was thought that it does not suit the data sets from the three phases, and the design of Mixed methods research in this PhD aimed to connect the phases in the interpretation phase.

Triangulation protocol

In this technique, the data is collected and analysed, then the triangulation takes place in the interpretation stage (168). A detailed description of the triangulation process was provided in the triangulation protocol that was developed for qualitative research by Farmer et al. (264). However, it could be used in Mixed methods research that utilises qualitative and quantitative methodologies (168).

Although the three triangulation techniques that were discussed above work in the context of Mixed methods research that adopts a pragmatic approach, this triangulation protocol technique is the only one that involved the term silence to indicate the absence of some findings from the results of the different methodologies (168). Silence was expected in some findings from the different phases in this PhD study because of the variable strengths of the different methodologies used in data collection (168, 264). Therefore, in this phase, the triangulation was informed by the triangulation protocol technique to allow the researcher to combine the qualitative and quantitative data in the

interpretation phase to enhance the credibility of the findings (152, 168). Additionally, following the triangulation protocol was considered suitable to critique the findings and gain a better understanding of the research problem (168). The following section will discuss the details of the triangulation technique that was utilised in this phase.

Triangulation technique that was used in phase 4

The triangulation method used in phase 4 was informed by the triangulation protocol that was developed by Framer et al. in 2006 that involved six steps (264). *Table 7-1* below presents the six steps and their application to this phase.

Table 7-1 Triangulation method followed in phase 4

Triangulation protocol steps (264)	Triangulation conducted by the researcher
1. Sorting the findings resulting from the analysis of data collected from different resources and generating themes from each source.	The findings from the three phases were sorted into three Word files, a file for each phase. The findings were summarised and categorised into three areas of interest that were informed by the theoretical framework of the PhD study. Those included: ▪ Issues with asthma management and opportunities for improvement ▪ Asthma patients who need further support ▪ Further opportunities for community pharmacy to enhance asthma care in adult patients This helped the researcher to organise the findings. Then, the files were explored by the researcher to identify common themes between the different data sets. Consequently, a composite list of the common themes along with their descriptions and supporting examples was generated.
2. Producing a convergence coding matrix that includes agreement, partial agreement,	The themes identified in step 1 were taken forward to the next step for comparison in terms of presence, meaning and examples from different data sets. Then

	silence and disagreement to assess convergence between themes provided by the findings. The silence is used to code themes that resulted from one resource of data but were not mentioned by the other data set.	a convergence coding scheme was developed and used to assess convergence. The scheme development was informed by Farmer and was used to compare the themes in the three files to decide the degree of convergence between the themes from the three phases.
3.	**Assessment of convergence in results using the coding matrix to consider where there is an agreement or not.**	The three files were fully compared to highlight similarities and differences. The researcher created a summary of the convergent results and highlighted the divergent results.
4.	**Assessment of completeness of data.**	Identify the main differences in the data sets that resulted from the different phases in terms of areas of coverage.
5.	**Researcher comparison by discussing the triangulation results with other researchers, identifying agreement and disagreement between different researchers and making final decisions.**	The findings of the triangulation were shared with the supervisory team for comments and discussion of any disagreement. Their feedback was used to refine the interpretations of the findings.

Pen Portraits

Looking for a clear, descriptive method to aid the analysis and summarise the findings from triangulation, the researcher thought to use Pen Portraits (265-267). Pen Portraits were used by researchers in different fields to describe research participants; a person or group of people; or as analytical aids to summarise the research findings (265-267). In this phase, Pen Portraits were considered suitable to induce creativity and innovation in summarising the interpreted findings (198).

There are many definitions for Pen Portraits according to the research field.

In education, Ann Campbell (198) has defined Pen Portraits as:

"Devices or biographical technique to employ if you want to illustrate and disseminate participants perceptions, experiences and feelings in a lively, authentic, meaningful and accessible way"

In social sciences, Pen Portraits are:

*"**To compose something that would enable a reader to perceive individual participants as real people"*** (267).

Finally, in qualitative research, Pen Portraits are defined as:

*"**Informal description of a person or group of people, this may cover the age and other hard variables, but it will focus on softer dimensions such as attitudes, appearance and lifestyles"*** (265).

In psychosocial research, Sutton and Gales (268) used Pen Portraits to describe the research participants using the data collected from interviews with intellectually disabled adults. A qualitative study that was conducted by Tod et al. (269) used Pen Portraits as an accessible vehicle to identify vulnerable older people. The Pen Portraits were used as an analytical tool to describe sub-groups of vulnerable older people to help the staff from health and social sectors to get a better understanding of the complexity of different vulnerable older people (269). Additionally, Nettleton et al. (270) developed a Pen Portrait using the data collected from semi-structured interviews with homeless drug users, which aimed to describe the life of the participants to the reader as part of the findings of the study.

Other researchers in health services research used the Pen Portraits as an analytic aid to summarise the data collected (271, 272). In 2011, Pleschberger et al. (271) summarised the data collected from six different studies that involved interviews with older people regarding end of life care in the form of Pen Portraits, which included key issues encountered in the interviews. The developed Pen Portraits were further used in the study along with other resources to identify key challenges in accessing older people and introducing end of life care in an interview (271).

More recently, in 2016, a study (272) was conducted in the UK to assess the implementation of a patient safety intervention in secondary care, which utilised Pen Portraits to document the 18 month journey of 17 hospital wards interacting with the intervention.

Pen Portraits were used in Mixed methods research to analyse, summarise or communicate the findings (266, 272). The researcher tried to use Pen Portraits in this phase of the PhD to summarise the findings from triangulation (271) and to build vignettes of different asthma patients who might benefit from further support with their asthma management (198, 266). The findings of the triangulation were converted into information, articulated and summarised using Pen Portraits (198, 265). Unfortunately, the resulting Pen Portraits were rigid and have not provided a full description of asthma patient groups, as intended (145, 198, 267). Therefore, the researcher shared the description of those patient groups and how they could be supported using a PowerPoint presentation. The rationale for summarising the findings was to allow for exploration of how further asthma support by community pharmacy can be tailored to those patients' needs and preferences.

7.3.2 Quality and trustworthiness

Triangulation

The use of the triangulation protocol technique allowed the researcher to conduct a systematic comparison of data sets that were collected by different methodologies (167, 168, 264). Following a published technique for triangulation enhanced its trustworthiness and allowed for transparency in reporting the triangulation conducted in phase 4 (168).

The quality of the triangulation was enhanced by sharing the findings with the research team for comments and refining (264). Moreover, the trustworthiness of the findings was ensured by sharing the findings with HCPs to get their feedback and further refine the findings (264). The findings from the discussion were used to refine the interpretation of the findings.

To ensure the credibility of the findings of triangulation, the researcher ensured the rigour of data collected in each phase (165). This was aided by different strategies depending on the data collection methodology utilised in the phase (165, 168). This was discussed separately in the methods section for each phase.

7.4 Findings of triangulation

The findings of the triangulation will be presented in this section in a way that aligns with the steps that were followed during the triangulation process.

7.4.1 Sorting

The sorting of the findings resulted in a composite list of five key themes that were all related to the three areas of interest that were discussed in 7.3.1.

Due to the limited sample number in phase 2 and its limited generalisability, it was used to support the findings from phases 1 and/or 3. However, the findings of phase 2 were not used solely to identify any of the themes.

A composite list of the key themes and sub-themes along with the descriptions of the themes was created. Moreover, each theme was supported by a quote and/or numeric findings from the phases 1,2 and/or 3 to allow the researcher to compare the themes. The key themes and sub-themes are listed in Appendix 19.

7.4.2 Convergence coding

The themes were compared in terms of presence, meaning and supporting examples using a convergence coding scheme that was developed by the researcher.

The convergence coding scheme involved four codes that included:

1. Agreement.

For themes that were found in the three phases and have the same meaning and examples.

2. Partial agreement.

For themes that were found in the three phases and have the same meaning but different examples.

3. Silence.

For the themes that were not found in all of the phases.

4. Disagreement.

For themes that were found in the three phases and have different meanings and examples.

The findings of the comparison are described below in *Table 7-2*.

Table 7-2 Results of convergence comparison of themes (AG: agreement, PA: partial agreement, S: silence and DA: disagreement)

Themes	**Sub-themes**	**The presence of the theme or sub-theme in phases 1, 2 and 3**			**Meaning and supporting evidence**	**Coding convergence**			
		Phase 1	**Phase 2**	**Phase 3**		**AG**	**PA**	**S**	**DA**
Theme 1: Issues with asthma management	Medication adherence	✓	✓	✓	There was an agreement in the meaning of this theme among the three phases. Phases 1 and 3 highlighted that one of the issues with asthma management in adult patients is overusing their reliever inhaler or underusing their preventer inhaler. This finding was supported by the results of phase 2.	✓			
	Inhaler technique	✓	✓	✓	There was an agreement on this theme across the three phases. Phases 1 and 3 showed that there are some issues with the inhaler technique check. Additionally, the findings of the case note review highlighted that the inhaler technique was not always checked and recorded for all the participants in phase 2.	✓			

Theme 2: HCPs	Diagnosis improvement	✓		✓	Phases 1 and 3 showed that there are some issues with asthma diagnosis that were supported by examples in the findings in the two phases. The case note review found 125 patients with possible asthma. However, this was not sufficient to support this sub-theme because the diagnosis of those patients requires a clinical decision that was not made by the end of the study.			✓	
	Quality and equity of asthma care	✓	✓	✓	The three phases partially agreed on this sub-theme because the theme was found in the three phases but the examples were different. Phase 1 highlighted variation in the quality of asthma care provided by different HCPs whereas phase 3 highlighted variability in the quality of care across different GP practices. Additionally, the case note review showed that quality checks of asthma patients' records might enhance asthma management in adult patients and the overall quality of asthma care		✓		
	Access to asthma care	✓	✓	✓	There was partial agreement on this sub-theme across the three phases.		✓		

					In phases 1 and 3, the participants highlighted the need to enhance the GP appointment system to enhance patients' engagement with asthma reviews. However, reviewing the records of patients in phase 2 showed that patients were invited on several occasions by letters, text messages and over the phone to attend their AARs.				
	Preventive care and non-pharmacological management	✓	✓	✓	There was partial agreement on this sub-theme across the three phases. Many non-pharmacological measures were highlighted in phases 1 and 3. The case note review showed that the provision and recording of AAPs to patients might need improvement.		✓		
	Co-ordinated care	✓	✓	✓	There was partial agreement on this sub-theme. The findings of the phase 2 and 3 suggested the need for co-ordinated care and communication between different HCPs. The case note review showed that letters were shared from secondary care to the GP to notify them regarding patients' visits to secondary		✓		

					care. However, the letters were stored in a different clinical database than the one the GP uses to record patients' medical records.				
	Community pharmacy	✓	Not applicable	✓	The findings of phases 1 and 3 support that community pharmacy could be utilised to enhance asthma care in adult patients. The silence of this theme in phase 2 was not surprising because it was conducted in the GP and utilised patients' medical records. Nevertheless, the case note reviews supported the evidence regarding some issues with asthma management that were mentioned in phases 1 and 3. Those issues could be addressed by interventions in the community pharmacy setting.			✓	
Theme 3: Relationship between patients and HCPs		✓	Not applicable	✓	This theme was identified in phases 1 and 3, however, the meaning and examples were different. In phase 3, the patients highlighted their need to communicate with HCPs and mentioned how they found it hard to build trust and rapport with their HCPs because of the incontinuity of care. In phase 1, the findings showed that some HCPs, including pharmacists, are still adopting paternalistic approaches for care that			✓	

					contradict person-centred care. Not all of the participants were aware if asthma patients were satisfied with the services provided to them or not, or about their perceptions of the services				
Theme 4: Technology		✓			This theme was mentioned in phase 1 only.			✓	
Theme 5: asthma patients who need further support	Patients with controlled asthma symptoms	✓	✓		Participants in phase 1 perceived that this group of patients can be easily supported in community pharmacy. In phase 2, the findings showed that some patients with controlled asthma had an asthma attack but this theme was missing in phase 3. Therefore, they could be supported in community pharmacy for further follow-up and support.			✓	
	Newly diagnosed asthma patients	✓		✓	Findings of phases 1 and 3 highlighted that newly diagnosed asthma patients could be provided with educational and motivational support. This sub-theme was not identified in the findings of phase 2.			✓	
	Patients with poorly controlled asthma symptoms	✓	✓	✓	There was an agreement on this sub-theme among the three phases. The participants in phase 1 highlighted that many asthma patients have poor control over their asthma symptoms and require further support. There were supporting examples in phase 3 regarding this sub-theme.	✓			

					Phase 2 showed that 18 out of 27 participants had poorly controlled asthma symptoms. Some of these had an asthma attack, others required a review because they were overusing their reliever inhaler or underusing their preventer inhaler.				
	Asthma patients who do not attend their asthma reviews	✓	✓	✓	There was agreement on the presence of this group of patients among the three phases.	✓			
	Asthma patients with high risk for future asthma attack	✓	✓	✓	In phase 1, the participants highlighted that post-hospital discharge patients require further support because they might develop an asthma attack. There were contradictions in the participants' views regarding supporting post-hospital discharge patients in community pharmacy. Some were hesitant to support those patients due to the complexity of their condition but others thought that those patients need further support. Patients in phase 3 suggested the provision of support for asthma patients after having an attack in order to minimise their chance of		✓		

					having another one. However, a participant with comorbid COPD and complex conditions preferred to be supported by a specialist and not in community pharmacy. The case note review showed that seven participants had an asthma attack in the last 12 months and all of them were referred to secondary care.				
	Asthma patients with comorbid depression		✓	✓	Interviewing some of those patients in phase 3, showed that they might need further support but they were not highlighted in phase 1. In phase 2, 16 of the participants had depression. Some were not engaged with their AARs. Some of them had an asthma attack and others required a review of their asthma.			✓	
	Asthma patients with comorbid allergic rhinitis			✓	Asthma patients with comorbid allergic rhinitis expressed their needs and how they were struggling to identify what triggers their asthma. Moreover, patients highlighted their need for further support. Those patients were not mentioned in phase 1 by HCPs and there was non-sufficient evidence regarding this group of patients because of the small sample number.			✓	

Agreement

Across the themes and sub-themes, there were five instances in which there was agreement in meaning and examples across the three phases. The agreement showed complementarity in the phases and highlighted that the three phases helped to answer the research question.

The agreement occurred in the theme of issues with asthma management. The three phases highlighted issues with asthma management that were related to medication adherence and inhaler technique. This agreement in the presence of those sub-themes in the three phases was not surprising and it agrees with the literature review as most of the studies aimed to improve asthma patients' medication adherence and/or inhaler technique. There was complementarity in the findings of the three phases and previous literature.

Again, agreement occurred in two sub-themes that were related to asthma patients who might benefit from further support. The agreement highlighted that some asthma patients might benefit from further support more than other asthma patients might. However, the agreement was not on supporting those patients in community pharmacy specifically.

Partial agreement

Across the themes and sub-themes, there were five instances in which there was partial agreement in the examples across the three phases.

The partial agreement helped to provide a further understanding of the issues covered by these two themes. For example, in the sub-theme quality of asthma care, the three phases provided different examples because of the differences in the data collection methodologies and participants across the phases.

The findings in phase 1 highlighted variation in the quality of asthma care among different HCPs that might be addressed by the provision of training to HCPs. On the other hand, the case note review showed that reviewing medical records of asthma patients in the GP practice might enhance the quality of care by highlighting patients who need review to improve the management of their condition. As well as this, the case note review highlighted issues with the provision and recording of AAPs and inhaler technique checks that could be addressed to enhance asthma management. Finally, in phase 3, the participants highlighted the need to enhance the equity in care provision and quality of asthma care.

Moreover, there was partial agreement on the access to asthma care sub-theme. The case note review provided a different example that might be more related to patients' engagement with their appointments. Whereas, phases 1 and 3 identified the need to improve the GP appointment system to enhance patients' engagement with their appointments.

Different examples of preventive care and non-pharmacological management were found in the three phases, therefore, there was partial agreement in this sub-theme.

Partial agreement occurred in the co-ordinated care sub-theme. In phase 2, the case note review showed that there is an established communication pathway between the secondary care and the GP practice that was undertaken by sending letters. However, the researcher found difficulties in extracting data regarding secondary care use. In phase 3, the patients mentioned more than one example with their asthma management in which there was a lack of communication between the different settings that affected their condition, their understanding of their asthma and medications. The need for co-ordinated care could be concluded from the findings of the phases. Phase 1 findings showed that the provision of co-ordinated care can enhance asthma management in adult patients and that it could be facilitated by improving the communication between different healthcare settings. Moreover, the participants in phase 1 concentrated on the poor communication between the community pharmacy and the GP practices.

Silence

Across the themes and sub-themes, there were seven instances in which there was silence. Among these seven instances, four themes were absent in the case note review only. Additionally, some sub-themes covered issues that cannot be identified from the patients' medical records. These themes and sub-themes included diagnosis improvement, patients with controlled asthma symptoms, newly diagnosed asthma patients, community pharmacy and relation with HCPs.

Unsurprisingly, the sub-theme about community pharmacists was not highlighted in phase 2 because the study utilised patients' medical records in the GP practice. The GP cannot know if the patients collected their prescriptions from community pharmacy or not because of the lack of communication between community pharmacy and GP practice regarding the dispensing of the prescriptions. However, the absence of this sub-theme supports the need to further improve communication between community pharmacy and the GP practice and this might help to improve asthma care.

Four other instances in which there was silence were in the sub-themes that described different asthma patient groups including patients with controlled asthma symptoms, asthma patients with high risk for an asthma attack, asthma patients with comorbid depression and asthma patients with allergic rhinitis.

This variation in the presence of the different asthma patient groups in the findings across the three phases was related to the different participants in phases 1 and 3 that led to different views and perspectives. For example, the HCPs perceived that patients with controlled asthma symptoms might need further support to step down their asthma medication to decrease unnecessary medication use and side effects. This rationale might not be seen by patients because it seems that they are happy as long as they do not have symptoms and might not necessarily think about reducing side effects.

The findings regarding the technology theme were only found in the findings of phase 1. The absence of this theme in phase 2 is expected because solutions cannot be extracted from reviewing medical records. In phase 3, patients did not mention anything regarding using technology and this might be related to the limited representativeness of the sample as all the participants were recruited from the same GP practice. Additionally, HCPs in phase 1 highlighted that patients might be happy with what was provided to them because asthma patients might have low expectations regarding their asthma care.

Disagreement

Disagreement did not occurred in any of the themes or sub-themes.

7.4.3 Convergence assessment

There was partial or full agreement in more than half (10 out of 17) of the themes and examples in the data from the three phases. Although there was no disagreement in any of the themes, silence occurred in the other seven themes. The silence might be the closest to disagreement in themes between the different data sets. Among the seven themes in which the silence occurred; the theme was found in only one phase in two instances.

The absence of the themes in one or two of the phases might be related to the differences in the scope and nature of the collected data among the phases. For example, the absence of the sub-theme regarding the relationship between patients and HCPs in the findings of phase 2 can be related to the focus of phase 2 and the source of data.

Although silence might not be a favourable result because it might affect the convergence of the findings from the three phases, the presence of a theme or sub-theme in one or two phases broadened the findings. This was evident in theme 3 that covered groups of asthma patients that might benefit from further support. For example, two groups that included asthma patients with comorbid depression and allergic rhinitis were not highlighted in phase 1 but were mentioned by the patients in phase 3. Involving different participants allowed to expand and enrich the findings by utilising multiple perspectives and views.

On the other hand, the occurrence of silence of a theme in a phase might be related to the limited representativeness of the sample in the phase. For example, phase 3 was conducted in a single region and participants were recruited from one GP practice.

7.4.4 Completeness comparison

In this step, the researcher compared the findings from the three phases to highlight similarities and differences in the contribution of each phase to the research question. Moreover, it allowed the researcher to assess the complementarity of the findings from the three phases.

This helped the researcher to create a summary of the unified findings from the three phases and identify divergent findings that were used to explain and expand the findings. Consequently, a summary of the unified findings from the three phases was created and will be discussed in this section in themes.

Theme 1: Issues with asthma management

The findings of the case note review showed that four out of 27 participants had control over their asthma symptoms. The three phases highlighted issues with asthma management in adult patients that could be addressed to enhance their asthma symptoms control.

The findings highlighted that overusing and underusing asthma medication is perceived to be the main reason for poor asthma symptoms control. Additionally, the inhaler technique was shown in the findings of the three phases as an issue that could be addressed to enhance asthma patients' management of their condition.

In phases 1 and 3, the participants highlighted that further education regarding inhaler technique might enhance asthma symptoms control in adult patients. Moreover, in phases 2 and 3 the findings highlighted the need for a systematic approach for inhaler technique check and recording. An example for the improvement of inhaler technique check is using the inhaler In-Check device as

perceived by the participants in phase 1. Furthermore, the stakeholders and patients in phases 1 and 3 felt that the inhaler technique should be checked more than once a year.

Theme 2: HCPs

Issues with asthma care that are related to HCPs were covered in theme 2 in the findings of triangulation and included six sub-themes.

Diagnosis improvement

The participants in phase 1 highlighted the need to improve the current diagnosis of asthma, for example, they concentrated on the use of FeNO for diagnosis. This was supported by the findings of phase 3 in which the participants expressed occasions where they felt that their diagnosis with asthma was not confirmed.

An example that clarifies this point was found in phase 1, where the participants expressed that asthma patients should be diagnosed by a specialist to overcome the problem of misdiagnosis in asthma. Although there was silence in this sub-theme in phase 2, the case note review identified 125 patients with a possible asthma diagnosis who require a clinical decision to review their condition.

Quality of asthma care

The findings of the three phases highlighted issues with the quality of asthma care. It was evident from the findings of phases 1 and 3 that there is a variation in the quality of asthma care across different HCPs and different GP practices in different areas. In phase 1, the participants were located in different healthcare settings and GP practices and were aware of this variation in quality. Whereas, in phase 3 the participants were all from the same GP practice, however, two of them moved their living area and changed their GP practice. Those participants experienced variation in the care provided to them in different GP practices.

According to the findings, supporting HCPs to improve their knowledge and skills could help to enhance the quality of asthma care. Additionally, improving the HCPs' communication and motivational skills might ensure that person-centred care is adopted in asthma care provision. Accordingly, patients' engagement with their asthma reviews and self-management plans could be improved.

Moreover, regular checks of patients' medical records might enhance the quality of asthma care and identifying patients who might benefit from a review and/or further support. This will allow the provision of proactive care to patients with asthma.

Access to asthma care

Inequity in access to asthma care and the need to improve the GP practice appointment system were highlighted in phases 1 and 3. Participants were keen to have flexible appointments in the early morning, late in the evening or at the weekend. Moreover, HCPs and patients highlighted that the short period of the appointments in the GP practice might be affecting the quality of the review and therefore patients are not engaging with their appointments.

On the other hand, the findings highlighted issues with asthma patients' engagement with their AARs. As perceived by the participants in phases 1 and 3, asthma patients' engagement with their appointments might depend on the patients themselves; their awareness of their condition and their perception of their asthma compared to other LTCs that they have.

Moreover, having symptoms from other comorbidities or mobility problems might affect their ability to attend their AAR. In the GP at which the case note review was conducted, patients who failed to attend their AAR were re-invited on several occasions; nevertheless, they did not attend for an asthma review.

Preventive care and non-pharmacological management

The need to enhance the provision of preventive care was evident in the findings of the three phases. The participants in phases 1 and 3 suggested many measures for preventive care and non-pharmacological management in asthma patients that included:

- The provision of more frequent reviews to asthma patients to be able to highlight any issues with the management of their asthma before they experience an asthma attack or poorly controlled asthma symptoms.

  Furthermore, more frequent reviews may allow the patients to discuss their condition with an HCP and get the appropriate advice. The nature of the review was not identified by the participants in any of the phases but they were keen for reviews that suit patients' needs that could vary across different patients.
- Patient education regarding their condition, self-management skills, asthma triggers and exercises.

The findings of phases 1 and 3 suggested that patient engagement could be enhanced via the provision of education regarding the rationale for their treatment plan, and any changes in the management of their asthma. The findings suggested that patient education should be more person-centred in a way that aims to satisfy patients' needs and respects differences between patients. Asthma patients may need education regarding asthma triggers, how to minimise the risk of an asthma attack and how to respond to changes in symptoms correctly.

- Health coaching to help asthma patients to identify their needs and help them to achieve their treatment goals and enhancement in the provision of AAPs.

  These findings were complementary with the findings of phase 2 that showed a need to enhance the provision and recording of AAPs, as only 12 participants had a recorded and/or updated AAP within the last 12 months. Moreover, seven participants had an asthma attack in the last 12 months that might have been avoided by enhancement in the provision of preventive care. Overall, more efforts should be made to ensure that all adult asthma patients are provided with a written AAP that is updated regularly and supported to self-manage their condition and achieve their treatment goals.

- Smoking cessation.

  Some participants in phase 1 thought that asthma patients could be provided with support to stop smoking and this might enhance their asthma symptoms control.

Co-ordinated care

Although there is an established communication pathway between secondary care and the GP practice, there is a need to establish communication between the GP practices and community pharmacy. This was highlighted by the participants in phase 1 and showed in the results of phase 2.

Whilst conducting the case note review, the review of asthma medication use in the patients identified the number of inhalers prescribed but it was impossible to know if the patients had picked up their prescriptions or not. Moreover, the participants in phase 3, mentioned situations in which they felt that different HCPs who are involved in their asthma care are not communicating, data is not being shared in a way that affected their asthma care.

