Optimising pharmacist-led medication reviews in primary care to improve patient outcomes for those with long-term conditions.

By

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Thesis Abstract

Pharmacist-led medication reviews are a regularly used intervention in UK practice to help patients manage their long-term conditions and support the appropriate use of medicines. There is wide variation in how medication reviews are operationalised in the UK, and it is not known how this variation affects patient outcomes. The research presented in this thesis investigated how pharmacist-led medication reviews in primary care (general practice) could be optimised to improve patient outcomes for those with long-term conditions.

This research followed a structured, multi-phase approach using the MRC NIHR framework for complex interventions to optimise pharmacist-led medication reviews. The chosen methodologies included evidence syntheses exploring existing literature and identifying key components of pharmacist-led medication reviews, and co-design to develop an optimised intervention, which included early testing of a guidance document for pharmacists conducting medication reviews.

The scoping review found that the implementation of pharmacist-led medication reviews was generally poorly described, with substantial variation in outcomes, which makes it difficult to ascertain what a high-quality medication review looks like and what leads to good outcomes. The subsequent systematic review identified themes and components of pharmacist-led medication reviews were associated with improved outcomes for patients; these included patient involvement in goal setting and action planning, and additional support and follow up from healthcare professionals. Focus groups elicited stakeholders' opinions of pharmacist-led medication reviews and agreed areas where they can be improved. A guidance document to support pharmacists delivering medication reviews was co-designed and tested for acceptability. Pharmacist-led medication reviews in primary care can be optimised by patients and pharmacists preparing for the review, patients being actively involved in the process and agreeing treatment goals and scheduling

appropriate follow-up appointments. The next step is to engage a wider group of stakeholders to refine the document before testing it on a larger scale.

Visual summary of research undertaken in this thesis

Background

Pharmacist-led medication reviews are a recognized intervention in UK NHS policy and practice to help manage patients with long-term conditions. Medication reviews are used to support the appropriate use of medicines. Medicines can cause problems as well treating the condition. Several factors can lead to medicines related problems, e.g., inappropriate prescribing, non-adherence. There is wide variation in how medication reviews are operationalised in the UK; this may influence patient outcomes.
The thesis research question is **how can pharmacist-led medication reviews in primary care be optimised to improve patient outcomes for those with long-term conditions?**

Methodology	Methods	Chapter
Evidence syntheses	Scoping literature review	Chapter 3 Scoping review
	Systematic literature review	Chapter 4 Systematic review
Co-design	Focus groups & semi-structured interviews	Chapter 5 Stakeholders opinions (OPen study phase 1)
	Acceptability testing through semi-structured interviews	Chapter 5 Co-design and acceptability testing (OPen study phase 2)

Scoping review

Research Question: What is the systematic review evidence about the nature and effectiveness of medication review interventions conducted by pharmacists, and what are the gaps in knowledge that can inform future research direction?
Results: Nature of the intervention poorly reported. Evidence for effectiveness was uncertain. A systematic review exploring individual components of medication reviews and linking these to outcomes was indicated to ascertain their effectiveness.

Systematic review

Research Question: Which components of pharmacist-led medication reviews are associated with positive outcomes for patients, practitioners, and the health system?
Results: Common themes and components associated with positive outcomes from pharmacist-led medication reviews were identified.

OPen study

Research Question: How can Pharmacist-led medication reviews in primary care be optimised to improve outcomes for people with long-term conditions?

Phase 1

Results: Focus groups/ interviews with participants identified key uncertainties to be addressed in the co-design workshops.

Phase 2

Results: Themes and components identified in the systematic review and the key uncertainties from the stakeholder groups were considered by the participants in the co-design of a guidance document to optimise medication reviews.
The document was refined following pharmacist and patient feedback before it was tested by a small number of pharmacists and was found to be acceptable and practical.

Overall Conclusions

The systematic literature identified themes and components that may improve outcomes for patients with long-term conditions. These themes and components were incorporated in the co-designed guidance document to optimise medication reviews. Pharmacists reported this document was acceptable and practical. A randomised controlled trial over a period of several months would need to be undertaken to determine the economic considerations i.e., resource and outcome consequences of using this guidance document.

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Dedication

To the loving memory of my mother, **Georgina Ann Evans**, who always dreamed of one of her children graduating with a “floppy hat” and becoming a “doctor,” and my husband, **Justin Lee Craske**, who gave me the courage to embark on this research journey.

Justin, your love and unwavering belief in me were my greatest sources of strength—you were my loudest cheerleader until you could cheer no more.

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“That which we persist in doing becomes easier to do, not that the nature of the thing has changed but our capacity to do has increased.” -Heber J. Grant

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1.0 Chapter 1 Introduction

1.1 Thesis structure

This thesis comprises several chapters, including an introduction and conclusion, which collectively address the overall research question: **"How can pharmacist-led medication reviews in primary care be optimised to improve patient outcomes for those with long-term conditions?"**

Chapter Overview

- Chapter One (Introduction):

  Discusses the rise of long-term conditions and the associated pharmacological management. It provides the rationale for medication reviews, examines the role of pharmacists, and outlines the international policy context.

- Chapter Two (Methodology)

  Outlines the theoretical frameworks, philosophical foundations, and methodological approaches underpinning the research in this thesis.

- Chapter Three

  Describes the literature review to explore the current pharmacist-led medication review literature.

- Chapter Four

  Describes the literature review exploring components of pharmacist-led medication reviews and their link to outcomes.

- Chapters Five and Six

  Describe the designing and testing of an optimised pharmacist-led medication review.

- Chapter Seven (Discussion):

  Summarises the findings of the research, provides an overarching conclusion, and offers recommendations for future research.

1.2 Introduction to the problem

Pharmacist-led medication reviews are widely accepted in policy and practice as an intervention for managing patients with long-term conditions, both in the UK and internationally, to help manage patients with long-term conditions. This chapter will:

- define long-term conditions, describing their prevalence and some of the challenges of living with these conditions
- describe the use of medicines to treat long-term conditions and problems associated with them
- describe the interventions to support appropriate medicines use
- outline the changes in UK policy landscape that make provisions for pharmacist-led medication reviews

This introduction chapter outlines the need for research into optimising pharmacist-led medication reviews in primary care to improve patient outcomes for individuals with long-term conditions. As the first point of contact within the healthcare system, primary care includes general practice, community pharmacy, dental, and optometry services [1]. However, as dental and optometry services fall outside the scope of this research, the focus will be on general practice and community pharmacy.

1.3 Long-term conditions

Long-term conditions (LTCs) or chronic diseases have been defined as “diseases which have one or more of the following characteristics: they are permanent, leave residual disability, are caused by non-reversible pathological alteration, require special training of the patient for rehabilitation, or may be expected to require a long period of supervision, observation, or care” [2]. Long-term conditions are diseases which are managed over a period of years or decades with medicines and other treatments [2,3]. Examples of chronic conditions include cardiovascular disease, chronic

obstructive pulmonary disease, diabetes, musculoskeletal disorders, cancer, and mental health disorders, such as depression and schizophrenia [3].

1.3.1 Prevalence of long-term conditions

Cardiovascular disease, chronic obstructive pulmonary disease, and diabetes are among the leading causes of illness and health burden in developed countries such as Australia, United States of America (USA) and United Kingdom (UK) [4–6]. The most recent global prevalence data indicate that there were 621 million cases of cardiovascular disease in 2021 [7], 480 million cases of COPD in 2020 [8], and 537 million adults living with diabetes (all types) in 2021 [9]. The prevalence of COPD is projected to increase by 23.3%, reaching 592 million cases by 2050, while the number of adults with diabetes is expected to rise to 783 million by 2045 [9,10]. In 2021, the global prevalence of mental health disorders exceeded 1 billion cases across all genders and age groups; dementia is expected to have an increasing societal impact due to its higher prevalence among aging populations [11]. In 2019, an estimated 57.4 million people were living with dementia, with projections suggesting this figure will rise to 152.8 million by 2050 [12].

The rise in long-term conditions can be attributed to a combination of demographic, socioeconomic, and lifestyle factors. As populations age, the prevalence of these conditions is expected to increase significantly, leading to a greater burden on healthcare systems globally [13–16]. However, age-standardised prevalence is often constant or even falling, but the ageing population leads to greater numbers of people with the condition, and a greater population burden[17]. The UK census 2021 reported the number of people aged 65 years was over 11 million, rising from 16.4% of the population in 2011, to 18.6% [18]. The incidence of frailty and multimorbidity increases with age, particularly among older adults who often present with multiple long-term conditions

simultaneously [16]. Multimorbidity (multiple long-term conditions), defined as the "coexistence of two or more chronic conditions (physical or mental) in an individual", is a common challenge in ageing populations. Frailty, on the other hand, is a clinically recognised age-related decline in function across multiple physiological systems, resulting in a reduced ability to manage every day or acute stressors [19]. Both frailty and multimorbidity are critical concerns as they are strongly associated with adverse outcomes, including disability, hospitalisation, and mortality—factors that significantly impact individuals and place substantial burdens on healthcare systems.

People living in areas of high socio-economic disadvantage have a higher prevalence of multiple long-term conditions and are at risk of developing them at an earlier age [19]. The wider determinants of health—such as income, wealth, education, housing, transport, and leisure—play a significant role in overall well-being [20]. However, the strong influence of socio-economic factors means that long-term health conditions often develop regardless of individual lifestyle choices. The prevalence of long-term conditions creates a burden for individuals and their families, and health and social care systems [21].

1.3.2 Health burden of long-term conditions

Approximately 15 million people in England have a long-term condition [22,23]. In 2009, 58% of adults aged 60 and over, living in England, were reported to have at least one long-term condition [21]. The prevalence of long-term conditions is projected to increase significantly over the coming years, rising from 6.6 million adults in 2019 to 9.3 million by 2040, with the largest growth among those aged 70 and older [24]. Disability is defined as "difficulty or dependency in carrying out activities necessary for independent living, including roles, tasks needed for self-care and household chores, and other activities important for a person's quality of life" [25,26]. Overall, long-term

conditions have a profound impact on individuals' lives, affecting their ability to work, socialise, and perform daily functions [23].

One of the challenges of living with multiple long-term conditions is that patients often receive treatment for individual illnesses as if they exist in isolation. Standard clinical guidelines are often based on evidence from studies that focus on narrower, more homogeneous populations, which may not reflect the complexities of managing multiple, often interacting, conditions in older adults or those with diverse health profiles [27]. This leads to complicated and duplicated interactions with healthcare professionals within the healthcare system and can lead to poorer patient outcomes [28].

Long-term conditions often require ongoing management to reduce their impact on individuals' quality of life. The approach to managing long-term conditions is usually multifaceted and may include:

- Medical Interventions: This involves the use of prescribed medications to manage symptoms, slow progression, or prevent complications associated with the condition.
- Surgical Interventions**:** In some cases, surgery may be needed to treat or alleviate symptoms of certain long-term conditions, such as joint replacements for osteoarthritis or bypass surgery for heart disease.
- Behavioural Interventions: These include lifestyle changes, such as adopting a healthier diet, increasing physical activity, smoking cessation, or weight management. These changes can significantly improve health outcomes for individuals with long-term conditions [29–32].
- Psychological Interventions**:** Psychological support, such as cognitive-behavioural therapy (CBT) or counselling may be indicated for patients suffering from mental health conditions,

such as anxiety and depression, or to help individuals cope better with the emotional impact of managing a long-term condition [30,33].

People living with a long-term condition are encouraged to modify their behaviour to support their physical and psychological well-being. In addition, people are encouraged to adhere to treatment regimes, regularly attend appointments with healthcare professionals, monitor their health and make decisions about their care [3]; with these responsibilities contributing to an individual's health burden.

In 2016, Katusiime et al. published a systematic review exploring medicine-related experiences and their associated burden [34]. This review reports that medicine burden is just one aspect of treatment burden, but it can lead to nonadherence and poor clinical outcomes, in addition to affecting patient satisfaction and quality of life. The authors suggest that patients' experiences of medicine burden may be underrepresented in the literature. They concluded that a patient-generated, multidimensional measure is needed to assess how interventions affect treatment burden and patient experience. Such measures can help identify patients struggling with long-term medicines and support more tailored, patient-centred care.

An integrative review by Lee et al. published in 2024 [35] explored treatment burden in patients living with multimorbidity and identified four healthcare tasks (i.e., self-care activities, knowledge acquisition, paperwork, and ongoing prioritisation) and the social, emotional, and financial impact. The review highlighted contextual and personal factors (multimorbidity context, individual circumstances, and internal/external resources) that shape treatment burden. Their integrated map shows the dynamic links between these factors, treatment burden, and health outcomes, offering a framework to better understand and address patients' experiences.

A comprehensive multifaceted approach that considers treatment burden is key to managing long-term conditions effectively, improving patient outcomes, and enhancing quality of life [26]. Furthermore, people with long-term conditions are frequent users of health services across various settings, including primary care, acute care, and emergency or urgent care [21] and the treatment of long-term conditions accounts for 70% of the UK health and social care budget [22,23]. In 2022, total long-term health and social care expenditure stood at £68.2 billion, with £32.4 billion spent on medicines during the same year[36]. This demonstrates the impact of the use of medicines in the management of long-term conditions.

1.4 Use of medicines to treat long-term conditions

The rise in prevalence of long-term conditions and the development of new drugs and lowering of thresholds for pharmaceutical treatment, has led to a substantial increase in the prescribing and dispensing of medicine and the 2022 UK pharmaceutical expenditure on medicines was £39.4 billion [36]. The increasing prevalence of multimorbidity is leading to an increase in the prescribing of multiple medicines (polypharmacy). There are multiple definitions of polypharmacy, with “the prescribing of five or more medicines” being the most widely used [37]. Polypharmacy is particularly prevalent in older populations and those with multiple long-term conditions. The global data on polypharmacy, such as the 20% prevalence in Australia, 46% prevalence in Hong Kong for adults aged 65 and over, 47% in UK for adults 75 years and older, shows that this issue is not confined to one region [38,39]. As populations age globally and the prevalence of chronic conditions rises, polypharmacy is becoming a more widespread concern [40].

There are benefits and risks to polypharmacy; the benefits are managing multiple chronic conditions through appropriate medicines which can improve health outcomes, reduce complications, and enhance quality of life individuals. However, polypharmacy also raises concerns, especially when medications are prescribed without clear indications or when they interact in ways that cause harm.

It has been reported that polypharmacy increases the likelihood of adverse outcomes such as mortality, falls, adverse drug reactions and longer hospital stays [41,42].

The increasing complexity of polypharmacy in managing long-term conditions has led to an important distinction between appropriate polypharmacy and problematic polypharmacy. Appropriate polypharmacy is defined as "prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence" [41]. This includes:

- Inappropriate prescribing, such as using medications with a higher risk of adverse effects when lower-risk alternatives are available, or prescribing drugs at higher doses or for longer than necessary [43].
- Drug-drug and drug-disease interactions, that can worsen health outcomes or cause new health problems, particularly in in older adults due to alteration of the way the body biologically responds to the medication or the way that it moves through the body (pharmacodynamics and kinetics) [41,44].
- Under-prescribing, particularly among older adults, where potentially beneficial medications are withheld due to concerns about medication complexity or side effects [45].
- Non-adherence, where patients fail to take their prescribed medicines as directed, often because of the number of medications they are asked to manage, or because their preferences have not been adequately considered by the prescriber [46].

Polypharmacy can lead to prescribing cascades, which occur when a drug causes an adverse drug event (ADE) that is misinterpreted as a new medical condition, resulting in the prescription of an additional drug to treat the drug-induced problem [47]. A literature review by Dreischulte et al. [48] distinguishes intentional from unintentional prescribing cascades, and appropriate from inappropriate ones. Unintentional prescribing cascades occur when adverse effects of a medication are not recognised as such, but instead misdiagnosed, leading to new, possibly unnecessary

treatments. Intentional prescribing cascades occur when the prescriber recognises the adverse drug reaction (ADR) but chooses to prescribe another medication to prevent or manage that ADR, often weighing benefits against risks. Appropriate prescribing cascades are when the benefits outweigh the harm. Inappropriate cascades are when the harms outweigh the benefits or where the cascade was avoidable [48]. The Dreischulte review concludes that, like polypharmacy more generally, prescribing cascades are not inherently problematic; in certain clinical contexts they may be justified and necessary parts of good prescribing practice.

Whilst the use of medicines is predominantly associated with treatment of illness, they also have a role in disease prevention. The two main approaches to disease prevention are: population-level prevention, which focuses on reducing risk factors across entire communities (e.g., promoting less smoking, increased physical activity, reduced alcohol consumption, and healthier diets), and healthcare-based prevention, which involves diagnosing and treating early symptoms or disease markers, often followed by prescribing medications such as antihypertensives or statins [49]. This health-care emphasis on preventative medicine, particularly for asymptomatic patients, has contributed to the rise in polypharmacy [50]. While the intention is to reduce the future burden of disease, this approach can lead to overdiagnosis and the unnecessary prescription of medications [51]. Clinicians need to balance clinical guidelines with the patient's personal preferences and values to achieve the best outcome. The BMJ's *Too Much Medicine* initiative highlighted the risks of overdiagnosis and overprescribing, particularly in terms of unnecessary care and wasted resources [52].

The UK Department of Health and Social Care's *"Good for you, good for us, good for everybody"* report published in 2021 outlines plans to reduce overprescribing and improve patient care and safety [53]. It specifically targets inappropriate polypharmacy, aiming to:

- Improve adherence to prescribed medications by reducing the number of unnecessary prescriptions.
- Ensure that prescribing is patient-centered and evidence-based, particularly for individuals with multiple chronic conditions.

A narrative literature review identified the following health outcomes associated with polypharmacy [54]:

- Frailty: Polypharmacy increases frailty risk independently of other factors, potentially leading to poorer health outcomes [55].
- Hospitalisation: A higher number of medications is associated with increased hospital admissions. Up to to 11% of unplanned hospital admissions are related to medication harm, with nearly 50% being preventable [44,56].
- Mortality: A meta-analysis of 47 studies found a strong link between polypharmacy and mortality, with a dose-response effect as medication count rises [57].

Certain populations are at increased risk of medication-related harm due to physiological vulnerability, multimorbidity, and social or cognitive factors. Older adults are particularly susceptible because of age-related pharmacokinetic changes, polypharmacy, and multimorbidity, which heighten the risk of adverse drug events, falls, and prescribing cascades [58,59]. Individuals with multiple long-term conditions are more likely to have complex medication regimes, an increased risk of treatment burden and adverse effects [56]. Those with mental health conditions or chronic pain may experience high levels of polypharmacy, particularly involving psychotropics or opioids, leading to metabolic complications, dependence, or suboptimal monitoring [60,61].

As polypharmacy increases, patients are less likely to adhere to their medication regimens with studies indicating that the more medications a person is prescribed, the lower the likelihood of full adherence [62]. This is not just due to the complexity of managing multiple medications, but also

due to the physical and cognitive burden that can accompany polypharmacy, especially in older patients.

Adherence

The 2003 World Health Organisation (WHO) report, "Adherence to Long-Term Therapies: Evidence for Action," provides a comprehensive review of adherence to long-term therapies [62]. It defines adherence as “the extent to which a person’s behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider”, and notes that up to half of the medications prescribed for long-term conditions are not taken as prescribed [62].

Despite being over two decades old, the report's findings remain relevant today. Poor adherence to long-term therapies, including medicines, leads to poorer health outcomes and increased health costs [63]. The challenge of medication adherence continues to be a significant issue in healthcare, with ongoing research striving to address and improve adherence rates.

The 2003 WHO report highlights that adherence involves various health-related behaviours and identifies five interacting dimensions that affects it [62]. The five dimensions affecting adherence are:

- Social and economic factors: Examples include socioeconomic status, poverty, illiteracy, education level, employment status, living conditions, culture and belief systems.
- Health care team and system-related factors: Examples include patient-provider relationship, poorly developed health services, poor medication distribution systems, lack of knowledge and training for health care providers.

- Condition-related factors: Examples include severity of symptoms, level of disability (physical, psychological, social and vocational), rate of progression and severity of the disease, availability of effective treatments.
- Therapy-related factors: Examples include complexity of the medication regimen, duration of treatment, previous treatment failures, the immediacy of beneficial effects, side-effects.
- Patient-related factors: These include the resources, knowledge, attitudes, beliefs, perceptions, and expectations of the patient.

Non-adherence can contribute to poor patient outcomes and increased use of NHS resources (including medicines waste) [64]. Research undertaken by the York Health Economics Consortium, University of York, and the School of Pharmacy, University of London suggested that each year between £100 - £800 million worth of dispensed NHS medicines go unused and are then discarded. That is equivalent to approximately £1 in every £25 spent on primary care and community pharmaceutical products used [65].