Overall, the examples mentioned among the three phases highlighted that the enhancement in the provision of co-ordinated care might enhance asthma care in adult patients and continuity in care

provision. Co-ordinated care requires information sharing between different healthcare settings including secondary care, GP practices and community pharmacy and assigning a care co-ordinator who is responsible to manage patients care.

Community pharmacists

Ease of access to community pharmacy and long opening hours were appreciated by the participants in phases 1 and 3. Furthermore, a less formal relationship between asthma patients and community pharmacists, based on trustworthiness and rapport, was identified in phase 3, based on patient experience. However, the HCPs highlighted that the community pharmacists might need further training to be able to provide reviews for asthma patients.

Phase 1 findings highlighted paternalism in the suggestions of the HCPs that included seven community pharmacists out of 17 participants. This might raise the need for further training for HCPs including community pharmacists to be able to provide person-centred care. Overall, the findings showed that community pharmacists could provide interventions to asthma patients if trained and provided with suitable funding, equipment, guidelines for treatment and access of the community pharmacists to the patients' medical records.

According to the findings, community pharmacists can support asthma patients by providing frequent or additional reviews of their medication, inhaler technique, medication adjustment and/or the provision of an AAP. Some patients suggested that the ease of access to community pharmacy can be utilised in the provision of urgent care to asthma patients.

Other participants in phase 1 suggested the inclusion of an asthma clinic in the community pharmacy. In this clinic, patients would be seen by the community pharmacist or an independent pharmacist prescriber and would provide a flexible appointment system that adapts to the patient's availability and work commitments.

Furthermore, the overall findings suggested that more frequent reviews could be provided to asthma patients in the community pharmacy setting, which could improve asthma control in adult patients, and develop the communication between asthma patients and community pharmacists.

On the contrary, in phase 3, the findings highlighted that not all asthma patients will be receptive to more reviews, education and support. Moreover, not all asthma patients will be receptive to having their asthma reviewed in community pharmacy. However, the findings of the three phases identified

asthma patients who might benefit from further support. Those patients were grouped based on their needs and described in theme 5.

Theme 3: Relationship between patients and HCPs

Theme 2 described opportunities to enhance asthma care that are related to HCPs and other organisational challenges that could be addressed to enhance asthma management. Additionally, theme 3 concentrated on asthma patients. This theme concentrated on the relationship between HCPs and patients.

The findings of phases 1 and 3 on this theme were complementary and explained each other. In phase 1, the HCPs were heavily concentrating on patient education rather than motivating patients to manage their asthma. Additionally, HCPs were not aware of patients' satisfaction with asthma care. This explained the findings in phase 3 in which the patients expressed that they need to communicate with HCPs and they were dissatisfied by the HCPs' assumptions regarding their knowledge, skills and condition. Moreover, the patients mentioned that the short duration of appointments in the GP practice and incontinuity of care are affecting their trust and relationship with their HCPs.

Theme 4: Technology

This theme was found in the findings of phase 1. Its absence in phases 2 and 3 was related to the scope and nature of the phases and the participants.

Findings of phase 1 highlighted a promising role of technology to enhance asthma care. Most of the suggestions were based on utilising technology to improve medication use among asthma patients. Issues with medication use were identified in the findings of the three phases as discussed earlier in theme 1.

Smart inhalers, smartphone apps and smart cards could be utilised to monitor asthma patients' adherence to their medication, their inhaler technique and/or monitor their symptoms.

Theme 5: Asthma patients who might benefit from further support

The findings of phases 1, 2 and 3 highlighted patients who might benefit from further support. In phases 1 and 3, the participants suggested asthma patients that require support and/or could be easily provided with an intervention in community pharmacy.

The rationale for providing more support for those groups of patients, as perceived by the participants in phases 1 and 3 was to:

- Help those patients to satisfy their asthma care needs by supporting them in managing their asthma.
- Provide asthma interventions to patients who might benefit the most and who need it to enhance their acceptance of the intervention. Accordingly, this will ensure patients engagement with their reviews and treatment.
- Support the GP practice with their high workload and reorganise it toward more complicated cases or other patients who cannot be supported elsewhere.
- Decrease patients' use of secondary care because their condition will be reviewed more frequently and this might help to decrease their future risk for an asthma attack.

The findings on asthma patients who might benefit from further support were connected together in this theme. This theme contained seven sub-themes that present different groups of asthma patients that were suggested by the participants in phases 1 and 3.

Some of the groups were identified only in phase 1 or phase 3 but none of them were identified only in phase 2. This is because of the small sample size in phase 2. Additionally, those groups are not mutually exclusive because they were suggested by the participants among the two phases and in individual interviews.

The seven sub-themes and rationale for their selection are discussed below.

Patients with controlled asthma symptoms

According to the participants, those patients with controlled asthma symptoms can be supported by stepping down their asthma medication. This might decrease unwanted side effects and the costs of the medications. On the other hand, some participants thought that those patients can be supported safely in community pharmacy to support the GP practices with their high workload.

Newly-diagnosed asthma patients

The HCPs, service commissioner and patients in the phases 2 and 3 were keen on the provision of an intervention to this group of patients that involve education and motivation in the very early of their asthma diagnosis. The findings of phases 1 and 3 showed that newly diagnosed asthma patients should be provided with better education regarding their asthma and inhaler technique.

The HCP suggested that those patients require more reviews to check their knowledge and that they can use their inhalers correctly.

The participants in phase 1 expressed that diabetic patients are being supported better than asthma patients in their early diagnosis and this is should be provided to asthma patients.

Patients with poorly controlled asthma symptoms

The participants in phase 1 suggested that young adult asthma patients might be more susceptible to poorly controlled asthma symptoms because they pay for their medication and sometimes they might not be able to afford it.

Asthma patients who do not attend their asthma reviews.

The findings from the phase 1 highlighted that young adult asthma patients might belong to this group because they have a busy lifestyle due to their work and/or family commitments that prevent them from attending their AARs.

Moreover, in phase 1 and 3, the findings showed that asthma patients might not attend their appointments because they do not appreciate the benefits of attending their AARs, perceive that other comorbidities or LTCs are much more important to be followed up rather than asthma or because of mood changes or symptoms that they are experiencing from other comorbidities. Other issues that are related to asthma patients' engagement with their AARs were discussed earlier in theme 2.

Asthma patients with high risk for a future asthma attack.

This theme was found in the findings of the three phases and partial agreement occurred in this sub-theme.

Although the participants in phase 1 were hesitant to provide this group of patients with further support in community pharmacy, this group was taken forward because it was supported by examples in phases 2 and 3. Moreover, the participants in phase 1 were concentrating only on post-hospital discharge asthma patients who might have an asthma attack.

Asthma patients with comorbid depression

This theme was found in the findings of phases 2 and 3. None of the stakeholders in phase 1 addressed issues regarding the presence of other comorbidities and their effect on asthma

management. This might be considered as an additional reason to take this group of asthma patients forward and try to explore their needs with HCPs in the interviews.

Asthma patients with comorbid allergic rhinitis and/or seasonal allergy.

This group of patients was only highlighted in the findings of phase 3. Patients in phase 3 expressed how their asthma symptoms are changing in different seasons or in response to certain triggers and thought that they might benefit from further support.

Summary

This section provided a summary of the triangulated findings from the three phases. The themes and sub-themes included data from the three phases to enhance the completeness in answering the research question using multiple perspectives. The themes included complementary findings, where the three phases agreed and confirmed some of the themes and sub-themes.

On the other hand, findings from the three phases were utilised in some themes and sub-themes to provide a unique contribution to the findings. This allowed the use of the findings from one phase to confirm or extend the findings of the other phase(s).

7.4.5 Researcher comparison

The themes and convergence comparison were shared with the supervisory team and discussed. Amendments were undertaken based on their feedback.

A PowerPoint presentation that contains the seven asthma patient groups was prepared and shared with HCPs before being interviewed over the phone. The findings of the interviews will be displayed in chapter 8.

7.5 Discussion

In this phase, the findings were compared and connected (168, 264). The overall results of the triangulation showed that the findings from the three first phases were complementary to each other by identifying occasions of agreement and partial agreement (168, 264). In triangulation, the findings were compared and connected (168, 264).

In the literature review, medication adherence and inhaler technique were targeted in most of the included studies to enhance asthma symptoms in adult patients. However, the findings of triangulation highlighted the need for a systematic approach for inhaler technique check and recording in adult asthma patients. This supports the findings from the Asthma UK annual survey

that identified some patients who have attended their AARs but have not been provided with appropriate inhaler technique checks (8).

The findings of triangulation highlighted that asthma diagnosis could be improved to enhance asthma care in adult patients. The NRAD report (1) identified the need to enhance asthma diagnosis and NICE guidance (12) positioned the Fractional Exhaled Nitric Oxide (FeNO) in the diagnosis algorithm. However, this might increase the workload on secondary care because of the limited availability of FeNO testing in primary care (24).

Unsurprisingly, the findings of triangulation showed that there is a need to enhance the quality of asthma care, access to asthma care and co-ordination of the care provided to asthma patients, as perceived by participants in phases 1 and 3. These issues were highlighted before as issues in healthcare in general (273) and in asthma care too (22). One of the main NHS priorities is to enhance quality in health care provision as outlined in the NHS FYFV and the King's Fund briefing on health care quality improvement (43, 256). The Institute of Medicine outlined that ensuring equity in the care provided to all people is essential to ensure health care quality (43). Additionally, Asthma UK reported in their annual report in 2019 that there were differences in the quality of asthma care and poor asthma care in the deprived areas of the UK (8).

The need for enhancement in the provision of AAPs in adult asthma patients was supported by the findings of the case note review. Some asthma patients in the case note review had no AAP. Unsurprisingly, the Asthma UK annual survey in 2019 found that some asthma patients who attended their AARs were not provided with an AAP (8). Recently, the updated QOF outcomes for asthma for 2021 included recording a written AAP on the same day of conducting the AAR to achieve the requirements for the AAR (274).

Additionally, one of the domains that were framed by the Institute of Medicine to ensure health care quality is person-centred care, which ensures that the care is in preference to the individual's needs (43). The provision of supported self-management is an important approach for enhancing person-centeredness in care but it needs a collaborative relationship between patients and HCPs (39). This was highlighted by the findings of triangulation that showed a need to enhance relationship communication between patients and their HCPs. The findings also suggested that continuity of care might help to improve the relationship because seeing the same HCP in each appointment will help to build trust. Poor communication between asthma patients and their HCPs

might be improved by enabling HCPs with resources and training to improve their skills, as suggested by a qualitative study that was conducted in Scotland (254). The study was discussed earlier in section 6.7.

The findings of triangulation showed that to ensure that asthma patients are engaging with the support provided to them in community pharmacy, the community pharmacy should provide flexible appointments and/or walk-in support in community pharmacy. However, the community pharmacy has time limitations that might prevent them from providing a flexible appointment system (55). The new CPCF enhanced the role of community pharmacists by expanding the NMS to be provided to more patients and by launching new essential services (65). For example, the Discharge Medicine Service became a new essential service in February 2021. This and other services require further efforts from community pharmacists that might limit their availability for the provision of further support.

Moreover, community pharmacists need funding and training to implement an asthma intervention in community pharmacy. An additional training need was highlighted by participants, which is motivational skills and interviewing skills. This will help to decrease the paternalism in care provision that was highlighted in the findings of triangulation.

Although the findings suggested that there is a relationship of trust between community pharmacists and asthma patients, some asthma patients might not require and/or accept further support in community pharmacy. Patients' reception of an asthma intervention or support in community pharmacy might affect the implementation of it as suggested in the Fuller, et al. study that was included in the literature review in chapter 2 (113). Therefore, asthma patients with COPD and those who have been discharged from hospital might not benefit from support in community pharmacy as perceived by HCPs in phase 1 or might not be receptive to support in community pharmacy as suggested by patients in phase 3. Moreover, community pharmacists might not be able to support some patients because of the complexity of their condition.

The participants including patients and HCPs mentioned patients who might benefit from further support with their asthma. The triangulation findings sorted those patients into seven groups of asthma patients that could be supported to satisfy their needs.

Unsurprisingly, the participants in the PhD study including patients and others felt that asthma patients need more education upon getting the early diagnosis. An evaluation of the NMS in 2012

showed that among patients who received NMS; those who were prescribed new asthma and/or COPD medication had a greater percentage of patients who do not know how to use their medication compared to patients prescribed with other new medications (87).

Additionally, the participants suggested that patients with poorly controlled asthma symptoms and those who do not attend their annual asthma might benefit from further support in community pharmacy. Those asthma patients were targeted by other studies in the literature. For example, patients with poorly controlled asthma symptoms were targeted by the intervention in six of the studies that were included in the literature review. However, there was variation in the identification of those patients across different studies, as discussed in the literature review before.

As well as this, asthma patients who do not attend their AARs were targeted by an intervention in England and Scotland and the findings showed an increase in their engagement (77, 80). However, there is no service or referral pathway for those patients from the GP to community pharmacy in England. In the Craske et al. study (80), a list of those patients was shared with community pharmacy then patients were approached. Whereas, in Scotland (77), a message was written on the prescription to notify the community pharmacists that those patients were not attending their AARs. Those referral pathways can be used to engage those and other asthma patients with an intervention in community pharmacy.

On the other hand, this PhD study might be the first study that suggested that patients with controlled asthma symptoms and those with comorbid depression can benefit from further support in community pharmacy. According to the HCPs in phase 1, this might allow shifting the GP practice appointments toward more severe cases and utilising community pharmacy to support the GP with their current workload (46, 53)

Again, as the participants were keen for the provision of preventative and proactive care in asthma patients, they felt that patients who are at risk for an asthma attack can be supported with more reviews to prevent them from having an attack. This agrees with the NHS FYFV (256) and the CPCF (65) priorities to provide preventive care to patients with LTCs and the NRADS recommendations to decrease the risk for future attacks in asthma patients (1). Moreover, the patients with comorbid allergic rhinitis asked for support in phase 3, they thought that they need preventative care to decrease their visits to the A&E. Those patients are more susceptible to

asthma attacks and can mix between allergy and asthma symptoms as found by other studies (237, 275).

The opportunity to use technology to enhance asthma care was highlighted by the participants in phase 1. Technology can be used to monitor patients, remotely as shown in the findings of phase 1 (204). It may help to capture the full picture of the asthma condition in each patient, followed by the provision of support to patients based on their needs (16, 204). One of the existing applications for technology in asthma is the provision of a personalised AAP using specific algorithms that utilise patient data (16, 204). Moreover, technology could be used to improve patient engagement by changing the method of service delivery, which adapts to patients' circumstances and responsibilities (136, 276).

7.6 Implications for thesis

The triangulation highlighted that although asthma patients can be supported in community pharmacy to enhance their asthma care, some patients might benefit from the support more than other patients. Additionally, some patients might not be receptive to this support.

Although the triangulation highlighted seven groups of asthma patients, those groups are not mutually exclusive, there is still a need to know what the criteria are for identification of those patients and if it is feasible to support them in community pharmacy.

Additionally, the triangulation highlighted some needs among those patients and suggestions for support that included more frequent reviews, self-management support and others. However, there is still a need to explore how community pharmacy can provide tailored support to those patients to enhance their asthma care and meet their preferences.

Based on these findings and issues raised from the interpretation of the triangulation findings, the findings of triangulation were shared with HCPs in phase 5 to get their feedback and to explore further opportunities for community pharmacists to support those patients.

The next chapter will discuss phase 5.

8 Phase 5: Interviews with HCPs to get their feedback

The previous chapter discussed the triangulation of the findings of phases 1, 2 and 3. The findings of triangulation informed the development of an interview schedule for phase 5 that aimed to get HCPs' feedback on the findings of triangulation.

This chapter will present the aim and objectives, methods and findings of phase 5. Then, it will present core findings from this phase, triangulation and how they were utilised to draw the answer for the PhD research question. This will be followed by a discussion and implications for the thesis.

8.1 Introduction

The findings of triangulation identified seven groups that were summarised shared with the HCPs to get their feedback and to identify which asthma patients are most likely to benefit from community pharmacy-based asthma intervention. Additionally, the interview schedule contained questions that aimed to expand the knowledge (that was gained by the triangulation of phases 1, 2 and 3) on suggestions regarding the way that community pharmacists can provide tailored support to those patients. Finally, the interviews aimed to explore any changes in asthma care provision in response to the pandemic that could be utilised to enhance asthma care for adult patients.

This final phase of the PhD was conducted to enhance the trustworthiness of the findings of the triangulation by getting HCPs' feedback on them. Additionally, the findings were utilised along with findings from the triangulation to summarise and describe the final results of the PhD study. Finally, to draw the answer for the research question of the PhD.

8.2 Aim and objectives

The aim of phase 5 was to get HCPs feedback on the findings from triangulation in phase 4.

The objectives were:

- To explore healthcare practitioners' views on which asthma patient groups are most likely to benefit from community pharmacy-based asthma intervention or further support.
- To explore healthcare practitioners' perspectives on how community pharmacy can provide tailored support for those patients.
- To explore any changes in asthma care delivery during the COVID-19 pandemic.

8.3 Methods and methodology

Semi-structured telephone interviews were conducted with HCPs across the North West of England. HRA (see Appendix 9) and REC (see Appendix 10) approvals were obtained on 29th August 2019.

8.3.1 Study design

This final phase used qualitative interviews with HCPs who were involved in the delivery of asthma care. The sample of stakeholders included HCPs from a variety of specialities. During the interviews, the seven asthma patient groups were discussed with participants.

Semi-structured interviews allowed the participants to express their perceptions on the different patient groups (144, 145, 152). Additionally, it helped the researcher to get HCPs' feedback on the findings of the triangulation and provided the flexibility for the HCPs to suggest any enablers for community pharmacy to support adult patients' management of their asthma (144, 145, 152). Using an interview schedule enabled the researcher to maintain consistency in the topics covered throughout each interview and probe for further detail where appropriate (144, 145, 152).

The interviews were conducted over the telephone because the data collection period took place during the COVID-19 lockdown period and face-to-face interviewing was impractical due to social distancing rules. The ethical approvals that were obtained for this phase, earlier in 2019, were to conduct the interviews face-to-face or over the telephone. Therefore, other interviewing methods including Zoom or Teams were not a viable option.

Moreover, the researcher intended to include asthma patients in this phase and the patients' consent was already obtained. However, the COVID-19 lockdown restricted the researcher's ability to visit the GP practice and interview patients.

8.3.2 Research sites and participants

The study was carried out with HCPs in the North West of England. The interviews were undertaken over the telephone. Relevant stakeholder organisations acted as gatekeepers and were approached to nominate participants and/or participate in the interviews. Participants for this phase included community pharmacists, practice pharmacists, a GP and a practice nurse.

Inclusion Criteria

The inclusion criteria for this phase included stakeholders involved in the delivery of services to adult asthma patients in the North West of England.

Exclusion Criteria

The exclusion criteria for this phase included stakeholders who were not involved in service delivery for adult asthma patients or those based outside the North West of England.

Recruitment of participants

All participation was voluntary. Participants could withdraw from the interview at any time and could choose not to answer the questions. Participants could withdraw after the interview had been conducted up until the data had been anonymised.

Email addresses for all gatekeepers were obtained from the NHS Choices website (178). Gatekeepers were then invited to participate and/or nominate potential participants, including pharmacists based in GP practices, community pharmacists, practice nurses, nurse practitioners and service commissioners. A gatekeeper invitation email outlining the study (see Appendix 19) was sent to each gatekeeper with a gatekeeper information sheet (see Appendix 22) and a gatekeeper consent form (see Appendix 23).

An invitation email outlining the study (see Appendix 24) was sent to each potential participant with a participant information sheet (see Appendix 25) and a consent form (see Appendix 26) to enable participants to make an informed decision regarding participation. The participant information sheet included the following information: background to the research and the researcher, what participating would involve, benefits and possible disadvantages, why they had been chosen to participate, confidentiality and participant's rights. The participant information sheet also highlighted that the interviews would be audio-recorded to ensure that they were comfortable with this. The researcher's contact details were provided so that potential participants could contact the researcher to ask for further information if required. Potential participants were asked to complete and sign the consent form and return it before the interview.

Nonresponding stakeholders were contacted with a reminder email a minimum of three working days after sending the invitation email to determine their willingness to participate and/or nominate the most appropriate person to be interviewed. This was considered sufficient time for the participants to review the study documents and make an informed decision. A mutually convenient time for the interview was then arranged.

Sample size

A purposive sampling strategy was followed in this phase. The researcher aimed to interview GPs, nurses, practice pharmacists and community pharmacists. Three of the participants in this phase were interviewed earlier in phase 1. This might lead to bias in the findings; however, it allowed to

enhance the trustworthiness of the findings because those participants had the opportunity to give feedback on the findings from triangulation.

8.3.3 Data collection

Interview schedule

A semi-structured interview schedule was developed by the researcher to achieve the aims and objectives of this phase of the study and was guided by the results from triangulation and discussion with the supervisory team. Non-leading questions and prompts were developed by the researcher. The interview schedule was reviewed by the supervisory team prior to the first interview. The interview schedule can be seen in Appendix 27.

A PowerPoint presentation containing the summary of the seven asthma patient groups was sent by email to the participants before the interview. The interview schedule contained a combination of close-ended questions and open-ended questions. Open-ended questions were asked to collect data regarding each patient group. This was followed by questions about issues related to the provision of tailored support to those patients in the community pharmacy setting. The interview schedule also contained a number of prompts to facilitate the researcher to probe participants for more information about the topic.

All participants were asked if they would like to add anything else regarding each topic. This was to ensure that participants were given every opportunity to mention any issues they considered important which were not directly addressed in the interview questions. Any extra issues identified by participants were further clarified by the researcher for better understanding.

Pilot study

The first interview was used as a pilot to determine if the methods of recruitment, data collection and data entry were suitable and yielded appropriate data for analysis. A review of the participants identified, and the transcript of the pilot interview was undertaken by the supervisory team. No amendments were required. Subsequently, the pilot interview was used and analysed.

Procedure

Having pre-arranged the interview at a mutually convenient time, each interview began with a verbatim introductory script, ensuring that each participant was given the same information about the study before the interview. The researcher confirmed with participants that a signed consent form had

been completed and returned as part of the introduction. If the researcher had not received this form from the participant, then the consent form was read out and verbal consent was obtained and recorded before the telephone interview commenced. The participants were then asked to complete the signed consent form and return it as soon as possible.

Individual demographic data collected from the stakeholders included the participant's work setting. The participants were then asked a range of open-ended questions to discuss issues concerning the proposed Patient groups, integration of community pharmacy to asthma management and current support provided to asthma patients during the COVID-19 pandemic. In addition, the participants were prompted to express their perceptions and suggestions throughout the interview. During the interviews, no topics were discussed that any of the participants found distressing.

The interviews were conducted in the participants' 'natural setting' by calling them. The participants were advised to be in a quiet room for the interview. This allowed the participants to answer the questions freely without interruption. The same researcher conducted all the interviews in a quiet room free from interruptions, to ensure the trustworthiness of the data collected. The interviewee was made aware that the interview would take up to 40 minutes so that they were able to make appropriate arrangements. Sufficient time was allocated to ensure all questions were asked and answered thoroughly.

The interviews were audio-recorded, and the audio recording device was tested by the researcher before each interview. Handwritten notes were taken on a printed interview schedule for each participant during the interview.

Safety issues

Interviews allowed both the interviewer and the interviewee to be in a safe environment during the interview. Neither were put at risk. No obvious sensitive topics were discussed. If the interviewee had found any topics distressing, this would have been handled tactfully by the interviewer. Every effort was taken to ensure that the interviewee was comfortable with the topics being discussed.

8.3.4 Data analysis

The interview transcripts were analysed thematically by the researcher. The thematic analysis process adopted by the researcher is detailed in section 4.3.7, however, the researcher used the combination coding scheme in this phase.

Use of a combination coding scheme was selected to allow the researcher to enrich the description of the data (152, 187). Additionally, it was considered suitable to help the researcher create a balance between the data related directly to the feedback of HCPs on the patient groups and findings that emerged from the HCPs' views and thoughts during the interviews (187). Framework analysis was not selected because it is considered more suitable for large data sets, has to be conducted by a multidisciplinary team and cannot be conducted by one researcher (186) Additionally, use of a thematic analysis that utilises a combination coding was thought to allow for flexibility and to be appropriate to achieve the aim and objectives of the phase (152, 187).

Interview transcription

The interviews were transcribed verbatim by an independent transcriber. The same procedure was undertaken in phase 3 (for details see section 6.3.4).

Coding

After the interviews were transcribed, the researcher re-listened to the audio recordings and read the transcripts more than once to become familiar with the data. The coding process used in this phase is different from that used in phases 1 and 3.

In this phase, the researcher used a combination coding scheme that involved pre-assigned codes to obtain the participants' feedback on the seven patient groups. Moreover, new codes that emerged from the analysis of the interview transcripts were added to the preassigned codes and applied to all the interview transcripts.

Theme generation

The resultant codes were grouped into themes and sub-themes.

8.3.5 Ethical issues

Interviews were audio-recorded. Audio recordings using a digital voice recorder were downloaded onto a secure, password-protected LJMU computer, after which the file was securely deleted from the digital voice recorder. The electronic, password-protected file containing the audio recording was securely deleted after it was transcribed and checked for quality.

Confidentiality was maintained by allowing only the independent transcriber, researcher, and supervisory team to access the interview recordings and transcripts. Furthermore, a transcriber

confidentiality agreement (see Appendix 18) was signed by the independent transcriber to ensure confidentiality. The transcriber agreed to keep the audio recordings and the transcripts secure as password-protected files and to securely delete all files related to the research after the transcription task was completed.

8.3.6 Quality and trustworthiness

The researcher followed the same strategies to enhance quality and ensure trustworthiness in the data collection and analysis of the qualitative phases 1, 3 and 5. Those strategies were described in chapter 4 (for details see section 4.3.9).

8.4 Findings

8.4.1 Participant demographic data

Data collection took place between 27th April 2020 and 28th May 2020. A total of six participants were involved in this phase. The average duration of the interviews was 35 minutes (ranging from 24:36 to 47:08 minutes).

The participants included community pharmacists, who were involved in dispensing asthma patients' monthly inhalers, alongside other services as discussed in phase 1 (see section 4.4.1).

The GP who participated was involved in the overall management of asthma, starting from diagnosis, whilst the pharmacists and a nurse who participated were based in GP practices and were involved in providing annual asthma reviews for adult patients.

A full list of the participants and their occupations can be seen in *Table 8-1*.

Table 8-1 Participants demographic data in phase 4.

Participant number	Job title	Setting
1	Practice pharmacist	GP practice
2	Community pharmacist	Community pharmacy
3	Community pharmacist	Community pharmacy
4	Practice pharmacist	GP practice
5	GP	GP practice
6	Practice nurse	GP practice

8.4.2 Themes

The interview transcripts were analysed to identify HCPs' feedback on the proposed patient groups and to explore how community pharmacy can provide tailored support to those patients.

The first key theme was derived deductively from the aim and objectives of this phase. Other themes and sub-themes emerged inductively from the analysis of the interview transcripts. Themes and sub-themes are summarised below in *Table 8-2*.

Table 8-2 Summary of themes and sub-themes of the interviews with HCPs

Theme	Description	Sub-themes
HCPs' feedback on the suggested asthma patient groups	This theme summarised and compared HCPs' perceptions of the seven groups.	▪ Asthma patients who do not attend their AARs ▪ Asthma patients who attend their AARs ▪ Newly diagnosed asthma patients
What do community pharmacists need to provide further support for asthma patients?	This theme covered the enablers to deliver further asthma support in the community pharmacy setting.	▪ Asthma patients' identification ▪ Resources
Organisational barriers	This theme described limitations and barriers that could face the implementation of further support for asthma patients in the community pharmacy setting.	▪ Engagement of community pharmacists with a new intervention ▪ The willingness of the GP to refer patients to community pharmacy

The themes will be discussed below in detail. Each theme includes an overview and description of the sub-themes. Anonymised quotes were included to support the findings.

Theme 1: HCPs' feedback on the patient groups

The participants showed variable responses to the suggested asthma patient groups. This theme included three sub-themes to describe the HCPs' feedback on the seven patient groups.

The findings of the analysis showed that the groups that were proposed might overlap. Some patients who might fit into a group might not be mutually excluded from all other groups. The participants felt that patients across the seven groups might share some needs and might be addressed by the same sort of support that is tailored to their needs. The seven groups were merged into three groups.

The following sub-themes will discuss the three groups of asthma patients.

Sub-theme 1: Asthma patients who do not attend their AARs.

The participants focused on asthma patients who do not engage with their appointments and mentioned them in the discussion of each of the seven groups.

Some of the participants highlighted that in the GP practice, the HCPs, including the practice pharmacists and nurses, strived to enhance asthma patients' engagement through telephone reviews but patients were not engaging:

"We try to [engage] them by phone reviews but again if these patients could be picked up when they're collecting their prescriptions, the community pharmacy does tend to see a lot more of these patients and they could be followed up as a, "how have you got on since your prescription was increased or decreased?", as a sort of a final check or an intermediate check, shall I say? I think that would be again, sort of benefit," Practice pharmacist.

One of the participants (who was a community pharmacist) suggested that it could be difficult to engage this group of patients in community pharmacy:

"I am not sure if they will come to us [community pharmacy]," Community pharmacist.

The participants expressed how hard it is to engage patients with comorbid depression. Therefore, those patients can fit into the group of patients who do not attend their reviews. However, this does not mean that all asthma patients with depression are not attending their AARs.

Only two of the participants supported the provision of support for asthma patients with comorbid depression in the community pharmacy setting to enhance their engagement:

"I suppose particularly [community] pharmacists with some sort of training and things like motivational interviewing and the concept of cycles of change and things might be able to make a big difference here, which is why having a bit more time and being another way that patients can access that sort of support," GP, GP practice.

On the contrary, other participants felt that patients might be difficult to communicate with in this setting and any service that could be provided to them would be time-consuming. The participants perceived that it would be better to refer them to mental health services in secondary care or the community rather than community pharmacy:

" [Asthma patients with] anxiety group are very time consuming, for having done reviews of them myself, there's quite a lot of extra support that they'd need and they'd probably need to come back several times, it wouldn't just be like one review, it would be several reviews so that's fine if you're going to be able to put that level of follow-up in but I'm just not sure if that would be possible," Practice pharmacist.

According to the participants, asthma who do not attend their AARs should be provided with a flexible appointment system that overcomes the current difficulties in booking an appointment with the GP practices:

"Getting an appointment with the surgery, it's usually quite a long time in advance, we [community pharmacy] could probably organise an appointment much quicker from a pharmacy," Community pharmacist.

"I think this service would be very useful in community pharmacy, if they were going to be able to offer maybe appointments at different times, it would work around people working and things like that. But yes, we would probably have quite a lot of patients that could be managed within the community pharmacy setting," Practice pharmacist.

Additionally, virtual appointments can be utilised to engage asthma patients:

"During the COVID-19 pandemic, it has forced us into looking at different ways to undertake reviews. The GPs here are starting, successfully, using video call reviews, I think that's potentially now going to be fed down to the long term condition reviews, so we could be doing video call reviews for asthma and things like that as well, to try and engage people that way," Practice pharmacist.

Moreover, the extensive spread of information regarding COVID-19 on television, newspapers, the internet and social media led to an increase in awareness of asthma patients of the importance of reviewing their condition. Therefore, asthma patients (including patients who did not usually attend their appointments) were highly engaged with their reviews:

"Certainly with this pandemic, I've seen some patients who haven't had inhalers for months and months and then maybe think, "oh, I might need to get my asthma sorted" and have come in and got an inhaler, so they're patients that haven't had them since November last year and then they've all of a sudden started taking them again, getting them dispensed," Community pharmacist.

Sub-theme 2: Patients who attend their reviews

Among the patients who attend their AARs, there are patients with high future risk for an asthma attack (including those who need seasonal care and patients with poorly controlled asthma symptoms) and patients with controlled asthma symptoms.

According to some participants, those patients could be supported in community pharmacy to allow them to communicate with more than one HCP in different healthcare settings to adapt to their circumstances and minimise future risk for an asthma attack:

"Again, these tend to be the ones [asthma patients with future risk of an asthma attack] that don't really like coming in very often but obviously, sometimes they can be collecting their medication regularly and using it appropriately but they still just, they're still having regular exacerbations so having a review in the community will make a difference, hopefully just having somebody else to look at their medication and titrate it up as needed," Practice nurse.

However, other participants felt that this group of patients were already provided with sufficient follow-up in the GP practice and secondary care by different HCPs and there is no need for further support in community pharmacy:

"So possibly it might be useful for certain patients but I don't think they'd be the core group that you'd necessarily be aiming at with a community pharmacy-led service because I think there's quite a lot of other services open to those patients, they often have input from a respiratory nurse specialist, they're often being seen with me in general practice and so maybe they're not necessarily the group that you'd want to target through pharmacy, would be my perspective," GP, GP practice.

Two of the participants suggested that patients with poorly controlled asthma symptoms should be followed up by the GP or practice nurse but not by community pharmacists:

"I don't know if [community pharmacy-based intervention] fits so well with this group [patients with poorly controlled asthma] as it fitted with your first group [patients with controlled asthma], because I suppose, if we've had someone in and identified their control is poor, we should probably feel more of a responsibility maybe to follow that up ourselves and maybe feel less comfortable with trying to delegate it to somebody else," GP, GP practice.

On the other hand, the participants were keen to support patients who need seasonal care to reduce their risk for an asthma attack. Most of the participants felt that reviewing them more regularly in the season at which their asthma symptoms increase might help them to manage their asthma:

"I think that would be really useful as a lot of patients have seasonal asthma, who obviously could be very well managed in the community pharmacy," Practice pharmacist.

"They're probably a group whose contact with the community pharmacy could be enhanced in order to provide them with monitoring and some sort of specialist care," GP, GP practice.

Additionally, those patients might need a prescription of allergy medication or medication adjustment just before the season at which their symptoms deteriorate but this is not needed for all patients with

future risk for an asthma attack. Moreover, community pharmacists can provide over the counter medications for those who have allergies so their condition will not deteriorate.

In addition, the community pharmacists interviewed showed an interest in being involved in the provision of a service for this group of asthma patients:

"Targeting asthma patients who need seasonal care would be more interesting for me and I could see more of a benefit of that than the other groups," Community pharmacist.

The six participants in this phase showed positive opinions regarding the referral of patients with controlled asthma from their GP practice to community pharmacy for reviews instead of being reviewed in the GP practice. According to the participants, those reviews might help to decrease the workload on the GP practices:

"Having them [patients with uncontrolled asthma] being able to be seen in the community, by the community pharmacists, I think might be quite a good service and take some of the pressure off the clinics and the doctors," Practice nurse.

"If we did have these services, the patient wouldn't have to wait a year to get their next review, we could keep a closer eye on them because they do attend our pharmacies on a regular basis and we do see these people every month or every other month, so it would be beneficial for our patients," Community pharmacist.

No negative thoughts were directly related to this group of asthma patients among the interviews.

Sub-theme 3: Newly diagnosed asthma patients

Although there was consensus regarding the benefit of supporting newly diagnosed asthma patients, participants showed a variable response to supporting them in the community pharmacy setting.

Two of the participants felt that community pharmacists might be well prepared to educate asthma patients on their early diagnosis:

"I think that would be a very good group to target for education and support," Practice pharmacist.

According to other participants, there is no need for an intervention for those patients in community pharmacy because this group of patients were provided with regular follow-ups in the GP practice through face-to-face appointments and telephone reviews. Additionally, the participants felt that newly

diagnosed asthma patients need long appointments, detailed education, and may require adjustments to their medication choice or dose that could not be provided in community pharmacy.

On the other hand, the participants showed some worries regarding the encroachment between different professions. This might affect their opinions regarding supporting asthma patients in community pharmacy:

"I would probably say that this [service for newly diagnosed asthma patients] is something that we do and are quite comfortable doing, I wouldn't particularly have any wish to hand over to another professional group. Obviously, diagnosis tends to be made by GPs and then we all direct patients to our asthma nurses to see them and educate them. I think we have quite a robust provision of that care and we probably, certainly in our practice, we wouldn't particularly be looking to hand that to anyone else, it's useful to know exactly what education they're getting at the outset and what the conversations have been, and so personally I think I would want to keep that in house rather than sending it to somebody else," GP, GP practice

The findings highlighted a need for improvement of the current NMS implementation and delivery in community pharmacy for newly diagnosed asthma patients. Two of the participants felt that the NMS could be better utilised by enhancing the GP referral of newly diagnosed asthma patients from the GP practice to community pharmacy for NMS:

"GPs know about NMS and MURs but they don't ever ask us to do them so I think it would all be dependent on the GP being involved and handing the patient to us and saying, "this patient needs a review" and then hand them over for us to deal with them," Community pharmacist.

Theme 2: What do community pharmacists need to provide further support for asthma patients?

Sub-theme 1: Asthma patient identification

The participants showed a positive response towards providing support for asthma patients in community pharmacy. However, they perceived that community pharmacists may find difficulties in the identification of asthma patients who fit into each group.

"It [identifying a certain group of asthma patients] would take a bit of work to see whether they were controlled or not because you'd have to have a look at their patient medical record to see when they last had inhalers. You'd probably have to interview them to see if they were getting symptoms. It wouldn't be straightforward to see whether they were controlled or not, it would take some time," Community pharmacist.

The participant felt that asthma patients could be referred from the GP practice to community pharmacy for an asthma intervention.

The two community pharmacists highlighted that referring patients to them from the GP practice could identify a larger number of asthma patients who need support, help the community pharmacist to spend time on delivering the service rather than searching for patients and encourage community pharmacists to communicate with the GP practice if they felt that the patients may need further support:

"We could definitely do that [refer patients to community pharmacy], that wouldn't be difficult to set up, it's just ensuring that we're all doing the same thing and we're all highlighting the same patients, so you would need quite robust standard operating procedures and inclusions and exclusions but with those in place, definitely this could be rolled out," Practice pharmacist.

One of the participants suggested that the clinical databases used in the GP practices and electronic prescriptions could be utilised to identify asthma patients who need support and refer them to community pharmacy. For example, a referral message to the community pharmacy could be added to the prescriptions to help the community pharmacist to identify asthma patients who need support:

"We're all [GP practices] set up now for using electronic prescriptions so we can sort of use the functions of the descriptions on there and when we send out a repeat prescription, we can put a message, "pharmacy [review]", so we could potentially utilise those functions of the computer system to highlight them [groups of asthma patients]," Practice Pharmacist.

Some of the participants suggested that asthma patients might refer themselves to community pharmacy when they feel any changes in their symptoms.

Sub-theme 2: Resources

The participants expressed that the implementation and provision of asthma services in community pharmacy may require the training of the community pharmacists:

"I think we've got the facilities and with the right training pack, I think every pharmacist would want to be given a refresher course on asthma control, it doesn't have to be an arduous training pack but just to give them an up to date, what the patient outcomes are that we're hoping for and a clear guidance, I think every pharmacist could do it," Community pharmacist.

Overall, the participants showed negative feelings towards amending medication in community pharmacy and highlighted that community pharmacists could change the doses of the medications or inhaler devices but not the medication:

"I think simple step up and step downs, doubling doses within standard dose ranges of inhaled corticosteroids and things like that, I think is probably fine, probably moving whole steps on the BTS guidelines, I'd probably be a bit more wary about that," GP, GP practice.

One of the participants (who was a practice pharmacist) perceived that community pharmacists cannot perform any change in the medication or the dose, and an independent prescriber pharmacist could be better placed to do so:

"I think it [stepping up or down medication in community pharmacy] would probably be on a bit dicier ground," Practice pharmacist.

Overall, the participants identified some training needs, including:

1. The provision of an AAP.
2. How to adjust asthma medications.
3. Inhaler technique check.
4. How to interview patients and motivate them.

Some of the participants suggested that clear guidance or protocols should be provided to the community pharmacists to be able to provide the services effectively.

"I think as long as patients are being reviewed and that everybody's trained to the same standards and everyone's following the same process, to me as long as the patient's being reviewed, it doesn't matter where the setting is," Practice pharmacist.

In this phase, the stakeholders were asked about the feasibility of introducing an asthma clinic in community pharmacy. The participants showed a positive response to this and suggested that one qualified community pharmacist could run one or two-day asthma clinics to ensure the availability of the qualified community pharmacist if needed. Although the provision of the asthma clinic could help to provide patients with appointments, it may require the availability of two community pharmacists during the opening time of the clinic:

"If we got paid for it [proposed services] and if it was managed well, so say we had a morning session for all these asthma reviews, if we did that with the second pharmacist, if it was worthwhile money-wise, it would definitely be worthwhile doing it," Community pharmacist.

"I work for an independent [pharmacy], we wouldn't be involved unless [the service] was funded," Community pharmacist.

One participant highlighted that community pharmacists in chain pharmacies may not be able to provide services due to the lack of supporting staff and the extensive managerial workload of the community pharmacist in this setting. Moreover, the change of staff between branches could affect service provision as the qualified community pharmacist may not be available in a certain branch at all times, to provide the service.

Other participants felt that in terms of funding and cost-effectiveness, an ad-hoc service in community pharmacy could be more feasible than implementing an asthma clinic. An ad-hoc service could be provided to asthma patients only when needed and would not require a lengthy appointment. As well as this, the patients could self-refer themselves for review in community pharmacy which could save HCPs time spent to identify patients.

Based on the perceptions of the participants, another challenge that could restrict the expansion of community pharmacy role in supporting patients with asthma and other LTCs, is their limited access to patient data:

"Obviously [community pharmacists would] need to have access to patients' notes and stuff, so they can actually see what medication they've been on and how long they've had asthma and all those kind of things because patients quite often don't know," Practice nurse.

In this phase, the participants highlighted that an open line of communication between the community pharmacists and the GP practice could provide professional support to community pharmacists:

"There's nothing to say that that could not be managed in community pharmacy, with again the right protocols, the right structures and the right training and then also with the right support, that if they have a concern, that there's a mechanism that they can get advice and support quickly and appropriately," Practice pharmacist.

Some of the participants felt that community pharmacy could have been utilised better during the COVID-19 pandemic if there was a well-established route of communication between the GP practice and the community pharmacy. For example, asthma patients could be referred to community pharmacy and get face-to-face support from community pharmacists, then, feedback could be sent to the GP practice for follow-up or to help the community pharmacist to make a clinical decision if needed.

The participants in this phase highlighted that for the proposed services to be successfully implemented, an efficient feedback process from community pharmacy to the GP practice should be developed.

The participants thought that a proper feedback pathway requires enhancement of information sharing between the GP practice and community pharmacy and this could be done by:

1. Implementing clinical systems in community pharmacies that are compatible with those used in the GP practice, for example, the EMIS clinical database.
2. Another way of sharing information between the community pharmacy and the GP practice is a secured email system, which was suggested by the participants in this phase, to get feedback from the community pharmacy.

Theme 3: Barriers

This theme discusses some issues that should be taken into consideration during the implementation and provision of services in the community pharmacy setting that were highlighted by the participants. These limitations could affect the implementation of services in the community pharmacy setting in general and not only for asthma patients.

Sub-theme 1: Engagement of community pharmacists with new interventions

The participants felt that expanding the role of community pharmacists to provide more interventions could increase their workload, alongside the growing workload of their essential role in dispensing:

"The checking and the counselling and everything else we've got to do, to have this on top of it, it might be quite challenging," Community pharmacist.

The community pharmacists that were interviewed suggested that the engagement with services could vary between different community pharmacists:

"I think it's [service provision in community pharmacy] something that can be done, however, you will get some pharmacists who think their workload is already too high, so they may not think it's manageable, so it depends on the experience of the pharmacist," Community pharmacist.

Furthermore, a better relationship between community pharmacists and patients may be developed in the independent pharmacy, which may facilitate the development of trust between patients and the pharmacist, allowing them to support them in the management of their asthma.

Sub-theme 2: The willingness of the GP to refer patients to community pharmacy

When the participants were asked about the feasibility of the provision of the proposed services in the community pharmacy setting, HCPs other than community pharmacists were reluctant and showed concerns about supporting the provision of the services. Those concerns can be grouped under two issues:

Some of the participants felt that expanding the role of community pharmacy to support asthma patients may limit the role of the nurses in the GP practice, who have been trained and are qualified to provide services to asthma patients.

Those participants (who were based in the GP practice) highlighted that some services in the community pharmacy setting could duplicate the workload of the GP practice rather than decrease it. For example, some services include reviewing patients in the community pharmacy, followed by sending a feedback form with recommendations or referring patients to the GP practice for follow-up. The participants highlighted that HCPs in the GP practice will review the patients again before taking any action:

"We [GP practices] have a long-established funding stream for care and monitoring of asthma patients and we have resources to do that, we have trained nurses and so anything added to our workload wouldn't be worth to use it, so it would have to be a very simple referral process," GP, GP practice.

One of the participants (who was a GP) perceived that the implementation of asthma interventions in community pharmacy may financially affect the GP practices, because it may decrease the services provided to asthma patients within the GP practices:

"My only query would probably be about funding, obviously we're funded as part of our general medical services to do chronic disease management and we're set up to do it, we have the capacity to do it, to be honest with you, I think we'd be reluctant to hand it over to pharmacy if it was going to affect our funding stream because we have the capacity to do it," GP, GP practice.

Another aspect that was highlighted by the participants was the effect of the provision of the services on the QOF. The participants perceived that the elements of the proposed services should be compatible with the QOF, to help the GP practices obtain their QOF points if they engaged with the services:

"It would have to be a service that isn't in competition with the GP practice, it would have to benefit it for us to buy into it and send the patients to the community pharmacy, so we want them to be recording information that we could use for our QOF and things like that, so the GP practice isn't going to feel like they're financially losing out by sending reviews to the community pharmacist rather than doing it in house," Practice pharmacist.

8.5 Summary of the findings of phase 5

The findings of the interviews showed that community pharmacists can enhance asthma care in adult patients.

The participants perceived that **there is a need for enhancement of the provision of the NMS**, especially referring asthma patients for NMS by their GPs. Additionally, the findings highlighted the need to enhance awareness of newly diagnosed asthma patients regarding the available services in community pharmacy including NMS.

According to the findings, asthma patients who do not attend their AARs, patients with controlled asthma and patients who have risk for a future asthma attack (patients with poorly controlled asthma symptoms and those with allergic rhinitis or who need seasonal care) can be provided by support in community pharmacy.

The feedback from HCPs on the asthma patient groups was utilised to enrich the description of patients who might benefit from an intervention in community pharmacy. The seven were combined into three groups based on the findings from this phase. Moreover, the needs of those patients informed the design of the intervention that could be provided to them in community pharmacy. The intervention will be discussed in detail in the following section.

8.5.1 Community pharmacy-based asthma intervention

The core findings of triangulation, feedback with HCPs and literature review were utilised to propose a possible structure for a community pharmacy-based asthma intervention. This intervention might be suitable for evaluation in a future study.

The core findings and the rationale for their inclusion to propose the intervention will be presented in *Table 8-3* below.

Table 8-3 core findings and rationale for inclusion in the intervention

Core finding	Rationale for inclusion
Asthma patients who might benefit from support in community pharmacy	The rationale for each group was discussed in section 8.5.1. The HCPs in phases 1 and 4 highlighted that some asthma patients do not need further support or cannot be supported in community pharmacy.
Referring patients from the GP practice to the community pharmacy	Community pharmacists interviewed in phases 1 and 4 perceived that there is a need to refer patients from the GP to community pharmacy to allow for the identification of more patients. Moreover, the lack of access to patients' data restricts their ability to identify patients.
Identification of asthma patients who might benefit from the intervention	The HCPs in phase 5 perceived that a well-established referral pathway that includes a clear inclusion/exclusion criteria might be essential to implementing an asthma intervention in community pharmacy. According to the findings of phase 5, community pharmacists can highlight asthma patients who are over-using their reliever inhaler. However, they cannot assess their asthma control until they review them. The literature review highlighted some difficulties in identifying patients in community pharmacy. On the other hand, HCPs in the GP practice have more information that could be utilised to identify patients easily.

Training for pharmacists	There was variability in the HCPs' opinions regarding community pharmacists' knowledge and skills to provide the intervention. The triangulation and phase 5 highlighted training needs for community pharmacists. The literature review highlighted that community pharmacists were trained face-to-face in most of the included studies to deliver the asthma intervention.
Flexible appointments system	Patients perceived that they could benefit from community pharmacy because they will not need to book an appointment. On the other hand, community pharmacists highlighted that the current workload and time restrictions might affect their availability for no appointment system. Therefore, patients will be able to use a drop-in asthma clinic or pre-booked asthma appointments based on their needs and preferences. Moreover, the appointments and walk-in hours might be provided early in the morning or late in the evening. Additionally, remote appointments could be provided as suggested by the participants in phases 1 and 5.
Supporting staff	The community pharmacists in phase 5 highlighted the need for the presence of two pharmacists during the opening time of the clinic or an independent prescriber.
The focus of the intervention	In patients with poorly controlled asthma symptoms: the intervention will focus on

	medication adherence, inhaler technique and an AAP as suggested from findings of triangulation and by HCPs in phase 5. In patients with comorbid allergic rhinitis and those who need seasonal care, the intervention will involve management of their allergic reaction as suggested by HCPs in phase 5. In patients with controlled asthma, the intervention will focus on medication review to step down medication if needed as suggested by participants in phase 1. In asthma patients who do not attend their AARs, the intervention involves a review of their asthma symptoms, medication, inhaler technique and an AAP.
Inhaler technique check	The findings of the case note review and phases 1 and 3 highlighted the need for a systematic approach for checking and recording the inhaler technique in asthma patients and that it needs to be conducted more than once a year. The inhaler technique check will utilise the inhaler In-Check device to ensure a systematic approach rather than a verbal one, as suggested by participants in phase 1. The literature review showed variation in conducting inhaler technique checks among the different studies. Additionally, the case note reviews found a poor recording of inhaler technique checks in the study sample.
Setting: Community pharmacy	The intervention will be provided in community

	pharmacy because of ease of access and convenient environment as discussed in the introduction and perceived by the participants in phase 1. Patients in phase 3 and HCPs in phase 5 appreciated the stress-free environment in community pharmacy and the trustful relationship with community pharmacists. Overall, it might help to enhance asthma patients' access to reviews.
Data sharing and communication between community pharmacists and HCPs based in the GP practice	The triangulation showed that one of the enablers for the provision of an intervention in community pharmacy is sharing patients' data with community pharmacy. Moreover, there should be a proper feedback pathway to share the data between community pharmacy and the GP practice, as perceived by the findings. Finally, HCPs in phases 1 and 4 perceived that HCPs based in the GP practice can support community pharmacists in delivering the intervention to asthma patients.
Funding	The HCPs highlighted that proper funding should be provided to community pharmacy to provide the intervention.
Advertisement	The participants in phases 1, 3 and 5 highlighted that there is a need to enhance asthma patients' awareness of their condition and the interventions that could be provided to them. Advertising in social media, newspapers, GP practices and community pharmacy might

help to enhance asthma patients' engagement.

Those core findings were utilised to inform the proposal of the intervention that is presented below in *Figure 8-2* and discussed in the following sections.