Intentional and non-intentional non-adherence

Given the multidimensional nature of adherence, non-adherence is typically classified as either intentional or non-intentional. Intentional non-adherence is a deliberate choice, where patients actively decide not to take medications as prescribed [66,67]. This form of non-adherence often arises from patients weighing the benefits and drawbacks of the medication. Addressing intentional non-adherence involves exploring patients' beliefs and preferences that shape their perceptions of treatment. Key factors include their knowledge and beliefs about the illness, motivation to manage it, expectations of treatment outcomes, concerns about potential side effects, and confidence in managing the burden of medication while maintaining a "normal" life [62]. For instance, a patient with asymptomatic hypertension may not perceive the need for medication if they are not experiencing any noticeable symptoms. The experience or anticipation of side effects is a known

reason for skipping, altering or delaying medication, as is the general reluctance to be reliant on medication [68].

Unintentional non-adherence typically occurs when patients lack the capacity or resources to take their medication as prescribed [66]. This may involve difficulties understanding usage instructions, administering the medication, or simply forgetting to take it [69]. Forgetting to take medication is one of the most reported reasons for non-intentional nonadherence and is applicable in three distinct ways: forgetting to take medication, forgetting whether medication had already been taken, and forgetting to reorder prescriptions on time [68]. In some health systems, financial constraints also limit access to medicines, further affecting adherence [69–71].

The WHO adherence report suggests that interventions that promote adherence can help bridge the gap between the clinical efficacy of treatments and their real-world effectiveness, thereby enhancing the overall efficiency and impact of the health system [62].

1.5 Interventions to review medicines use

Interventions to support medicines use and resolve medicines-related problems can be at multiple levels, from healthcare system level to tailored approaches for individuals. Healthcare system level interventions are those delivered by healthcare professionals in line with regional or national guidelines [72] whilst individual approaches are variable and could include shared decision making and adherence aids [69]. Well-designed healthcare system interventions can generate better outcomes, increase safety, and improve efficiency [73]. At a UK NHS health care system level several interventions have been developed to support appropriate medicines use. These interventions centre on the appropriate review of medicines by healthcare professions, such as doctors, nurses, pharmacists and pharmacy technicians, and include:

- Medication (medicines) review [74]: a diagnostic/ educational intervention to support medicines use.
- Structured medication review [75,76]: a review delivered by clinical pharmacists, general practitioners (GPs) and advanced nurse practitioners in primary care as part of the GP contract.
- Medicines reconciliation [76]: an intervention to ascertain an accurate list of a person's current medicines and comparing it with those an individual currently uses, including herbal supplements and other medicinal products purchased.
- Medicines optimisation [77]: an intervention with the goal of ensuring that the right patient gets the right medicine at the right time. It aims to improve patient outcomes, enable correct use of medicines, avoid unnecessary usage, improve safety, and reduce waste.
- Medicines management [78]: an approach that emphasises systems, handling, prescribing budgets, and medicine control rather than direct patient engagement.
- Appropriate prescribing [79]: a six-step approach as defined by the World Health Organisation:
    1. Identify the patient's problem.
    2. Define the therapeutic objective.
    3. Select the appropriate medicine.
    4. Provide information, warnings, and non-pharmacological advice.
    5. Initiate treatment and monitor the patient.
    6. Regularly evaluate therapy to ensure continued benefit.
- De-prescribing [80]: an approach defined as the 'planned and supervised process of dose reduction or stopping of medication that might be causing harm or no longer be of benefit'. De-prescribing must be supervised and planned in partnership with the patient to avoid withdrawal effects or worsening of the condition.

- Medicines Use Review (MUR) [81]: a community pharmacy advanced service in 2005 to align with policy and professional ambitions. These ambitions aimed to improve services for patients, reward the quality of services provided, and leverage the skills of pharmacists and support staff. MURs were primarily adherence-focused interventions intended to assess a patient's actual use of their medications, their understanding of and experiences with taking them, and to identify, discuss, and resolve issues related to poor or ineffective medication use. Additionally, MURs sought to identify side effects and drug interactions that could impact patient compliance and improve the clinical and cost-effectiveness of prescribed medicines.

In 2016, an independent review of community pharmacy services, commissioned by the Chief Pharmaceutical Officer and led by Richard Murray, made several key recommendations [82]. Among these was a proposal to redesign the existing Medicines Use Reviews (MURs) within the pharmacy contract. The redesigned service would include ongoing monitoring and regular follow-up with patients, forming an integrated part of a multifaceted approach to managing long-term conditions. The report concluded that MURs should evolve into full clinical medication reviews incorporating independent prescribing, which would require access to patients' full medical records, a capability not currently available in community pharmacies [82].

The updated community pharmacy contractual framework, announced in 2019, announced that MURs would be phased out by 2021 [80]. Funding previously allocated to MURs was redirected to support the delivery of structured medication reviews in primary care. These structured medication reviews could be delivered by several healthcare professionals including pharmacists [75,84].

Whilst many of the terms identified above are used interchangeably, it is clear from their descriptions that there are subtle differences in definitions, approaches, aims and objectives for

these interventions. *Room for review (2002)* [85] was the first major publication that sought to define a medication review. It acknowledged healthcare professionals lacked common terminology when describing the review process. The authors proposed a definition that was later adopted by the National Institute of Health and Care Excellence (NICE) (Box 1) [86].

Box 1: NICE definition of a structured medication review

> A structured medication review is "a critical examination of a person's medicines with the objective of reaching an agreement with the person about treatment, optimising the impact of medicines, minimising the number of medication related problems and

The Pharmaceutical Care Network Europe (PCNE) has also provided a definition of medication reviews (Box 2) [87].

Box 2: PCNE definition of medication reviews

> A medication review is "a structured evaluation of a patient's medicines with the aim of optimising medicines use and improving health outcomes". This entails detecting drug-related problems and recommending interventions.

NICE recommends that patients who are prescribed medicines should have them reviewed regularly but does not dictate which healthcare professional should undertake the medication review [88]. The NICE definition has been adopted by NHS England and is aimed at the healthcare team and not to specific practitioners. NICE describes a medication review as more of a process and implies continued monitoring. Both NICE and PCNE definitions describe a structured assessment of medication to help patients make the most of their medicines. However, the PCNE definition was agreed upon by a body of pharmacists and the outcome is to recommend interventions, thereby transferring the management of any issues to another healthcare professional. It describes a

medication review as a one-off intervention and does not appear to reflect the evolving role of the pharmacist [89].

1.6 Changes in the health policy landscape to support the appropriate use of medicines in the UK

There have been several significant developments in the UK NHS healthcare system related to workforce integration and the expanding role of pharmacists. These are summarised below:

- Five Year Forward View (2014**)** [50]: Focused on creating new models of care to better integrate services, adapting to population changes.
- General Practice Forward View (2016) [90]: Addressed the rising demand for GP services by proposing upskilling and utilising practice team members (e.g., nurses, pharmacists). This included piloting the general practice clinical pharmacist role and introducing the Pharmacy Integration Fund (PhIF) to develop pharmacists and pharmacy technicians for integrated care models. It also piloted the Medicines Optimisation in Care Homes (MOCH) programme, aimed at enhancing patient care and medication use.
- NHS Long Term Plan (2019) [49]: Recognised pharmacists as key healthcare professionals for leading medication reviews [53].

These developments in the UK health landscape highlight the increasing reliance on pharmacists in delivering integrated, patient-centred care.

1.7 Pharmacists' roles in supporting patients and their medicines use

Medication reviews are widely used by pharmacists internationally to support patients with their medicines. In UK primary care, pharmacists across various organisations are involved in providing different types of medication reviews, including:

- Retail (community pharmacy): Pharmacists delivering adherence-focused New Medicine Reviews [91] and a Discharge Medicines Service (DMS) which aims to improve patient safety and medication management during transitions from hospital to home [92].
- Integrated Care Boards (ICBs): Pharmacists adopting a medicines management approach, ensuring prescribing aligns with formulary and clinical prescribing guidelines [93].
- GP practices: Clinical pharmacists conducting medication reviews for patients with long-term conditions [94].
- Primary Care Networks (PCNs): Pharmacists delivering patient-facing structured medication reviews in settings such as GP practices, care homes, or domiciliary visits, as well as medicines reconciliation following hospital discharge [95]. PCNs have prioritised enhanced care for care home residents, people living with frailty, and patients with complex needs, aligning with national goals to deliver more proactive and personalised care in the community. As part of this, PCNs are required to provide structured medication reviews and optimise medicines use, particularly for individuals at high risk of medication-related harm, such as older adults, those experiencing polypharmacy, and care home residents. Additionally, PCNs aim to improve patient access to resources and support self-management, empowering individuals to take a more active role in managing their health and medications [84]. A systematic literature review exploring interventions to improve medicines optimisation for older people with frailty identified a need for high-quality interventions for this population in primary care [96].

These descriptions highlight the range of procedures in primary care that fall under the broad definition of a medication review.

Pharmacists' roles in delivering medication reviews align with the responsibilities outlined by the General Pharmaceutical Council (GPhC), the regulatory body for pharmacists in Great Britain. According to the GPhC, pharmacists are responsible for:

- Ensuring that the medicines prescribed to patients are suitable.

- Advising patients about their medicines, including how to take them, potential reactions, and addressing patients' questions.

Additionally, pharmacists “advise other healthcare professionals about safe and effective medicines use, and the safe and secure supply of medicines” [97]. Given these responsibilities, it is appropriate for pharmacists to play a key role in medication reviews.

1.9 Summary and next steps

This chapter has discussed the growing number of people living with long-term conditions and the challenges associated with medication use. While medicines are effective in treating disease, they can also contribute to problems such as hospital admissions and reduced quality of life. Inappropriate prescribing along with non-adherence, can lead to adverse outcomes. These issues highlight the need for interventions that improve medication management.

Medication reviews are widely used to optimise medicine use, and UK government policy has increasingly recognised pharmacists’ key role in promoting medication safety. Pharmacists are now central to initiatives aimed at improving prescribing and reducing harm. However, there remains substantial variation in how medication reviews are defined, structured, and delivered, which may influence their effectiveness. Despite limited evidence demonstrating consistent impact, governments continue to invest in medication review services, aiming to improve safety and outcomes. Yet, poor outcomes persist; for example, the proportion of emergency hospital admissions in England related to adverse drug reactions increased from 1.2% in 2008/09 to 1.6% in 2014/15 [98].

Further research is required to establish optimal criteria for conducting medication reviews to ensure a consistent, high-quality, and patient-centred approach. The optimisation of pharmacist-led medication reviews can be defined as a "deliberate, iterative and data-driven process to improve a health intervention and/or its implementation to meet stakeholder-defined public health impacts within resource constraints" [99]. This reflects a growing research focus in the UK, exemplified by the NIHR-funded OSCAR project (Optimising Structured Medication Reviews), supported by the National Institute for Health and Care Research Applied Research Collaboration (ARC) in 2023. OSCAR aims to examine how structured medication reviews are currently implemented by GPs and pharmacists for patients with multiple long-term conditions and to provide recommendations for improvement [100]. While sharing similar aims, my research focuses specifically on *pharmacist-led* medication reviews, whereas OSCAR includes both GPs and pharmacists. At the time of writing, OSCAR has not yet published its findings.

The wide range of interventions designed to optimise medication use has generated a substantial body of research. Much of this work has focused on specific populations, such as older adults or those with multimorbidity, and on targeted interventions, such as deprescribing [101]. However, despite this extensive evidence base, there remains variability in how medication reviews are conceptualised, delivered, and evaluated. In particular, the pharmacist's role, although central to medicines optimisation, has not been consistently defined or supported by robust implementation research. Consequently, further work is required to clarify how pharmacists can most effectively deliver medication reviews and to develop sustainable models that can be embedded into routine primary care practice.

In conclusion, the overarching aim of my thesis is to investigate how pharmacist-led medication reviews in primary care can be optimised to improve patient outcomes for those with long-term conditions. The objectives are:

- Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction.
- Identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts.
- Design and test an optimised pharmacist led medication review (PLMR) in primary care.

2.0 Chapter Two Methodology

This chapter presents the theoretical frameworks that inform and support my research. It also outlines the philosophical underpinnings of the study and details the methodological approaches employed to address the research objectives.

2.1 Medication reviews as a complex intervention

Chapter One (Introduction) outlined the approaches used to support medication use and highlighted the range of professionals and methods involved. Several realist syntheses have examined the relationships between context, mechanisms, and outcomes in medicines-related interventions such as deprescribing and medicines management, illustrating their inherent complexity [101–103]. Similarly, medication reviews are recognised as complex interventions, as defined by the Medical Research Council (MRC) and National Institute for Health and Care Research (NIHR) framework [104]. This complexity arises from the multiple behaviours they target, the diverse skills required to deliver them, and the variability in their implementation across settings. They are also designed to achieve multiple, interrelated outcomes, such as improved clinical parameters, reduced medicines-related harm, enhanced adherence, and better patient experiences, which further reinforces their classification as complex interventions. While definitions from NICE and the Pharmaceutical Care Network Europe (PCNE) provide a useful foundation [88,105], they do not specify key components such as content, duration, or frequency. Consequently, careful consideration is needed when selecting approaches to optimise medication reviews to improve patient outcomes.

The aim of this thesis was to optimise pharmacist-led medication reviews, given the wide variation in how these are currently operationalised across the UK and the potential implications for patient outcomes. I planned to use evidence syntheses to describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction (objective one) and to

identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts (objective two). I planned to use qualitative methods to design and test an optimised pharmacist led medication review (PLMR) in primary care (objective three).

2.2 MRC NIHR framework for developing and evaluating complex interventions

Optimising complex interventions has been described as the process of "evaluating or testing intervention components and/or drafted interventions to identify what works and what does not work within the intervention (medication review) under design" [106]. A scoping review conducted by Levati et al. examined strategies used to optimise complex health interventions[106]. Their review identified four key frameworks commonly applied in this field: the Multiphase Optimisation Strategy (MOST) [107], the Medical Research Council (MRC) Framework (2000 [108] and 2008 [109] versions), Process Modelling in Implementation Re-search (PRIME) [110], and Normalisation Process Theory (NPT) [111]. The review outlines how each framework addresses the four stages of complex intervention development, namely development, piloting, evaluation, and implementation. These frameworks were evaluated to determine which would be most appropriate to address the objectives for this PhD research.

Intervention optimisation is situated within the piloting phase in both the PRIME and NPT frameworks. As this PhD research did not seek to pilot an intervention, these frameworks were not considered appropriate. Both the Medical Research Council (MRC) Framework and the Multiphase Optimisation Strategy (MOST) offer structured approaches to the development and evaluation of complex interventions, but they differ in emphasis and suitability depending on the research objectives.

As described in the Levati scoping review, the MRC Framework (2000 [108] and 2008 [109]) places strong emphasis on understanding context and mechanisms of action, making it particularly appropriate for investigating how medication reviews function in practice. It encourages the grounding of interventions in theory and evidence, aligning closely with this study's objective to synthesise existing literature and stakeholder perspectives to inform future research. Since the Levati et al. scoping review, the framework has continued to evolve to reflect updated definitions of complex interventions and incorporate new methodological and theoretical developments [104,108,112,113]. Its most recent iteration, developed in collaboration with the National Institute for Health and Care Research (NIHR)[104], emphasises the importance of context and process evaluation alongside outcomes, providing a more comprehensive approach to intervention optimisation. The framework also supports iterative development, feasibility testing, and real-world implementation; key elements for ensuring that research findings can be effectively translated into practice.

In contrast, the Multiphase Optimisation Strategy (MOST) is primarily suited to interventions where the goal is to optimise specific components using experimental designs, such as factorial trials. As this research was exploratory and developmental, focused on understanding, designing, and preliminarily testing an optimised complex intervention rather than isolating and testing individual components under controlled conditions—the MRC Framework was deemed the more appropriate choice.

The most recent version of the MRC (NIHR) framework informed the design of my research. This guidance divides complex intervention research into four phases and identifies six core elements that should be implemented in each phase [104]. **Figure 2.1** identifies each of these phases and the core elements.

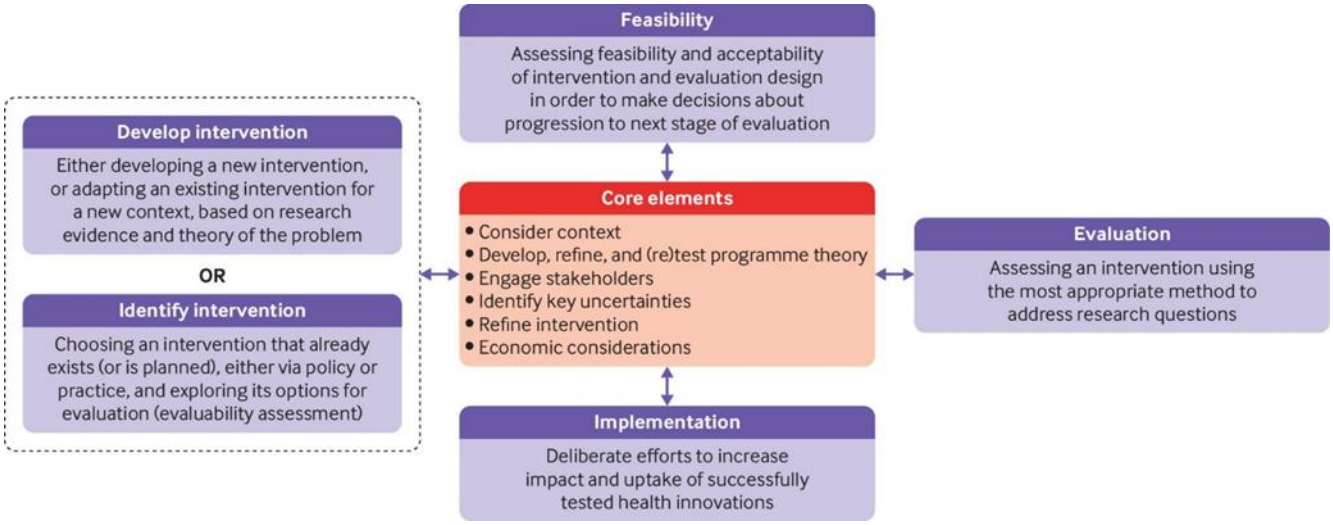

Figure 2.1 Framework for developing and evaluating complex interventions.[104]

My PhD research is positioned in the "develop intervention" phase. This phase allows for the development of a new intervention or for exploring options for evaluation of an existing intervention that has been identified. A range of approaches can be employed during this phase to guide the development or optimisation of an intervention.

To support developers in selecting appropriate approaches, O'Cathain et al. [114] conducted a systematic review and developed a taxonomy of intervention development strategies. Two categories from this taxonomy are particularly relevant to my research:

- **Partnership**: This involves the active engagement of the target population in the intervention development process. Participants are involved in decision-making throughout and hold equal decision-making power alongside members of the research team. Defined approaches include co-production, co-creation, co-design, experience-based co-design. The partnership approach used in my thesis is described in section 2.4.3.
- **Theory and Evidence-Based**: This integrates published research evidence with formal theoretical frameworks (e.g. psychological or organisational theories) or theories specifically developed for the intervention in question. Defined approaches include MRC Framework for

developing and evaluating complex interventions, behaviour change wheel and intervention mapping. As already stated, the MRC NIHR framework for the development and evaluation of complex interventions is the theoretical framework underpinning my thesis.

These approaches provide a structured foundation for ensuring that the intervention is both contextually relevant and theoretically grounded.

The six core elements of the MRC NIHR framework are to be applied across all four phases of research. These elements should be revisited throughout the research. This will help researchers to determine whether they should proceed to the next phase, for example between intervention development and feasibility testing. **Table 2.1** describes how the research objectives for my PhD (positioned in the develop intervention phase) align with the core elements from the MRC NIHR framework for complex interventions.

Table 2.1 Alignment of Research Objectives with MRC NIHR Core Elements

MRC core element	**Objective 1 — Describe existing systematic review literature**	**Objective 2 — Identify components of pharmacist-led medication reviews & link to outcomes**	**Objective 3 — Design & test an optimised pharmacist-led medication review**
Consider context	Define inclusion criteria to capture setting, population, and delivery context.	Code contextual factors during data extraction (e.g., community, hospital, general practice, access to clinical notes) and examine their relationship to outcomes.	Use purposive sampling to engage stakeholders. Conduct testing in real primary care settings to reflect local workflows.
Develop, refine & (re)test programme theory		Synthesise evidence to identify building blocks for programme theory.	
Engage stakeholders			Engage stakeholders (patients, pharmacists, GPs) in the design of the optimised intervention. Gather stakeholder feedback during acceptability testing.
Identify key uncertainties	Identify research gaps from the existing systematic review literature.	Extract data to identify components and assess the strength of evidence linking them to outcomes.	Use stakeholder engagement to identify key uncertainties based on lived experience.
Refine the intervention			Design an optimised intervention and revise it following testing in primary care.
Economic considerations		Extract data related to resource implications of medication reviews.	Collect qualitative data on resource implications of pharmacist-led medication reviews.