Figure 8-1 Possible community pharmacy-based asthma intervention

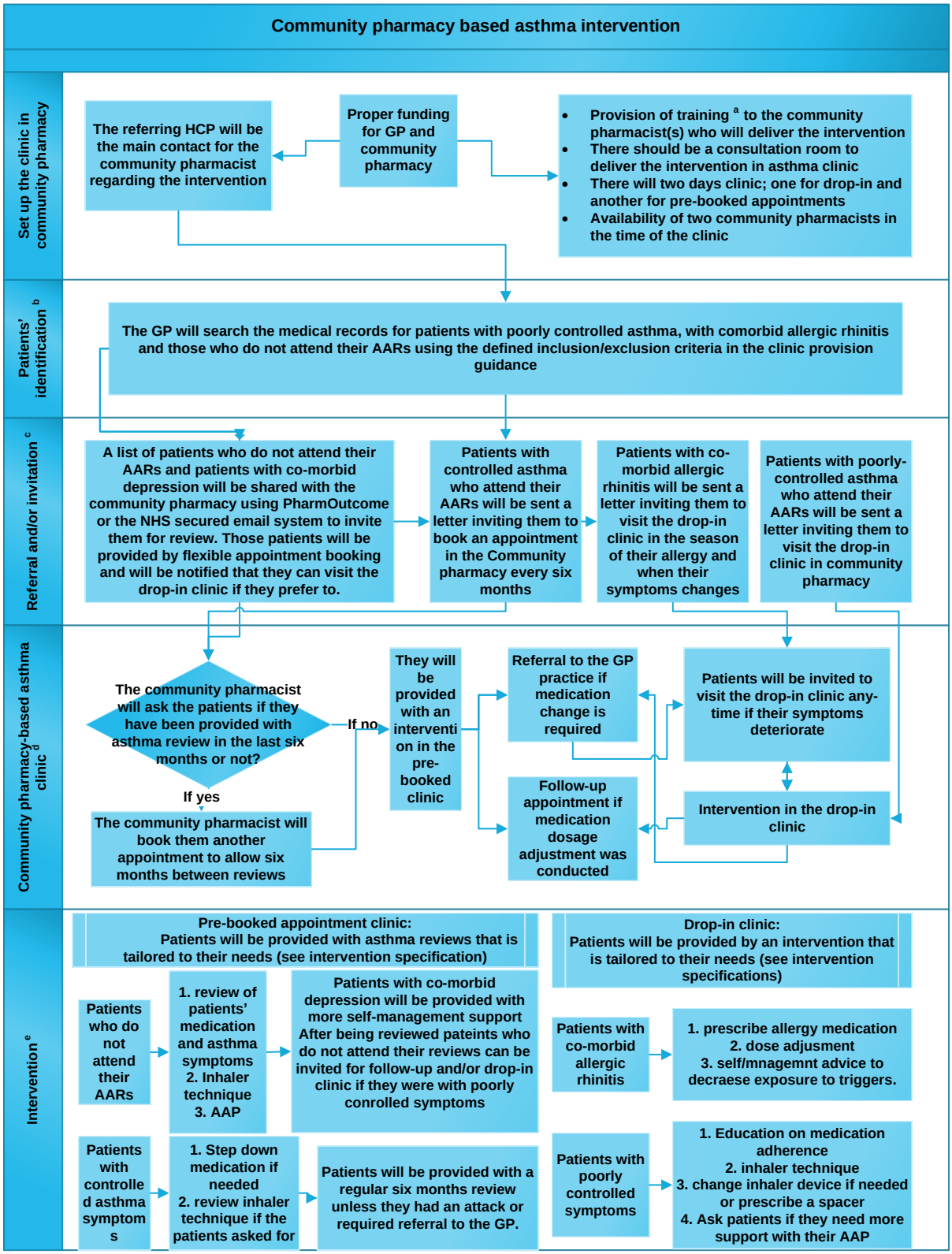


Figure 8-2 Legend for figure 8-4

Description or specifications of the intervention

Pharmacists

Two community pharmacists will be available during the opening time of the clinic; one to deliver the intervention. Community pharmacists will be able to contact an HCP based in the patients' GP practice to consult on medication adjustments if needed.

Training

To ensure safety in delivering the intervention, community pharmacists should complete proper training that will involve three areas:

1. The operational aspects of the clinic, for example, data protection, confidentiality and how to send feedback to the GP practice.
2. Knowledge and skills to deliver the intervention including the provision of an AAP; how to adjust asthma medications and step down medications; and inhaler technique check using the inhaler In-Check device.
3. Communication and motivational skills.

Community pharmacists already have access to CPPE online training resources for asthma (for example, asthma workshop) and other training on communication with patients and motivational skills (for example, training on consultation skills for pharmacy practice. However, there is a need to develop a specific training course on the provision of an AAP; how to adjust asthma medications and step down medications; and inhaler technique check before delivering the intervention. This might be overcome by having an independent prescriber in the clinic.

Patient identification:

There will be more than one identification pathway; patients can be identified by the GP practice or community pharmacy.

The GP practice will be asked to identify different asthma patients depending on the classification that was highlighted earlier. Those patients include:

1. Asthma patients with comorbid allergic rhinitis are subject to the following criteria:

- Diagnosed with asthma

- Aged more than 17
- Attend their AARs
- And have been diagnosed with allergic rhinitis and/or hay fever.

2. Patients with poorly controlled asthma symptoms are subject to the following criteria:

- Diagnosed with asthma
- Aged 17 or more
- Attend their AARs
- And have poorly controlled asthma symptoms with respect to the following:

  ACQ score less than 20, using more than six reliever inhalers in the last six months and/or prescribed no ICS inhaler.

3. Patients with controlled asthma symptoms are subject to the following criteria:

- Diagnosed with asthma
- Aged more than 17
- Attend their AARs
- And have controlled asthma symptoms with respect to the following:

  ACQ score of 20-25

4. Patients who do not attend their AARs.

Patient referral and invitation

Patients with controlled asthma symptoms:

Patients with controlled asthma symptoms will be referred to the community pharmacy by their GP to have the intervention every six months. Patients will be invited by a letter that includes details regarding the intervention and their details will be shared with the community pharmacists. The patients are free to accept the invitation and visit the community pharmacy for an appointment or refuse to have the intervention and use their usual care.

Patients who have risk for a future asthma attack:

The GP practice will create a list of patients with poorly controlled asthma symptoms and refer them to community pharmacy by sending them a letter to book an appointment when they feel that their symptoms might deteriorate. Moreover, patients who need seasonal care, for example, those with allergic rhinitis will be notified by the walk-in clinic and can refer themselves to the community pharmacy for an intervention if they need it.

Patients who do not attend their AARs:

The GP practice will create a list of patients who do not attend their AARs and refer them to community pharmacy by:

1. Sharing a list of the identified patients and their contact details with the community pharmacy. Consequently, the community pharmacist will invite them for a review in pre-booked appointment clinic by letter and notify them that they can visit the drop-in clinic at any time if their symptoms change.

Or 2. Writing a message on the electronic prescription indicating that those patients do not attend their AARs and require a review. Consequently, the community pharmacist will be able to invite patients for a review when they pick their prescription and notify them that they can visit the drop-in clinic at any time if their symptoms change.

Sharing information with community pharmacy

A list of those patients will be shared electronically with the community pharmacy that contains their demographics and referral number for each patient to be used in future communication between the community pharmacist and the GP practice. This will ensure that community pharmacists can contact patients' GPs for information and/or clarifications and share any intervention provided to them and the GP can co-ordinate the care provided to those patients.

Clinic

The clinic will provide drop-in and pre-booked appointments to provide flexible appointments within the community pharmacy resources and time restrictions.

Walk-in clinic

A one-day clinic for patients who refer themselves or have been referred by the GP. Those patients will be able to visit the pharmacy outside the clinic hours if needed but they might need to wait. Patients will share the letter that was used to invite them with the community pharmacy so community pharmacists can check that the patients' name is on the referral list. Patients who refer themselves will provide some information to the community pharmacist so they can identify them on the list.

The intervention provided will be tailored to patient needs:

- Patients with allergic rhinitis and those who need seasonal care will be provided with:

1. Prescription of an allergy medication if needed.

2. Medication adjustment if needed.

3. And/or self-management to reduce the effect of their asthma triggers.

Those patients will still be able to refer themselves to the clinic when their symptoms deteriorate.

- For patients with poorly controlled asthma, the intervention will focus on:

1. Education on medication adherence if they were using more than six reliever inhalers in the last six months.

2. Inhaler technique check using inhaler In-Check device.

3. Check appropriateness of the inhaler device and if they need a spacer.

4. Ask patients if they need further support with their AAP.

Pre-booked appointment clinic

One-day appointment clinic that provides appointments for asthma patients. The clinic will involve appointments in the out of work hours, early in the morning or after 5pm.

- Patients who do not attend their AARs will be provided with:

1. A review of patients' medication. The community pharmacist will conduct medication dosage changes but cannot change the medication.

2. Inhaler technique check using inhaler In-Check device.

3. An update or provision of an AAP.

- Patients with controlled asthma will be targeted by

1. A review of their medication to decrease the dose if needed (stepping down to decrease side effects).

2. Review their inhaler technique if the patients have asked for it.

3. Patients will be reviewed every six months as long as they have not required referral to the GP practice or had an asthma attack.

Referral to other services or GP

- Patients will be referred to the GP practice if the community pharmacist finds that they need to be prescribed a new medication or that their medication requires change.
- Patients who are smoking can be referred to a smoking cessation service.

Follow-up

Patients who required medication dose adjustment will be followed up with an appointment after one month and will be advised to visit the drop-in clinic if they need help or a telephone consultation, based on their preference, but it has to be within the clinic's opening times.

Pharmacist's access to data

The pharmacist can collect patients' data by different methods depending on the referral pathway. Patients who will be referred by their GP practice by letter will be asked to take the letter with them to the community pharmacy because it will contain the required data.

If patients referred themselves, the community pharmacist will contact the GP practice before the appointment to get their data, if they consented.

The data required include:

1. Demographics of patients including name, age, postcode and referral code. The contact details will be shared for patients who do not attend their AARs.

2. List of patients' medications including the name, strength, form, dose and frequency.

3. When they last attended their AAR.

4. The presence of other comorbidities including allergic rhinitis and depression.

5. Smoking status.

6. History of asthma attacks if patients were attending their AARs.

7. Contact details of a practice nurse or pharmacist in the GP practice that the community pharmacists can contact for enquiries and support.

The community pharmacist will ask patients themselves if they have an AAP or not.

Feedback

The GP practice will be notified regarding patients who referred themselves to community pharmacy, other patients who have not been provided with asthma intervention in community pharmacy will continue with their routine care.

Patients' data and the intervention will be filled into PharmOutcomes to be shared with the GP practice. If the community pharmacy and/or GP practice does not have access to PharmOutcomes or another IT infrastructure, a paper form of the service will be filled in and shared with a referring HCP using NHS secured email system.

Funding

Both the GP and community pharmacy will be paid for the intervention. The funding should include a setup fee for the intervention in community pharmacy to cover the training of the pharmacists and any other fees.

Implications for GP practices

The intervention will not replace the GP practice but it might allow cross-sector work in supporting asthma patients. Moreover, it might help in the provision of proactive and preventive care approaches.

The GP practice will be provided with feedback regarding the intervention provided to the patient. Additionally, the community pharmacist will contact the referring HCP for additional information or clarification if needed.

Implications for asthma care in adult patients

The intervention is evidence-based and this was discussed in Table 8-3. The intervention involves multidisciplinary work that involves community pharmacists and HCPs based in the GP practice.

Moreover, the intervention supports the provision of preventive care for asthma patients by providing an intervention for patients with risk for an asthma attack and proactive care by allowing patients to refer themselves to community pharmacy for an intervention in the season when their asthma symptoms deteriorate. Additionally, it allows for self-referral of patients, which enhances the person-centeredness of the intervention.

The rationale of the intervention is:

1. Protecting asthma patients with a risk for a future asthma attack from having an attack.

2. Providing patients with asthma with an additional contact point in community pharmacy. This will help to utilise the less stressful environment (for patients) of community pharmacy and might increase engagement in patients who do not attend their AARs and those with comorbid depression. Moreover, patients will be able to seek urgent advice from their a HCP when needed.

3. Enhancement in inhaler technique in asthma patients by conducting a further check in community pharmacy that utilises an inhaler In-Check device rather than a verbal check. This might have an effect on those who do not use their inhaler correctly because currently the inhaler check is conducted in the GP practices as good practice but not a QOF requirement.

4. Increase the provision and ownership of AAPs in asthma patients.

5. Enhancement in the provision of smoking cessation advice for asthma patients.

6. Decrease unwanted medication side effects in patients with controlled asthma symptoms by stepping down their medications if not needed.

8.6 Discussion

The HCPs interviewed in this phase agreed that a community pharmacy-based asthma intervention that is tailored to the needs of asthma patients might benefit the patients and decrease the workload of the GP practice. These findings agree with evidence on utilising community pharmacy in supporting patients with LTCs and the CPCF and NHS FYFV (42, 45, 46, 65, 133, 256)

Being easily accessible, with 89% of the population in England being within 20 minutes walking distance, and having a less formal and convenient environment (55), could encourage patients to engage with interventions in community pharmacy, as perceived by patients and HCPs in phases 1 and 3. Moreover, the provision of a community pharmacy-based asthma intervention may help to decrease the workload on the GP practice and release appointments to be provided to other patients that cannot be seen in other healthcare settings (208). Furthermore, a well-established relationship between community pharmacists and patients could be utilised to improve asthma patients' engagement with their asthma services (52). A relationship of trust between patients and community pharmacists was mentioned by participants in phases 1 and 3.

According to the findings of the interviews, three groups of asthma patients were identified as groups of patients that can benefit the most from a community pharmacy-based intervention that is tailored to their needs. Those groups included: asthma patients who do not attend their AARs, patients with controlled asthma and patients with high future risk for an asthma attack. Additionally, the findings of this phase were used to describe a possible intervention using a visual model for clarity.

The intervention suggested referring patients from the GP practice to community pharmacy, based on the HCPs' suggestions. This will not only help in patients' identification but it might allow the GP practice to share patients' data that can be utilised to deliver the intervention. Moreover, it will help to overcome the limited ability of community pharmacists to identify all patients who are eligible for the intervention using their dispensing records and save their time, as perceived by HCPs in phase 5.

Referral of asthma patients from their GP to community pharmacy for an asthma review was done before in England (80) by sharing a list of asthma patients who need a review and in Scotland (77) by writing a message to the community pharmacists on the prescription. The review was delivered to patients in community pharmacy (77, 80). However, barriers for implementation of the intervention were highlighted including workload on community pharmacy, lack of communication with the GP practice and lack of compatible clinical databases between the GP practice and community pharmacy (77, 80). Similar barriers were highlighted in this phase that was conducted in the North West of England, along with low engagement with community pharmacists and willingness of the GP to refer patients to community pharmacy.

Additionally, using a self-referral pathway with patients who have a risk for an asthma attack will provide those patients with the opportunity of getting help in community pharmacy besides what they get in primary care. Although self-referral can improve asthma patients' access to the intervention in community pharmacy and enhance the person-centeredness of the intervention, it might be overused by patients. Self-referral to interventions tends to attract worried well patients (277, 278).

After being referred, the patients will be provided with the suggested asthma intervention that is tailored to their needs. Booking an appointment for patients who need it is quite challenging in community pharmacy unless there is supporting staff. This highlighted that the ease of access to community pharmacy to pick a prescription does not mean that community pharmacists are available any time to provide interventions. The workload on community pharmacy as well as time and funding limitations might affect the community pharmacists' engagement with the intervention (57, 77, 80).

To decrease the time needed to deliver the intervention. The suggested intervention included the identification of patients in the GP practice and the sharing of their information. Additionally, identifying patients based on the inclusion criteria described earlier in the description of the intervention will provide community pharmacists with an idea about the main focus of the intervention

before meeting the patient. This might overcome barriers in other asthma interventions that were included in the literature review, which required the community pharmacists to survey the patients or use a validated tool to be able to identify their eligibility for the intervention. Additionally, in some asthma interventions in the literature review, the interventions involved many visits and the first one was to assess the patients' needs, asthma symptoms control, medication use and if they attend their AARs or not. In the suggested intervention in this chapter, the time needed for the intervention will be reduced by sharing patient's information with the community pharmacy. This time can be invested to allow the patients to express their needs during the appointment rather than collecting their clinical data.

Although HCPs and patients appreciate the advantages of continuity of care, GPs sometimes found it challenging to provide continuity (279). If funding and supporting staff were available for community pharmacy, a community pharmacist will be assigned for the intervention, which can help to enhance the continuity of asthma care in those patients, which in turn will strengthen the relationship between patients and community pharmacists, quality of care and enhance patients' engagement with their care (279). However, this might be more difficult to ensure in chain pharmacies compared to independent pharmacies, as perceived by community pharmacists in phase 5.

Like any intervention, there are barriers to its provision and implementation. However, identification of these barriers in the development stage might help to overcome those barriers or limit their effect on the implementation of the intervention (57, 82, 85). The intervention will involve changing medication dose, prescribing allergy medications and the provision of an AAP by community pharmacists rather than referring patients back to GP as in the MURs or Asthma referrals service. This can overcome the issues with the MURs, in which patients were referred back to their GP and this increased the workload of the GP practices (57, 255). Therefore, there was a low engagement of the GPs with the MURs and this was considered one of the main reasons that led to the decommissioning of the MURs (57, 255).

However, medication changes by community pharmacists might require full access to patients' records and training for community pharmacists (46), this agrees with the findings from this phase. In this phase and phase 1, participants suggested that the asthma clinic could be run by an independent prescriber to ensure safety when conducting medication changes. Another suggestion was the

availability of two community pharmacists during the opening hours of the clinic. To ensure availability for the clinic and the pharmacists who run the clinic, they will be provided with appropriate training. However, the latter suggestion requires the provision of proper training to the community pharmacists to deliver the intervention safely.

To implement an asthma intervention in community pharmacy successfully, there should be well-established referral and feedback pathways. In his review, Smith (56) discussed the need for the 'connected community pharmacy', where community pharmacies use electronic communication between themselves and other healthcare settings, and to refer patients to community pharmacy. The participants in this phase suggested that using the current NHS secured email system might facilitate communication between the community pharmacists and GPs. However, this email system is not followed up regularly by the GP practices, as perceived by the participants. Based on this, the secured email system may require enhancement to be an efficient method for communication between the GP practice and community pharmacy.

According to Smith's review (56), there is a need for utilising or developing a compatible clinical system for community pharmacy and GPs. This might facilitate the participants to ensure that the feedback provided to them from community pharmacy is compatible with the QOF. The participants who were based in the GP practice in this phase felt that if they refer asthma patients to the GP practice, they might not be able to achieve the QOF requirements for asthma. Therefore, a compatible system in community pharmacy and the GP, and sharing feedback, might overcome this issue.

Web-based pharmacy service applications have been developed and implemented in community pharmacy to enhance information sharing between the GP practice and community pharmacy (56). For example, PharmOutcomes (71), which allows community pharmacists to record any interventions provided to the patient and then transfer them to the GP practice, such as the administration of a flu vaccine (56). PharmOutcomes was used for the recording of asthma reviews in patients who do not attend their AAR, which notified the patients' GP practice if they received the review in community pharmacy (80). PharmOutcomes is being used in CPCS and DMS to share information with community pharmacy.

In Murray's review in 2016 (46) and the recent CPCF (65), it is suggested that the introduction of technology for dispensing would help to expand the role of community pharmacists. This could

decrease the time and efforts spent by the community pharmacist on dispensing, allowing them to provide services to patients with LTCs and other illnesses (46, 65). Another use of technology is to monitor patients remotely as shown in the findings of this phase (204). It may help to capture the full picture of the asthma condition in each patient, followed by the provision of support to patients based on their needs (16, 204).

During the pandemic, GP practices moved to a total triage system that utilised online or telephone methods to refer patients to other healthcare settings for treatment. Furthermore, the GP practices' priorities were to deliver all care remotely, and to provide support for patients at high risk for COVID-19, including patients with respiratory conditions, for example, those with asthma or COPD (86).

8.7 Implications for thesis

The possible intervention that was described in this chapter resulted from the findings of the triangulation of the findings of phases 1, 2 and 3 and the interviews with HCPs in phase 4. Therefore, the development of the suggested intervention utilised data collected from HCPs and asthma patients using different methods. Although the visual model of the intervention requires further research to be improved and feasibility tested, it can be considered as a starting point for an evidence-based, person-centred intervention for asthma patients in community pharmacy.

Overall, the intervention suggested supports the FYFV aims to improve the management of patients with LTCs and decrease the load on GP practices (32). Additionally, the suggested intervention adopted the vision of the recent CPCF that aimed to enhance the clinical role of community pharmacy in the management of patients with LTCs, including asthma (65, 66). Moreover, the intervention involves communication between HCPs in the GP practice and community pharmacy that supports the multidisciplinary approach for care in patients with LTCs.

This intervention might overcome the limitations of other interventions from the literature review that showed difficulties in patients' identification in community pharmacy and the time required for the identification of patients and delivering the intervention. This might increase community pharmacists' uptake of the intervention. Additionally, the intervention was suggested based on evidence and involved HCPs and patients. Involving patients in the development enhanced the person-

centeredness in the intervention, as well as this the self-referral of patients to enable them to take the lead in their treatment decisions can enhance person-centeredness in care.

Finally, the intervention might not cause a duplication of the work of the GP practice that was considered a limitation of other community pharmacy-based interventions or services.

The next and final chapter will present the overall discussion of the PhD study. It will present insights into methodological limitations and reflexivity. Moreover, it will describe the implications on asthma care and practice, and will end with the implications on research.

9 Discussion

This chapter will discuss the overall findings of the PhD study. It will start with an introduction that will summarise the PhD study and main findings, then it will discuss the strengths and limitations; implications for asthma care and practice; the reflexivity; and implications for research. Finally, it will end with a proposal for future work.

9.1 Introduction

The overall aim of the PhD was to explore how community pharmacy can enhance asthma care in adult patients and suggest solutions to enhance asthma care. To achieve the aim, five objectives were identified and guided the research conducted.

The first phase of the PhD aimed to explore HCPs' and service commissioners' perspectives on the management of asthma in adult patients. The aim was achieved and participants in phase 1 highlighted challenges with asthma management and made some suggestions on the opportunities to enhance asthma management. The first phase was followed by a quantitative phase that aimed to assess asthma management in a general practice in the North West of England. Phase 2 highlighted issues with asthma management in the study sample and showed the importance of conducting checks of patients' records. Although the generalisability of the findings of phase 2 was limited and cannot be extrapolated to more than the study sample, it highlighted issues with the provision and recording of AAPs and inhaler technique in the study sample. Those were highlighted in the Asthma UK annual surveys as issues with asthma care in the UK (8, 17, 18).

A purposive sample of patients in phase 2 was selected and interviewed in phase 3 to explore their experiences with their asthma management. Asthma patients in phase 3 expressed their thoughts and perceptions on asthma management and highlighted opportunities for community pharmacy to enhance asthma management. Although all patients were from one GP practice, the sample included patients of different ages and having different comorbidities, which enriched the dataset. Moreover, the sample included patients who changed their GP practice and those highlighted issues with inequity in care provision in different GP practices. Finally, phase 3 helped to include patients' voices in answering the research question on how community pharmacy can enhance asthma care in adult patients.

Overall, the three phases provided multi-perspective insights into asthma management using quantitative and qualitative methodologies.

In phase 4, triangulation protocol was used to triangulate the findings from phases 1, 2 and 3. The triangulation identified patients who need support with managing their asthma and recommendations to enhance asthma management that were collected from the three phases. Due to the limited generalisability of the sample in phase 2, the findings were used to support those from phases 1 and 3.

In phase 5, the HCPs' feedback was utilised to identify inclusion/exclusion criteria for patients who can benefit the most from support in community pharmacy. Moreover, the findings of the interviews highlighted enablers for asthma interventions in community pharmacy and how community pharmacy can enhance asthma care in those patients.

The findings of the triangulation, literature review and of phase 5 were used to answer the research question: How can community pharmacy enhance asthma care in adult patients? The answer was:

1. Enhancement in the provision of the NMS to asthma patients. This might be achieved by enhancement in the referral of patients from the GP to community pharmacy.

2. The core findings were utilised to propose a visual model of a possible asthma intervention in community pharmacy.

The suggested intervention is evidence-based because it utilised evidence from the three phases and person-centred because it involved patients in the development of the intervention and utilised their perceptions and thoughts. Moreover, the intervention will help to enable patients to self-manage their asthma by allowing them to refer themselves and seek help when they think they need it. Finally, the intervention adopted a proactive and preventive approach by allowing patients to visit the walk-in clinic for deterioration of their symptoms.

As with any community pharmacy-based intervention, this intervention has its own limitations. There is a need to share the intervention with stakeholders before feasibility testing. Additionally, there is a need to develop proper training for the community pharmacists to ensure patients' safety in delivering the intervention. For community pharmacy to be able to deliver the intervention, they need a consultation room and IT infrastructure to share feedback with the GP practice, for example, PharmOutcomes.

9.2 Strengths and limitations

The Mixed methods research that was used in this PhD study strengthened the overall methodology as discussed earlier in chapter 3. Using Mixed methods research in this PhD allowed the researcher to overcome the limitations and weaknesses of each methodology, however, it has its own limitations.

Mixed methods research can be **time-consuming**, particularly in the process of design and conduct of the different research phases (152, 160, 161, 168). This was addressed by developing a

well-structured research protocol for the five phases before conducting the research, along with a timeline for conducting the research and writing the results (160). Both the research protocol and timeline were reviewed continually during the PhD study to address any issues that arose during the research.

Another limitation was **the training** required for the researcher to improve her skillset toward interviewing skills and qualitative and quantitative data analysis (160). However, training needs were identified at the beginning of the study and were incorporated into the study timeline. Improving the researcher's skill set was essential to ensure good quality research throughout the study. Finally, the support that was provided by the supervisory team members, who had both qualitative and quantitative knowledge and experience, ensured that the research was conducted in line with normal practice to ensure trustworthiness in the overall findings (160).

Furthermore, the participant sample that was recruited through the different phases of the PhD study included a range of HCPs, commissioners and asthma patients. This allowed the integration of different perspectives to answer the same research question, which ensured the robustness of the research methodology (145, 194, 264). The researcher strived to recruit participants from different backgrounds to enhance the quality, richness and trustworthiness of the data collected (145, 194). Moreover, HCPs were recruited in phase 5 to assess the findings of the research and include their perspectives on the final findings and conclusions of the study, supporting the robustness and trustworthiness of the research methodology (191, 264).

For this reason, the findings for each phase of the PhD study were triangulated, then the findings of triangulation were reviewed by HCPs in phase 5 (168, 264). In addition, the discussion of the findings throughout the thesis was conducted in a way that provided evidence without judgments about the transferability of the findings between different settings or different situations (145, 165, 194). The limitation of triangulation will be discussed below.

9.2.1 Triangulation

One limitation was in the mixing of the qualitative and quantitative data and triangulating the findings of the 3 phases in phase 4. This required further efforts and critical thinking to develop links and connections during the comparison of the results across the phases (168, 264, 280). A monthly meeting was held with the supervisory team to discuss the findings and highlight the main points that could be addressed in the next phases (165, 263). This helped to enhance the integrity

of each phase alone but the phases were still connected to some point (165). For example, phases 2 and 3 were connected and the sample for phase 3 was identified during the data analysis of the data collected in phase 2.

Using triangulation as a methodology has it is own limitations. In this phase, the triangulation protocol was used to connect the findings from the three phases and allowed for comparison of the findings from the qualitative and quantitative data from the three phases (168, 264). The comparison showed complementarity in the findings of the three phases that was shown by the occurrence of agreement and partial agreement in more than half of the themes (168, 264). The partial agreement was related to differences in perspectives of participants across the phases, which allowed for the expansion of the findings. Triangulation allowed the researcher to enhance and broaden the interpretation of the findings (168, 264). For example, the findings from the case note review showed that some asthma patients were not attending their AARs and this supports the findings from phase 1 that there is a cohort of asthma patients who need support to enhance their engagement.

The occurrence of silence in the findings was expected because of the scope and nature of the data collected in the three phases. Therefore the triangulation protocol was selected because it allows for comparison of the presence of the findings in different data sets and uses silence code to show that some findings were in some of the datasets (168, 264). The silence has helped to explain some of the findings. For example, patients with comorbid allergic rhinitis expressed that they need further support but this was absent in phase 1. This indicated that those patients have issues with their asthma that might not be recognised by HCPs. However, this might be related to the limited representativeness of the sample of phase 1.

The researcher aimed to select the appropriate method for triangulation and displayed the findings in transparency to ensure the trustworthiness of the findings (168, 263, 264). Additionally, to enhance the trustworthiness of triangulation, the researcher conducted several strategies to ensure the trustworthiness of the data collected across the three phases (165, 263). The steps of triangulation were presented in the findings to enhance the credibility and trustworthiness of the findings of triangulation (168, 264).

Additionally, to enhance the trustworthiness of triangulation, the researcher should ensure the trustworthiness of each of the methodologies used in data collection (165). In the five phases of the

PhD, the researcher aimed to enhance the quality of data collected by many strategies that were discussed in each phase (152, 165, 194).

Moreover, during triangulation, the researcher should be aware of the different weights of the data from different resources (263). In this PhD study, the quantitative phase had less weight across the phases because of the limited sample number and the expected absence of findings that are related to community pharmacy. The other two qualitative phases were treated the same because both phases explored asthma management in adult patients. Although phase 1 involved more participants than phase 3, this was not considered a limitation because the two phases involved different participants.

There were limitations in each of the phases and triangulating the data from the three phases helped to broaden the knowledge resulting from the three phases (168, 263, 264). This is because phases 1 and 3 provided insights into HCPs and patients' views that were supported by quantitative data from a GP practice in the same region. However, the findings are still limited because the three phases were conducted in a limited geographical area.
The following sections will discuss the strengths and limitations in the sampling and data collection of the PhD study.

9.2.2 Sampling

Phase 1

Qualitative research helps to give an understanding of the experience of people in providing or receiving health care for LTCs (247). Therefore, phase 1 involved HCPs and a service commissioner to provide insights into asthma management from the experience of the professionals and patients themselves (247). Although the researcher strived to recruit a range of participants of different perspectives to enhance the representativeness of the sample (145, 194), neither a GP nor a nurse was recruited. However, some of the participants were based in the GP practice, so they provided some information and discussed issues regarding the GP practice services provided to asthma patients. These factors might limit the transferability of the findings to other regions in the North West of England (191, 194), however, an inherent limitation of qualitative research is that it is difficult to generalise the findings to a wider region (145). The sample was described to allow the reader to judge the transferability of the findings. Moreover, this might cause non-respondent bias because potential participants who have not been involved in the study might have additional opinions and views that could have affected the findings.

Phase 2

In phase 2, recruiting participants was a challenge. The recruitment limitations, including the sample size, the limited geographical area and the limited representativeness of the sample recruited have restricted the generalisability of the results of phase 2. The limited generalisability was taken into account when writing the findings of phase 2 and during the triangulation.

The sample size was limited because of ethical constraints that required patients' consent to review their records. However, there was diversity in age, gender, comorbidities and AAR engagement. Case note reviews (244, 281) conducted in the UK included more patients but their case notes were reviewed without patient consent because the researchers were NHS workers. One of the studies involved a multisite retrospective case note review (281), which was conducted in 2010 to evaluate the prevalence of prescribing and monitoring errors in general practices in England. In this case note review, the time frame of the study also limited the ability to collect data from multiple GP practices. Moreover, conducting the case note review in more than one GP practice might cause bias or missing data because of the differences in clinical databases across different GP practices.

The small sample number limited the representativeness of the sample (238). This was shown in the results where a high number of the participants needed a review, needed referral or have been referred to secondary care. The low participation of asthma patients in this phase has limited the representativeness in the sample and caused response bias and non-response bias. The researcher missed the opportunity to review the medical records of those who had not responded and who might have enriched the data set because they might be different from those who participated in the study.

Additionally, the process of recruitment might have caused bias because patients who had not responded were re-invited to participate by different methods. Among those who had been called over the telephone, 171 participants declined to participate. On the other hand, most of the consent was obtained by letter invitations. This might be because the participants read the invitation letter and the study information sheet on their own time, unlike in the phone calls.

Phase 3

Phase 3 was carried out in a single region; all of the participants were recruited from one GP practice only and this limited the transferability of the findings. On the other hand, conducting the research locally allowed the researcher to conduct more face-to-face interviews.

Although the sample of participants interviewed in this phase showed some variability, the limited sample number of participants who consented to participate in phases 2 and 3 restricted the representativeness of the sample. This limitation might have been overcome if patients were invited separately for phases 2 and 3 and not simultaneously. However, inviting patients for the two phases in one invitation was thought to be a convenient option for patients and the GP practice administration staff and it helped to decrease the cost of recruitment. Additionally, potential participants who had not consented to participate might have caused non-respondent bias because those patients might have different experiences and views that could have enhanced the richness of the findings in phase 3.

Phase 5

The final phase involved a small sample of six participants; however, the participants represented a range of HCPs in the primary care team who were based in the community and GP practices. Purposive sampling was followed in phase 5. Although the sample size was small, it was appropriate to achieve the aim of phase 5 to get feedback on the groups of asthma patients.

Moreover, some participants were already interviewed in phase 1 and this might affect the representativeness of the findings, however, this phase aimed for a better understanding of asthma patient groups and how they could be supported in community pharmacy. Additionally, this might have limited the representativeness of the findings and caused bias because participants will have the same perceptions and might tend to confirm their previous opinions in phase 1; however, respondent bias was limited by using open-ended questions.

Another type of bias from participants might be non-respondent bias, where the opinions of those who have not participated in the research might cause a difference in the findings. However, a GP and nurse were interviewed to explore their perceptions to overcome the limitation of the sample in phase 1 that had neither a nurse nor a GP.

9.2.3 Qualitative data collection

Qualitative interviewing has a risk of bias from the interviewer (145, 194). In this case, the interviewer had the experience of working in a community pharmacy, which could lead to possible bias during the data collection and analysis. This was overcome by many strategies that were discussed in phases 1, 3 and 5. The researcher aimed to minimise this risk of bias as much as possible. During the interviews, the researcher maintained a neutral manner and avoided using

leading questions and prompts (145, 194). The researcher's background as a pharmacist helped her to understand the terminology used by the stakeholders during the interviews in phases 1 and 4. However, the researcher's influence on the findings was acknowledged by introducing reflexivity in the qualitative phases to enhance the trustworthiness of the findings (173, 192, 196, 197).

To further minimise the risk of bias, regular meetings were held with the supervisory team that included pharmacists from different backgrounds to discuss methods of research, analysis and the findings. This helped to integrate different perspectives and viewpoints during the research process. Additionally, when interpreting the findings, the researcher linked the findings to published evidence to enhance its trustworthiness (145).

Using both face-to-face and telephone interviews in phases 1 and 3 may affect the quality of the findings due to the loss of non-verbal data and the difficulty in building rapport in telephone interviewing (248). This was overcome by the researcher making every effort to build trust and rapport with the participants to decrease response bias, regardless of the interview method (248). In phase 1, some of the telephone-interviewed participants were distracted as they were interviewed during their lunch break, in their busy work environment and in one case, at a train station. This was a limitation, but the participants were busy due to their work commitments. However, telephone interviewing is considered to result in a rich and detailed data set because participants might be more relaxed during the telephone interview (248)

All the interviews in phase 5 were conducted over the telephone in compliance with the social distancing guidance implemented across the UK due to the COVID-19 pandemic. Conducting the interviews over the telephone may affect the data collected because it is harder to build trust and rapport with the participants through this method; however, the researcher strived to gain the participants' trust during the interviews. Additionally, some of the participants in this phase were interviewed in phase 1 so an established relationship existed which helped to elicit full and rich responses.

Response bias was decreased by using semi-structured interview schedules in the qualitative phases to ensure that all the questions were asked clearly (145, 152). Moreover, the interview schedule was discussed with the supervisory team to ensure that no leading questions were included. Not all participants answered all of the questions and not all participants showed the same articulation and involvement. This could cause some response bias (152, 282). To overcome

this, the researcher asked extra prompts or rephrased the questions if appropriate to assist the participants to answer.

Additionally, as English is not the first language of the researcher, this could have affected the wording of interview questions, communication with the interviewee and the validity of data collected. This was overcome by using a semi-structured interview schedule, conducting a pilot interview to test the language clarity and the validity of the questions, rephrasing the questions before starting the interview and using prompts for better understanding. Although the researcher was familiar with the expressions and terms related to the interview topics, the researcher discussed any unfamiliar expressions or wordings with the supervisory team after the interviews to gain a better understanding.

9.2.4 Quantitative data collection

In the quantitative phase 2, the researcher used a data collection tool and predefined variables to collect the data that helped to enhance the reliability of the findings (152, 165, 263). To the best of the researcher's knowledge, this is the first case note review of asthma patients' medical records that was conducted in the North West of England. A major strength of phase 2 was that it involved a detailed review of asthma management in the GP.

Although retrospective case note review is a popular methodology in healthcare research including quality assessment, epidemiology and clinical research, the majority of studies that used this methodology have not followed methodological standards in conducting or reporting the case note review (238). Using a systematic process for the case note review strengthened the study and improved its robustness and consistency (152, 238). Moreover, a retrospective case note review is considered a straightforward method to collect a large data set within a limited budget (217). Using routinely recorded data as a source of data may not be reliable (217, 226), however, this was overcome by selecting a GP with a relatively high Quality Outcomes Framework (reward system for general practice achievements in the UK) achievement of 100% in asthma (229) to ensure the usefulness of collected data (217, 226).

Another limitation was the validity of the data collected, which was ensured by using a validated data collection tool as discussed earlier in chapter 5 (see section 5.3). The development of a data collection tool and abstraction method allowed the researcher to extract the data accurately from the records (217, 238). As well as this, the abstraction of the data using the developed data

collection tool and according to the definitions of the variables of the tool enhanced the reliability of the data collected (217, 238). Conducting a pilot to detect any inaccuracies before completing the data collection and reviewing the records by one researcher only, enhanced the reliability of the case note review (217, 238). The data and variables collected were influenced by the PRIMIS Asthma Quality Improvement Tool, which allowed the presentation of the variables in the form of categorical variables rather than numerical variables. The categorical variables allowed assessment of the variables to decide whether the targets for an asthma review, medication use and other variables were met or not, but some information was lost. However, it is a suggested approach to enhance the reliability of the data collected in case note reviews (226).

9.2.5 COVID-19 lockdown

Conducting and writing research during the lockdown affected this PhD study. The lockdown restrictions limited the researcher's ability to recruit more patients for the case note review from different GP practices as discussed earlier (in section 5.3.3). Moreover, no patients were interviewed in phase 5, although their consent was already obtained.

In addition to the pandemic's effect on the sample sizes for phases 2 and 5, it affected the researcher personally. The researcher experienced the lockdown in the UK without any kind of social or family support. Although the researcher overcame many barriers during her PhD journey as any international PhD student, conducting the final phases of the PhD during the pandemic was an extraordinary situation. The researcher faced many challenges, for example, setting up a work area in the house, limited access to data, library sources and other technical issues.

Being isolated from friends, colleagues and face-to-face support from the supervisory team made the final year of the PhD study more challenging than expected. The researcher missed the chance for those quick discussions with colleagues and the supervisory team during lunchtime, in the lift or even at the end of a formal meeting. Although the regular supervisory team meetings were conducted using Microsoft Teams, the researcher missed many of the advantages of the face-to-face meetings and had to cope with the new situation. Additionally, the researcher missed the opportunity for discussing her thoughts and knowledge with other researchers.

All those missed opportunities and challenges had an impact on the researcher and the PhD study, however, it provided the researcher with the opportunity to develop her skills to work remotely and utilise virtual resources, such as; becoming more knowledgeable about how technology can

support this work in unusual circumstances; navigating and problem-solving concerns in a virtual format; and becoming more resourceful in accessing materials to support this project.

9.3 Reflexivity

In qualitative research, the researcher is part of the research process as their interests, preconceptions and values continually affect the collected data (196). Reflexivity was used in the PhD study to improve the trustworthiness of the findings (173, 196, 197). The researcher reflexivity was introduced in the qualitative data collection and interpretation of the findings. Being reflexive and understanding how the researcher's values and perceptions could affect the findings of the qualitative research, enhanced the credibility of the research (152, 196). As discussed in chapter 4, the researcher kept a research diary to record her thoughts and self-reflection. The research diary helped the researcher to be aware of her self-reflections during the research process. Consequently, the influence of the researcher and the bias of her self-reflection were reduced as much as possible.

Phase 2 was quantitative and the researcher used a validated tool for the data collection to ensure that the variables collected were based on evidence and not on the preconceptions of the researcher. The researcher strived to be neutral while drawing conclusions based on the findings. Moreover, a sample of patients was selected from this phase to be interviewed in phase 3. The purposive sample of patients selected in phase 3 was informed by the findings of the literature and phases, not the preconceptions of the researcher.

In phase 3, the researcher used the skills she learned in phase 1 to build trust and rapport with patients at the beginning of the interviews. Although the researcher had a background regarding each patient based on the data collected in phase 2, she showed openness and respect to patients' perceptions, feelings and experiences. Additionally, the researcher utilised the experience of qualitative data collection used in phase 1 to ensure the trustworthiness of phase 3.

In phase 5, the qualitative interviewing skills of the researcher were improved through the PhD study and that helped her to conduct this phase with confidence. Although the interviews were conducted over the telephone, the researcher found it easier to build trust with the interviewees in this phase because of the improvement of her skills. Furthermore, the researcher was neutral and showed openness to stakeholders' perceptions during the interviews.

The PhD study allowed the researcher to develop her qualitative research skills gradually throughout the phases of the study; introducing reflexivity into the research helped her to improve her qualitative knowledge and skills to collect and analyse qualitative data.

9.3.1 What could have been done differently?

Overall, the PhD study provided evidence to propose a possible community pharmacy-based asthma intervention that utilises community pharmacists and HCPs in the GP practice to support asthma patients. The methods selected for this PhD study were considered appropriate and feasible to complete the research within the time frame of the PhD study. Additionally, the limitations were highlighted for each phase and the overall study in this chapter and were taken into consideration while interpreting the findings. However, different methods or further investigation could be applied to address the same research question.

- I could have not used convenience sampling in phase 1 because it limited the representativeness of the sample and transferability of the findings. Instead, I could have used a purposive sampling strategy to ensure that the sample includes nurse(s) and GP(s). Nevertheless, GPs and nurses were invited to participate in the phase, some of them did not respond and others rejected the invitation to participate.
- Further information regarding the assessment of the management of asthma could have been collected in phase 2. A larger number of medical records could have been reviewed in phase 2 if it were conducted by an HCP in the GP practice, who is known by the patients and whom they could trust to access and use their data for research purposes, rather than the researcher. However, this option was limited to ensure that the PhD study was conducted independently by the researcher herself (171).

- Clinical Practice Research Data (CPRD) (283) is another approach that could have been used to collect asthma patients' data in phase 2 rather than the retrospective case note review. Although the CPRD could allow for reviewing data for a very large sample of patients, the case note review allowed the researcher to look directly at individual records and this cannot be conducted using the CPRD (283). Another limitation for using CPRD in reviewing asthma patients' records is the difficulty of obtaining some of the data, for example, data regarding attendance of patients in their AARs, AAPs, answers to RCP questions and inhaler technique check. The primary care data that can be collected from CPRD includes demographic characteristics, diagnoses and

symptoms, drug exposures, vaccination history, laboratory tests and referrals to hospital and specialist care (283). However, the use of CPRD might facilitate the data collection regarding secondary care use because the CPRD provides direct linkage between primary care data and other datasets including hospital care (283).

- The Pen Portraits could have been introduced earlier, for example, after phase 1 and used as an analytical framework that could have helped more in the identification of those patients and could have strengthened the patients' voices in the research. This is because their perceptions of each of the different groups could have been explored. Additionally, this would have led to the description of the groups in a better way and helped HCPs to perceive those groups.
- To expand the findings and overcome the limitation in the samples. The feedback on the findings of the triangulation in phase 5 could involve a survey and qualitative interviews. This could have helped to get feedback from a larger number of HCPs and allow for deep exploration at the same time. Additionally, a different sample of participants from those who participated in phase 1 could have been used to reduce the risk of bias.

9.4 Implications for asthma care

The findings support that there is a need to enhance asthma care and that the main issues with asthma management are medication adherence and inhaler technique. This agrees with the NRAD report (1), Asthma UK (8, 15, 17) and NICE guidance (12) that focus on improving those two issues.

The participants provided the following suggestions to enhance asthma care:

1. The evidence that resulted from this thesis was utilised to propose a possible community pharmacy-based asthma intervention.

- The intervention involved the suggestion of a walk-in clinic in community pharmacy to provide preventive intervention to asthma patients who are at high risk of an asthma attack. The provision of preventive and proactive care in community pharmacy complies with the priorities of CPCF and NHS FYFV (66, 256).

- Moreover, the intervention utilised patients' voices in the development stage to ensure that it is person-centred and responds to patients' demands (38, 39, 43). Additionally,

the intervention is considered to adopt a person-centred approach by allowing patients to self-refer themselves to community pharmacy.

- The intervention focused on the enhancement of engagement in patients who do not attend their AARs and patients with comorbid depression by offering appointments early in the morning or late in the evening that cannot be offered in the GP practices. Additionally, the intervention will allow those patients who do not engage with their AARs to have an additional contact point in community pharmacy that might help them to respond to changes in symptoms.
- The intervention focused on providing an additional review for patients with controlled asthma symptoms to provide proactive care to those patients and to support the GP with their increasing workload. However, GPs might not be receptive to this approach and might not accept the referral of those patients to community pharmacy. This requires further research to ensure that implementing a service for those patients in community pharmacy will not be a duplication of the work of the GP and cost for the NHS (46, 57, 207).
- The intervention showed novelty in providing support to asthma patients with comorbid allergic rhinitis. Allergic rhinitis is among the comorbidities that are listed by NICE as common morbidities in asthma patients that affect the management of their condition (12).

2. Although the findings of the case note review were limited because of the sample limitations, it highlighted some issues with asthma care.

- The findings showed the importance of conducting regular quality checks of patients' medical records. The new QOF allows the GP practice to check their progress with their QOF outcomes on a daily basis so they can assess their progress with the QOF outcomes for all LTCs daily (274).
- The findings of the case note review highlighted patients who needed a review, the need for enhancement in the provision and recording of an AAP and inhaler technique and the difficulties in identifying patients with controlled or poorly controlled asthma symptoms using the RCP score in the sample. Some of those issues were recently addressed by the new QOF requirements for the year 2021. The QOF outcomes for asthma were updated for 2021/2022 and for the GP practice to earn the points for the AAR, the HCP should assess the patients' asthma control using a validated tool; record the score; and provide and record a written AAP. This update will allow the GP practices

to identify patients with controlled and poorly controlled asthma symptoms and enhance the number of patients who have an AAP among asthma patients. However, there were no updates regarding the inhaler technique check and recording. There is a need to ensure that the inhaler technique is being checked and recorded regularly in asthma patients.

3. Across the thesis, the participants were keen to utilise technology in asthma care, the significance of utilising technology in asthma care was highlighted by the Asthma UK report in 2019 (204).

- According to the participants, asthma care could be enhanced by utilising technology to enhance communication between different healthcare settings that will enhance the provision of co-ordinated care to asthma patients as discussed before in Smith's review (56).
- Moreover, technology can be used in an innovative way in the monitoring of asthma patients. There are smart inhalers that can monitor patients' medication adherence and inhaler technique. One of the existing applications for technology in asthma is the provision of a personalised AAP using specific algorithms that utilises patient data (16, 204). Moreover, technology could be used to improve patient engagement by changing the method of service delivery, which adapts to patients' circumstances and responsibilities (136, 276).

  Those might provide the solution to those two major issues with asthma care that include medication adherence and inhaler technique. According to the participants, community pharmacists might play a role in interpreting the data collected electronically and supporting the patients. However, utilising technology solutions requires data protection, funding and training (56, 204). Additionally, some patients who pay for their prescriptions might not be able to pay for a smart inhaler. One of the goals of the NHS Long Term Plan is to ensure that patients with respiratory LTC are receiving and using the right medication in the right way. To achieve this, the NHS Long Term Plan promised to conduct a pilot to test the effectiveness of using smart inhalers and highlighted that pharmacists might support the uptake of smart inhalers by patients with respiratory LTCs (45, 284).

9.5 Implications for practice

1. The thesis highlighted the need to improve the communication between community pharmacy and GP practice.

In his review, Smith highlighted that community pharmacy is still separated from other healthcare settings (56). Additionally, the thesis supports the evidence from other research (46, 57, 207, 255) that there are barriers for implementation of interventions in community pharmacy that are related to acceptance of the GP to refer patients to community pharmacy and barriers between different professions. Developing such intervention that involves HCPs from the GP and community pharmacists might contribute to dissolving those barriers between the two settings.

2. Referral of patients from the GP practice to community pharmacy.

When first conducting the research for this PhD, there was limited communication between community pharmacy and the GP practice. During the PhD, the CPCF reported changes in the priorities of services in the community pharmacy (65). These priorities were based on enhancing the role of community pharmacy in preventive care, public health and urgent care (65). This was achieved by new services including the DMS and CPCS (65, 66). Both services involve the referral of patients to community pharmacy from other settings.

In 2020, the GP started referring patients to the community pharmacy and PharmOutcomes was used for this purpose and allowed for referring patients and sharing their data. This complies with the findings of the thesis that highlighted the need to refer patients from the GP practice to community pharmacy to facilitate their identification. Difficulties in patient identification and low referral were limitations in the implementation of other services including NMS and MUR (57, 87). This development in the referral pathway can be utilised in asthma patients and other patients with LTCs.

3. This thesis provided evidence for the selection of patients to be provided by an intervention.

The HCPs, service commissioner and patients' views and review of patient medical records were utilised to provide evidence as recommended by the MRC framework (82, 85). Although the limitations in the sample affected the generalisability of the quantitative findings and the transferability of the qualitative findings, it showed that research can be conducted in the development stage to identify inclusion/exclusion criteria of patients who will be provided with an intervention. Moreover, it highlighted ethical restrictions in conducting retrospective case note

reviews for this purpose. Nevertheless, it showed the importance of reviewing patients' medical records in highlighting issues with recording and provision of care in patients with asthma that can be addressed to enhance the care in adult patients. This was shown in the updated QOF for 2021/2022 that allows for a daily update in QOF achievements to allow the GP practice to assess their progress on a daily basis and identify patients who need to be reviewed.

Involving HCPs and patients in the early stages of intervention development agrees with the MRC framework (82, 85). This helped to develop an evidence-based intervention, which is needed for developing interventions in community pharmacy. As shown from the literature review, not all the community pharmacy-based interventions were evidence-based and/or did not involve patients in the development stage.