2.3 Other frameworks supporting the research in my thesis

As described in **Table 2.1** the MRC NIHR Framework for Developing and Evaluating Complex Interventions [104] forms the primary theoretical foundation for this thesis. It guided the overall research design, ensuring a systematic and theory-informed approach to understanding and optimising pharmacist-led medication reviews.

However, given the complexity of medication review practice and the multiple methodological stages involved, additional frameworks and theories were incorporated at different points in the research to support specific purposes, such as data extraction, synthesis, and interpretation. These supplementary frameworks were selected to ensure that the study was grounded in both conceptual rigour and practical relevance.

The following sections describe the theoretical and methodological approaches that informed distinct aspects of the research. Each subsection outlines the purpose for which a framework or theory was applied (for example, guiding evidence synthesis, informing data analysis, or structuring implementation considerations) and explains the rationale for its selection over alternative approaches.

2.3.1 TIDieR Framework

The Template for Intervention Description and Replication (TIDieR) checklist and guide [115] is a reporting tool designed to improve the completeness, clarity, and replicability of how interventions are described in research publications. To identify components of pharmacist-led medication reviews, systematic and comprehensive extraction of data is essential. The TIDieR checklist is a widely accepted tool to facilitate the clear and consistent documentation of essential components of an intervention.

The 12-item checklist prompted detailed descriptions of various aspects of medication reviews, including:

- Who delivered the intervention (e.g. professional background, expertise),
- What materials and procedures were used,
- When and how much the intervention was delivered (e.g. frequency, duration, dosage),
- How the intervention was delivered (e.g. mode of delivery such as face-to-face, telephone, or written),
- Where the intervention took place,
- Tailoring, modifications, and fidelity of delivery (including strategies to monitor or improve adherence).

The TIDieR checklist was used in Chapter Four to systematically compare diverse studies, helping to clarify inconsistencies in how pharmacist-led medication reviews are defined, delivered, and reported in the literature.

2.3.2 Behaviour Change Technique Taxonomy v1

To extract and systematically code information about the content of pharmacist-led medication reviews included in the systematic review (Chapter Four), the Behaviour Change Technique (BCT) Taxonomy v1 [116] was employed. The BCT Taxonomy v1 is a comprehensive, standardised classification of 93 discrete behaviour change techniques, organised into 16 groupings. It provides a common language for describing the active ingredients of interventions designed to influence behaviour.

The use of the BCT Taxonomy aligns directly with the objective to identify the components of pharmacist-led medication reviews and explore how these link to outcomes in different contexts.

Medication reviews often involve multiple behavioural targets, including changes in prescriber decision-making, patient adherence, and interprofessional communication. The BCT framework therefore offered a systematic method to identify and classify the specific behavioural components underpinning these processes. Although many clinical interventions, including medication reviews, are not explicitly labelled as "behaviour change interventions", they frequently include BCTs, often implicitly, as core elements. Medication reviews aim to optimise patient outcomes by addressing issues such as inappropriate prescribing, non-adherence, and the need for shared decision-making. Achieving these outcomes requires changes in behaviour among various actors, including healthcare professionals (e.g., pharmacists, GPs), patients, and system-level stakeholders (e.g., commissioners or policymakers). By applying the taxonomy, this study was able to move beyond broad descriptions of "medication review" interventions to understand what actually happens within them, and which techniques may contribute to observed outcomes.

This level of specificity was essential for developing the subsequent guidance document (Chapters Five and Six), ensuring that recommendations were grounded in an evidence-based understanding of how pharmacists can effectively support behaviour change in both themselves and their patients.

2.3.3 EPOC taxonomy

To support consistent classification and comparison of interventions across studies included in the systematic review (Chapter Four), the Effective Practice and Organisation of Care (EPOC) taxonomy of health systems interventions [117] was utilised. The EPOC taxonomy was developed to assist researchers and decision-makers in systematically categorising health system interventions based on conceptual and practical similarities. It provides a structured framework that distinguishes between intervention types such as professional, organisational, financial, and regulatory strategies. Pharmacist-led medication reviews operate within complex healthcare systems and often involve multiple interacting components at the professional and organisational levels. Applying this

taxonomy allowed for consistent categorisation of the diverse intervention types identified across studies.

Figure 2.2 is an illustration of how the MRC NIHR framework and other conceptual frameworks underpinned the work in this thesis.

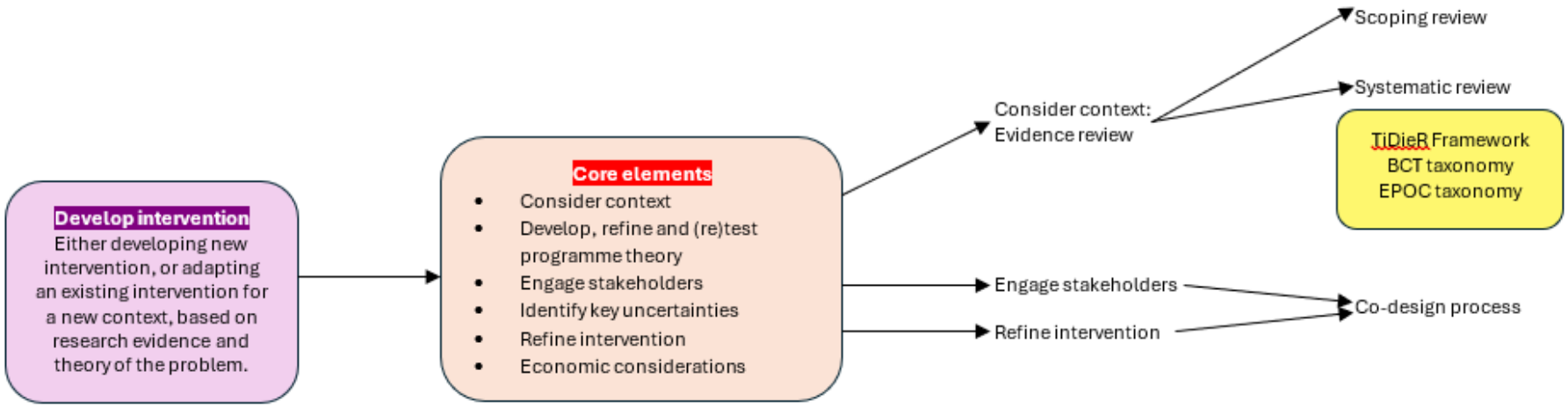

Figure 2.2 Illustration of the MRC NIHR Framework and how it supports the work in my thesis

2.4 Methods

This section describes the methods used to address the aims and objectives of this thesis.

2.4.1 Evidence synthesis

Chapter One describes how the evidence regarding pharmacist-led medication reviews is extensive but fragmented, with wide variation in definitions, delivery models, and reported outcomes. To address these gaps, an evidence synthesis was selected as the logical starting point. Evidence syntheses collate and summarise results from several studies to establish the evidence base to determine the overall effectiveness of an intervention [118]. The choice of evidence synthesis is determined by the nature of the data that is collected and the research question. **Table 2.2** describes examples of evidence synthesis that were considered to address the research questions in my PhD.

To describe the existing systematic review literature on pharmacist-led medication reviews and inform future research directions, a scoping review was undertaken. Scoping reviews are particularly well-suited to identifying and analysing knowledge gaps, and this review is reported in Chapter Three. Although realist reviews have previously been used to explore medication reviews [101,103,119,120], a systematic review was selected to identify the specific components of pharmacist-led medication reviews and examine how these components are linked to outcomes across different contexts. Systematic reviews support the structured extraction and comparison of intervention components, which is especially valuable when aiming to identify elements that are more consistently associated with positive outcomes. This systematic review is presented in Chapter Four.

Table 2.2 Examples of evidence synthesis

Method	**When used**
Scoping reviews [121]	• Identify the types of available evidence in a given field. • Clarify key concepts/ definitions in the literature. • Examine how research is conducted on a certain topic or field. • Identify key characteristics or factors related to a concept. • As a precursor to a systematic review. • Identify and analyse knowledge gaps.
Systematic reviews [121,122]	• Uncover the international evidence. • Confirm current practice/ address any variation/ identify new practices. • Identify and inform areas for future research. • Identify and investigate conflicting results. • Produce statements to guide decision-making.
Narrative reviews [123]	• Develop a preliminary synthesis of findings of included studies. • Explore relationships in the data. • Assess the robustness of the synthesis.
Realist reviews [124]	• Explain why outcome patterns occur in health systems or complex interventions. • Address questions about how, why, for whom, in what contexts and to what extent health systems, programmes and/or policies function. • Based on the premise that for any observed outcome, there are one or more causal processes (called “mechanisms”) that only become active in certain contexts: Context (C) + Mechanism (M) = Outcome (O).

2.4.2 Qualitative research

Qualitative research methods are designed to explore and understand the meanings, experiences, and perspectives of participants within their social, cultural, and contextual environments [125]. In contrast to quantitative methods, which aim to measure variables and test hypotheses, qualitative approaches seek to generate rich, detailed insights into how individuals interpret and make sense of their world [126,127]. Qualitative methods are particularly valuable when investigating complex interventions, behaviours, or processes in healthcare, where context, interpretation, and interaction play a significant role.

In this study, qualitative methods were employed to explore stakeholder experiences and perspectives, as part of the process to design and test an optimised pharmacist led medication review in primary care. The lived experiences of pharmacists and patients were central to uncovering real-world barriers, facilitators, and practical considerations that influence the delivery of medication reviews.

Focus groups bring together a small group of participants to discuss a specific topic and is particularly effective for creating debate and discussing differences within the group, which can lead to a deeper understanding of the subject matter [127]. Focus groups encourage interaction among participants, allowing them to build on each other's ideas, challenge one another, and articulate their perspectives in a dynamic environment [128]. Focus groups foster a sense of community among participants, which can encourage more open and honest discussions where participants may feel more comfortable sharing their thoughts and experiences when they see others doing the same. The data generated from focus groups tend to be more detailed due to the interactive nature of the discussions. As participants respond to one another, they may elaborate on their initial thoughts, providing context and depth to their responses [127,129].

Focus groups were selected as an initial qualitative method to explore how pharmacists and patients perceive and experience medication reviews, and to identify factors that influence their implementation in primary care. The group format was particularly suited to this stage of the research because it enabled participants to share and compare their perspectives, creating opportunities for debate and collective reflection on current practice. The approach also supported the co-design element of the study, allowing participants to discuss potential components of an optimised pharmacist-led medication review and to collectively shape the development of an optimised medication review.

Interviews can be used to explore the experiences, values, and beliefs of individuals [127]. By facilitating in-depth, detailed accounts, they enable researchers to explore the complexities of participants' lives and the meaning they attribute to their experiences [127]. Semi-structured interviews enable capture of rich and complex data through topics-based questions [126,127]. This method is particularly suited to studying areas where little is known, where subjective interpretation is essential, or where research requires a nuanced understanding of individual or group behaviours and attitudes. This approach allows researchers to focus on a specific topic while maintaining the flexibility to adapt the conversation based on participants' responses. As a result, participants can express themselves in their own words and share insights that may not have been anticipated by the researcher, contributing to a deeper understanding of the subject matter [130].

Following the testing of the guidance document, semi-structured interviews were conducted to explore participants' experiences of an optimised pharmacist-led medication review in practice. The purpose of these interviews was to evaluate the acceptability, feasibility, and perceived usefulness of the intervention from the perspective of those directly involved in its delivery.

2.4.3 Co-production

As identified in Section 2.2, approaches from two categories of intervention optimisation were used in this thesis. Having already described the theory-based framework in that section, this section focuses on partnership approaches and outlines the rationale for the chosen method. A partnership approach was adopted to ensure that the development of an optimised medication review was collaborative, feasible, and grounded in real-world practice. Involving pharmacists and patients in the design and refinement process helped ensure the resulting intervention was both theoretically informed and practically relevant. Several partnership approaches actively engage the people affected by or involved in an intervention. These include co-production, co-creation, co-design, experience-based co-design (EBCD), and accelerated EBCD.

Co-production involves individuals who use health and care services, carers, and communities working as equal partners to determine how resources and assets can be more effectively utilised in the implementation of an existing intervention [131,132]. Over time, the use of co-production in health research has expanded, reflecting a broader shift towards participatory approaches and shared ownership of service development. It is often described as an umbrella term encompassing a range of collaborative activities involving diverse stakeholders [133]. The concept of co-production has evolved over time, reflecting a shift in how stakeholders engage in the creation and delivery of services. Its meaning has expanded, with definitions varying across different settings and contexts. Effective co-production requires the direct and active contribution of participants, distinguishing the roles of service users from those of professionals [133]. Smith et al. [134] further emphasise that co-production is not simply transactional but a transformative process, where shared power among stakeholders enhances the quality and relevance of services.

Co-creation extends this concept by involving stakeholders throughout all stages of intervention development, from problem identification to solution design, implementation, and evaluation [131].

However, because this study focused on optimising an existing intervention rather than developing one from the beginning, a co-creation approach was not used.

Co-design focuses on stakeholders' insights to improve an existing intervention. It involves "active collaboration between stakeholders in the design of solutions to a pre-specified problem" [131]. The method draws on lived experiences to shape practical improvements and typically progresses through four stages: identifying the problem, analysing stakeholder experiences, defining priorities for development, and designing and testing the intervention [131,135]).

Experience-Based Co-Design (EBCD) and its adapted form, accelerated EBCD, use patient and staff narratives to identify areas for improvement. These approaches often involve filmed patient stories that evoke emotional responses among staff and patients to guide joint improvement work [136]. While EBCD is well suited to improving a specific service in a single setting, it is resource-intensive and less appropriate for the broader optimisation aim of this research.

For these reasons, co-design was selected as the most appropriate partnership method for this thesis. It provided a structured yet flexible approach for collaboratively refining pharmacist-led medication reviews. Co-design workshops were used to bring together pharmacists and patients to share experiences, identify challenges, and generate practical solutions. Workshops are particularly effective for producing reliable and contextually relevant insights while fostering a collaborative environment where researchers and participants can work together toward shared goals [137].

In this thesis, the co-design method served as a bridge between the evidence synthesis from the systematic review and implementation in practice, enabling the development and testing of an optimised pharmacist-led medication review that is both evidence-informed and grounded in the realities of primary care.

2.4.4 Data analysis

This section outlines the approaches used to analyse the data collected throughout my PhD. Data analysis was guided by the research objectives and the nature of the data, which included both qualitative and quantitative sources. Each dataset was analysed using appropriate and complementary methods to ensure rigour, transparency, and relevance to the process of developing and optimising the pharmacist-led medication review intervention. Both secondary (published literature) and primary (focus groups, workshops, and interviews) data were analysed.

Narrative Descriptive and Narrative Synthesis Approaches

A narrative descriptive approach [137] was used to analyse data from the scoping review (Chapter Three), and a narrative synthesis [123] was used for the systematic review (Chapter Four). These approaches were selected because the included studies varied considerably in design, population, and context, making statistical pooling inappropriate. Narrative-based methods allow for the systematic summarisation and integration of findings using text rather than quantitative techniques and are particularly suited to complex interventions such as medication reviews, where interventions and outcomes are heterogeneous. The narrative synthesis followed the framework outlined by Popay et al. are [123], which includes four key elements:

- Developing a theory of how the intervention works, why and for whom
- Developing a preliminary synthesis of findings of included studies
- Exploring relationships in the data
- Assessing the robustness of the synthesis.

This process enabled the identification of key components, mechanisms, and contextual influences underpinning pharmacist-led medication reviews, thereby informing the early stages of intervention development and refinement in later phases of the PhD.

Analysis of Qualitative Data

Several qualitative analytical techniques were considered for analysing data from focus groups, workshops, and interviews, including:

- Constant comparison analysis, which groups codes into categories and themes across datasets [138];
- Keywords-in-context, which examines word use and meanings in context [138]; and
- Discourse analysis, which focuses on how participants construct and account for experiences in conversation [138].

After consideration, thematic analysis was chosen as the most appropriate approach for the qualitative phases of the research (Chapters Five and Six). Thematic analysis provides a systematic yet flexible method for identifying, organising, and interpreting patterns of meaning (themes) within qualitative data [139]. It is particularly suited to applied health research, where the aim is to capture both shared and divergent perspectives to inform the practical design and optimisation of interventions.

The analytical approaches adopted in this research align closely with the MRC NIHR Framework for Developing and Evaluating Complex Interventions [104]. The narrative synthesis builds an evidence-informed theoretical understanding of how pharmacist-led medication reviews work and under what conditions. The thematic analyses of qualitative data provide insights into stakeholder experiences, contextual influences, and practical considerations for implementation. Together, these iterative cycles of evidence synthesis, qualitative analysis, and stakeholder engagement embody the MRC NIHR framework's emphasis on integrating theory, empirical evidence, and real-world context to inform the design of robust and implementable complex interventions.

2.5 Philosophical stance

Outlining research paradigms, philosophical assumptions, and methodological choices is essential when addressing research questions, particularly in qualitative research, where the researcher's worldview significantly influences the study design and interpretation of findings. In qualitative inquiry, the research approach is not value-free or purely objective; instead, it is shaped by the researcher's beliefs about reality (ontology), the nature of knowledge (epistemology), and the relationship between the researcher, participants and research process (axiology) [126,127].

2.5.1 Ontology

Ontology refers to the nature of the world and what there is to know about it. There is a scale of ontological positions, from realism, which supposes that an external reality exits independent of beliefs or understanding, to idealism, where no external reality exists independent of beliefs and understanding [127]. At the realist end of the spectrum, it is believed that phenomena exist objectively, whether or not they are observed or understood. This ontological position is often associated with a positivist philosophical paradigm, which assumes that reality can be measured and objectively known through empirical observation and scientific methods [126]. This positivist view is considered problematic and often unachievable in research involving human behaviour, where subjective experience, social context, and individual interpretation are central. In such contexts, alternative ontological positions—such as constructivism or relativism—are more appropriate. These positions acknowledge that reality is not fixed or universally shared but is instead constructed through human interaction, language, and the process of meaning-making that occurs within specific social, cultural, and professional contexts [126]. From this perspective, understanding human behaviour requires interpretative approaches that explore how individuals experience and make sense of their world.

Positioned between the extremes of realism and idealism, is relativism, which asserts that there is no single, shared social reality; rather, there are multiple, co-existing realities, each shaped by individual experience, language, culture, and context [140]. Social constructivism is a specific ontological stance within this relativist view, emphasising that these multiple realities are actively co-created through human interaction, shared language, and cultural norms [140]. I adopted a social constructivist position, recognising that understanding of pharmacist-led medication reviews is not discovered but collaboratively constructed through the experiences and interactions of patients, pharmacists, and other stakeholders within their social and cultural contexts. This perspective informed the design and conduct of my research by emphasising co-design and stakeholder engagement, ensuring that the development of the guidance document was grounded in the shared meanings, practices, and realities of those directly involved in medication reviews.

2.5.2 Epistemology

Epistemology is the branch of philosophy concerned with ways of knowing and learning about the world, and how this forms the basis of our knowledge [127]. It highlights the relationship between the inquirer and the known (knowledge). There are several epistemological stances that researchers may take, including positivism, interpretivism, critical theory, and pragmatism [141]. *Positivism* has already been described above (section 2.4.1) assumes that knowledge is objective and can be measured through empirical observation and scientific reasoning [126,141]. *Interpretivism* is based on the belief that knowledge is constructed through human interpretation and social interactions. It emphasises the subjective and interpretive nature of human experience [142]. *Critical theory* is grounded in the belief that knowledge is shaped by power dynamics and social structures; a useful stance if seeking to uncover and challenge power imbalances and injustices in society [141,142]. *Pragmatism* focuses on the practical application of knowledge, emphasising whether a theoretically sound intervention can be effectively implemented in real-world settings. [141,143].

As a registered pharmacist, my initial academic and professional training was aligned more closely with positivist principles, reflecting the biomedical foundations of pharmacy education. However, as pharmacy practice has evolved toward a more patient-centred model, my epistemological stance has shifted. An interpretivist perspective now better reflects my current approach, recognising the importance of understanding patients' lived experiences, values, and the social contexts in which care is delivered.

2.5.3 Axiology

Axiology refers to the role of values and ethics in the research process, acknowledging that all forms of inquiry are influenced by the researcher's beliefs, assumptions, and professional background. In qualitative research, it is recognised that complete objectivity is neither possible nor desirable; instead, the researcher's values become an integral part of the research process, shaping the questions asked, the interpretation of findings, and the relationships established with participants [144].

As a mature pharmacist with extensive experience in community pharmacy and higher education, my professional identity has inevitably influenced this study. My PhD journey has deepened my interpretivist perspective and strengthened my reflexivity as a practitioner-researcher. I've come to acknowledge that my professional identity, values, and assumptions inevitably shape the research process. Rather than perceiving this as a constraint, I now embrace it as a means to engage more authentically with participants and generate findings that resonate with real-world experiences. An interpretivist perspective now better reflects my current approach, recognising the importance of understanding patients' lived experiences, values, and the social contexts in which care is delivered. This stance supports the use of qualitative methods that allow for a deeper exploration of meaning and experience in complex healthcare settings.

2.6 Summary

This chapter has outlined the methodological framework that guided my PhD research, explaining how the principles of the MRC NIHR framework for developing and evaluating complex interventions informed each stage of the PhD. The rationale for using a multi-method approach, combining evidence synthesis, qualitative research, and co-design, was to ensure that the optimisation of pharmacist-led medication reviews was both evidence-based and grounded in real-world practice. The choice of analytical methods, including narrative synthesis and thematic analysis, reflected the complexity of the intervention and the need to integrate findings from diverse data sources to inform intervention development.

Together, these methods were used to address the three overarching objectives of the thesis: (1) to describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction, (2) to identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts, and (3) to design and test an optimised pharmacist-led medication review for primary care.

The next chapter (Chapter Three) presents the Scoping Review, which maps the existing literature on pharmacist-led medication reviews. This review provides the foundation for subsequent stages of the research by identifying current approaches, conceptual variations, and key gaps in knowledge that inform the design of the systematic review and the development of the optimised intervention.

3.0 Chapter Three Pharmacist-led medication reviews: A scoping review of systematic reviews

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3.1 Introduction

Chapter One (Introduction) outlined the increasing prevalence of long-term conditions and the associated benefits and risks of medication use, including adverse drug reactions, non-adherence, and inappropriate prescribing—factors that can lead to hospital admissions or reduced quality of life. It also introduced pharmacist-led medication reviews as a UK NHS policy intervention to support patients with long-term conditions. However, significant variation exists in how medication reviews are specified and delivered, potentially affecting their impact. The next step is to explore the literature on pharmacist-led medication reviews to assess existing evidence and identify gaps, which this thesis aims to address. This approach aligns with the MRC guidance for process evaluation of complex interventions [109], which highlights the importance of describing the intervention and how it is implemented, with assumptions about how it will work in context. Evidence synthesis serves as a valuable method for examining the pharmacist-led medication review literature.

To identify the types of available evidence on pharmacist-led medication reviews, analyse knowledge gaps and determine the direction of future research, I undertook a scoping review to identify the extent (geographical distribution and target populations in primary studies), range (study design and types of interventions included in systematic reviews), and nature (description and key components of medication reviews) of research in this field.

Given the number of systematic reviews already published in this field, my scoping review focussed on these systematic reviews and not the primary research, to avoid repetition of existing work. Jokanovic et al. (2017) conducted the only known overview of systematic reviews examining the effectiveness of pharmacist-led medication reviews in community settings [145]. This review has been cited in Canadian and UK national guidelines. However, since its publication, additional systematic reviews have emerged. Therefore, my scoping review aimed to capture the most recent evidence on pharmacist-led medication reviews across all settings and populations, providing a broader and updated perspective.

3.1 Aim and objectives

The aim of my scoping review is to summarise the systematic review evidence on the nature (description and key components) and effectiveness of pharmacist-led medication reviews, while also identifying knowledge gaps to guide future research. This will be achieved through the following objectives:

- describe the extent and range of pharmacist-led medication reviews
- report medication review nature as described in the literature
- describe evidence for their effectiveness
- identify research gaps.

3.2 Method

I used the Arksey and O'Malley framework and Levac's advanced methodology, to conduct the scoping review [146,147]. The Arksey and O'Malley framework was developed to help ensure that scoping reviews were rigorous, reproducible, and reliable. The framework suggests five stages to a scoping review [125]:

- identifying the research question
- identifying relevant studies

- study selection
- charting the data
- collating, summarising, and reporting the results.

Levac et al. [147] made some recommendations to enhance the Arksey and O'Malley framework. They suggested that the purpose for the scoping review be considered alongside the research question; this is evidenced in the research question for this scoping review. Levac et al. also suggests methodological quality assessments of included studies, as this is more likely to better represent the extent and nature of gaps in the literature review. Methodological quality assessment also helps to determine whether a full systematic review would be beneficial.

3.2.1 Search strategy (identifying relevant studies)

I used the Jokanovic review [145] as a source for systematic reviews up to and including 2015. A supplementary search of Embase and MEDLINE databases using the OVID platform identified reviews published between January 2016 and January 2023 (the time of the search) (**Appendix 1**). The following search terms were used: pharmac* AND ["medicine review" OR "medication review" OR "medicines review"] AND "systematic review". The search was restricted to abstracts. Titles and abstracts were reviewed, and full text retrieved of those that met the inclusion criteria. Through forward and backward reference searching, other articles of interest were identified. In addition, I searched the Cochrane database of systematic reviews for relevant systematic reviews published after December 2015 ('medication review' and 'pharmacist').

3.2.2 Methodological quality assessment

I used an (updated) measurement tool (AMSTAR 2) critically appraise the quality of the included systematic reviews [148]. The systematic reviews were critically appraised by only one reviewer.

3.2.3 Inclusion/ Exclusion criteria (study selection)

The inclusion and exclusion criteria for the systematic reviews is as follows:

- All adult (≥18 years) recipients of medication reviews regardless of the setting or medical history.
- Participants received a medication review. To be included, at least 50% of the primary studies must have utilised a medication review as the intervention.
- Results and/or discussion make specific reference to the implementation and impact of medication review.
- Reviews reported all outcomes.
- Systematic reviews containing all types of studies.

Reviews were excluded if:

- full text was not available.
- pharmacists did not have a leading role in delivering the interventions.
- not available in the English language; time and financial constraints did not allow for translation from other languages.

3.2.4 Data extraction (charting the data)

Data extracted from the systematic reviews included the number and design of included studies, population, setting, main results, and description of intervention. I did this using a bespoke data collection form, which was tested using papers included in the Jokanovic review [145]. The systematic reviews were studied for details of the nature of the intervention and whether the authors of the reviews reported on these components during their results, discussion, or conclusion. The Pharmaceutical Care Network Europe (PCNE) agreed a classification of medication reviews, where they were classified as type 1, 2 or 3 [105]. The components of interest of the medication review were type of review (PCNE level 2 or 3 [105]), mode of delivery (e.g. face-to-face, telephone), setting (e.g. community pharmacy, hospital), duration (how long), intensity (how often), and

collaboration with other healthcare professionals. A PCNE level 2 reviews medication history available in the pharmacy alongside information from clinical records or obtained directly from the patient. A level 3 review utilises information obtained from medication history, clinical records and directly from the patient. The main results at the systematic review level were summarised and reported as evidence of no effect, uncertain effect, or evidence of effect.

To address the final objective, the authors' commentary on gaps in the literature and recommendations for future research were extracted and summarised.

3.2.5 Data synthesis

The synthesis of findings was conducted using a narrative descriptive approach [149], appropriate for scoping reviews aiming to map the breadth and nature of evidence. Extracted data were grouped and summarised according to characteristics of the medication review interventions, including:

- Resources and activities in medication review
- Intensity
- Collaboration with other healthcare professionals
- Reported outcomes

Findings were organised around these characteristics. Where possible, the impact of each component on reported outcomes (e.g. clinical, process, patient-reported) was noted and categorised as:

- Evidence of effect
- Uncertain effect
- No effect

In line with Levac et al.'s recommendations [147], methodological quality (assessed using AMSTAR 2 [148]) was considered during synthesis to contextualise the strength of evidence.

3.3 Results

The results from the scoping review are collated, summarised, and reported in this section.

3.3.1 Study selection

The searches yielded 85 titles after deduplication. Following the application of inclusion and exclusion criteria, 23 systematic reviews were included. **Figure 3.1** outlines the selection process for this scoping review.

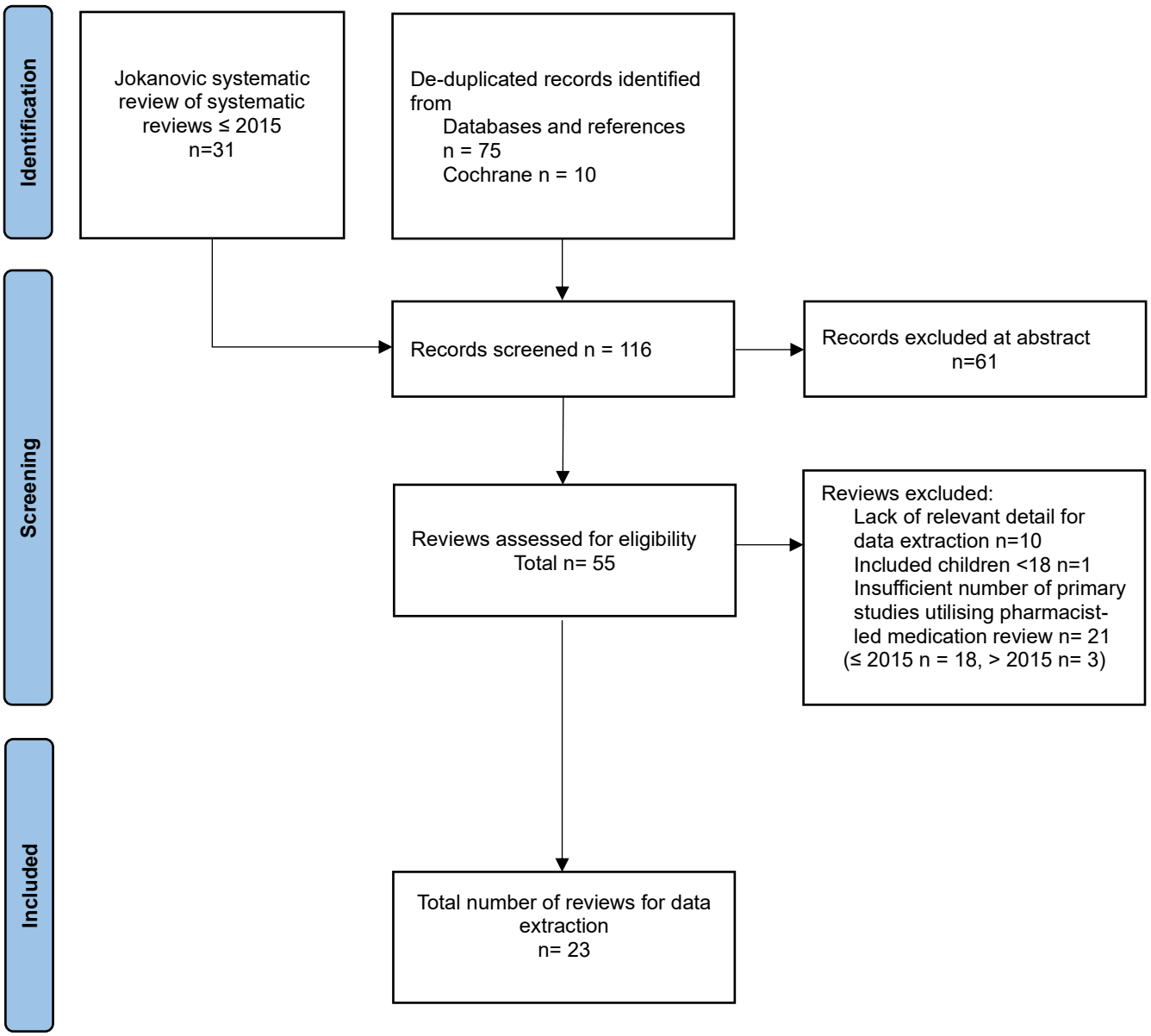

Figure 3.1 Flow diagram for literature review [186]

3.3.2 Description of the extent and range of pharmacist-led medication reviews

Twelve systematic reviews included only randomised controlled trials (RCTs) [150–161], one included only non-randomised studies [162] and all other reviews included both randomised and non-randomised trials [42,163–171].

Original studies included in the 23 systematic reviews were conducted in a wide range of countries across five continents. Seven of these reviews restricted the population of the studies to older adults [42,150,153,155,164,172,173]. Two reviews included patient populations with cardiovascular disease and/ or other chronic conditions [157,158]. Four reviews included restricted settings: two included studies based only in hospital [153,154], one in care homes [155], and another in ambulatory care [170].

The full AMSTAR 2 assessment is reported in **Table 3.1**. Sixteen of the 23 reviews were rated as critically low confidence in the methods and results, two as low, three as moderate, and two as high. Sixteen reviews did not report a registered protocol and thirteen did not provide sufficient justification of the exclusion of studies; these are critical domains. Where one critical flaw is observed, these reviews can only be low confidence. Where more than one critical flaw was observed, these reviews were assessed as critically low. If authors had indicated a published protocol and included more detailed description of excluded studies, overall confidence in results would have been greater.

Table 3.1 Complete AMSTAR 2 assessment

Author (year)	1.Did the research questions and inclusion criteria for the review include the components of PICO?	2.*Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report*	3.Did the review authors explain their selection of the study designs for inclusion in the review	4.*Did the review authors use a comprehensive literature search strategy?*	5.Did the review authors perform study selection in duplicate?	6.Did the review authors perform data extraction in duplicate?	7.*Did the review authors provide a list of excluded studies and justify the exclusions?*	8.Did the review authors describe the included studies in adequate detail?	9.*Did the review authors use a satisfactory technique for assessing the risk of bias (RoB) in individual studies that were included in the review?*	10.Did the review authors report on the sources of funding for the studies included in the review?	11.*If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?*	12.If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis	13.*Did the review authors account for RoB in individual studies when interpreting/ discussing the results of the review?*	14.Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	15.*If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its*	16.Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	**OVERALL RATING**
Post 2015 systematic reviews																	
Alldred 2016 [155]	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No MA	No MA	Yes	Yes	No MA	Yes	High
Bulow 2023 [175]	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No MA	No MA	Yes	Yes	No MA	Yes	High
Al- babtain 2022 [161]	Yes	Yes	No	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	No	No	Yes	Yes	Yes	Moderate
Atey 2022 [174]	Yes	Yes	No	Partial Yes	Yes	Yes	Partial Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Moderate
Fadaleh 2022 [173]	Yes	Yes	Yes	Partial Yes	Yes	Yes	Partial Yes	Partial Yes	Partial Yes	No	Yes	No	Yes	Yes	Yes	Yes	Moderate
Martinez-Mardones 2019 [157]	Yes	No	No	Yes	Yes	Yes	Partial Yes	Partial Yes	Partial Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Low
Ahumada-Canale 2019 [158]	No	Yes	No	Partial Yes	Yes	No	Partial Yes	Yes	Partial Yes	Yes	No MA	No MA	No	No	No MA	Yes	Critically Low
Bou Malham 2021 [170]	Yes	No	No	Partial Yes	Yes	Yes	Partial Yes	Yes	No	Yes	Mo MA	No MA	No	No	No MA	Yes	Critically Low
Hikaka 2019 [162]	Yes	No	No	Yes	Yes	No	No	Partial Yes	No	No	Mo MA	No MA	No	No	No MA	Yes	Critically Low
Huiskes 2017 [156]	Yes	No	No	Partial Yes	Yes	Yes	No	Partial Yes	Partial Yes	No	Yes	Yes	Yes	Yes	No	Yes	Critically Low

Jokanovic 2016 [169]	No	No	No	Yes	Yes	Yes	No	Yes	Partial Yes	Yes	No MA	No MA	Yes	No	No MA	Yes	Critically Low
Before 2015 systematic reviews																	
Bayoumi 2008 [165]	Yes	No	No	Partial Yes	Yes	Yes	Yes	Partial Yes	Yes	No	No MA	No MA	Yes	Yes	No MA	Yes	Low
Castelino 2009 [151]	No	No	No	Partial Yes	No	No	No	No	No	No	No MA	No MA	No	No	No MA	No	Critically Low
George 2008 [164]	Yes	No	No	Partial Yes	Yes	Yes	Yes	Partial Yes	No	No	No MA	No MA	No	No	No MA	Yes	Critically Low
Geurts 2012 [166]	No	No	No	Partial Yes	Yes	Yes	No	No	No	No	No MA	No MA	No	No	No MA	Yes	Critically Low
Hatah 2014 [167]	Yes	No	Yes	Partial Yes	Yes	Yes	No	Partial Yes	Partial Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Critically Low
Holland 2008 [150]	Yes	No	Yes	Partial Yes	Yes	Yes	No	Yes	Partial Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Critically Low
Kucukarslan 2011 [152]	No	No	No	Partial Yes	No	No	No	No	No	No	No MA	No MA	Yes	No	No MA	Yes	Critically Low
Kwint 2013 [153]	No	No	No	Partial Yes	Yes	Yes	Yes	No	Partial Yes	No	Yes	Yes	Yes	No	No	Yes	Critically Low
Rollason 2003 [42]	No	No	No	No	No	No	No	Partial Yes	No	No	No MA	No MA	No	No	No MA	Yes	Critically Low
Royal 2006 [163]	No	No	Yes	Yes	Yes	Yes	No	Partial Yes	Partial Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Critically Low
Tan 2014 [154]	No	No	No	Yes	Yes	Yes	No	Partial Yes	Yes	No	Yes	Yes	Yes	Yes	No	No	Critically Low
Viswanathan 2015 [168]	Yes	Yes	Yes	Partial Yes	Yes	Yes	No	No	Partial Yes	No	Yes	Yes	Yes	Yes	No	Yes	Critically Low

3.3.3 Reported nature of the medication review

The components of the nature of the medication review that I focused on included resources and activities, intensity, and collaboration. The extent to which these components were discussed varied significantly across the literature, with all but one review [163] addressing at least one of these aspects.

Resources and activities in medication review

A meta-analysis by Martinez-Mardones et al. [157] examined the effects of different components of medication reviews such as access to clinical records, education, self-monitoring, lifestyle advice, and medicines-related problems. It showed that medication reviews that include a patient interview, in addition to access to medication and clinical data, led to greater reductions in blood pressure, glycated haemoglobin, and cholesterol, than a medication review which did not include a patient interview or access to clinical records. Hatah et al. undertook a subgroup analysis and reported that face-to-face medication reviews with or without access to full clinical notes reduced unplanned hospital admissions more than reviews merely assessing issues relating to patients' medication-taking behaviour [167]. Bulow et al. were unable to determine the effect of medication review components on reported outcomes [175].

Hikaka et al.'s description of included studies identified components of the nature of the intervention such as type of review (medicines use review or comprehensive medication review), setting (home or pharmacy), and delivery mode (face-to-face or telephone) [162]. The inclusion of low-quality and observational studies, in addition to the varying outcomes reported, made it difficult to establish the effect of the different components on outcomes [162].

Bulow reports that medication reviews in combination with other interventions, e.g., patient education and medication reconciliation, reduced hospital readmissions when compared to usual care, but standard medication reviews did not [175].

Intensity

Huiskes' review included medication reviews delivered during a short intervention period (≤3 months) [156]. They recommended the development and evaluation of interventions with multiple contacts between practitioner and patient. Rollason also suggested that more than one medication review contact could lead to better outcomes [42].

Collaboration

Collaboration between healthcare professionals was the most frequently reported component. However, most reviews did not explore intervention components in depth. Two reviews aimed to investigate the effectiveness of collaboration between pharmacists and doctors and the effect on outcomes [153,166], one sought to examine the components of medication reviews to better support a specific population [162], whilst another described the presence of specific activities reported in the medication reviews [157]. A further three reviews reported on one or more of intensity, type of medication review, and mode of delivery in their results [152,161,167]. The authors of the remaining systematic reviews referred to the nature of the intervention in the discussion only.

Geurts et al. and Kwint et al. aimed to examine whether collaboration between pharmacists and general practitioners (GPs) influenced patient outcomes [153,166]. These reviews observed that GP implementation of pharmacist recommendations was more likely with increased collaborative working between pharmacists and general practitioners. Tan et al. highlighted that a positive effect on patient outcomes was more likely to be observed if the medication review was combined with

interprofessional face-to-face communication [154]. Jokanovic concluded that medication reviews conducted by medical practice-based pharmacists were associated with higher rates of implementation of recommendations [169].

3.3.4 Reported outcomes and evidence for effectiveness of medication reviews

The authors' outcomes of interest are reported in **Table 3.2**.

Healthcare utilisation

The most frequently reported outcome was the effects of medication reviews on healthcare utilisation, which includes hospital admissions, re-admissions, and access to primary care physicians. Eight of the seventeen reviews [150,153,154,162,166,167,173,174] reported that there was no evidence of a positive effect on healthcare utilisation following a medication review. Six reviews [151,155,161,168–170] reported mixed evidence of a positive effect on healthcare utilisation and that the effect of medication reviews was uncertain, whilst one high-quality and one critically low review [163,175] reported a reduction in hospital (re)admissions. Four reviews reported mixed evidence of medication review effect on medicines costs [155,167–169].

Medication adherence

Effects of medication reviews on medication adherence was the second most reported outcome. Two critically low reviews reported that medication reviews improved adherence [162,164], another stated that there was no evidence of a positive effect [153], whilst the remaining reviews were uncertain of the impact due to mixed results in primary studies [150,156,161,167,169,170,173].