4. Training needs.

The participants highlighted training needs in community pharmacists that are related to asthma and others that are related to communication and motivation skills. This applies to the intervention developed from the thesis but also to the provision of other interventions that include self-management support and those that aim to enhance patients' engagement (38).

The intervention requires community pharmacists to be able to step up or step down asthma medications. Although this might not be possible to be learned during an online course or workshop and it requires a degree or a qualification, this could be applied easily in the future because of the new changes to the pharmacists' qualification. Newly qualified pharmacists will be able to prescribe from the first day of registration by 2025/2026 regarding the new General Pharmaceutical Council initial education and training standards for pharmacists that was approved in December 2020 (285). Based on this, the provision of medication adjustment in community pharmacy might not be as restricted as now, however, this might require improving community pharmacists' access to patients' data.

5. Enhancement of current services in community pharmacy.

The participants highlighted that the NMS service requires enhancement. According to the participants, the GP must notify patients about the service and refer them to the community pharmacy. This agrees with the NMS evaluation that was conducted in 2012, which showed that 99.6% of conducted NMS were for patients identified by community pharmacy (87).

Recently, the CPCF have made changes to the NMS to involve more patients who can be provided with the service starting from September 2021 (49). Additionally, pharmacists are allowed to provide telephone and video consultations or at home to adapt to patients' needs (49). However, there is still a need to motivate the GPs to refer patients to community pharmacy for the NMS because currently there is no obligation or requirement for the GP to do so.

9.6 Implications for research

The thesis highlighted opportunities for further research to be conducted.

- The literature review showed complexity in the community pharmacy-based interventions and the absence of a structured way to report those interventions. This was overcome in the thesis by using an intervention characterisation tool that was informed by the DEPICT tool (91-93). Future research could be conducted to validate the tool to use for the evaluation and reporting of community pharmacy-based asthma interventions.
- Participants in phase 1 were keen to use technology in the monitoring of asthma patients and to enhance their medication adherence. Asthma UK published the connected asthma report that presented technology solutions to enhance asthma care (204). There is still a need to identify which technology is feasible to be used in the UK (136, 204). More research could be conducted on the cost-effectiveness of the use of smart inhalers and INCA devices in patients with asthma (200, 284). Those might help to enhance patients' adherence to their medication and inhaler technique.

  Additionally, a smartphone app might be used in day-by-day monitoring of asthma and this might help to overcome the limitations in the current validated tools to assess asthma control that depends on patients' memory recall. The data collected can be interpreted by community pharmacists remotely, who can help patients with their asthma remotely. Further research could be conducted to assess the feasibility and cost of such an approach and if community pharmacists can help to facilitate the uptake of technological solutions by asthma patients.
- Conducting a case note review in multiple sites to get better insights into asthma management in the GP practice and to get findings that could be generalised to a broader area. The findings can be used to develop an intervention and to highlight issues that could be addressed to enhance the quality of asthma management and recording, for example,

inhaler technique check. This will help to complement this study and might help to broaden the findings.

9.6.1 Proposal for future research

To evaluate the effectiveness of the proposed intervention, a feasibility study could be conducted in a GP practice and the surrounding community pharmacies.

The Feasibility study will involve:

1. Preparation of the intervention material: invitation letters for patients, feedback forms and referral forms.

2. Training workshops for community pharmacists.

3. Identification and recruitment of patients by the GP practice and referral to community pharmacy.

4. The provision of the intervention in the participated community pharmacies.

The primary outcomes that could be measured include ACQ, to assess asthma control and the number of visits to secondary care. Whereas the secondary outcomes, which could be measured, include medication adherence (by calculating the ratio of reliever to preventer inhalers), inhaler technique assessment (using physical demonstration and inhaler technique checklist) and patients' knowledge and beliefs using a validated questionnaire.

Conducting a feasibility study first could help to explore the logistical issues regarding information sharing between the GP practice and community pharmacy, and the provision of a flexible appointment system in the community pharmacy. Additionally, it will help to evaluate the uptake of the intervention by asthma patients and HCPs.

9.7 Conclusions

Regardless of the limitations of the PhD study, it has achieved its aim. The thesis provided evidence for a possible community pharmacy-based asthma intervention that can be tested for feasibility. The research helped to identify which asthma patients might benefit the most from the intervention using a multi-perspective approach and highlighted training needs in community pharmacists. The intervention is within the context of the MRC framework for intervention development that involves research before feasibility testing of the intervention (82, 85).

Additionally, the thesis provided good quality evidence for other researchers to use and identified areas for future research.

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Appendices

Appendix 1 *Liverpool John Moores University ethical approval for phase 1*

Dear Aseel

With reference to your application for Ethical Approval

REF: 18/PBS/004 - Aseel Mahmoud - PGR – A new care model for asthma patients Phase 1: Face-to-face or telephone interviews with stakeholders to explore asthma management in North West England (Rachel Mullen/Peter Penson)

UREC decision: Approved with provisos

The University Research Ethics Committee (UREC) has considered the above application by proportionate review. I am pleased to inform you that ethical approval has been granted subject to the provisos listed below. Once the final version of the ethics application with the provisos addressed has been emailed to ethicsPR@ljmu.ac.uk, the study can commence.

Provisos:

1.Page 25, Highlight (Yellow):
Content: "to host part of our project within your organisation facilities."
Comment: Please specify whether or not the interviews taking place within the organisation will be during working hours.

Approval is given on the understanding that:

- any adverse reactions/events which take place during the course of the project are reported to the Committee immediately by emailing researchethics@ljmu.ac.uk;
- any unforeseen ethical issues arising during the course of the project will be reported to the Committee immediately emailing researchethics@ljmu.ac.uk;;
- the LJMU logo is used for all documentation relating to participant recruitment and participation eg poster, information sheets, consent forms, questionnaires. The LJMU logo can be accessed at http://www2.ljmu.ac.uk/corporatecommunications/60486.htm

Where any substantive amendments are proposed to the protocol or study procedures further ethical approval must be sought (https://www2.ljmu.ac.uk/RGSO/93205.htm)

Applicants should note that where relevant appropriate gatekeeper / management permission must be obtained prior to the study commencing at the study site concerned.

Please note that ethical approval is given for a period of five years from the date granted and therefore the expiry date for this project will be **9th April 2023**. An application for extension of approval must be submitted if the project continues after this date.

Yours sincerely

Charlotte McLean

LIVERPOOL JOHN MOORES UNIVERSITY
Charlotte Mclean, BA (Hons), MSc
PR REC Manager
(Research Ethics and Governance)
Research and Innovation Services
Exchange Station, Tithebarn Street, L2 2QP
c.n.mclean@2014.ljmu.ac.uk

Appendix 2 *Gatekeeper invitation email for phase 1*

Gate keeper invitation email for phase 1

Subject: Invitation to take part in developing new care model for asthma patients.

Dear (name)

I am a pharmacist currently undertaking research towards a PhD at Liverpool John Moores University, looking to provide evidence for a new care model for asthmatic patients that is built around patient needs and targeted to patient groups.

I am currently recruiting participants for the first phase of the research, which aims to explore the issues concerning the management of adult asthma patients within primary care and identify opportunities for improvement. This will involve a semi-structured, face-to-face or telephone interviews lasting up to 20 minutes. You have been invited to participate due to your experience in commissioning and delivery of adult asthma patients services in the North West of England. Your contact details were obtained via the NHS Choices website.

I have attached a participant information sheet and a consent form. Please take your time to read through the information provided and decide if you would like to take part. You will be contacted after three working days of receiving this email to determine if you wish to participate in the study and to nominate a potential candidate from your staff to participate. If you do agree to participate, you will be required to complete a consent for (copy attached).

Participation is voluntary and I appreciate that you are busy, however developing a new care model for asthma patients is very important to improve the management and control of asthma patients. Your participation will be very helpful.

Yours sincerely,

Aseel Mahmoud

MSc. Aseel Mahmoud
Postgraduate Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 01512312377

Appendix 3 *Gatekeeper information sheet for phase 1*

LIVERPOOL JOHN MOORES UNIVERSITY

Face-to-face or telephone interviews with stakeholders to explore asthma management in North West England

1. What is the reason for this letter?

   You are being invited to assist in a research study. Before you decide it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.

2. What is the purpose of the study/rationale for the project?

   This study will form the first phase of a four phases PhD project. The overall study aims to provide evidence for a new care model for asthma patients that is built around patient needs and targeted to patients groups. This first phase involves a personal interview exploring the issues concerning the management of adult asthma patients within primary care and identify opportunities for improvement. The first phase will also explore stakeholders opinions on the management and control of asthma, identify how asthma management and control could be improved, investigate innovative ways of utilising pharmacy and particularly community pharmacy in the management and control of adult asthmatic patients, and explore opinions on evolving asthmatic Medicines Use Reviews (MURs) and the New Medicine Service (NMS) for asthma therapy into full clinical medication reviews using independent prescribing.

3. What we are asking you to do?

   You are being contacted to nominate the most appropriate person to be interviewed from your staff, to authorise participation to take place and to host part of our project within your organisation facilities during working hours.

4. Why do we need access to your facilities/staff?

   You have been invited to participate due to your organisation role in commissioning and delivery of adult asthma patients services in the North West of England. We are looking to interview stakeholders who are involved in the commissioning and delivery of adult asthma patients services in the North West of England. Each participant should have the required knowledge of at least one aspect of asthma management and control.

   Participation in this phase will involve a personal interview only (face-to-face or telephone). After receiving the information about the study by email, the researcher will contact the participants to determine if they have read the information and if they decided to participate.

   If they choose to participate, a mutually agreed time will be arranged for the interview to take place. The interview will be semi-structured and will take up to 20 minutes, depending on the extent of the discussion. The interview questions will be based on the control of asthma patients at your clinical practice setting. In addition, the questions will promote discussion of any innovative ways of utilising pharmacy in the management of adult asthma patients. As a participant, he/she is free to refuse to answer to any questions he/she feels inappropriate or in comfortable with. The interview will be recorded to aid the researcher with note taking and analysis.

5. If you are willing to assist in the study what happens next?

   If you choose to assist, then you will nominate (a) potential participant(s) to be interviewed. After nomination of the participant(s), you will send us their contact details or you will send them recruitment email directly to participate in the study.

6. How we will use the Information/questionnaire?

   Once all data has been collected and analysed, the results will be disseminated to all participants for your information. The results will also be included in the PhD thesis. No further participation will be required in later phases of the overall project.

7. Will the name of my organisation taking part in the study be kept confidential?

   Personal data that will be collected includes the name of the interviewee, their workplace and workplace address and occupation. Hard copies of personal data will be stored in a locked cupboard and any electronic data with personal information will only be stored on an LJMU, a password protected computer. Personal data will not be transported by USB drives or other portable media. Any personal data will be securely destroyed once it is no longer needed at the end of the study.

   Audio recordings using a digital voice recorder will be downloaded on to an LJMU, password protected computer, and then the file will be securely deleted from the digital voice recorder. The electronic, password-protected file containing the audio recording will be stored for five years and then securely deleted.

   Confidentiality will be ensured by allowing only the researcher and supervisory team access to interview recordings and transcripts. All data will be anonymised at the transcription stage, by removing any participant identifiable information and coding the transcripts to enable participant identification only by the researcher.

   For the write up of results, no organisation and individual participants will be identified. All reports or papers produced will discuss the data in general terms only.

8. What will taking part involve? What should I do now?

   - Send us contact details of potential participants in your organisation or invite them to participate.
   - Sign and return the **Gatekeeper consent form** provided.

   Should you have any comments or questions regarding this research, you may contact the researchers:

   Contact Details of Researcher

   Aseel Mahmoud
   Postgradute Research Student
   Pharmacy and Biomolecular Sciences, Liverpool John Moores University
   Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
   e: A.M.Mahmoud@2017.ljmu.ac.uk
   Tel: 0151-231-2377

   Contact Details of Academic Supervisor

   Director of the Studies
   Dr. Rachel Mullen PhD BSc Clin Dip IP MRPharmS, FHEA
   Senior Lecturer in Clinical Pharmacy, Pharmacy and Biomolecular Sciences
   James Parsons Building, Byrom Street, Liverpool, L3 3AF
   e: R.Mullen@ljmu.ac.uk
   Tel: 0151-231-2173

This study has received ethical approval from LJMU's Research Ethics Committee (18/PBS/004).

If you have any concerns regarding your involvement in this research, please discuss these with the researcher in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.

Appendix 4 *Gatekeeper consent form for phase 1*

LIVERPOOL JOHN MOORES UNIVERSITY GATEKEEPER CONSENT FORM

Face-to-face or telephone interviews with stakeholders to explore asthma management in North West England

Please tick to confirm your understanding of the study and that you are happy for your organisation to take part and your facilities to be used to host parts of the project.

This research forms part of a PhD study looking to provide evidence for a new care model for asthmatic patients that is built around patient needs and targeted to patient groups. This first phase will explore stakeholder opinions via face-to-face or telephone semi-structured interviews to explore issues related to asthma control.

1. I confirm that I have read and understand the information provided 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 participation of our organisation and members in the research is voluntary and that they are free to withdraw at any time, without giving a reason and that this will not affect legal rights. ☐

3. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐

4. I agree for our organisation and members to take part in the above study. ☐

5. I agree to conform to the data protection act. ☐

Name of Gatekeeper: Date: Signature:

Name of Researcher: Date: Signature:

Researcher contact details:
Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e-mail : A.M.Mahmoud@2017.ljmu.ac.uk
Tel:0151-231-2377

Appendix 5 *Participant invitation email for phase 1*

Participant invitation email for phase 1

Subject: Invitation to take part in developing new care model for asthma patients.

Dear …(name)

I am a pharmacist currently undertaking research towards a PhD at Liverpool John Moores University, looking to provide evidence for a new care model for asthmatic patients that is built around patient needs and targeted to patient groups.

I am currently recruiting participants for the first phase of the research, which aims to explore the issues concerning the management of adult asthma patients within primary care and identify opportunities for improvement. This will involve a semi-structured, face-to-face or telephone interviews lasting up to 20 minutes. You have been invited to participate due to your experience in commissioning and delivery of adult asthma patients services in the North West of England. Your contact details were obtained via (the NHS Choices website / GP surgery you are working on/ Chief pharmacists at the hospital you are working in).

I have attached a participant information sheet and a consent form. Please take your time to read through the information provided and decide if you would like to take part. You will be contacted after three working days of receiving this email to determine if you wish to participate in the study. If you do agree to participate, you will be required to complete a consent for (copy attached).

Participation is voluntary and I appreciate that you are busy, however developing a new care model for asthma patients is very important to improve the management and control of asthma patients. Your participation will be very helpful.

Yours sincerely,

Aseel Mahmoud

Postgraduate Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 01512312377

Appendix 6 *Participant information sheet for phase 1*

LIVERPOOL JOHN MOORES UNIVERSITY

Face-to-face or telephone interviews with stakeholders to explore asthma management in North West England

You are being invited to take part in a research study. Before you decide it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.

What is the purpose of the study?

This study will form the first phase of a four phases PhD project. The overall study aims to provide evidence for a new care model for asthma patients that is built around patient needs and targeted to patients groups. This first phase involves a personal interview exploring the issues concerning the management of adult asthma patients within primary care and identify opportunities for improvement. The first phase will also explore stakeholders opinions on the management and control of asthma, identify how asthma management and control could be improved, investigate innovative ways of utilising pharmacy and particularly community pharmacy in the management and control of adult asthmatic patients, and explore opinions on evolving asthmatic Medicines Use Reviews (MURs) and the New Medicine Service (NMS) for asthma therapy into full clinical medication reviews using independent prescribing.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do you will be given this information sheet and asked to sign a consent form. You are still free to withdraw at any time and without giving a reason.

What will happen to me if I take part?

Participation in this phase will involve a personal interview only (face-to-face or telephone). After receiving the information about the study by email, the researcher will contact you to determine if you have read the information and if you decided to participate.

If you choose to participate, a mutually agreed time will be arranged for the interview to take place. The interview will be semi-structured and will take up to 20 minutes, depending on the extent of the discussion. The interview questions will be based on the control of asthma patients at your clinical practice setting. In addition, the questions will promote discussion of any innovative ways of utilising pharmacy in the management of adult asthma patients. As a participant, you are free to refuse to answer to any questions you feel inappropriate or in comfortable with. The interview will be recorded to aid the researcher with note taking and analysis.

Once all data has been collected and analysed, the results will be disseminated to all participants for your information. The results will also be included in the PhD thesis. No further participation will be required in later phases of the overall project.

Are there any risks/benefits involved?

There are no identified benefits for the individual participants.

The findings of this study will help to provide evidence for a new care model for adult asthma patients and may improve adult asthma patients control and management.

Will my taking part in the study be kept confidential?

Personal data that will be collected includes the name of the interviewee, their workplace and workplace address and occupation. Hard copies of personal data will be stored in a locked cupboard and any electronic data with personal information will only be stored on an LJMU, a password protected computer. Personal data will not be transported by USB drives or other portable media. Any personal data will be securely destroyed once it is no longer needed at the end of the study.

Audio recordings using a digital voice recorder will be downloaded on to an LJMU, password protected computer, and then the file will be securely deleted from the digital voice recorder. The electronic, password-protected file containing the audio recording will be stored for five years and then securely deleted.

Confidentiality will be ensured by allowing only the researcher and supervisory team access to interview recordings and transcripts. All data will be anonymised at the transcription stage, by removing any participant identifiable information and coding the transcripts to enable participant identification only by the researcher. An anonymization log will be created to identify all replacements and coding of the transcripts, the log will be stored on a separate password-protected file from the anonymised data files.

For the write up of results, no individual participants will be identified. All reports or papers produced will discuss the data in general terms only.

Funding/Sponsors
This project has been funded as part for the researcher PhD degree funding.

This study has received ethical approval from LJMU's Research Ethics Committee (18/PBS/004)

Contact Details of Researcher

Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 0151-231-2377

Contact Details of Academic Supervisor

Director of the Studies
Dr. Rachel Mullen PhD BSc Clin Dip IP MRPharmS, FHEA
Senior Lecturer in Clinical Pharmacy, Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: R.Mullen@ljmu.ac.uk
Tel: 0151-231-2173

If you any concerns regarding your involvement in this research, please discuss these with the researcher in the first instance. If you wish to make a complaint, please contact researchethics@ljmu.ac.uk and your communication will be re-directed to an independent person as appropriate.

Appendix 7 *Consent form for phase 1*

LIVERPOOL JOHN MOORES UNIVERSITY CONSENT FORM

PARTICIPANT CONSENT FORM

A new care model for asthma patients

Please read the points below and initial each box to confirm that you agree before signing. The completed form will need to be returned to the researcher by email or by hand just before the interview. See contact details below.

1. I confirm that I have read and understand the information provided 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, without giving a reason and that this will not affect my legal rights. ☐
3. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐
4. I agree to take part in the above study by interview. ☐
5. I understand that the interview will be audio recorded and I am happy to proceed ☐
6. I understand that parts of our conversation may be used verbatim in future publications or presentations but that such quotes will be anonymised. ☐

Name of Participant Date Signature

Name of Researcher Date Signature

Researcher contact details:
Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e-mail : A.M.Mahmoud@2017.ljmu.ac.uk
Tel:0151-231-2377

Appendix 8 *Interview schedule for phase 1*

Interview Schedule

Face-to-face or telephone interviews with stakeholders to explore asthma management in North West England

Introduction

Hello, my name is XXX.

I'm just going to start with a bit of an introduction to the project. As mentioned in the original email I am a pharmacist currently undertaking research towards my PhD at Liverpool John Moores University. This interview forms part of the first four phases of the PhD, which is exploring the issues concerning the management of adult asthma patients within primary care and identify opportunities for improvement.

The first phase will also explore stakeholders opinions on the management and control of asthma, identify how asthma management and control could be improved, investigate innovative ways of utilising pharmacy and particularly community pharmacy in the management and control of adult asthmatic patients, and explore opinions on evolving asthmatic Medicines Use Reviews (MURs) and the New Medicine Service (NMS) for asthma therapy into full clinical medication reviews using independent prescribing.

You have been asked to participate due to your experience in commissioning and delivery of adult asthma patients services in the North West of England.

I would just like to reiterate that I am recording this interview for analysis purposes only. Everything that you tell me will be kept confidential and you remain anonymous in any reports published. If any issue related to patients care are raised during the interview, I will discuss these issues with the PhD supervisory team. If an incident requires further action, then it will be reported to the participant's organisation including the clinical commissioning group, the community pharmacy, the general practice or the NHS Trust.

n.b. if not yet received consent form, read out consent form and obtain recorded signed consent.
OR: I have received your signed consent form thank you.

Can I just confirm that you are happy to be interviewed?

Please feel free to interrupt to ask any questions or for clarification throughout the interview.

This will be a semi-structured interview. I will start with some straight forward questions about demographic data, before moving to a discussion about asthma management and control, opportunities for asthma control improvement, and utilising pharmacy in the management of asthma patients.

For each question asked, the following question prompts will be used throughout the interview:
Where did it happen? When did it happen?
Can you give a more detailed description of what happened?
Can you help me to better understand your position/why you felt that way/why you say that?
Could you give me an example about that/tell a story about that?
Are there any times when it doesn't work?

Clinical practice setting demographic information

Setting:

Setting address:

Job title of participant:

-What your thoughts on how well controlled asthma patients are?
Prompts:
What are the problems and issues regarding asthma control?

-How do you think the control of asthma patients can be improved?

Prompts:
Any innovative services?

How could it be done?

What do patients thinks about the current services you providing to them?

-How can pharmacy support asthma control?
Prompts:
It does not matter if it is unrealistic.

-If you could change anything about how asthma patients are managed, what would it be? What about community pharmacy in particular?

Could community pharmacists be involved successfully in managing adult asthma patients?
Do you think NMS/MUR services could be improved to integrate community pharmacists in managing adult asthma patients?
How can community pharmacists support certain groups of adult asthma patients?

Any thing else? Can you tell me a little bit more?

That brings us to the end of the interview. I'd just like to thank you for giving up your time to participate. Would you be interested in receiving a copy of the results in a report once this phase is complete? If yes, is this ok via the email address that I originally contact you on.

Thank you and goodbye.

Appendix 9 *HRA and Health and Care approval for phases 2, 3 and 4*

Dr Rachel Mullen
Lecturer/Senior Lecturer
Liverpool John Moores University
Liverpool John Moores University
James Parson building
Byrom Street, Liverpool
L3 3AF

Email: hra.approval@nhs.net
HCRW.approvals@wales.nhs.uk

19 August 2019

Dear Dr Mullen

HRA and Health and Care

Study title:	**Development and evaluation of a patient-centred and evidence-based new care model for adult asthma patients**
IRAS project ID:	**254289**
Protocol number:	**NA**
REC reference:	**19/IEC08/0025**
Sponsor	**Liverpool John Moores University**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

Appendix 10 *REC ethical approval for phases 2, 3 and 4*

Social Care REC
Ground Floor
Skipton House
80 London Road
London
SE1 6LH

Telephone: 0207 104 8171

19 August 2019

Dr Rachel Mullen
Lecturer/Senior Lecturer
Liverpool John Moores University
Liverpool John Moores University
James Parson building
Byrom Street, Liverpool
L3 3AF

Dear Dr Mullen

Study title:	**Development and evaluation of a patient-centred and evidence-based new care model for adult asthma patients**
REC reference:	**19/IEC08/0025**
Protocol number:	**NA**
IRAS project ID:	**254289**

Thank you for your letter of , responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, 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, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Appendix 11 *Invitation letter for phases 2 and 3*

Participant invitation letter for the case note review and interview

Patient address

Date

Subject: Invitation to take part in a study about asthma patients.

Dear …(name)

In collaboration with Liverpool John Moores University, we are carrying out research with our asthma patients. As a registered asthma patient in this practice we would like to invite you to take part in this research which will involve a research student from Liverpool John Moores University:

- reviewing your medical records to explore how your asthma is managed, then
- inviting you to take part in one or more face-to-face or telephone interviews lasting up to 20 minutes. The interview questions will explore how your asthma is being managed and also how this could be improved.

We have enclosed the following for further information about the study:

- A participant information sheet v xxx, dated xxx.
- A consent form vxxx dated xxx.

Please take your time to read through the information provided and decide if you would like to take part. If you agree to participate, please sign and return the consent form in the stamped address envelope provided. The practice will contact you by telephone after two weeks of receiving this letter to check that you understand the information provided and offer the opportunity to speak to the researcher if you require further clarification.

Participation is voluntary and you are free to withdraw at any time by informing the practice and without giving a reason and without affecting your rights, any future treatment or service you are receiving.

We appreciate that you are busy, however research to help improve how asthma patients are managed is very important and your participation will be extremely helpful.

Yours sincerely,

Medical practice's address

Aseel Mahmoud
Postgraduate Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 01512312377

Appendix 12 *Participant information sheet for phases 2 and 3*

LIVERPOOL JOHN MO
Participant Informati
Asthma P

IRAS ID: 254289
NHS REC Reference: 19/IEC08/0025

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

A new care model for adult asthma patients: Case note review

- You are being invited to take part in a study. Before you decide it is important for you to understand why the study us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

1. Who will conduct the study?

- **Study Team Chief Investigator and Director of Studies:** Dr. Rachel Mullen, Senior Lecturer in Clinical Pharmacy, James Parsons Building Byrom Street, Liverpool, L3 3AF.
  Principal Investigator: Aseel Mahmoud, PhD student, LJMU, James Parson building Liverpool, L3 3AF.
  Local Principal Investigator: Barbara Jones, Practice Manager, Millbrook Medical Centre, Kirkby, Merseyside.