Patient-orientated outcomes

Thirteen reviews reported at least one patient-orientated outcome [150,152,153,155,156,162,166–170,173,175], the most frequent being quality of life (12/13). Three reviews [152,153,168] reported that the medication review did not improve quality of life, but the remaining nine reviews showed

mixed results. Seven reviews reported mixed outcomes for patient satisfaction following medication reviews [150,152,154,162,168,170,173]. Evidence for medication reviews having a positive effect on medication-related problems is inconclusive due to mixed results. Reviews reported that pharmacists were able to identify medicines-related problems; this was quantified in five of these reviews [150,153,155,162,166] with the remaining reviews reporting this in results or discussion. However, the resolution of medicines-related problems was not reported or yielded mixed results.

Clinical outcomes

The systematic reviews reported mixed effects on clinical outcomes. Four reviews reported reductions in blood pressure and cholesterol levels; Al-babtain, Martinez-Mardonez, and Tan reported improvements in diabetes biomarkers [154,157,161,167]. Huiskes et al. reported that medication reviews had a positive effect on falls reduction [156]. Other reviews reported mixed results on the effect of medication reviews on clinical outcomes [151,152,158,166,168]. The cost-effectiveness of medication reviews was reported in five systematic reviews [150,158,166,167,169] but was identified as an area for future research in another three [163,164,166].

Table 3.2 Description of systematic reviews and AMSTAR 2 ratings

Author, year	Research Question	Study design & number	Population & setting	Countries of origin	Meta-analysis	AMSTAR 2	Authors' outcomes of interest	Main results
Post 2015 systematic reviews								
Alldred 2016 [155]	What is the effect of interventions to optimise overall prescribing for older people living in care homes?	RCT n=12	People >65 years; Institutionalised care facilities	Australia, Finland, Israel, Netherlands, New Zealand, Spain, Sweden, UK, USA, and Canada	No	High	Adverse drug events	No effect 2/2 studies report evidence of no effect
							Hospital admissions	Uncertain effect 4/8 studies report reduction (these studies had flaws in their study design) 4/8 studies report evidence of no effect
							Mortality	No effect 6/6 studies reported evidence of no effect
							Quality of life (QoL)	Uncertain effect 1/ 2 studies reported no evidence for effect 1/ 2 studies reported a slower decline in QoL (this study had flawed statistical analysis)
							Medication-related problems (MRPs)	Evidence of effect: resolution of MRPs 7/7 studies reported an increase in identified MRPs, but these were diversly classified leading to lack of consistency and reliability of results
							Medication appropriateness	Evidence of effect: medication appropriateness 5/5 studies reported a reduction in potentially inappropriate medicines
							Medicine costs.	Uncertain effect: medicine costs 3/5 studies reported reduction in costs 2/5 studies reported no difference
Bulow 2023 [175]	Does delivery of a medication review by a physician, pharmacist or other healthcare professional leads to greater improvement in health outcomes of hospitalised adult patients?	RCT n=25	Adults; hospital	Sweden, Denmark, Belgium, USA, Ireland, Northern Ireland, Switzerland, Brazil, Canada, Netherlands, Norway, Germany, Scotland, Spain, Italy, Iceland, South Korea	Yes	High	Mortality	No effect: mortality 18 studies, 10108 participants **Risk ratio 0.96 [0.87, 1.05]**
							Hospital readmission	Evidence of effect: readmission reduction 17 studies, 9561 participants **Risk ratio 0.93 [0.89, 0.98]** favouring MR
							Hospital emergency department contacts	Evidence of effect: reduction in contacts 8 studies 3527 participants **Risk ratio 0.84 [0.68, 1.03]** favouring MR
							Health-related Quality of life	Uncertain evidence: change in QoL 4 studies 392 participants **Mean reduction 0.10 [-0.10, 0.30]** favouring MR

Al- babtain 2022 [161]	Impact of community-pharmacist-led medication review programmes on patient outcomes: A systematic review and meta-analysis of randomised controlled studies	RCT n=40	Adult patients; community pharmacy	USA, Canada, Netherlands, Australia, UK, Spain, Germany, Iran, Jordan, Croatia, Iraq, Malta, Portugal, Italy, Denmark	Yes	Moderate	Clinical outcomes measure	No effect: Mortality 3 studies 2/3 studies reported a slight decrease 1/3 study reported a slight increase
								Evidence of effect: Blood pressure reduction MA of 9 studies 1642 participants Pooled results Systolic BP **-6.56 (95% CI -10.05, -3.08) MD** Pooled results Diastolic BP **-1.68 (95% CI -3.18, -0.18) MD**
								Evidence of effect: Total cholesterol (reduction) MA of 3 studies 379 participants Pooled results **MD -0.18; [-0.32, -0.05]; P=0.008; I^2=0%)**
								Evidence of effect: HbA1c (reduction) MA of 6 studies 1152 participants Pooled results **(MD -0.61; 95% CI -0.96, 0.25, P =0.0008 I^2=0%)**).
								Uncertain effect: Medicines Related Problems 6 studies 3/6 studies reported a reduction 1/6 study reported an increase 2/6 reported uncertain effect
								Uncertain effect: Adverse Drug Events 4 studies 2/4 studies report a reduction 2/4 studies report an increase
								Uncertain effect: Medication adherence 16 studies 15/16 studies reported an improvement 1/16 study reported a decrease
								Uncertain effect: Quality of Life 16 studies 11/16 studies reported an improvement 2/16 studies reported an uncertain effect 3/16 studies reported a decline
							Health service utilisation	Uncertain effect: Emergency department visits 5 studies 4/5 studies reported a reduction 1/5 study reported an increase
								Uncertain effect: Hospital admissions/ re-admissions 9 studies 4/5 studies reported a reduction in hospital admission rate 1/5 study reported an increase in admission rate 2/4 studies reported a reduction in hospital admission days 1 /4 study reported an increase 1 /4 study reported an uncertain effect

Atey 2022 [174]	Does the delivery of interventions by pharmacists led to improved quality use of medicines for adult emergency department patients?	RCT n=3 Non-randomised studies n=28	Adults ≥ 18 years presenting to emergency department	USA, Belgium, Australia, UK, Colombia, Spain, Ethiopia, Taiwan, Egypt	Yes	Moderate	Medication errors	Evidence of effect: reduction in error rate Pooled results of 12 studies 4959 participants **Decrease of 0.33 per patient [95% CI -.42 to -0.23], p< 0.001 I^2 = 51%** Evidence of effect: decrease in proportion of patients having at least one error **MA of 10 studies 4742** **RR=0.27, [CI 0.19 to 0.40], p< 0.001 I^2 = 89%**
							Appropriateness of medications	Evidence of effect: increased appropriateness of prescribed medications Pooled results of 7 studies 2613 participants **RR=1.58 [CI 95% 1.21 to 2.06], p<0.001 I^2 =95%**
							Healthcare utilisation	No effect: length of hospital stay Pooled results of 6 studies 1233 participants Mean difference =0.28days [95% CI -0.88 to 1.45], p=0.018, I^2 =63.5% Evidence of effect: reduced incidence of being re-admitted Pooled estimated of 2 studies 291 participants RR=0.62 [95% CI 0.38 to 0.99], p=0.05 Evidence of effect: reduction of re-presenting to emergency department Pooled estimated of 2 studies 998 participants **RR=0.70 [95% CI 0.52 to 0.94], p=0.02**
Fadaleh 2022 [173]	What is the effect of home medication review in community-dwelling older adults?	RCT n=18	Adults ≥65 years; Community-dwelling	UK, Canada, Spain, Australia, USA, Denmark, Netherlands, Germany	Yes	Moderate	Healthcare utilisation	No effect: healthcare utilisation MA of 9 studies of 3413 participants **RR of 0.91 [95% CI 0.71, 1.15] I^2 =85%**
							Mortality	Uncertain effect: mortality 12/13 studies reported no effect 1/13 study reported a decrease in mortality
							Medication outcomes	Uncertain effect: medication changes 5/7 studies report improvements in number of drugs prescribed 2/7 studies reported no difference Uncertain effect: adherence 2/5 studies report [significant] improvement in adherence 3/5 studies report no change
							Patient-orientated outcomes	Uncertain effect: Quality of Life 4/6 studies reported no effect 1/6 studies reported uncertain effect 1/6 studies reported improvement (statistically significant) Uncertain effect: satisfaction 2/4 studies reported high patient satisfaction 2/4 studies reported no difference in satisfaction
							Economic outcomes	Evidence of effect: cost savings 4/4 studies reported significant cost savings
Martinez-Mardones 2019 [157]	What is the impact of pharmacist-led MRs on CVD risk	RCT n=69	Patients with CV risk; ambulatory care, community pharmacy	Spain, Portugal, Chile, Brazil Australia,	Yes	Low	CVD risk factors	Evidence of effect: Blood pressure reduction MA of 31 studies 7031 participants. **Pooled OR of 2.73 (95% PI, 1.05–7.08)** **I^2 = 71%**

	factors overall and in different ambulatory settings			Canada, USA, Jordan, Egypt, Denmark, Cyprus, Hong Kong, China, Thailand				Evidence of effect : Type 2 diabetes Mellitus MA of 25 studies 3452 participants **OR for achieving control was 3.11 (95% PI, 1.48–6.52 I^2=30%).**
								Evidence of effect: Achieving cholesterol goals MA of 11 studies 2012 participants **OR of 1.91 (95% PI, 1.05– 3.46), I^2=31%**
Ahumada-Canale 2019 [158]	Economic evaluations of pharmacist-led medication review in outpatients with hypertension, type 2 diabetes mellitus, and dyslipidaemia: a systematic review	RCT n=11	Adult patients; community pharmacy, primary care centre, outpatient clinics	USA, Brazil, Canada, China, Nigeria, Taiwan, UK	No	Critically low	Health economics	Uncertain effect: Incremental costs per patient 9/11 studies reported in an increase in costs per patient 2/11 studies reported a deduction in costs per patient
							CVD risk factors	Uncertain effect: Systolic blood Pressure 5/6 studies report a decrease 1/6 study report no effect
								Uncertain effect: Diastolic blood pressure 5/6 studies report a decrease 1/6 study report no effect
								Evidence of effect: BP goal 4/4 studies reported an increase in the number of patients achieving their treatment goal
								Evidence of effect: Cardiovascular Risk 2/2 studies reported a reduction in cardiovascular risk
								Evidence of effect: Life years gained 1/1 study reported life years gained for male and females
								Evidence of effect: HbA1c 1/1 study reported improvement in control
Bou Malham 2021 [170]	Impact of pharmacist-led interventions on patient care in ambulatory care settings: A systematic review	RCT n=27 Observation studies n=4	Patients in outpatient settings; community pharmacy, home, hospital admission/ discharge, outpatient clinics, healthcare centres	UK, USA, Jordan, Europe	No	Critically low	Clinical	No effect: Potentially inappropriate prescriptions 1/1 study
								Uncertain effect: Adverse Drug Events 6/7 studies reported a reduced incidence 1/7 study reported no effect
								Evidence of effect: (reduction) Medicines related Problems 3/3 studies report increased resolution following intervention
								Uncertain effect: Medication Appropriateness Index 2/3 studies report a reduction in the number of inappropriate medicines prescribed 1/3 study reported no effect
							Economic	Uncertain effect: Cost 5/6 studies reported a reduction in healthcare costs 1/6 study reported no effect
								No effect: Drug utilisation 1/1 study reported no effect
								Uncertain effect: Secondary care service utilisation

								5/10 studies reported in reduction in hospital attendance and admission 2/10 studies reported an increase in hospital attendance and admission 3/10 reported no effect on hospital attendance and admission
							Patient-orientated	Uncertain effect: Adherence 6/7 studies reported an improvement in adherence 1/7 study reported no effect on adherence
								Evidence of effect: Patient satisfaction 3/3 studies reported that patients were satisfied with the intervention
								Uncertain effect: Quality of Life 3 /4 studies report no effect 1 /4 study reports an improvement
								Evidence of effect: Symptom control 1/1 study reported an improvement in symptom control
								Evidence of effect: Patient knowledge 1/1 study reported an increase in knowledge
Hikaka 2019 [162]	What are the components of medicines use review service models utilised in New Zealand? How effective are these interventions?	Retrospective case studies n=3 Prospective case studies n=2 Semi-structured interviews n=1	Adult patients; Community pharmacy, home, outpatient clinic	New Zealand	No	Critically low	Medication-related Problems (MRPs)	Uncertain effect: number of MRPs 4/4 studies reported identification of MRPs 1/ 4 study reported a change in MRPs over time. This wasn't reported upon in other studies
							Adherence	Uncertain effect 1/3 study reported improved adherence over time 1/3 study reported reduced adherence 1/3 study did not clearly report results
							Medicines knowledge	Evidence of effect 3/3 studies reported increased knowledge of medicines
							Utilisation of secondary care services	No effect 1/1 study
							Quality of life	Evidence of effect: Improvement in QoL Reported in 2 different tests 1/1 study
							Patient satisfaction	Evidence of effect 3/3 studies reported that 78-93% of respondents were satisfied with their MR
Huiskes 2017 [156]	What is the evidence of medication reviews as performed in clinical practice?	RCTs n=31	All patient populations; all settings	UK, Australia, USA, Belgium, Netherlands, Sweden, Singapore, Denmark, Germany, Canada.	Yes	critically low	Clinical outcomes measure	No effect: clinical outcomes However, 6/6 studies report decrease in the number of falls MA of 4 studies 929 participants **(RR 0.68 (0.52, 0.90); I^2 = 41.0%, p=0.166).**
								No effect: mortality 11 studies 2403 participants **(RR 0.94 (CI, 0.76–1.17) I^2 = 22.0%, P = 0.234)**
								No effect: number of hospital admissions 11 studies 2041 participants

								(RR 0.94 (0.82, 1.08) I^2 = 42.3%, P = 0.139)
								No effect: health status, physical and cognitive outcome measures. 3/3 studies reported evidence of no effect on physical functioning 2/3 studies reported no changes in clinical or health status 1/3 trial reported a smaller decrease in health following MR 2/2 studies reported no difference in cognitive functioning
							Quality of life	Uncertain effect 3/8 studies using EQ-5D or SF-36 reported no difference in quality of life 5/8 studies using EQ-5D or SF-36 reported inconclusive results
							Drug-related outcome measures	Uncertain effect: number of drug changes
								Uncertain effect: number of medicines used
								Uncertain evidence: impact on adherence, knowledge, and adverse effects
Jokanovic 2016 [169]	What are the processes and outcomes of CMR in community-settings in Australia?	RCT n=7, non-RCT n=2, uncontrolled/ observational study n=34, Qualitative study n=11, survey research study n=9	All patient populations; hospital, patient's home	Australia	No	critically low	Economical	Evidence for effect 2/2 studies reported MR was cost-effective
								Uncertain effect: medication costs 4/6 studies reported reduced costs 2/6 studies reported no reductions
							Clinical	Uncertain effect: number of medicines prescribed ¾ studies report a reduction in the number of medicines prescribed ¼ studies reported no change
								Uncertain effect: Healthcare utilisation 3/5 studies report a reduction in healthcare utilisation 2/5 studies report no change
								Uncertain effect: Prescribing ¾ studies reported an improvement in prescribing ¼ studies reported no change
							Patient-orientated	Evidence for effect: adherence 2/2 studies report improved adherence
								Uncertain effect: Quality of life ¾ studies report no evidence of an improvement in QoL ¼ studies report an improvement in QoL
Systematic reviews up to and including 2015								
Bayoumi 2009 [165]	What is the efficacy of interventions to improve medication reconciliation among community-dwelling adults in primary care settings?	RCT n=1 before and after study n=3	Community-dwelling adults; primary care, ambulatory settings, or in transition into or out of hospital	USA, Canada, Northern Ireland	No	Low	Number of discrepancies in name, dose, and frequency between recorded and patient-orientated medications.	Uncertain effect ¾ studies reported an increase in the number of medication discrepancies identified ¼ studies reported no significant change
							Clinical relevance of the medication	Uncertain effect: clinical significance of discrepancies

							discrepancies detected	
Castelino 2009 [151]	Evaluation of interventions involving pharmacists, directed toward reducing sub-optimal prescribing	RCT n=12	Patients ≥ 65; inpatients, outpatients, and primary care	USA, Canada, Belgium, Australia	No	Critically low	Suboptimal prescribing (overuse, misuse, underuse)	Uncertain effect: inappropriate prescribing 9/11 studies report improved prescribing 2/11 studies report no significant difference
							Economic outcomes (hospital services use and healthcare use)	Uncertain effect 1/5 studies reported less hospital use 4/5 studies result not reported
							Clinical outcomes (mobility, confusion, pain, falls, resident behaviour, adverse drug events)	Uncertain effect 1/5 studies reported better pain control 4/5 studies result not reported
George 2008 [164]	What is the effectiveness of interventions to improve medication adherence in elderly community dwelling patients prescribed multiple long-term medications?	RCT n=7, non-randomised trial n=1, multiphase prospective study n=1	Elderly patients; all settings	Europe, Canada, USA, Australia	No	Critically low	Adherence	Evidence of effect: 4/8 studies reported a significant effect on adherence 4/8 studies did not report significant effect on adherence Mean relative change in adherence across 8 studies = + 11.4%
Geurts 2012 [166]	What is the impact of collaboration between pharmacists and GPs and what are the outcomes on patients' health?	RCT n=26, Other studies n=51	Variable adult population; Family practice, general practice, community pharmacy	Europe, USA, Canada, Australia, New Zealand	No	Critically low	Non-specific outcomes on patients' health	Uncertain effect: hospital admissions 5/9 studies reported decrease in hospital admissions 1/9 studies reported statistically significant increase in hospital admissions 3/9 studies reported no effect
								Evidence of effect: number of medication-related problems 2/2 studies reported positive effects on MRPs resolved
								Uncertain effect: improving prescribing of medication 2/6 studies reported a reduction in the number of prescribed medicines 4/6 reported no difference in the number of medicines prescribed 5/5 studies reported an increase in the number of drug changes
								Uncertain effect: quality-of-life scores 7/10 studies reported evidence of no effect on QoL 3/10 studies report improved QoL
								Uncertain effect: increasing compliance and patient knowledge

								Uncertain effect: improving clinical values, e.g., cholesterol levels
Hatah 2014 [167]	What is impact of fee-for-service pharmacist-led medication review on patient outcomes and quantify this according to the type of review undertaken?	RCT n=8, cohort studies n=17, Prospective before/ after study n=1	Elderly or patients with specific diseases; pharmacy, patients' home, community health centre, GP clinics	US, UK, Denmark, Germany, Canada, Netherlands, Australia, Chile, Belgium	Yes	Critically low	Mortality	No effect MA of 5 studies, 771 partipants **(OR 1.50, 95% CI 0.65, 3.46, P = 0.34)**
							Hospitalisation	No effect MA of 9 studies, 1324 partipants **(OR 0.69, 95% CI 0.39, 1.21, P = 0.19)**
							Clinical biomarkers	Evidence of effect: Improvement in the attainment of target biomarkers for blood pressure MA of 6 studies, 236 partipants **(OR 3.50,95% CI 1.58, 7.75, P = 0.002)** Evidence of effect: Improvement in the attainment of target biomarkers for LDL MA of 4 studies, 334 participants **(OR 2.35,95% CI 1.17, 4.72, P = 0.02)**
							Medication adherence	Uncertain effect 11/19 studies report improvements in adherence 6/19 studies report no difference 2/19 studies report differing results depending upon how outcome was measured
							Economic	Uncertain effect 1/6 studies report reduction in medication costs 2/6 studies favour usual care 3/6 studies report no difference
							Quality of life	Uncertain effect 6/13 studies reported improvement in QoL 5/13 studies reported no difference in QoL 2/13 studies reported QoL was better in intervention group
Holland 2008 [150]	What are the effects of medication review by pharmacists on substantive clinical outcomes (namely, hospital admissions and mortality) for older people across all care settings?	RCTs n=32	Elderly (average across trials 71 years); Hospital, clinic/primary care setting, community pharmacy, patient's home, nursing home	UK, USA, Canada, Singapore, Australia	Yes	Critically low	Hospital emergency admission	No effect: all- cause admission MA of 17 studies, 9,990 participants **(RR) of 0.99 [95% CI 0.87, 1.14, P <0.91].**
							All-cause mortality	No effect MA of 22 studies, 11,741 participants **(RR = 0.96, 95% CI 0.82, 1.13, P < 0.65)**
							Mean drugs prescribed	Evidence of effect: reduction in number of drugs prescribed MA of 15 studies, 6,358 partipants (**Weighted mean difference =-0.48, 95% CI -0.89, -0.07**) Marked heterogeneity ($P < 0.001$, $I^2 = 85.9\%$)
							Cost analysis	Uncertain effect 4/14 studies report significant positive effect 6/14 studies report nonsignificant positive effect 2/14 studies report evidence of no effect

								2/14 report evidence of a negative effect
							Medication-related problems (MRPs)	Evidence of effect 4/4 studies reported a significant positive effect on number of MRPs
							Knowledge	Uncertain effect 8/11 studies report improved knowledge 3/11 studies report no difference
							Patient satisfaction	Uncertain effect: satisfaction 2/4 studies report significant positive effect ¼ studies report nonsignificant positive effect ¼ studies report negative effect
							Quality of Life	Uncertain effect: QoL 4/12 studies report nonsignificant positive effect 8/12 report evidence of no effect
							Adherence	Uncertain effect: adherence 11/14 studies report improvement in adherence 3/14 studies report no effect on adherence
Kucukarslan 2011 [152]	What is the evidence of the impact of Medication Therapy Management (MTM) services on patient outcomes in order to assist healthcare professionals in improving services for their patients?	RCT n=8	Patients >18 years; Clinics, community pharmacy	USA, Canada, UK	No	Critically low	Patient outcomes	Uncertain effect: improvements to Clinical outcomes (e.g., BP, HbA1c LDL)
								Uncertain effect: Blood Pressure 3/ 4 studies reported a decrease 1/ 4 study reported no effect
								No effect: adherence 2/2 studies
								Uncertain effect: symptoms 1/ 2 study reported an improvement in symptoms 1/ 2 study reported no change
								No effect: Quality of Life 4/4 studies
								No effect: LDL 2/2 studies
								Uncertain effect: HbA1c 3/ 4 studies reported an improvement 1/ 4 study report no effect
								Uncertain effect: patient satisfaction 1/ 2 study reported an increase 1/ 2 reported no effect
							Drug or healthcare costs	No effect: healthcare utilisation 1/1 study
								Uncertain effect: costs 2/4 studies reported an improvement 1/ 4 study reported an increase 1/ 4 study reported no effect

Kwint 2013 [153]	How does the extent of collaboration between the general practitioner (GP) and the pharmacist impact on the implementation of recommendations arising from medication review?	RCT n=12	Older adults, mean age 70 years; home-dwelling, primary care	Canada, New Zealand, Netherlands, USA, UK, Australia	Yes + +Not for outcomes	Critically low	Implementation rate of recommendations following identification of medicines-related problems (MRPs)	Mean implementation rate of recommendations was 50 % (range 17–86) (12 studies).
							Clinical outcomes	No effect: quality of life 5/6 studies reported no effect on QoL 1/6 studies reported negative effects in some domains No effect on hospital admissions 4/4 studies reported evidence of no effect
							Intermediate outcomes (e.g., adherence)	No effect: adherence 2/2 studies reported evidence of no effect
							Process outcomes (e.g., drug changes, number of drugs)	Uncertain evidence: Process outcomes 2/6 studies reported a reduction in number of prescribed medicines 4/6 studies report no evidence of effect 5 studies reported an increase in number of drug changes
Rollason 2003 [42]	What is the role of pharmacists and pharmacist interventions in reducing polypharmacy	RCT n=7, controlled study n=7	Elderly patients (mean age across studies 64 – 86); outpatients, nursing home, inpatient, post discharge	USA, Canada, Belgium, UK, Korea	No	Critically low	Reduction in number of medications	Evidence of effect: reduction in number of medicines 7/14 studies reported a significant reduction in number of medicines 1/14 studies reported no difference between control and intervention 6/14 studies not reported
Royal 2006 [163]	What interventions delivered in primary care settings reduce preventable drug related morbidity?	RCT n= 29, Controlled before/after study n=8, retrospective study n=1	All patient populations; general practice	USA, Europe, Australia, New Zealand	Yes	Critically low	Reduce drug-related morbidity	No significant effect: falls MA of 9 studies, 4,748 participants **(OR 0.91 (95% CI 0.68 to 1.21)**
							Hospitalisation	Evidence of effect: reduction on hospital admission MA of 13 studies, 20,318 participants (OR 0.64 (95% CI 0.43 to 0.96) but significant heterogeneity; sensitivity analysis reduces the size of effect **OR 0.92, 95% CI 0.81 to 1.05**
Tan 2014 [154]	What is the effectiveness of clinical pharmacist services delivered in primary care general practice clinics	RCT n=38	Adults; General practice	USA, UK, Canada, South America, Asia	Yes	Critically Low	Appropriateness of prescribing	Evidence of effect: improving quality of prescribing and medication appropriateness
							Medication use	Evidence of effect: positive effect on resolution of medication-related problems
							Health service use	No effect
							Clinical, functional, practice or	Evidence of effect: Systolic BP reduction MA of 11 studies, No. of participants not reported **-5.72 mm Hg (95% CI, -7.05 to -4.39 P<0.001**

							economic outcomes	Evidence of effect : Diastolic BP reduction MA of 11 studies, No. of participants not reported **-3.47 mm Hg, (95% CI -4.35 to -2.58, P<0.001)**
								Evidence of effect : HbA1C reduction MA of 5 studies, No. of participants not reported **-0.88% (95%CI, -1.15 to -0.62, P<0.001)**
								Evidence of effect: LDL-cholesterol reduction MA of 3 studies, No. of participants not reported **-18.72 mg/dL (95% CI, -34.10 to -3.36, P <0.017)**
								No effect: quality of life or patient satisfaction.
Viswanathan 2015 [168]	What is the effect of a Medication Therapy Management (MTM) service in outpatient settings	RCT n=21, Non-RCT n=4, Cohort study n=19	All patient populations; ambulatory settings	USA, Australia, UK, Canada, Brazil	Yes	Critically low	Health outcomes	Uncertain evidence: clinical outcomes e.g., HbA1c, lipids, BP, anticoagulation.
							Mortality	Uncertain evidence: mortality 3/3 studies report insufficient evidence OR for studies 0.5-0.92 with wide confidence intervals
							Patient-centred functioning	Uncertain evidence: cognitive and affective function 3/3 studies report insufficient evidence
							Quality of life	No effect health-related Quality of Life 3/3 studies report evidence of no effect
							Satisfaction	No effect 3/3 studies report evidence of no effect
							Health care use and costs.	Uncertain effect: hospitalisations/ outpatient visits. MA of 3 studies, 2,208 participants standardized mean difference of outpatient appointments, **0.05; 95%CI, –0.03 to 0.13; P = 0.25** Weighted mean difference for hospitalisations **0.04; 95%CI, –0.01 to 0.08; P =0 .09**
								Uncertain effect: medication costs.

Key:		
	No effect	Evidence of no effect was reported as quantitative data. In the absence of a meta-analysis this information was extracted from authors' conclusions.
	Uncertain effect	This was reported when the systematic review included studies with positive and negative effects in outcomes, leaving uncertainty about the effect of medication reviews on a particular outcome measure
	Evidence of effect	Evidence of effect could be positive, in favour of the medication review, or negative, in favour of the control group. Evidence of effect was reported as quantitative data. In the absence of a meta-analysis this information was extracted from authors' conclusions

LDL= low density lipoprotein
CVD= cardiovascular disease
BP = blood pressure
CMR= Clinical Medication Review
MRPs= Medication-related problems; also known as drug-related problems
MD= Mean difference
MA= Meta-analysis
RCT= Randomised Controlled Trial
QoL= Quality of Life
MR= medication review

3.3.5 Gaps in the literature as identified by authors of the systematic reviews

Evidence for the effectiveness

All systematic reviews except two [153,168] reported that medication reviews had a positive effect on at least one reported outcome. However, evidence for the effectiveness of the clinical effect of medication reviews is not conclusive. Some authors stress the **need to shift focus from current outcomes**, such as documenting the number of medication changes, to clinical measures and outcomes that impact patients, such as medication-related morbidity [42,150,151,153,155,163,165]. Tan et al. reported that variations in measured outcomes make it challenging to compare results and suggest standardisation of outcome measures [154].

Heterogeneity of the interventions

Several authors commented on the challenge of data analysis given the heterogeneity of the interventions [153–156,168,169], and Alldred et al. reported challenges in conducting subgroup analyses for professional and organisation interventions [155]. Hatah et al. concluded that further research is needed to examine the impact of different types of medication review on patient outcomes [146]. Holland et al. and Martinez-Mardones et al. highlighted the need for a well-defined medication review, and Kwint recommended the identification of the key components of the medication review [150,153,157]. Geurts highlighted the need for a system that classifies the activities undertaken in a medication review that can be used across countries [166].

In summary, this scoping review has identified the following areas that required further exploration:

- Description of the components of pharmacist-led medication reviews
- Identification of outcomes that better document the impact of medication reviews.

3.4 Discussion

3.4.1 Statement of key findings and interpretation

This scoping review identified **23 systematic reviews** that reported significant variation in the evidence for the effectiveness of pharmacist-led medication reviews, only two of which were high quality. A high-quality review conducted in care home settings [155] found that medication reviews led to improvements and resolution of medicine-related problems, such as potential drug interactions or inappropriate dosing and indications. Another high-quality review [175] concluded that medication reviews in hospital settings reduced healthcare utilisation (e.g., hospital admissions or readmissions), but this reduction was not observed in care home settings [155].

Moderate- and low-quality reviews conducted in community pharmacy or ambulatory care settings reported improvements in clinical outcomes, such as reductions in blood pressure, cholesterol levels, and glycated haemoglobin [157,161]. However, the evidence for the effectiveness of medication reviews on other outcomes across different settings and patient populations remains uncertain. Notably, 71% of the reviews assessed had a critically low AMSTAR2 rating, indicating low confidence in their results. The number of reviews rated as high or moderate quality would have increased from 21% to 29%, and those rated as critically low would have decreased to 59%, if protocol papers had been referenced in five reviews.

A major limitation observed was the lack of detailed descriptions of the intervention, making it difficult to explain the variation in outcomes. This scoping review highlights uncertain evidence for the effectiveness of pharmacist-led medication reviews across different patient populations. There was significant variability in the reporting of outcomes, with the two most reported being healthcare utilisation and adherence. However, even these outcomes were assessed using diverse methods, making definitive conclusions challenging. Researchers should carefully consider the appropriateness of the outcomes and measures used to assess the effectiveness of medication reviews.

As more research is conducted to understand the range of outcomes associated with medication reviews, regardless of the professional delivering them [59,176], it may become easier to interpret the impact of these interventions across studies. Furthermore, many systematic reviews evaluated medication reviews alongside other interventions, and these co-interventions may have influenced the outcomes and conclusions.

The lack of standardised outcomes in medication review studies has been identified as a gap in the literature. Heterogeneity in reported outcomes poses a significant barrier to evidence synthesis and meta-analysis. To address this, Al Shaker et al. developed a core outcome set aimed at standardising outcome measurement in interventions targeting polypharmacy in older adults [177]. This work highlights the critical importance of consistent outcome selection and measurement to facilitate comparison and synthesis across studies.

A critical issue identified was the absence of definitions and detailed descriptions of the medication review as an intervention in most reviews. While NICE and the Pharmaceutical Care Network Europe (PCNE) have published definitions of medication reviews [88,105], these were rarely cited. Some reviews were published before the introduction of these definitions, which may explain their absence. This lack of standardised definitions and descriptions likely contributes to the variability and mixed results in reported outcomes. The findings of my scoping review align with an earlier overview by Silva et al., which concluded that substantial heterogeneity in definitions, terminologies, and delivery approaches for medication reviews affects the ability to evaluate their effectiveness [178].

Despite the lack of detailed descriptions, components that appear to positively influence outcomes include face-to-face contact with patients, pharmacist access to clinical notes, and collaborative working with physicians [153,157,166,167].

The variation in approaches to and descriptions of medication reviews impacts the ability to evaluate their effectiveness [153–156,168,169]. Standardising medication reviews could benefit future evaluations. Some researchers have recommended developing classification systems for medication reviews. For example, Geurts [166] proposed a classification system, while Alharti et al. identified terms and definitions used to describe medication review activities in primary studies [179]. These researchers concluded that developing an international taxonomy for medication reviews and their activities would be more beneficial than creating a single standardised intervention for all settings. Exploring individual components of medication reviews and linking these to outcomes may provide a better way to evaluate their effectiveness than relying on overall results alone. Silva et al. concluded that international agreement on the medication review process is necessary [178]. Alharti et al. expanded on this, identifying terms used to describe medication review activities [179].

The lack of confidence in the results of the systematic reviews underscores the need for future studies to explore these conclusions further. Future evidence syntheses could address the challenges posed by the heterogeneity of interventions by adopting stricter inclusion criteria. For instance, they could limit included studies to those with specific outcomes (e.g., health-related quality of life or medicines appropriateness) assessed using validated measures or to studies with detailed descriptions of the intervention.

3.4.2 Strengths and Limitations

This scoping review provides an overview of systematic reviews on pharmacist-led medication reviews across all settings. However, the search terms were limited; for instance, alternative terms such as 'drug review' were not included. This may have restricted the number of retrieved studies and introduced selection bias. Additionally, the Jokanovic systematic review, which was used as a source for pre-2015 studies, focused only on community settings and excluded care homes [169]. As

a result, my review may have overlooked systematic reviews on medication reviews in care homes published before 2015. Furthermore, paper screening and data extraction were conducted by a single researcher, increasing the margin of error compared to a multi-researcher approach.

3.5 Conclusions and next steps

This scoping review highlighted the significant variation in the evidence regarding the effectiveness of pharmacist-led medication reviews reported in the systematic reviews. Only two systematic reviews were assessed to have high confidence in the results; these indicated that medication reviews could lead to improvements and resolutions of medicine-related problems, as well as a reduction in healthcare utilisation. Other moderate- and low-quality reviews conducted in community pharmacy and/or ambulatory care settings reported improvements in clinical outcomes; however, the evidence for the effectiveness of medication reviews on other outcomes across various settings and patient populations remains uncertain. Additionally, many reviews failed to describe the nature of the intervention in detail. This lack of clarity complicates efforts to explain the inconsistent outcomes observed and makes it challenging to determine the characteristics of a high-quality medication review. These findings highlight the need for further research in this area. The next step is a systematic review to help determine what constitutes a high-quality medication review and identification of the components that contribute to positive patient outcome. **Table 3.3** summarises the conclusions from this chapter.

Table 3.3 Contribution to research alongside conclusions from previous chapters

	Introduction	**Scoping review**
Aim	**Overall aim of this thesis** Investigate how pharmacist -led medication reviews in primary care can be optimised to improve patient outcomes for those with long-term conditions.	Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction.
Results	Background information about long-term conditions and medication reviews. • Increasing prevalence of long-term conditions which adds to individual and health system burden. • Long-term conditions primary managed by medicines. • Some challenges associated with medication use include poor adherence, adverse drug reactions (ADRs), and inappropriate prescribing. • Medicines issues can potentially lead to poor patient outcomes, including hospitalisations and a reduced quality of life • Medication reviews aim to improve medication use and reduce adverse outcomes • UK government policies advocate for expanding pharmacists' roles in medication reviews.	• Significant variation in outcomes associated with pharmacist-led medication reviews. • Many reviews did not report the nature of the intervention; therefore, we cannot ascertain what a high-quality medication review looks like and what leads to good outcomes. • An additional literature search is necessary to identify the core components of pharmacist-led medication reviews and how these link to outcomes.

Chapter Four Components of pharmacist-led medication reviews and their relationship to outcomes: A systematic review and narrative synthesis.

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4.1 Introduction

The scoping review in Chapter Two identified that pharmacist-led medication reviews are implemented across various countries and highlighted the need to further explore the implementation of pharmacist-led medication reviews, given the significant variation in outcomes associated with these interventions. The sub-optimal evidence for effectiveness is partly due to the lack of studies exploring which components of the medication review generate positive outcomes [180]. The conclusions from the scoping review highlighted the need for further evidence synthesis to better understand the components of medication reviews and how they influence outcomes. This systematic review follows the MRC NIHR framework for evaluating complex interventions, which recommends examining which elements contribute to desired outcomes, the reasons behind their effectiveness, and the contexts in which they work best. This approach supports the development of interventions that are acceptable, feasible, cost-effective, and adaptable across different healthcare settings [104]. Unlike a realist review [124], this systematic review did not aim to identify or test specific causal mechanisms that explain how outcomes arise in particular contexts.

4.1.1 Aim and objectives

The aim of my systematic review was to explore the components of pharmacist-led medication reviews and their relationship to outcomes. This aim was achieved by pursuing the following objectives in relation to medication reviews:

1. Describe their components
2. Describe their implementation
3. Describe the reported outcomes
4. Examine potential mechanisms of impact

4.2 Method

Following consideration of the evidence syntheses described in section 2.4.1, a systematic review and narrative synthesis was conducted to answer the aims and objectives of this review. A systematic review is a structured approach to evaluating primary research, aiming to provide an up-to-date summary of findings to answer a specific research question [118]. The search strategy, inclusion/exclusion criteria, screening process, data extraction, and steps taken to ensure the trustworthiness of the results, are outlines in this section, thereby adhering to established review criteria.

Chapter three describes the heterogeneity in study design, intervention type, and outcomes measures, so I knew that statistical meta-analysis was an inappropriate approach. Medication reviews are complex, multifaceted interventions that vary according to context (e.g. care setting, patient population, professional role, and health system structure) and implementation processes. Unlike realist reviews, which focus on explaining how and why interventions work in specific contexts [160], a narrative approach allows for a more flexible and comprehensive overview of the

evidence. Therefore, narrative synthesis was chosen for this study to provide a broad, descriptive synthesis of the existing literature on medication reviews.

4.2.1 Search strategy

Using a pragmatic approach to literature searching, the systematic review by Huiskes et al. [156] was utilised to identify relevant papers on pharmacist-led medication reviews published before 2015. This review was chosen due to its comprehensive inclusion criteria. Additionally, this approach has been adopted by other systematic review authors, further supporting its relevance and rigor [103].

The MEDLINE, EMBASE and Web of Science databases were utilised for the literature search, from 2015 to September 2023, using the same search terms used by Huiskes et al [156]. The search terms used were “medication review”, “pharmacist” and “randomised controlled trial” and synonyms. The full search strategy is outlined in **Appendix 2.** The search was supplemented during data extraction by identifying companion papers for the included studies.

4.2.2 Inclusion/ Exclusion criteria

The identified papers were screened based on the following inclusion and exclusion criteria:

Population: adults 18 years and over who received a medication review delivered by a pharmacist, either alone or as part of a multi-disciplinary team, in any setting.

Intervention: medication review, which for the purpose of this review is defined as “a consultation between a pharmacist and a patient to review the patient’s total medicines use with a view to improve patient health outcomes and minimise medicines related problems”. Studies were excluded if the medication review was part of a wider intervention, for example, to improve diabetes care where medication review was just one part of the process.

Comparison: usual care (no medication review) or a medication review delivered by another healthcare professional.

Outcomes: studies reporting any outcomes.

Study design: randomised controlled trials and their protocol and process evaluation papers.

Time and financial constraints did not allow for translation from other languages, therefore only English language articles were included. Conference abstracts and articles where full texts were not available were excluded.

4.2.3 Screening

I independently screened titles/ abstracts and full-text articles, with twenty percent of abstracts and full-texts independently reviewed by a second reviewer. Disagreements were resolved through discussion, with a third reviewer when needed.

4.2.4 Data extraction

I extracted data from the full-text articles using a bespoke data collection form, informed by the TIDieR framework [115]. Details of the data collection form are included in **Appendix 3**. The form was piloted with several studies to ensure clarity and consistency. It captured study characteristics, descriptions of the intervention and comparator, implementation details, outcomes, and mechanisms of impact. Outcome classification was guided by the international core outcome set for clinical trials of medication reviews in multimorbid older patients with polypharmacy, alongside the patient-relevant outcomes identified in the scoping review by Kersting et al. [59,176]. Pharmacist implementation processes were mapped using the Cochrane Effective Practice and Organisation of Care (EPOC) taxonomy [117] to support systematic categorisation of intervention delivery.

The scoping review (Chapter Three) revealed substantial heterogeneity in how medication reviews were described and implemented across studies, including inconsistencies in terminology and intervention components. To address this, the EPOC taxonomy was applied during the systematic review to provide a standardised and reproducible framework for classifying the interventions. This facilitated clearer comparisons across studies and enabled the identification of patterns in how medication reviews were operationalised in different healthcare contexts. Applying this taxonomy also supported the contextualisation of behaviour change techniques, contributing to a more comprehensive and theoretically informed synthesis of the evidence.

The 2015 MRC framework emphasises that process evaluations are valuable for identifying key contextual factors that support the implementation of interventions. The MRC guidance for process evaluation of complex interventions highlights that the first step in such evaluations is to establish a clear description of the intervention, how it is implemented, and the assumptions about how it will work in its context [109]. This includes identifying external factors that may influence implementation. Consequently, defining the intervention and determining how it is described in the existing literature is a critical initial step in evaluating complex interventions. The most up-to-date MRC NIHR framework for developing and evaluating complex interventions [104] and the MRC guidance for their process evaluation [109] was used in this thesis.