  School/Faculty within LJMU: School of Pharmacy and Biomolecular Sciences.

2. What is the purpose of the study?

This study forms a part of a wider PhD research that aims to provide evidence for a new care model for asthma patients that is built around patient needs and targeted to patients groups.

This study hopes to answer the following questions:

- What are asthma patient groups that could be targeted to get the most of asthma services?
- How well adult asthma patients are controlled?
- What are patients' perceptions on the management and control of their asthma?
- How patient's asthma is managed and controlled?

3. Why have I been invited to participate?

You have been invited because you are an adult asthma patient and are currently provided asthma services by the medical practice.

Inclusion criteria: Adult patients aged 17 to 65 years of age diagnosed with asthma. An administration staff member at Millbrook medical centre identified you and was asked to invite you to participate in the study.

Exclusion criteria: Patients who are aged more than 65 or less than 17, any patients who are not diagnosed with asthma, patients who have acute cancer, patients who have severe mental illness and who are cognitively impaired and cannot consent, either within or outside North West of England will not be contacted to participate.

4. Do I have to take part?

- No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time by informing the researcher (contact details are provided in section 18 of this sheet) or Millbrook Practice manager (contact detail are provided in section 18 of this sheet) without giving a reason and without it affecting your rights/any future treatment/service you receive.

5. What will happen to me if I take part?

Participation in this study will involve:

- Reviewing your medical records, then
- The opportunity to take part in a one or more face-to-face or telephone interview(s)

After two weeks of receiving the information about the study by letter, a member of the administration staff from Millbrook Practice will contact you by telephone to determine if you have read and understand the information provided and will offer you the opportunity to discuss the study with the researcher to help inform your decision to participate.

If you choose to take part, you are asked to complete and sign a consent form agreeing for the researcher to review your personal medical record to collect anonymised data only. Anonymised data to be collected will include the following: your age and gender, your medical history relating to how your asthma is managed and treated with both inhaled and oral medications, and whether you have visited accident and emergency or been admitted to hospital because of your asthma. Anonymised data will also be collected on whether you have one or more other clinical conditions as well as asthma. These include: anxiety, depression, obesity and chronic obstructive pulmonary disease.

If you choose to participate in the interview(s), a mutually agreed time will be arranged for the interview(s) to take place in the medical practice or over the phone based on your preference. You will be asked to fill and sign a consent form before the interview commence. The interview will be semi-structured and will take up to 40 minutes, depending on the extent of the discussion. The interview questions will be based on your perceptions on the management and control of your asthma. In addition, the questions will promote discussion of patients' experience of how your asthma is managed and controlled.

You will also have the opportunity express your interest in being contacted again, inviting you to take part in a second, follow-up telephone or face-to-face interview during the next six months. This follow-up interview will explore your views on how asthma is managed using a new model of delivery.

If you consent to be contacted again your contact details will be stored safely and securely in a locked cupboard at LJMU.

6. Will I be recorded and how will the recorded media be used?

- The audio recording is essential to your participation but you should be comfortable with the recording process and you are free to stop the recording at any time

- The audio recordings of the interview made during this study will be used only for analysis. No other use will be made of them without your written permission.

- Interviews will be audio recorded on a password protected audio recording device and as soon as possible the recording will be transferred to secure storage and deleted from the recording device.

7. Are there any possible disadvantages or risks from taking part?

As this study involves a review of your medical records and face-to-face or telephone interview(s) undertaken at medical practice, it is unlikely to pose any additional risk. No obvious sensitive topics will be discussed.

As a participant, you are free to refuse to answer to any questions you feel inappropriate or in comfortable with.

If the interviewee does find any topics distressing, this will be handled tactfully by the interviewer. If further action is required, the interviewer will discuss this with the medical team in the medical practice and the supervisory team. Every effort will be made to ensure that the interviewee is comfortable with the topics being discussed.

8. What are the possible benefits of taking part?

Whilst will be no direct benefits to you for taking part in the study, but it is hoped that this work will influence the future provision of services for asthma which you may benefit from.

9. Will my General Practitioner/family doctor (GP) be informed of my participation?

With your permission a copy of your signed written consent form will be scanned to your medical records by an administration staff member in Millbrook Medical Centre. And information about your care maybe shared with the GP if necessary.

10. What will happen to the data provided and how will my taking part in this project be kept confidential?

The information you provide as part of the study is the **study data**. Any study data from which you can be identified (e.g. from identifiers such as your name, date of birth, audio recording etc.), is known as **personal data**. This includes more sensitive categories of personal data (**sensitive data**) such as your race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation.

When you agree to take part in a study, we will use your personal data in the ways needed to conduct and analyse the study and if necessary, to verify and defend, when required, the process and outcomes of the study. Personal data from your medical record will be accessible to the researcher only.

Personal data (from the interviews) will be accessible to the researcher, supervisory team and transcriber. In addition, responsible members of Liverpool John Moores University may be given access to personal data for monitoring and/or audit of the study to ensure that the study is complying with applicable regulations.

Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed). However, your consent form, contact details, audio recordings. will be retained for one year.

The researcher will collect anonymised data only from your medical records, data to be collected will include: your demographics (age and sex), your medical history (asthma treatment and medications), number of accident and emergency visits and hospital admissions and asthma services provided to you at the medical practice.

When we do not need to use personal data, it will be deleted or identifiers will be removed. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed). However, your consent form, contact details, audio recordings. will be retained for one year.

Personal data collected from you will be recorded using a linked code – the link from the code to your identity will be stored securely and separately from the coded data

You will not be identifiable in any ensuing reports or publications.

We will use pseudonyms in reports to help protect the identity of individuals and organisations unless you tell us that you would like to be attributed to information/direct quotes etc.

With your consent, we would like to store your contact details so that we may contact you about future opportunities to participate in an interview as part of a wider study.

The interview recordings will be sent to an independent company who will produce a transcript

11. Limits to confidentiality

The Investigator will keep confidential anything they learn or observe related to illegal activity unless related to the abuse of children or vulnerable adults, money laundering or acts of terrorism.

12. What will happen to the results of the study?

- The investigator intends to report the results back to the medical practice and to publish the results in a practice leaflet for the public to read as well as other staff.

- In addition, the investigator intends to publish the results in PhD thesis, a peer reviewed journal and at conferences.

13. What if we find something unexpected?

- If any issues or concerns relating to your health are identified during the study including, for example poor practice provided to the you or poor adherence to your medication, the researcher will discuss these issues with the practice manger and PhD supervisory team.

14. Who is organising and funding the study?

This study is organised by Liverpool John Moores University and funded as part of the researcher's PhD degree funding.

15. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, NHS Research Ethics Committee (Reference number 19/IEC08/0025)

16. What if something goes wrong?

If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The investigator should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact Dave Harriss, the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk; 0151 9046467).

17. Data Protection Notice

Liverpool John Moores University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study Liverpool John Moores University will keep identifiable information about you for one year after the study has finished

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Tina Sparrow, the Liverpool John Moores University Data Protection Officer at DPO-LJMU@ljmu.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful, you can complain to the Information Commissioner's Office (ICO).

18. Contact for further information

- **Contact Details of Local Principal Investigator**

Barbara Jones
Practice Mananger
Millbrook Medical Centre
Bewely Drive, Kirkby, Merseyside, L32 9PF
Tel: 0151-546-2480

- **Contact Details of Researcher (Principal investigator)**

Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 0151-231-2377

- **Contact Details of Academic Supervisor (Chief investigator)**

Director of the Studies
Dr. Rachel Mullen PhD BSc Clin Dip IP MRPharmS, FHEA
Senior Lecturer in Clinical Pharmacy, Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: R.Mullen@ljmu.ac.uk
Tel: 0151-231-2173

Thank you for reading this information sheet and for considering taking part in this study.

Appendix 13 *Participant consent form for phase 2*

LIVERPOOL JOHN MOORES UNIVERSITY CONSENT FORM

PARTICIPANT CONSENT FORM

A new care model for adult asthma patients: Case note review

Please read the points below and initial each box to confirm that you agree before signing. The completed form will need to be returned to the researcher by email or by hand just before the interview. See contact details below.

1. I confirm that I have read and understand the participant information sheet v 0.2 dated 19/08/2019) provided for the above study and 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. ☐
3. I understand that the researcher will review my medical records to extract data and I am happy to proceed ☐
4. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐
5. I agree/ disagree [please delete] to be contacted again by telephone in a period of six months, to be invited to participate in interview(s) as part of a wider study. ☐

Name of Participant Date Signature

Name of Researcher Date Signature

Researcher contact details:
Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e-mail : A.M.Mahmoud@2017.ljmu.ac.uk
Tel:0151-231-2377

Appendix 14 *Participant consent form for phase 3*

LIVERPOOL JOHN MOORES UNIVERSITY CONSENT FORM

PARTICIPANT CONSENT FORM

A new care model for adult asthma patients: interviews with patients

Please read the points below and initial each box to confirm that you agree before signing. The completed form will need to be returned to the researcher by email or by hand just before the interview. See contact details below.

1. I confirm that I have read and understand the participant information sheet v 0.2 dated (19/08/2019) provided for the above study and 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. ☐
3. I understand that the interview will be audio recorded and I am happy to proceed ☐
4. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐
5. I understand that parts of our conversation may be used verbatim in future publications or presentations but that such quotes will be anonymised. ☐
6. I agree to my General Practitioner being informed of my participation in the study. ☐
7. I agree to take part in the above study by face-to-face or telephone interview. ☐
8. I agree to be contacted again by the researcher within a period of six months, for a follow up interview. ☐

Name of Participant Date Signature

Name of Researcher Date Signature

Researcher contact details:
Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e-mail : A.M.Mahmoud@2017.ljmu.ac.uk
Tel:0151-231-2377

Appendix 15 *SPSS data collection sheet*

Patient ID (P) (Pseudo anonymised)	
Part A: patient demographics	
Variable name	Value
Age	--------
Sex	Female ☐ Male ☐ Other ☐
Part B: asthma prevalence	
Variable name	Value label
Population	Active asthma patient ☐ Possible asthma ☐
Part C: medical history	
BTS/SIGN treatment step	SABA ☐ Step 1 ☐ Step 2 ☐ Step 3 ☐ Step 4. ☐ Step 5 ☐

	Unclear ☐
Presence of a comorbidity	No comorbidity ☐ COPD ☐ Anxiety ☐ Obesity ☐ Depression ☐ Allergic rhinitis ☐ Other ☐
Royal College of Physicians (RCP) '3 questions'	Asked all 3 questions ☐ Asked 1 or 2 questions ☐ Not asked the RCP Questions ☐ Unclear ☐
RCP score	No to all questions ☐ Yes to 1 question ☐ Yes to 2 or 3 questions ☐ Unclear ☐
Number of (SABA) inhalers prescribed for patient	Over 12 ☐

over the last 12 months	9-12 ☐ 5-8 ☐ 1-4 ☐ 0 ☐ Unclear ☐
Number of ICS prescribed for the patients over the last 12 months	Over 12 ☐ 9-12 ☐ 5-8 ☐ 1-4 ☐ 0 ☐ Unclear ☐
Part D: secondary care engagement	
Admitted to hospital on the last 12 months (related to asthma)	Admitted ☐ Not admitted ☐ Unclear ☐
A&E attendance	Seen in A&E ☐ Not seen in A&E ☐

	Unclear ☐
Oral corticosteroids prescriptions over the last 12 months	6 or more ☐ Less than 6 ☐ No Oral CS ☐ Unclear ☐
Respiratory clinic	Referred ☐ Not referred ☐
Part E: asthma management	
Attendance at their annual asthma review	Reviewed in the last 12 months ☐ Not Reviewed in the last 12 months ☐ Unclear ☐
Smoking	Current smoker ☐ Non-smoking ☐ Smoking status not recorded ☐ Unclear ☐
Asthma attack	Oral CS prescribed over the last 12 months ☐ No oral CS prescribed over the last 12 months ☐

	Unclear ☐
Self-management plan	Recorded or updated over the last 12 months ☐ Not recorded or updated over the last 12 months ☐ Unclear ☐
Inhaler technique	Checked ☐ Non checked ☐ Unclear ☐
Part F: field notes	

Appendix 16 *Variables description sheet for phase 2*

Variable name	Variable definition	Value label	Value	Description	Source of the data
Age	Patient's age	Age		Age.	EMIS, on the top of the patient's record.
Sex	Patient's sex	Female Male Other	1 2 3	Gender.	EMIS, on the top of the patient's record.
Population	Asthma status	Active asthma patient	1	Patient is on asthma register.	Asthma listed on the patient's problems list.
		Possible asthma	2	Patient is not on asthma register but receiving asthma medication or spirometry on the last year.	Asthma not listed on the patient's problems list.
BTS/SIGN treatment step		SABA	1	When patient is treated with SABA.	Check the medication history of the patient during the last 12 months then user the BTS pharmacological treatment algorithm attached, to know which step of the treatment the patient is at. Check the BTS/SIGN table for ICS doses.
		Step 1	2	Low dose ICS.	
		Step 2	3	Inhaled LABA and low dose ICS.	
		Step 3	4	Inhaled LABA + medium dose ICS or Medium dose ICS only. OR Low dose ICS+ LABA + LTRA, SR-theophylline or LAMA.	

		Step 4	5	High dose ICS or Medium dose ICS + LTRA, SR-theophylline or LAMA.	
		Step 5	6	Oral CS +high dose ICS.	
		Unclear	7	Not enough data about the doses prescribed to the patients.	
Comorbid COPD		Yes No	1 2		Navigate the problems list and search for COPD.
Comorbid Anxiety		Yes No	1 2		Navigate the problems list and search for anxiety.
Comorbid Obesity		Yes No	1 2	Use the body mass index (BMI) to know if the patient is obese or not. If the BMI 30-39.9 (obese) BMI 40 or more severely obese. (NICE recommendations).	Navigate the problems list and search for obesity and check the BMI also.
Comorbid Depression		Yes No	1 2		Navigate the problems list and search for depression.
Comorbid Allergic Rhinitis		Yes No	1 2		Navigate the problems list and search for allergic

					rhinitis.
RCP	Royal College of Physicians (RCP) '3 questions'	Asked all 3 Qs Asked 1 or 2 Qs Not asked any Qs Unclear	1 2 3 4	The questions are: 1. Have you had difficulty sleeping because of your asthma symptoms (including cough)? 2. Have you had your usual asthma symptoms during the day (cough, wheeze, chest tightness, or breathlessness)? 3. Has your asthma interfered with your usual activities?	The RCP questions are mentioned in the consultations list and described under the asthma review consultation.
RCP score		No to all questions Yes to one question Yes to 2 or 3 unclear	1 2 3 4	This information is required to assess asthma control during the last 12 months.	Patients' answers to the RCP questions are mentioned in the consultations list and described under the asthma review consultation.
SABA	Number of (SABA) inhalers received by patient over the last 12 months	Over 12 9-12 5-8 1-4 0 Unclear	1 2 3 4 5 6	This information is required to assess patients who need review depending on the number of SABA inhalers during the last 12 months.	Review the medication history.

ICS	Number of ICS prescribed for the patients over the last 12 months	Over 12 9-12 5-8 1-4 0 Unclear	1 2 3 4 5 6	This information is required to highlight patients who are undertreated and have poor asthma control during the last 12 months.	Review the medication history.
Hospital	Admitted in last 12 months (related to asthma)	Admitted Not admitted Unclear	1 2 3	Count the number of hospital admissions related to asthma during the last 12 months.	Review patient's consultations, referrals and letters. To know if the hospital admission was related to asthma or not review the letters attached using DOCMAN.
A&E attendance	Attendance to the accident and emergency	Seen in A&E Not seen in A&E Unclear	1 2 3	Count the number of patient visits to the A&E that are related to asthma during the last 12 months.	Review patient's consultations, referrals and letters. To know if the A&E attendance was related to asthma or not. Review the letters attached using DOCMAN.
Oral CS	Oral CS prescriptions over the last 12 months	6 or more Less than 6 None Unclear	1 2 3 4	Count the number of oral CS prescribed to the patient during the last 12 months.	Review the medication history.
AAR	Attendance at their annual asthma review	Reviewed in the last 12 months Not reviewed in the last 12 months	1	Check if the patient has been reviewed or	Review the consultations list.

		Unclear	2 3	not during the last 12 months.	
Smoking		Current smoker Non-smoking Smoking status not recorded Unclear	1 2 3 4	Smoking status.	Heath checks.
Asthma attack		Oral CS prescribed over the last 12 months No oral CS prescribed over the last 12 months Unclear	1 2 3	Check if the patient has been prescribed oral CS or not during the last 12 months.	Review the medication history.
AAP		Recorded or updated over the last 12 months Not recorded or updated over the last 12 months Unclear	1 2 3	Asthma action plan or self-management plan provided to the patient usually as a part of the review.	Review the consultations list and review the details of asthma review.
Inhalation		Checked Non checked Unclear	1 2 3	Check if the patient's inhalation technique has been checked or not by during the last 12 months.	Review the consultations list and review the details of asthma review.

Appendix 17 *Interview schedule for phase 3*

Participant reference no:

Patients' interview Schedule

A new care model for adult asthma patients

Introduction

Hello, my name is Aseel Mahmoud.

I'm just going to start with a bit of an introduction to the project. As mentioned in the letter I am a pharmacist currently undertaking research towards my PhD at Liverpool John Moores University. This interview forms part of the third of four phases of the PhD, which is exploring patient perceptions on the management and control of their asthma.

This study will explore patient's experience of how their asthma is managed and controlled, explore patients' perceptions on how pharmacy supports them to manage and control their asthma and identify further opportunities for pharmacists to support patients manage and control.

You have been asked to participate because you are an adult asthma patient and you are currently registered in the GP research site.

I would just like to reiterate that I am recording this interview for analysis purposes only. Everything that you tell me will be kept confidential and you remain anonymous in any reports published. If any issue related to patients care are raised during the interview, I will discuss these issues with the PhD supervisory team. If an incident requires further action, then it will be reported to the participant's general practice.

I have received your signed consent form thank you.

Switch on the recorder

Can I confirm that you have had the opportunity to read the participant information sheet and that you are happy to be interviewed?

Please feel free to interrupt to ask any questions or for clarification throughout the interview.

This will be a semi-structured interview. We will discuss the services provided to you at the GP practice, the services provided to you by the community pharmacy, and your suggestion to improve asthma services.

For each question asked, the following question prompts will be used throughout the interview:
Where did it happen? When did it happen?
Can you give a more detailed description of what happened?
Can you help me to better understand your position/why you felt that way/why you say that?
Could you give me an example about that/tell a story about that?
Are there any times when it doesn't work?

-Can you tell me about asthma services provided to you in the GP practice?

Prompts:
What are the problems and issues regarding these services?

-What do you think about asthma services provided to you by the pharmacists/chemists?

Prompts:
Do you ever have New Medicine Service for your asthma medication?
Do you think it was useful?

-How can pharmacy better support your asthma control?

-If you could change anything about how your asthma is managed, what would it be?

What about community pharmacy in particular?

That brings us to the end of the interview. I'd just like to thank you for giving up your time to participate.
Thank you and goodbye.

Appendix 18 *Transcriber confidentiality agreement*

Transcriber Confidentiality Agreement

A new care model for adult asthma patients: interviews

This research is being undertaken by Aseel Mahmoud, PhD student in the school of pharmacy and biomolecular sciences, Liverpool John Moores University. The purpose of the research is to develop a new care model for asthma patients.

As a transcriber of this research, I understand that I will be hearing recordings of confidential interviews. The information on these recordings has been revealed by interviewees who agreed to participate in this research on the condition that their interviews would remain strictly confidential. I understand that I have a responsibility to honour this confidentially agreement.

I agree not to share any information on these recordings, about any party, with anyone except the Researcher of this project. Any violation of this and the terms detailed below would constitute a serious breach of ethical standards and I confirm that I will adhere to the agreement in full.

I, Nicola Brown of Transcribe It agree to:

1. Keep all the research information shared with me confidential by not discussing or sharing the content of the interviews MP3 audio recordings or word file transcripts with anyone other than the Researcher. □

2. Keep all research information in MP3 audio recordings and word file transcripts secure while it is in my possession. □

3. Return all research information in word file transcripts to the Researcher when I have completed the transcription tasks. □

4. After consulting with the Researcher, erase or destroy all research information in in MP3 audio recordings and word file transcripts regarding this research project that is not returnable to the Researcher (information stored on my computer hard drive). □

Transcriber:

Nicola Brown 21 October 2019

_____ _____ _____

(print name) (signature) (date)

Researcher:

_____Aseel Mahmoud_____ ____21 October 2019_____ _____

(print name) (signature) (date)

Appendix 19 *Description of themes resulted from triangulation and a supporting example from the data*

Themes	Description	Sub-themes	Supporting example
Theme 1: Issues with asthma management	This theme covers the main issues with asthma management that lead to poor symptoms control in adult asthma patients.	Medication adherence	*"I was just using the [reliever inhaler], but I was using it four or five times a day. When I spoke to the doctor, he said it was high usage," Asthma patient with comorbid depression.*
		Inhaler technique	*"Basically they [HCPs] just say, "Are you using [the inhaler] all right?" or, "Is everything all right?" Asthma patient with comorbid obesity and depression.*
Theme 2: HCPs	This theme covered opportunities to enhance asthma management in adult patients that are related to HCPs.	Diagnosis improvement	*"Once the diagnosis is made [once it is suspected], that seems quite quickly with spirometry. Use of respiratory FeNO [will ensure] that a correct diagnosis is made," Respiratory consultant.*
		Quality and equity in asthma care	*"I think, well I know when I moved back to the area because I lived in [area] for a while, I was never contacted once by the surgery I was registered with there to come and have an asthma check, and to check that everything was okay with the inhaler. So, I think I've experienced different service in different NHS areas, but I certainly think it's improved here to what I've experienced elsewhere," Participant-3.* *"I don't think I've had the same nurse every time I've come, but even with the different nurses, they will often have an assumption of a patient's ability, and what they know and they don't know," Asthma patient with*

			comorbid obesity and depression.
		Access to asthma care	*"Something that patients would like to improve maybe the access to prescriptions and visits to the doctor," Community pharmacist.* *"When I was in [name] GP, I didn't have an asthma review. But now since moving to [name] GP, I had a review to start me off, to ensure that they could give me the prescriptions in there," Asthma patient with comorbid depression.*
		Non-pharmacological management	*"[I suggest] some health coaching interventions on asthma [that provide] more talking and listening to the patients rather than passing health care messages into the patients. I have seen patient groups and things like that, are very helpful but [there] seem to be [more] focusing on the more effective and cost limited [interventions]. Certainly, healthcare coaching conversation would be quite useful," Community pharmacist.* *"I think a better explanation of asthma itself, and also guidelines on what to avoid. What exercise you can do, how far to push yourself," Asthma patient with comorbid depression.* *"I think smoking cessation would improve asthma control, I think community pharmacy is the ideal place to help with that," Hospital pharmacist.*
		Co-ordinated care	*"If we could have all the parts of the [healthcare] system working together better, [asthma management] will be improved," Long term conditions*

			manager.
		Community pharmacists	*"In community pharmacy, every single month they [community pharmacists] see the patient, so they can check that everything is okay, and I don't think any other professional role has that sort of regular contact with the patients," Practice pharmacist.* *"Again it is just around the multidisciplinary, so the pharmacist can be more involved, with checking the inhaler technique on the regular basis, making sure that they are reviewing the patient through an MUR or making sure that [patients] know how to use all new medicines they have by offering an NMS," Community pharmacist.* *"I might think I'm not that bad, and then all of a sudden there's something wrong. So they [community pharmacists] can pinpoint [any problem], whereas you might not see it," Asthma patient with comorbid depression and allergic rhinitis.*
Theme 3: Relationship between patients and HCPs	This theme covered issues regarding the relationship between asthma patients and their HCPs.		*"[AAR] has been brilliant, she's [the nurse] dead sympathetic, she knows her job, and she tells me what to do," Asthma patient with comorbid depression and obesity.*
Theme 4: Technology	This theme covered participants' suggestions on innovative use of technology		*"I think there is a massive role for technology in the monitoring of asthma [patients]," Respiratory pharmacist.*

	that could be used to enhance asthma management.		
Theme 5: Asthma patients who need further support	This theme covers asthma patient groups that could benefit from further support to enhance their asthma care.	Patients with controlled asthma symptoms	*"We got a cohort of patients who do speak to us, however when they are reviewed in the GP it doesn't seem to be noticed that they are not using salbutamol [reliever], but they don't get stepped down," Independent prescribing pharmacist.* *"Assessing and reviewing asthma patients that are well controlled [is] a key area where pharmacists may have a role," Respiratory pharmacist, hospital setting.*
		Newly diagnosed asthma patients	*"When you get told you have asthma it's a daunting thing, you're getting told that straightaway. Just let me know what I can do and how to manage this, it's easy, and what steps to take, that would have helped me so much more at the very beginning, so I know how to handle it going forward," Asthma patient with comorbid depression and obesity.*
		Patients with poorly controlled asthma patients	*"[Community pharmacists could] pick up patients who are not well controlled or do not have ICS or preventer, picking up patients that have a diagnosis of asthma but not on a steroid inhaler, pick up patients who are using less than 6 inhalers a year. [Those patients could be targeted by community pharmacy]," Respiratory specialist.* In phase 2, 18 out of 27 participants had poorly controlled asthma symptoms. Some of these had an asthma attack, others required a review because they were overusing their reliever inhaler or underusing their preventer inhaler.