As noted in Chapter Two, the MRC NIHR guidance [104] outlines the importance of describing the intervention and the influence of implementation, mechanisms, and context [109]. Evaluating whether an intervention was delivered as intended (fidelity) and the extent of delivery (dose) is essential for interpreting effectiveness. Given that complex interventions often require adaptation to local circumstances, documenting this tailoring process is equally important. Mechanisms of impact represent the intermediate processes through which intervention activities bring about

intended, or unintended changes [113], while contextual factors external to the intervention can strongly influence implementation success and outcomes [109].

Mechanisms of impact include:

- participant responses and interaction with the intervention (in this case, patients)
- mediators (intermediate processes which explain subsequent changes in outcomes) [113]
- the mediators extracted were at a participant level, where the participant was the pharmacist.
- moderators of effect (factors likely to influence intervention effectiveness) [113]
- unanticipated pathways and consequences.

Medication review outcomes are influenced, among other things, by pharmacist and patient behaviour change (supporting medication adherence and taking medication as prescribed [181] respectively). These are behaviour change components of medication reviews, but they have not been recognised explicitly in the medication review literature and their design. However, they are present, and it is therefore justified to extract behaviour change techniques (BCTs) using the BCT Taxonomy v1 [116], as done with other clinical interventions [182–184]. I used the taxonomy to extract BCTs used by the pharmacist during the consultation to support the patient in taking their medications as directed (adherence). This allows the field to understand common and promising BCTs, as well as evidence based BCTs which medication reviews have rarely included.

Many intervention reports do not provide clear descriptions of BCTs, so I coded any BCTs either as present in all probability (evidence not clearly reported) or present beyond all reasonable doubt (clear evidence reported for their presence) [185]. BCTs were coded in both the intervention groups (medication review) and comparison groups to understand unique BCTs included in the intervention only. I coded BCTs in relation to a specific behaviour (supporting medication adherence) employed

by one actor (pharmacist), whilst the implementation strategies apply to the whole intervention. BCTs and implementation strategies were coded independently from each other.

4.2.5 Rigour

This review has been reported in accordance with the PRISMA guidelines [186] and the protocol was registered in PROSPERO (CRD42020173907). Data extraction from 20% of randomly selected studies was checked by two of my supervisors, MJT and WH. In addition to the 20% random sample, WH checked BCT extraction of a further sample of six studies to check for consistency with coding BCTs. WH has extensive expertise in identification of BCTs as co-author of the BCT Taxonomy v1 [116]. Data extraction enabled the identification of shared characteristics, relationships, and patterns. Narrative synthesis of the extracted data enabled an analysis of these relationships and patterns which were discussed regularly by the research team.

Quality assessment

I assessed risk of bias by using the Cochrane risk of bias 2 tool for randomised controlled trials [187]. Twenty percent of randomly selected studies were assessed by a supervisor (MJT).

4.2.6 Data synthesis

Extracted data describing medication review components, implementation, and outcomes are presented in **Table 4.1**, **Table 4.2** and **Appendices 5** and **6**. These descriptions were narratively synthesised to draw out common themes. These data were narratively synthesised to identify common themes across studies. Narrative synthesis is particularly useful for generating ideas and theories about how and why an intervention might work, and under what circumstances [123]. During data extraction, I noted information that could inform the synthesis, especially descriptions of potential mechanisms of impact and contextual influences on medication review implementation reported in the results and discussion sections of the included studies.

To enhance the robustness of the synthesis, studies assessed as having a low risk of bias and reporting statistically significant results were used as the starting point for identifying common themes. Findings from studies with higher risk of bias were then compared and integrated to refine and expand these themes. The overall quality of evidence was assessed using the GRADE framework [188], which classifies evidence as high, moderate, low, or very low quality. Inconsistency, imprecision, and indirectness of reported outcomes were considered holistically when determining the quality of the evidence base.

Themes were inductively coded using the TIDieR framework (where, who, how, and how much) [115]. These themes were further refined into components reflecting the physical, organisational, and social dimensions of the health system context in which the medication review was implemented [104]. Findings were presented and discussed among the research team through a series of meetings to agree on the final synthesis and conclusions.

4.3 Results

4.3.1 Study selection

The literature search yielded 11,946 reports, with another 33 already identified by Huiskes et al. [156]. Deduplication reduced this to 10,947. Titles were screened and 597 abstracts were identified. Abstracts were reviewed by HAJ with substantial agreement as to which reports should be reviewed at full text (81% Cohen's κ =0.61). Screening of 534 abstracts reduced the total number of papers to be reviewed at full text to 246. Sixty-eight reports describing 50 individual studies were included for data extraction (see **Figure 4.1**). Interrater reliability at full text screening, identifying which reports should be included in the systematic review, was 89%, Cohen's κ =0.77, indicating good agreement [189].

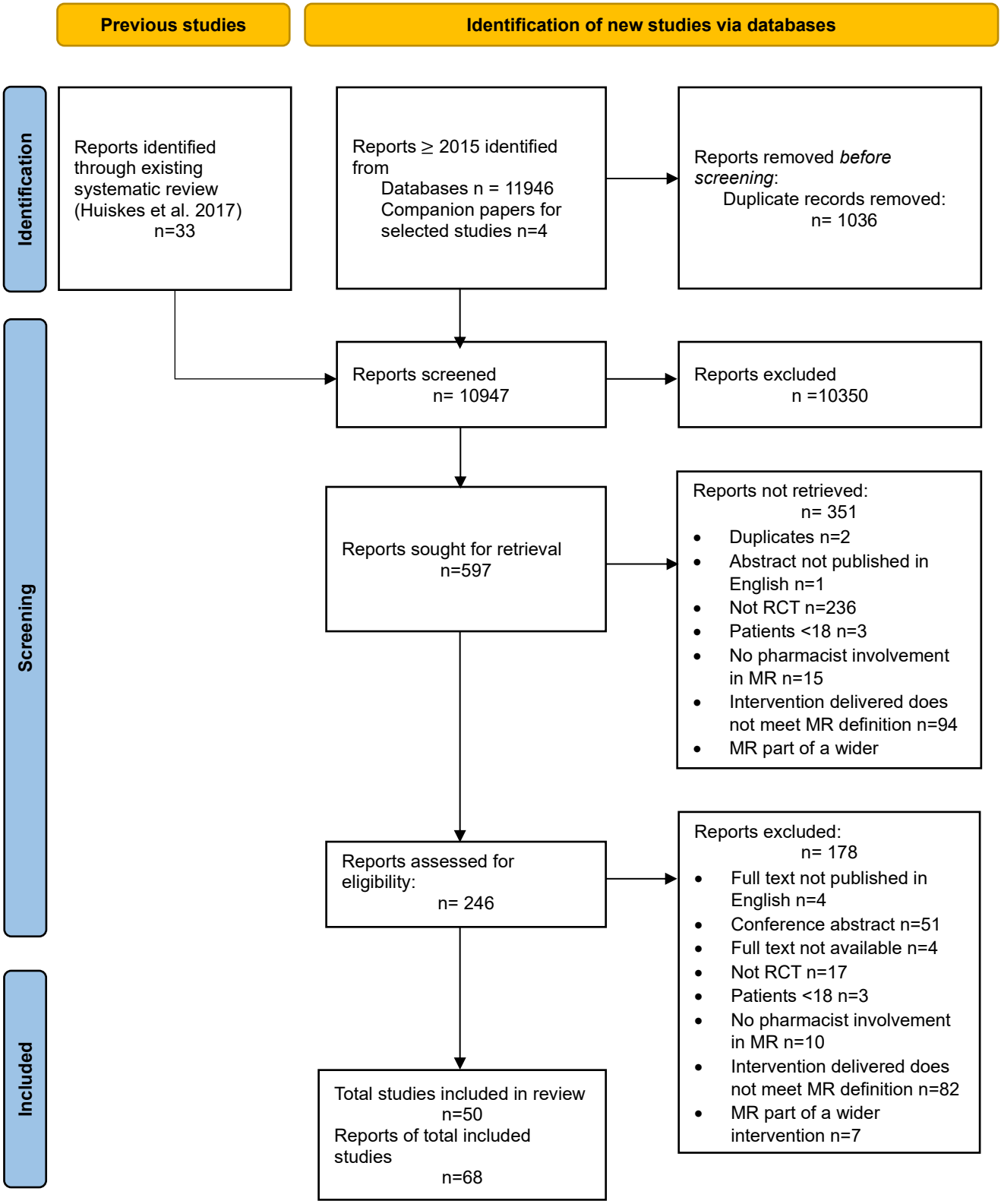

Figure 4.1 PRISMA diagram of literature search and study selection

4.3.2 Characteristics of included reports

Most studies included in this review were undertaken in Europe (23) [190–212], with twelve in Asia [213–223], eight in North America [224–231], and the remaining from Australia [232–235], South America [236,237] and Africa [238]. Nearly a third of studies (14) were undertaken in a hospital setting [190,193,194,196,200,202,203,208,209,217,218,221,232,233], with the remaining studies taking place in various primary care environments, except for six which were undertaken in outpatient departments [199,213,214,223,237,238]. Almost half of studies (22) recruited patients aged 60 years or older [190–192,194,195,197,198,200,201,203,205,210–214,222,223,226,229,232,233,235,236], with the other studies recruiting adult patients who had one or more long term conditions(s) or were taking at least four medicines. Study sample size ranged from 60 to 2637 participants. A detailed description of the characteristics of the medication reviews can be found in **Table 4.1**.

Table 4.1 Detailed description of the characteristics and content of the medication reviews

Author (Year)	Study characteristics			Intervention description										
	Country and setting	Population	No. of participants	Content of MR	Information availability	Pharmacist resolution of MRPs	Pharmacist changes	Physician referral and how	Follow up with patient	Follow up with prescriber	Mode of delivery	No. of times consultations delivered	Duration (mins)	Period intervention delivered over
Alalawneh (2022) [239]	Jordan, Domiciliary	>18 years ≥1 chronic condition, ≥ 5 medicines	109	ID of MRPs; Adherence; Education;	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	Yes	Face to face	2	<60	3 months
Anderegg 2018 [224]	USA, General Practice	≥18 years with HTN &/or DM or CKD	335	ID of MRPs; Adherence; Education;	Pt interview & medication history	Yes	Yes	Yes: Electronic or verbal	Yes	Yes	Face to face	6	NR	minimum 8 months
Graabaek 2019 [190]	Denmark, Hospital	>65 years MAAU	600	ID of MRPs; Adherence; Education (Only STAY)	Pt interview, medication history & clinical data	Yes	No	Yes: Electronic	Yes	No	Face to face	ED=1, STAY = 3	Median on unit 20; Median at discharge 20	ED= Once; STAY= duration of hospital stay
Lenaghan 2007 [191]	UK, Domiciliary	>80 years ≥4 medicines, ≥1 risk factor	136	ID of MRPs; Adherence; Education	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face	Yes	Yes	Face to face	2	2 hours for 2 visits	6-8 weeks
Lim 2004 [213]	Singapore, Outpatient	Elderly patients, >3 medicines to >9 doses per day	126	ID of MRPs; Adherence; Education; Other	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face	No	No	Face to face	1	10 to 30	One off
Lin 2018 [214]	Taiwan, Outpatient	≥65 years, ≥ 3 chronic diseases, ≥6 medicines	178	ID of MRPs; Adherence; Education; Other	Pt interview & medication history	Yes	No	Yes: Face to face	No	No	Telephone	NR	NR	NR
Maritnez-Mardones (2023) Ahumada-Canale 2021a, 2021b [236,240,241]	Chile, General Practice	≥65 years, ≥5 medicines, moderate to high CVD risk	324	ID of MRPs; Adherence; Education; clinical monitoring	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face	Yes	Uncertain	Face to face	4	35 (initial) 18 (subsequent)	12 months

Schulz 2019, Schulz 2020, Laufs 2018 [192,242,243]	Germany, Community Pharmacy	≥60 years with CHF	258	ID of MRPs; Adherence; Education; Clinical Assessment	Pt interview & medication history	Yes	No	Unclear	Yes	Yes	Face to face	Weekly (bi-weekly after 4 weeks)	Median; 14	Duration of study
Aguiar 2018 [237]	Brazil, Outpatient	Patients 40–79 years T2DM > 6 months	80	ID of MRPs; Adherence; Education; social/FH;	Pt interview, medication history & clinical data	Yes	No	Yes: Unclear	Yes	Yes	Face to face	2 or 3	1st 20-40 2nd 3-20	2 to 6 months
Basheti 2016 [244]	Jordan, Community Pharmacy	>18 years, ≥1 CMC, ≥ 3 medications	160	ID of MRPs; Social/FH; Baseline clinical biomarkers	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	No	Face to face	2	NR	3 months
Basheti 2018 [216]	Jordan, Community Pharmacy	>18 years, ≥1 CMC, ≥ 5 medications, >12 doses per day	84	ID of MRPs; Education	Pt interview & medication history	Yes	No	Yes: Written	Yes	No	Face to face	2	<60	3 or 4 months
Garcia 2015 [193]	Norway, Hospital	18 to 80, established CHD	102	ID of MRPs; Education; Social/ FH; Clinical assessment	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	No	Face to face	3	30-60	12 months
Jameson 1995 [225]	USA, General Practice	≥18 years cardiology outpatients	64	ID of MRPs; Education	Pt interview & medication history	No	No	Yes: Face to face	Yes	No	Face to face	2	45-60 (Phone call 5-10)	1 month
Lisby 2018 [194]	Denmark, Hospital	≥65 years, ≥4 medicines	108	ID of MRPs	Pt interview, medication history & clinical data	Yes	No	Yes: Written	No	No	Face to face	1	NR	one off
Sakthong 2018 [217]	Thailand, Hospital	>18 years, ≥5 prescribed medicines	528	ID of MRPs; Education	Pt interview, medication history & clinical data	Yes	No	Unclear	Yes	No	Face to face	2	NR	3 months
Sellors 2001 [227]	Canada, General Practice	>18 years, ≥4 prescribed medicines	132	ID of MRPs	Pt interview & medication history	No	No	Face to face	Yes	No	Face to face	2	NR	Up to 1 month

Williams 2004 [226]	USA, General Practice	≥65 years, ≥ 5 medicines	140	ID of MRPs;	Pt interview & medication history	Yes	No	Face to face	No	No	Teleph one	1	NR	one off
Zermansky 2002 [195]	UK, General Practice	>65 years	1188	ID of MRPs; Adherence; Education	Pt interview, medication history & clinical data	Yes	Yes	Written	Yes	No	Face to face	At least once	20	NR
Aburuz 2020 [218]	Jordan, Hospital	GS patients; > 18 years, chronic disease, ≥2 medicines	123	ID of MRPs Adherence Education	Pt interview, medication history & clinical data	Yes	No	Yes: Written, Face to face	Yes	Yes	Face to face	Daily	NR	Duration of stay
Al alawneh 2019 [219]	Jordan, Domiciliary	Syrian refugees >18 years ≥1 CMC, ≥ 5 medications, or > 12 doses/ day	106	ID of MRPs; Adherence; Education; Social/ FH;	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	Yes	Face to face	2	<60	3 months
Al-Qudah 2018, Basheti 2016 [215,220]	Jordan, Domiciliary	≥18 years, CMC, ≥ 5 medications, ≥12 doses / day	97	ID of MRPs; Adherence; Education;	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	Yes	Face to face	2	<60	3 months
Basger 2015 [232]	Australia, Hospital	Patients >65, ≥ 5 medications	183	ID of MRPs; Education;	Pt interview & medication history	Yes	No	Yes: Written	Yes	No	Face to face	2	NR	3 months
Bonnerup 2020 [196]	Denmark, Hospital	≥ 18 years, ≥ 1 regular medication	369	ID of MRPs; Adherence;	Pt interview, medication history & clinical data	No	No	Yes: Written	No	No	Face to face	1	NR	One off
Briggs 2015 [233]	Australia, Hospital	> 70 years, > 5 medications daily	1021	ID of MRPs; Adherence	Pt interview & medication history	Yes	No	Yes: Written	No	No	Face to face	1	NR	NR
El-Refae 2017 [221]	Jordan, Hospital	>18 year, ≥2 cardiac medications, current patient	100	ID of MRPs; Adherence; Education	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face, then written	Yes	No	Face to face	Daily	NR	3 months

Erku 2017 [238]	Ethiopia, Outpatient	≥ 18 years, T2DM, ≥1 antidiabetic medication	127	ID of MRPs; Adherence; Education; Health promotion	Pt interview & medication history	Yes	No	No None	Yes	No	Face to face	Regularly	45	3 to 6 months
Freeman 2021, Foot 2017 [234,245]	Australia, General Practice	≥ 18 years, ≥5 medicines or diagnosed with CHF/ COPD exacerbation	306	ID of MRPs; Adherence	Pt interview & medication history	Yes	No	Yes: Face to face	Yes	No	Face to face	2	45	5 days
Geurts 2016 [197]	Netherlands, community Pharmacy	>60 years, polypharmacy, ≥ 1 CV medicine	512	ID of MRPs; Adherence;	Pt interview & medication history	Yes	No	Yes: Electronic	No	Yes	Face to face	NR	NR	NR
Gurwitz 2021 [228]	USA, Domiciliary	≥50 years, discharged from hospital, ≥ 1 high-risk medication	459	ID of MRPs; Education; Social/ FH;	Pt interview & medication history	Yes	No	Yes: Electronic	Yes	No	Face to face	2	NR	14 days
Holland 2005, Holland 2010, Pacini 2007 [198,246,247]	UK, Domiciliary	≥80 years, ≥ 2 medicines, own/ warden control home	872	ID of MRPs; Social/FH;	*Pt interview & medication history	Yes	No	Yes: Written	Yes	Yes	Face to face	2	Mean 1st 61 2nd 42	4-6 weeks
Huiskes 2020 [199]	Netherlands, Outpatient	≥18 years, ≥2 risk factors	224	ID of MRPs, Adherence	Pt interview, medication history & clinical data	No	No	Yes: Written	Yes	No	Telephone	3	As long as needed	2 months
Kempen 2021, Kempen 2020, Kempen 2017 [200,248,249]	Sweden, Hospital	≥65 years	2637	ID of MRPs; Adherence; Education	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face	Yes (Int 2 only)	No	Face to face	1 (int 1) 3 (Int2)	NR	2 months
Krska 2001 [201]	UK, Domiciliary	≥65 years, ≥2 disease states, ≥4 regular medicines	332	ID of MRPs; Adherence; Social/ FH	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	Yes	Face to face	2	NR	3 months
Lea 2020 [202]	Norway, Hospital	≥18 years, ≥4 regular medicines, ≥ therapy classes	399	ID of MRPs; Adherence	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face	Yes	No	Face to face	At least 2	NR	Duration of stay