		Asthma patients who do not attend their asthma reviews	*"Maybe doing service in community pharmacy to reach those patients, they still pick up prescriptions from the pharmacy. They are not attending the GP practice for review but they could potentially be at their local community pharmacy. You know community pharmacy can be involved in [asthma review] and they can send the patient information back to us [GP practice]. Something like that might work, it is a little bit more practical for patients," Practice pharmacist.*
		Asthma patients with high risk for future asthma attack	*"When you have asthma and you start to struggle with your breathing, you tend to start to panic a little bit, because it's not a pleasant thing not to be able to get a good breath of air," Asthma patient with comorbid depression.*
		Asthma patients with comorbid depression	*"This is me normal, any other time I can't get out of the house because I feel low with the depression. Otherwise, I wouldn't have come if I was low, I wouldn't have been able to come," Asthma patient with comorbid depression.*
		Asthma patients with comorbid allergic rhinitis	*"I'd prefer to be seen two or three times a year because you've got the change in the weather. Now with this cold weather, I can't breathe, now come spring, my chest will change again, and come summer it will change again. So, I think once every three months, four months would do it, just to keep an eye on things," Asthma patient with comorbid depression and obesity.*

Appendix 20 *Summary of the findings from triangulation*

Patients with controlled asthma

Group name: patients with controlled asthma

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: controlled • AAR attendance: attend their AAR regularly	• Patients who fit into this group could be referred from GP to community pharmacy for the service. In community pharmacy the patient's condition and medication will be reviewed every 6 months. In addition the community pharmacist will update their AAP. The community pharmacist could refer patients back to the GP if they had an asthma attack or their asthma control changed.

Patients with poorly controlled asthma

Group name: patients with poorly controlled asthma

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: poorly controlled but not referred to the secondary care • AAR attendance: attend their AAR regularly	• Patients who fit into this group could be referred from GP to community pharmacy for the service. In community pharmacy the patient's condition and medication and inhaler technique will be reviewed every 6 months. In addition the community pharmacist will update their AAP. The community pharmacist could refer patients back to the GP if they had an asthma attack or their asthma control changed.

Asthma patients who do not attend their appointments

Group name: asthma patients who do not attend their appointments

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: any, except poorly controlled patients who were referred to secondary care • AAR attendance: Do not attend their AAR regularly • Collect their medication from the same community pharmacy for six months	• Patients who do not attend their AAR could be highlighted by the GP practice then referred to community pharmacy for an asthma review that includes medication, symptoms and inhaler technique review. During the review patients will also be provided with an AAP and/or referred to the GP if needed.

Newly diagnosed asthma patients

Group name: newly diagnosed asthma patients

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: any except poorly controlled patients who were referred to secondary care • AAR attendance: not applicable • Patient who were diagnosed with asthma within 0-12 months	• Newly diagnosed patients could be educated regarding their disease, medication, self-management and inhaler use in community pharmacy. In addition, their knowledge could be tested using a validated questionnaire to identify their educational needs that could be targeted in their next appointment.

Asthma patients with anxiety and/or depression

Group name: asthma patients with anxiety and or depression

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: any • AAR attendance: any	• Patients in this group could be referred by the GP or self refer themselves for a review in community pharmacy. The frequency of the review depends on their asthma symptoms and could include the same elements of the service provided to patients who do not attend their AAR (see pen portrait 3).

Asthma patients with future risk of an asthma attack

Group name: asthma patients with future risk for an asthma attack

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: any except poorly controlled patients who were referred to secondary care • AAR attendance: attend their AAR regularly • This group includes asthma patients with history of previous asthma attack or overusing their SABA inhaler	• Patients could be referred from the GP to community pharmacy and provided with an extra asthma review in community pharmacy to prevent or reduce asthma attacks. The review could include the same elements of the service provided to poorly controlled asthma patients (see pen portrait 2) . In addition, further efforts will be made to educate the patients regarding their asthma triggers and how to avoid them. Moreover, patients will be able to contact a community pharmacist if they felt that their asthma symptoms are worsening.

Group name: asthma patients who need seasonal care

Group characteristics	Suggested service
• Age: 17-65 • Asthma control level: any except poorly controlled patients who were referred to secondary care. • AAR attendance: attend their AAR regularly. • Asthma patients whom asthma is triggered by cold air, hay fever or pollens.	• Patients who fit into this group could be referred from GP to community pharmacy for the service or refer themselves. In community pharmacy the patients with seasonal triggers could be contacted in the summer, winter or spring to get an extra review in community pharmacy. The review will be the same as that provided to asthma patients with risk for an asthma attack (see pen portrait 6).

Gatekeeper invitation email for stakeholder interviews

Subject: Invitation to take part in developing a new care model for asthma patients.

Dear …(name)

I am a pharmacist currently undertaking research towards a PhD at Liverpool John Moores University, looking to provide evidence for a new care model for asthmatic patients that is built around patient needs and targeted to patient groups.

I am currently recruiting participants for this study which aims to evaluate a proposal of a new care model for adult asthma patients. This will involve a structured, face-to-face or telephone interview lasting up to 40 minutes. You have been invited to participate due to your experience in commissioning and delivery of adult asthma patients services in the North West of England. Your contact details were obtained via the NHS Choices website.

I have attached a participant information sheet and a consent form. Please take your time to read through the information provided and decide if you would like to take part. You will be contacted after three working days of receiving this email to determine if you wish to participate in the study and/ or to nominate a potential candidate from your staff and patients to participate. If you do agree to participate, you will be required to complete a consent for (copy attached).

Participation is voluntary participants will be able to withdraw at any time without giving a reason, they can choose not to answer any of the questions and without affecting their rights, any future treatment, or service they receive.

. I appreciate that you are busy, however developing a new care model for asthma patients is very important to improve the management and control of asthma patients. Your participation will be very helpful.

Yours sincerely,

Aseel Mahmoud

Aseel Mahmoud
Postgraduate Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 01512312377

Appendix 21 *Gatekeeper invitation email for phase 5*

Appendix 22 *Gatekeeper information sheet for phase 5*

LIVERPOOL JOHN MOORES UNIVERSITY

A new care model for adult asthma patients: interviews with stakeholders

1. What is the reason for this letter?

You are being invited to assist in a research study. Before you decide it is important that you understand why the research is being done and what it involves. Please take time to read the following information. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you want to take part or not.

2. What is the purpose of the study/rationale for the project?

This study will form a part of a wider PhD research that aims to provide evidence for a new care model for asthma patients that is built around patient needs and targeted to patients groups. As part of this study I have proposed a new care model for asthma patients. Which will be evaluated through a face-to-face or telephone interview exploring the issues concerning the proposed model feasibility. This study will also explore stakeholder's opinions and suggestions to improve the proposed model.

3. What we are asking you to do?

You are being contacted to nominate the most appropriate person to be interviewed from your staff, to authorise participation to take place within your organisation facilities during working hours.

4. Why do we need access to your facilities/staff?

You have been invited to participate due to your organisation role in commissioning and delivery of adult asthma patients services in the North West of England. We are looking to interview stakeholders who are involved in the commissioning and delivery of adult asthma patients services in the North West of England. Each participant should have the required knowledge of at least one aspect of asthma management and control.

Participation in this phase will involve hosting personal interviews (face-to-face or telephone) with stakeholders. The interview will be structured and will take up to 40 minutes, depending on the extent of the discussion. The interview questions will be based on the developed new care model for asthma patients. The participants are free to refuse to answer to any questions they feel inappropriate or in comfortable with. The interview will be recorded to aid the researcher with note taking and analysis.

After receiving the information about the study by email, the researcher will contact the gatekeepers to determine if they have read the information and if they decided to participate. If they choose to participate the gatekeeper will be asked to fill and sign a gatekeeper consent form (see gatekeeper consent form v 0.2 dated 09/01/2019) to authorise participation to take place

If the participants choose to take place in the study, a mutually agreed time will be arranged for the interview to take place. The participants will be sked to fill and sign consent form (see Participant consent form v 0.2 dated 09/01/2019) before the interview commence.

5. If you are willing to assist in the study what happens next?

If you choose to assist, then you will nominate (a) potential participant(s) to be interviewed. After nomination of the participant(s), you will send us their contact details or you will send them the recruitment email directly to participate in the study.

6. Are there any risks/benefits?

As this study is a face-to-face or telephone interview undertaken at participant's natural setting, it is unlikely to pose any additional risk. No obvious sensitive topics will be discussed. If the interviewee does find any topics distressing, this will be handled tactfully by the interviewer. If further action is required, the interviewer will discuss this with the supervisory team. Every effort will be made to ensure that the interviewee is comfortable with the topics being discussed.

If any issues or concerns relating to patients' care are identified during the interview including, for example poor practice provided to the patients, the researcher will discuss these issues with the PhD supervisory team. If an incident is considered to require further action, then it will be reported to the participant's organisation including the clinical commissioning group, the community pharmacy, the general practice or the NHS Trust.

The findings of the study may influence the future provision of services for asthma which patients may benefit from.

7. How we will use the Information/questionnaire?

When you agree to take part in a research study, your organisation information will only be used by the researcher to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. And the data will be collected with accordance to Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information.

Personal data that will be collected includes the name of the interviewee, job title, email address and place of work. The researcher will use participants' information in order to undertake this study.

Hard copies of personal data will be stored in a locked cupboard and any electronic data with personal information will only be stored on an LJMU, a password protected computer. Personal data will not be transported by USB drives or other portable media. The researcher will keep identifiable information about your organisation for one year after the study has finished.

Audio recordings using a digital voice recorder will be downloaded on to an LJMU, password protected computer as soon as possible, and then the file will be securely deleted from the digital voice recorder. The electronic, password-protected file containing the audio recording will be securely deleted after it has been transcribed and checked for quality.

Once all data has been collected and analysed, the results will be disseminated to all participants for your information. Participants will be consented to publish the results in papers and PhD thesis in general terms only and without participant identification (see Participant consent form v 0.2 08/01/2019). Also Anonymised quotations could be included in the published results using a pseudonyms participant identification code.

8. Will the name of my organisation taking part in the study be kept confidential?

All data collected during the course of this study will kept confidential including your organisation name. We will not tell anyone that your organisation has participated in the study.

The confidentiality of interview recordings and transcripts will be maintained by allowing the researcher, the transcriber and supervisory team to access the interview recordings and transcripts. Also, a confidentiality agreement will be signed with the hired transcriber to ensure confidentiality. The transcriber will be required to agree to keep the audio recordings and the word transcripts files secure as password protected files and to securely delete all the files that are related to the research after the transcription task is completed.

All data will be anonymised by the researcher by removing any participant identifiable information and coding the transcripts to enable participant identification only by the researcher.

For the write up of results, no organisation and individual participants will be identified. All reports or papers produced will discuss the data in general terms only.

9. What will taking part involve? What should I do now?

- Identify potential participants to take part in the study.
- Send us contact details of potential participants in your organisation or invite them to participate.
- Sign and return the **Gatekeeper consent form v 0.2 dated 09/01/2019** provided.

10. Who is organising and funding this study?

This study is organised by Liverpool John Moores University and funded as part of the researcher's PhD degree funding.

11. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, the NHS Research Ethics Committee (Reference number: xxx) dated ( ).

12. What if something goes wrong?

If you have a concern about any aspect of this study, please contact the researcher who will do their best to answer your query. The researcher should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk) and your communication will be re-directed to an independent person as appropriate.

13. Data protection notice.

Liverpool John Moores University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Liverpool John Moores University will process your personal data for the purpose of research. Research is a task that we perform in the public interest.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
You can find out more about how we use your information at URL and/or by contacting secretariat@ljmu.ac.uk.

If you are concerned about how your personal data is being processed, please contact LJMU in the first instance at secretariat@ljmu.ac.uk. If you remain unsatisfied, you may wish to contact the Information Commissioner's Office (ICO). Contact details, and details of data subject rights, are available on the ICO website at: https://ico.org.uk/for-organisations/data-protection-reform/overview-of-the-gdpr/individuals-rights/

14. Contact for further information.

Contact Details of Researcher (Principal Investigator)

Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 0151-231-2377

Contact Details of the Chief Investigator and Academic Supervisor

Director of the Studies
Dr. Rachel Mullen PhD BSc Clin Dip IP MRPharmS, FHEA
Senior Lecturer in Clinical Pharmacy, Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: R.Mullen@ljmu.ac.uk
Tel: 0151-231-2173

Appendix 23 *Gatekeeper consent form for phase 5*

LIVERPOOL JOHN MOORES UNIVERSITY
GATEKEEPER CONSENT FORM

A new care model for adult asthma patients: interviews with stakeholders

Please tick to confirm your understanding of the study and that you are happy for your organisation to take part and your facilities to be used to host parts of the project.

This study forms part of a wider research looking to provide evidence for a new care model for asthmatic patients that is built around patient needs and targeted to patient groups. This study will explore stakeholder and patient opinions via face-to-face or telephone structured interviews to evaluate a proposal of a new care model.

1. I confirm that I have read the gatekeeper information sheet v 0.5 dated (24/06/2019) and understand the information provided 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 participation of our organisation and members in the research is voluntary. ☐
3. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐
4. I agree for our organisation and members to take part in the above study. ☐
5. I agree to conform to the data protection act ☐

Name of Gatekeeper: Date: Signature:

Name of Researcher: Date: Signature:

Researcher contact details:
Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e-mail : A.M.Mahmoud@2017.ljmu.ac.uk
Tel:0151-231-2377

Appendix 24 *Participant invitation email for phase 5*

Participant invitation email for stakeholder interviews

Subject: Invitation to take part in developing a new care model for asthma patients.

Dear (name)

I am a pharmacist currently undertaking research towards a PhD at Liverpool John Moores University, looking to provide evidence for a new care model for asthmatic patients that is built around patient needs and targeted to patient groups.

I am currently recruiting participants for this study which aims to evaluate a proposal of asthma patient target groups (attached as PowerPoint presentation). This will involve a telephone interview lasting up to 40 minutes. You have been invited to participate due to your experience in commissioning and delivery of adult asthma patients services or because you are an adult asthma patient in the North West of England. Your contact details were obtained via (the NHS Choices website / GP surgery/ Chief pharmacists at the hospital you are working in/asthma UK organisation).

I have attached a participant information sheet and a consent form. Please take your time to read through the information provided and decide if you would like to take part. You will be contacted after three working days of receiving this email to determine if you wish to participate in the study. If you do agree to participate, you will be required to complete a consent for (copy attached).

Participation is voluntary and you are free to withdraw at any time by informing me and without giving a reason, also you can choose not to answer any of the questions. I appreciate that you are busy, however developing a new care model for asthma patients is very important to improve the management and control of asthma patients. Your participation will be very helpful.

Yours sincerely,

Aseel Mahmoud

Aseel Mahmoud
Postgraduate Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 01512312377

Appendix 25 *Participant information sheet for phase 4*

LIVERPOOL JOHN MOORES UNIVERSITY
Participant Information Sheet for

NHS REC Reference: (19/IEC08/0025)

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

A new care model for adult asthma patients: interviews with stakeholders

You are being invited to take part in a study. Before you decide it is important for you to understand why the study us being done and what participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

1. Who will conduct the study?

Study Team Chief Investigator and Director of Studies: Dr. Rachel Mullen, Senior Lecturer in Clinical Pharmacy, James Parsons Building Byrom Street, Liverpool, L3 3AF.
Principal Investigator: Aseel Mahmoud, PhD student, LJMU, James Parson building Liverpool, L3 3AF.
School/Faculty within LJMU: School of Pharmacy and Biomolecular Sciences.

2. What is the purpose of the study?

This study forms a part of a wider PhD research that aims to provide evidence for a new care model for asthma patients that is built around patient needs and targeted to patients groups. As part of this study I have proposed a new care model for asthma patients. This will be evaluated through a face-to-face or telephone interview exploring the issues concerning the proposed model feasibility. This study will also explore stakeholders' opinions and suggestions to improve the proposed model.

3. Why have I been invited to participate?

You have been invited because you are involved in the commissioning and/or delivery of adult asthma patient services in the North West of England.

Inclusion criteria: Stakeholders who are involved in the commissioning and/or delivery of adult asthma patient services in the North West of England. Each participant will have the required knowledge of at least one aspect of asthma management and control.

You were identified by your organisation as a potential participant.

Participants will also include adult asthma patients (from patients' interviews) who agree to be involved in this phase.

Exclusion criteria: Stakeholders who are not involved in any aspect of commissioning or service delivery for adult asthma patients, either within or outside the North West of England.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw at any time by informing the researcher (contact details are listed on section 18 of this sheet) without giving a reason and without it affecting your rights/any future treatment/service you receive.

5. What will happen to me if I take part?

Participation in this phase will involve a personal interview only (face-to-face or telephone). After receiving the information about the study by email, the researcher will contact you to determine if you have read the information and if you decided to participate.

If you choose to participate, a mutually agreed time will be arranged for the interview to take place in the medical practice (for patients only), in yours natural setting (for stakeholders only) or over the phone based on your preference. You will be asked to fill and sign a consent form before the interview commence. A handout of the proposed new model for asthma patients will be sent to you via email for telephone interviews or will be given to you at the beginning of the face-to-face interviews.

The interview will be semi-structured and will take up to 40 minutes, depending on the extent of the discussion. The interview schedule covers a range of topics relating to asthma management and control of adult patients. In addition, you will be prompted to discuss the feasibility of the new care model.

6. Will I be recorded and how will the recorded media be used?

The audio recording is essential to your participation but you should be comfortable with the recording process and you are free to stop the recording at any time

The audio recordings of the interview made during this study will be used only for analysis. No other use will be made of them without your written permission.

Interviews will be audio recorded on a password protected audio recording device and as soon as possible the recording will be transferred to secure storage and deleted from the recording device.

7. Are there any possible disadvantages or risks from taking part?

As this study is a face-to-face or telephone interview undertaken at medical practice, it is unlikely to pose any additional risk. No obvious sensitive topics will be discussed.

As a participant, you are free to refuse to answer to any questions you feel inappropriate or in comfortable with.

If the interviewee does find any topics distressing, this will be handled tactfully by the interviewer. If further action is required, the interviewer will discuss this with the medical team in the medical practice and the supervisory team. Every effort will be made to ensure that the interviewee is comfortable with the topics being discussed.

8. What are the possible benefits of taking part?

Whilst will be no direct benefits to you for taking part in the study, but it is hoped that this work will influence the future provision of services for asthma which asthma patients may benefit from.

9. What will happen to the data provided and how will my taking part in this project be kept confidential?

The information you provide as part of the study is the **study data**. Any study data from which you can be identified (e.g. from identifiers such as your name, date of birth, audio recording etc.), is known as **personal data**. This includes more sensitive categories of personal data (**sensitive data**) such as your race; ethnic origin; politics; religion; trade union membership; genetics; biometrics (where used for ID purposes); health; sex life; or sexual orientation.

Personal data will be collected will includes the name of the interviewee, job title and email address.

When you agree to take part in a study, we will use your personal data in the ways needed to conduct and analyse the study and if necessary, to verify and defend, when required, the process and outcomes of the study. Personal data will be accessible to the researcher, supervisory team and transcriber. In addition, responsible members of Liverpool John Moores University may be given access to personal data for monitoring and/or audit of the study to ensure that the study is complying with applicable regulations.

When we do not need to use personal data, it will be deleted or identifiers will be removed. Personal data does not include data that cannot be identified to an individual (e.g. data collected anonymously or where identifiers have been removed). However, your consent form, contact details, audio recordings will be retained for one year.

Personal data collected from you will be recorded using a linked code – the link from the code to your identity will be stored securely and separately from the coded data

You will not be identifiable in any ensuing reports or publications.

We will use pseudonyms in transcripts and reports to help protect the identity of individuals and organisations unless you tell us that you would like to be attributed to information/direct quotes etc.

With your consent, we would like to store your contact details so that we may contact you about future opportunities to participate in an interview as part of a wider study.

The interview recordings will be sent to an independent company who will produce a transcript

10. Limits to confidentiality

The Investigator will keep confidential anything they learn or observe related to illegal activity unless related to the abuse of children or vulnerable adults, money laundering or acts of terrorism.

11. What will happen to the results of the study?

The investigator intends to share the results to all participants for your information. In addition, the investigator intends to publish the results in PhD thesis, a peer reviewed

journal and at conferences. Anonymised quotations could be included in the published results using a pseudonyms participant identification code

12. What if we find something unexpected?

If any concerning finding relating to patients' care is raised during the interview including, for example poor practice provided to the patients or patient poor adherence to their medication, the researcher will discuss these issues with the PhD supervisory team.

13. Who is organising and funding the study?

This study is organised by Liverpool John Moores University and funded as part of the researcher's PhD degree funding.

14. Who has reviewed this study?

This study has been reviewed by, and received ethics clearance through, NHS Research Ethics Committee (Reference number: xxx).

15. What if something goes wrong?

If you have a concern about any aspect of this study, please contact the relevant investigator who will do their best to answer your query. The investigator should acknowledge your concern within 10 working days and give you an indication of how they intend to deal with it. If you wish to make a complaint, please contact Dave Harriss, the chair of the Liverpool John Moores University Research Ethics Committee (researchethics@ljmu.ac.uk; 0151 9046467).

16. Data Protection Notice

Liverpool John Moores University is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study Liverpool John Moores University will keep identifiable information about you for one year after the study has finished

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information by contacting Tina Sparrow, the Liverpool John Moores University Data Protection Officer at DPO-LJMU@ljmu.ac.uk

If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

17. Contact for further information

Contact Details of Researcher (Principal investigator)

Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: A.M.Mahmoud@2017.ljmu.ac.uk
Tel: 0151-231-2377

Contact Details of Academic Supervisor (Chief investigator)

Director of the Studies
Dr.Rachel Mullen PhD BSc Clin Dip IP MRPharmS, FHEA
Senior Lecturer in Clinical Pharmacy, Pharmacy and Biomolecular Sciences
James Parsons Building, Byrom Street, Liverpool, L3 3AF
e: R.Mullen@ljmu.ac.uk
Tel: 0151-231-2173

Thank you for reading this information sheet and for considering to take part in this study.

Appendix 26 *Participant consent form for phase 5*

LIVERPOOL JOHN MOORES UNIVERSITY CONSENT FORM

PARTICIPANT CONSENT FORM

A new care model for adult asthma patients: interviews with stakeholders

Please read the points below and initial each box to confirm that you agree before signing. The completed form will need to be returned to the researcher by email or by hand just before the interview. See contact details below.

1. I confirm that I have read and understand the participant information sheet v 0.5 dated (24/06/2019) provided for the above study and 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. ☐
3. I understand that the interview will be audio recorded and I am happy to proceed ☐
4. I understand that any personal information collected during the study will be anonymised and remain confidential. ☐
5. I understand that parts of our conversation may be used verbatim in future publications or presentations but that such quotes will be anonymised. ☐
6. I agree to take part in the above study by face-to-face or telephone interview. ☐

Name of Participant Date Signature

Name of Researcher Date Signature

Researcher contact details:
Aseel Mahmoud
Postgradute Research Student
Pharmacy and Biomolecular Sciences, Liverpool John Moores University
Room 7.46, James Parsons Building, Byrom Street, Liverpool, L3 3AF
e-mail : A.M.Mahmoud@2017.ljmu.ac.uk
Tel:0151-231-2377

Appendix 27 *Interview schedule for phase 5*

Participant reference no:

Stakeholders' interview schedule

A new care model for adult asthma patients

Introduction

Hello, my name is Aseel Mahmoud.

I'm just going to start with a bit of an introduction to the project. As mentioned in the original email I am a pharmacist currently undertaking research towards my PhD at Liverpool John Moores University. This interview forms part of the fourth of four phases of the PhD, which is developing a new care model for asthma patients.

As part of this study I have proposed solutions to improve asthma management and control which I would like to evaluate. I will share this with you in the form of handouts and then I will ask you some questions to discuss the model. Your feedback will be used to improve the model.

I would just like to reiterate that I am recording this interview for analysis purposes only. Everything that you tell me will be kept confidential and you remain anonymous in any reports published. If any issue related to patients' care are raised during the interview, I will discuss these issues with the PhD supervisory team. If an incident requires further action, then it will be reported to the participant's general practice.

n.b. if not yet received consent form, read out consent form and obtain recorded signed consent.
OR: I have received your signed consent form thank you.

Switch on the recorder…

Can I just confirm that you have had the opportunity to read the participant information sheet and you are happy to be interviewed?

Please feel free to interrupt to ask any questions or for clarification throughout the interview.

This will be a semi-structured interview. We will discuss your opinion about the proposed model, suggestions for improvements and if you think the model will improve asthma management and control or not.

For each question asked, the following question prompts will be used throughout the interview:
Where did it happen? When did it happen?
Can you give a more detailed description of what happened?
Can you help me to better understand your position/why you felt that way/why you say that?
Could you give me an example about that/tell a story about that?
Are there any times when it doesn't work?

Asthma patients-target groups

We will go through the seven suggested groups that were included in the handouts.

Asthma patient group 1: controlled asthma patients

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manage their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Asthma patient group 2: uncontrolled asthma patients

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manage their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Asthma patient group 3: DNA asthma patients

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manages their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Asthma patient group 4: the newly diagnosed asthma patients

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manages their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Asthma patient group 5: asthma patients with anxiety and depression

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manages their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Asthma patient group 6: asthma patients with high future risk

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manages their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Asthma patient group 7: asthma patients who needs seasonal care

Can you recognise any asthma patients that fit into this group?

Can you describe how asthma patients in this group manages their condition?

Do you think the suggested service is feasible? Explain how it could be provided to the patients?

Prompts:
Anything else to add?

Anything else to add?

Are you aware of any support provided by the pharmacists to asthma patients during COVID-19 outbreak? Do you think there is anything they could do to support asthma patients during this period?

That brings us to the end of the interview. I'd just like to thank you for giving up your time to participate.

Thank you and goodbye