Lenssen 2018 [203]	Germany, Hospital	≥65 years, care home resident	60	ID of MRPs	Pt interview, medication history & clinical data	Yes	No	Yes: Face to face	No	No	Face to face	Regularly	NR	Duration of stay
Liou 2021 [222]	Taiwan, Care Home	≥65 years, ≥ 3 chronic diseases,≥6 medicines	80	ID of MRPs; Adherence; Education;	Pt interview, medication history & clinical data	Yes	No	Yes: Written	Yes	Uncertain	Face to face	4	NR	13months
Lyons 2016 [204]	UK, Online Pharmacy	≥18 years, ≥ 1 medicine for type 2 diabetes and/or lipid regulation	677	ID of MRPs; Adherence; Education;	Pt interview & medication history	Yes	No	Uncertain: Unclear	Yes	No	Telephone	2	Median 1st 16 min 40 s Median 2nd 5 min 36 s	4-6 weeks
Malet-Larrea 2016, Jodar-Sanchez 2015, Varas-Doval 2020 [205,250,251]	Spain, Community Pharmacy	>64 years, ≥ 5 medicines	1403	ID of MRPs; Adherence; Education; *clinical assessment	Pt interview & medication history	Yes	No	Yes: Oral and written	Yes	No	Face to face	6	Mean 1st interview 44.57	6 months
Messerli 2016, Messerli 2018 [206,252]	Switzerland, Community Pharmacy	>18 years, ≥4 prescribed medicines for >3 months.	450	ID of MRPs; Adherence;	Pt interview & medication history	Yes	Yes	Yes: Unclear	Yes	No	Face to face	2	Mean 29.8	28 weeks
Nabergoj Makovec 2021 [207]	Slovenia, Community Pharmacy	≥18 years, ≥ 1 medicine for a chronic condition	169	ID MRPs	Pt interview & medication history	Yes	No	Uncertain: unclear	Yes	Uncertain	Face to face	2	NR	12 weeks
Östbring 2021, 2018 [208,253]	Sweden, Hospital	Adults with CVD	316	ID MRPS, Adherence	Pt interview, medication history & clinical data	Yes	Uncertain	Yes: Face to face	Yes	Uncertain	Face to face	2 to 5	60	7 months
Ravn-Nielsen 2018, Rasmussen 2019 [209,254]	Denmark, Hospital	>18 years, ≥5 prescribed medicines	1467	ID of MRPs, Education	Pt interview, medication history & clinical data	No	No	Yes: Written	Yes	Yes	Face to face	Basic = 1. Extended=3	Mean 26.0 Mean (extended) 114.0	One Off Extended: Duration of stay + 3-5 days post discharge
Roughead 2022 [235]	Australia, Care Home	Elderly Residents on ≥4 medicines or ≥1	248	ID MRPs	Pt interview, medication	No	No	Yes: Face to face	Yes	Uncertain	Face to face	6	NR	12 months

		anticholinergic			history & clinical data									
Sellors 2003 [229]	Canada, General Practice	≥65 years, ≥5 medicines	889	ID of MRPs	Pt interview & medication history	Yes	No	Written	Yes	Yes	Face to face	3	NR	3 months
Shim 2018 [223]	Malaysia, Outpatient	≥65 years, ≥5 medicines	160	ID of MRPs; Adherence; Education	Pt interview & medication history	Yes	No	Face to face	Yes	Yes	Face to face	4	NR	6 months
Tuttle 2018 [230]	USA, Domiciliary	≥18 years, CKD stages 3–5, hospitalised for acute illness	159	ID of MRPs, Adherence; Education	Pt interview & medication history	Yes	No	Telephone or electronic	No	No	Face to face	1	60-120	one off
van der Heijden 2019, Ahmad 2010 [210,255]	Netherlands, Domiciliary	≥60 years, ≥5 medicines	340	ID of MRPs; Adherence; Education	Pt interview, medication history & clinical data	Yes	No	Unclear	Yes	No	Face to face	At least 1	NR	NR
Verdoorn 2019, Verdoorn 2018, Verdoorn 2021 [211,256,257]	Netherlands, Community Pharmacy	≥70 years, ≥7 long term medications	629	ID of MRPs; Adherence; Other	Pt interview, medication history & clinical data	Yes	No	Face to face	Yes	Yes	Face to face	3	Mean Pt interview 50 Total pharmacist time 107	3 months
Zermansky 2006 [212]	UK, Care Home	≥65 years, ≥ 1 medicines, care homes	661	ID of MRPs	Pt interview, medication history & clinical data	Yes	No	Written	No	No	Face to face	1	NR	One off
Zillich 2014 [231]	USA, Community Pharmacy	Patients admitted for short home health care	961	ID of MRPs	Pt interview & medication history	Yes	No	Unclear	Yes	No	Teleph one	At least twice	1st 30 2nd 20	30 days
Mins= minutes NR= Not reported ID of MRPs = identification of Medicines Related Problems Pt= Patient FH= Family History GS= General Surgery DM= diabetes T2DM= type 2 diabetes mellitus CMC= chronic medical conditions CV= cardiovascular CVD= cardiovascular disease														

4.3.3 Quality assessment

Following the application of the Cochrane risk of Bias 2 tool [187], most studies (33/50) were deemed to be at high risk of bias (ROB) [198,201–203,205,207,209–211,218–223,233,234,238], nine studies at some ROB [193–195,216,217,225,226,237,244] and eight were rated low [190–192,213,224]. **Appendix 4** shows the risk of bias for each study in more detail. Sample sizes of the low risk of bias studies ranged from 80 to 600 participants. The domain that led to most studies being assessed at high risk was "Bias in measurement of the outcome". As pharmacists conducting the medication reviews were largely responsible for identification and measurement of the primary outcome measure i.e., medication related problems, this led to a high risk of bias in many studies.

4.3.4 Content of medication review

A detailed description of the content of the medication reviews can be found in **Table 4.1**. In summary, all 50 medication reviews sought to identify medicines related problems; 33 to address patient adherence [190–192,195–197,199–202,204–208,210,211,214,218–224,230,233,234,236–239], and 29 to educate patients on their medicines/ conditions [190–193,195,200,204,205,209,210,213,214,216,217,219–225,228,230,232,236–239]. In 42 studies, pharmacists aimed to resolve medicines-related problems during the medication review. In three studies [195,206,224], pharmacists could make prescription changes following the review. Follow up with patients was part of the medication review in 40 studies but follow up with prescribers following referrals occurred less frequently and was only reported in fourteen [191,192,197,201,209,211,218–220,223,224,229,237,239].

4.3.5 Reporting of Behaviour Change Techniques (BCTs) in studies

The quality of intervention reports was insufficient to make a definitive judgment about BCTs. However, all studies included at least one BCT relating to intervention patients taking their

medicines. The BCTs are summarised in **Table 4.2**. The BCT "monitoring outcome(s) of behaviour by others without feedback" was present in all probability in 37 studies [190–194,196,197,199–208,210,211,213,214,216–218,220,222,223,225,227,229,232–236,239,244], in terms of identifying medicines-related problems. The BCT "monitoring of behaviour by others without feedback" was present in all probability in 23 studies where medicines were reviewed and questions asked about patients' use of medicines [190,192,196–201,205,206,209–211,218,220,223,224,226,230,231,233,234,238]. The BCT "information about health consequences" was present beyond reasonable doubt in six studies where patients were advised about the importance of taking their medicines as prescribed and possible consequences of non-adherence [184,186,190,202,206,219]. In five studies, goal setting in relation to behaviour was present beyond reasonable doubt, where an action plan or goals were established to help with patients' medicines or health [195,205,208,210,211].

Table 4.2 BCTs and Implementation strategies reported in studies included in systematic review

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
Alalawneh 2022 [239]	2.5 Monitoring of outcomes of behaviour by others without feedback “identify treatment related problems” 2.7 Feedback on outcome of behaviour “pharmacist answered questions about adherence” 5.1 Information about health consequences “counselling and education about illness, medications and adherence" Usual care 2.5 monitoring of outcomes of behaviour “identify MRPs”	NR
Anderegg 2018 [224]	1.3 Goal setting (outcome) "Care plan with BP goal and medication recommendation” 2.1 Monitoring of behaviour by others without feedback "medication review... issues related to adherence” **5.1 information about health consequences** " Importance of following the pharmacotherapy plan properly" 11.1 Pharmacological support “make changes to medicines” **12.5 Adding objects to the environment** "wallet card listing medications, adherence aid, medication logs, medication boxes"	Communication between providers “Pharmacist recommendations in letter to physician who returned letters to pharmacists with decisions”
Graabaek 2019 [190]	12.5 Adding objects to the environment "new list of medication to use after discharge" 2.1 Monitoring of behaviour by others without feedback "medication history" 2.5 Monitoring of outcomes of behaviour by others without feedback "medication related problems" 3.1 social support (unspecified) "patient counselling"	Communication between providers "Recommendations for medical changes were reported to the physician” Use of information and communication technology “Reported to the physician” electronically"
Lenaghan 2007 [191]	1.7 Review outcome goal(s) [at follow up] “reinforce advice and check for further issues 2.5 Monitoring of outcomes of behaviour by others without feedback “drug interactions” 5.1 Information about health consequences “educated patient and removed out of date medications” 12.5 Adding objects to the environment “adherence aids filled by patient, carer of community pharmacy”	Communication between providers "Held regular meetings"
Lim 2004 [213]	2.5 Monitoring of outcomes of behaviour by others without feedback "the patient was evaluated for medication related problems" **4.1 Instruction on how to perform a behaviour** “Proper administration of inhalers and insulin”	NR

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
	3.2 Social support (practical) “non-compliance strategies such as pill boxes, administration tables and labels” 5.1 Information on health consequences “provided counselling on medication knowledge” 12.5 Adding objects to the environment “pill boxes, administration tables and labels”	
Lin 2018 [214]	2.5 monitoring of outcomes of behaviour without feedback “identification of MRPs”	Role expansion or task shifting "Pharmacist trained to provide direct patient care services" Environment "Implemented the … program in stand-alone pharmaceutical care clinic" Teams "(complex) cases presented to team to propose resolutions" Communication between providers "Patient-centred discussion between pharmacist and prescribing physician"
Maritnez-Mardones (2023) Ahumada-Canale 2021a, 2021b [236,240,241]	2.5 monitoring of outcomes of behaviour without feedback “identify and resolve MRPs” 2.7 Feedback on outcome of behaviour “Pharmacists followed up on actions from previous interviews”	Educational meetings “15 hours training in various topics” “pharmacists trained in patient simulations” Educational outreach “practice change facilitators visited site”
Schulz 2019, Schulz 2020, Laufs 2018 [192,242,243]	1.5 review behaviour goal “follow up on issues” 2.1 Monitoring of behaviour by others without feedback “medication review and review adherence” 2.5 monitoring of outcomes of behaviour “check for MRPs” 3.1 Social support (unspecified) "[bi] weekly visits to the pharmacy ..follow up on issues" 5.1 Information on health consequences “potential side effects, signs and symptoms of decompression” **12.5 Adding objects to the environment** "weekly dosing aid and printout of med plan"	Educational material “SOPs for BP measurement distributed"
Aguiar 2018 [237]	1.1 Goal setting (behaviour) “plans to achieve goals of therapy” **2.4 Self-monitoring the outcome(s) of behaviour** "self-monitoring of blood glucose" **5.1 Information about health consequences** "information about medication, adverse effects **12.5 Add objects to the environment** "Patients received a medication chart to assist in correct use of medicines"	Environment “Pharmacists added to outpatient care team” Role expansion or task shifting “Pharmacists previously only involved with inpatient discharge counselling and prescription review.”
Basheti 2016 [244]	2.5 monitoring of outcomes of behaviour without feedback “type and prevalence of MRPs”	Communication between providers “Report delivered to physician who returned it to pharmacist with recommendations.”

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
	Usual care 2.5 monitoring of outcomes of behaviour “type and prevalence of MRPs”	Role expansion or task shifting “Using community pharmacists to deliver MMR”
Basheti 2018 [216]	2.5 monitoring of outcomes of behaviour without feedback “medication review, identification of MRPs” 5.1 Information on health consequences "counselling"	Communication between providers “Letter delivered to physician who returned it to pharmacist with approved recommendations.”
	Usual Care 2.5 monitoring of outcomes of behaviour without feedback “medication review, identification of MRPs”	
Garcia 2015 [193]	**1.2 problem solving** “suggest solutions to problems “ 2.5 Monitoring of outcomes of behaviour without feedback "identify MRPs" **3.1 Social support (unspecified)** “motivational interviewing... education about medicines” 5.1 Information about health consequences “Patient education concerning medications, lifestyle behaviour and risk reduction”	NR
Jameson 1995 [225]	2.5 monitoring of outcomes of behaviour without feedback “identification of MRPs” 5.1 Information about health consequences “educational sessions about regime and medicines”	Communication between providers “Pharmacist met with treating physician to discuss findings. A new regime was developed by collaborative dialogue”
Lisby 2018 [194]	2.5 monitoring of outcomes of behaviour without feedback “information on side effects”	Communication between providers "Pharmacist and pharmacologist discussed and agreed upon recommendations. Written on standardised form and given to orthopaedic physician"
Sakthong 2018 [217]	1.1 Goal setting (behaviour) “Discussed therapeutic goals and developed care plans” **1.2 Problem solving** “solve problems through counselling or referral” 2.5 monitoring of outcomes of behaviour without feedback “identification of MRPs” 2.7 Feedback on outcome of behaviour "assessed outcomes at of interventions at follow up"	NR
Sellors 2001 [227]	2.5 monitoring of outcomes of behaviour without feedback “identify MRPs” 2.7 Feedback on outcome of behaviour “identify MRPs at follow up”	NR
Williams 2004 [226]	**1.4 Action planning** “Changes were discussed with subject to arrive at a modified medication regime fully acceptable to the subject” 2.1 Monitoring of behaviour by others without feedback	Teams “physician, nurse, consultant pharmacist… met to discuss pharmacy recommendations"

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
	"adherence" 3.1 Social support (unspecified) "Education, attention to relationship development, positive feedback, written instructions" 5.1 Information about health consequences "education" 12.5 Adding objects to the environment "self-monitoring checklists"	
Zermansky 2002 [195]	**1.1 Goal setting (behaviour)** "Negotiate a plan to help them use it correctly" **1.4 Action planning** "Negotiate a plan to help them use it correctly" 3.1 social support (unspecified) "Liaison with local pharmacy to change the manner in which the medication is packaged" 5.1 Information about health consequences "Appropriate information or advice" 11.1 Pharmacological support "make changes to medicines"	Environment "Pharmacist added to the GP practice" Role expansion or task shifting "Agreement with GP of the level of intervention that pharmacist could make without prior approval from GP" Communication between providers "Pharmacist agreed to keep records for clear communication according to specific steps"
Aburuz 2020 [218]	2.5 monitoring of outcomes of behaviour without feedback "identify MRPs" 5.1 Information about health consequences "medication counselling, answered questions" **2.1 Monitoring of behaviour by others without feedback** " assessed and encouraged adherence" Usual care 2.5 monitoring of outcomes of behaviour without feedback "identify MRPs"	Environment "Clinical pharmacists on clinical rounds" Communication between providers "Discussions with physician about recommendations"
Al alawneh 2019 [219]	3.1 social support (unspecified) "counselling directed at the behaviour, and adherence"	Communication between providers "Recommendation letters delivered to physician who returned letter to pharmacists with decisions" Outreach services "Patients visited in their homes by pharmacist"
Al-Qudah 2018, Basheti 2016 [215,220]	**2.1 Monitoring of behaviour by others without feedback** "Assessed patients' use of medicines and counselled on the importance of adherence" 2.5 monitoring of outcomes of behaviour without feedback "identify MRPs" **5.1 Information about health consequences** "Counselled on the importance of taking medicines on time and needed lifestyle modifications"	Communication between providers "Pharmacist recommendations in letter to physician who returned letters to pharmacists with decisions"

Author (year)	BCTs (patients taking medications as directed) Usual care 2.1 Monitoring of behaviour by others without feedback “Assessed patients’ use of medicines	Implementation strategies
Basger 2015 [232]	**1.2 problem solving** “ recommendations for resolution and prevention” 2.5 monitoring of outcomes of behaviour without feedback “identify MRPs”	NR
Bonnerup 2020 [196]	**2.1 Monitoring of behaviour by others without feedback** “Assessed patients’ drug treatment” 2.5 monitoring of outcomes of behaviour without feedback “monitoring toxicity etc”	NR
Briggs 2015 [233]	**2.1 Monitoring of behaviour by others without feedback** "Concerns about medication overuse; non-compliance; duplication of therapy; missing therapy” 2.5 Monitoring of outcomes of behaviour by others without feedback "suspected adverse reactions"	NR
El-Refae 2017 [221]	**3.2 Social support (practical)** " Telephone follow up reminders" 5.1 Information about health consequences "Information leaflets and counselling about medicines" 12.5 Adding objects to the environment "variety of compliance aids”	Communication between providers "Pharmacist discussed cases with the treating physician"
Erku 2017 [238]	2.1 Monitoring of behaviour by others without feedback “medication review and review adherence”	NR
Freeman 2021, Foot 2017 [234,245]	2.1 Monitoring of behaviour by others without feedback "assess adherence") 2.5 Monitoring of outcomes of behaviour by others without feedback "a comprehensive medicines review to identify drug related problems"	Teams “A pharmacist began working in the practice and conducted the intervention” Environment “A pharmacist began working in the practice” Payment methods for health workers “Practices were remunerated for consultation time" Communication between providers “Pharmacist discussed the outcomes of the consultation with the patient’s regular GP.” Educational meetings “Pharmacists received 1 day of training"
Geurts 2016 [197]	***1.1*** Goal setting (behaviour) “proposed care interventions to reach treatment goals” 2.1 Monitoring of behaviour by others without feedback “review adherence” 2.5 Monitoring of outcomes of behaviour by others without feedback "identify MRPs"	The use of information and communication technology "combined clinical medication review with web-based pharmaceutical care plan…document the integrated information ad interventions for follow-up" Educational meetings “1 day training on communication skills" Educational materials “Additional written information about performing a CMR”

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
Gurwitz 2021 [228]	**4.1 Instruction on how to perform the behaviour** “distributed medication safety education materials that featured medication instructions, dose timing, precautions, guidance” 5.1 Information about health consequences “medication safety education materials”	The use of information and communication technology "findings of the visit by the clinical pharmacist were communicated via the HER immediately following the visit to alert the primary care team”
Holland 2005, Holland 2010, Pacini 2007 [198,246,247]	2.1 Monitoring of behaviour by others without feedback "review discharge medication” 3.2 Social support (practical) " recommended an adherence aid filled by the pharmacist or patient/ care” 12.5 Adding objects to the environment “wide variety of aids, such as large-print labels for sight problems, non-childproof lids for grip problems, and ensuring the time schedule of drugs coincided where possible and fitted a patient’s routine” 5.1 Information about health consequences "educated the patient and carer"	Educational meetings "Pharmacists participated in 2-day training course” Referral systems “Pharmacists faxed discharge letter and patient information sheet, provided feedback to the patient’s GP and local pharmacist” Payment methods for health workers "pharmacists were paid a fee"
Huiskes 2020 [199]	1.2 Problem solving “solve MRPs” 2.1 Monitoring of behaviour by others without feedback “Patients report their drug utilisation” 2.5 Monitoring of outcomes of behaviour by others without feedback "identify MRPs" Usual care 2.5 Monitoring of outcomes of behaviour by others without feedback "identify MRPs"	Educational materials “Pharmacists practised performing medication review as described in study protocol” Communication between providers “pharmacists communication form to cardiologist” The use of information and computer technology “computer assisted MR (technology to support the delivery of care)” Environment “Communication form attached to the patient’s medical record prior to cardiologist visit”
Kempen 2021, Kempen 2020, Kempen 2017 [200,248,249]	Both groups **1.3 goal setting outcome** “minimise MRPs” **2.1 Monitoring of behaviour by others without feedback** "medicines reconciliation" **2.5 Monitoring of outcomes of behaviour by others without feedback** "effect of medication changes will be monitored" **4.1 Instruction on how to perform the behaviour** “practical use of meds, how to use an inhaler etc” 12.5 Adding objects to the environment “medication list given to all upon discharge from hospital” Additional BCTs Intervention 2 **1.2 problem solving** “actions taken …problems that had arisen” 3.1 social support (unspecified) “counselling, motivational boost”	Referral systems "referral by pharmacist in consultation with physician to patients GP" Educational meetings "Two days training"
Krska 2001 [201]	1.1 Goal setting (behaviour) “desires outputs and actions”	NR

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
	1.2 Problem solving “issues resolved by pharmacist” 1.4 Action planning “pharmaceutical care plan” 2.1 Monitoring of behaviour by others without feedback " use of medicine" 2.5 Monitoring of outcomes of behaviour by others without feedback “pharmaceutical care issues”	
Lea 2020 [202]	1.2 Problem solving “discussed possible solutions” 2.5 Monitoring of outcomes of behaviour by others without feedback “identify MRPs” **5.1 Information about health consequences** “Written and verbal information tailored to patient’s needs… to increase adherence” **12.5 Adding objects to the environment** “multidose delivery if needed / written information about meds to take away”	Teams "MDT discussion of medicine discrepancies and DRPs… and possible solutions" Environment "inclusion of clinical pharmacist in patients MDT team throughout hospital stay"
	Usual care 2.5 Monitoring of outcomes of behaviour by others without feedback “identify MRPs”	
Lenssen 2018 [203]	1.2 Problem solving “discussed solutions to MRPs” 2.5 Monitoring of outcomes of behaviour by others without feedback “identify ADRs”	Communication between providers "discussed recommendations with healthcare team" Environment “clinical pharmacists in the healthcare team on the wards.”
Liou 2021 [222]	2.5 Monitoring of outcomes of behaviour by others without feedback “identify ADRs” **12.5 Adding objects to the environment** “provided with dosing aids”	Environment “pharmacist visited the care home to conduct the medication review” Educational meetings “pharmacists trained in the approach”
Lyons 2016 [204]	2.5 Monitoring of outcomes of behaviour by others without feedback “Identify problems patient experiencing” 2.7 Feedback on outcome(s) of behaviour “review issues discussed” 3.1 Social support (unspecified) "medicines reminder chart posted to patient" “what medicine is for, how and when to take” **5.1 Information about health consequences** "Importance of continuing to adhere to medication, offered dietary, weight loss smoking cessation advice"	NR

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
	12.5 Adding objects to the environment "medicines reminder chart posted"	
Malet-Larrea 2016, Jodar-Sanchez 2015, Varas-Doval 2020 [205,250,251]	**1.1 Goal setting (behaviour)** "action plan around medicines is agreed upon by the patient" 2.1 Monitoring of behaviour by others without feedback "Patients medication use" 2.5 Monitoring of outcomes of behaviour by others without feedback "identify MRPs"	Educational outreach visits " A trained pharmacist helped pharmacists… identify barriers…and providing solutions" Educational meetings "Pharmacists received 5 days off site training"
Messerli 2016, Messerli 2018 [206,252]	2.1 Monitoring of behaviour by others without feedback "patients report their adherence" 2.5 Monitoring of outcomes of behaviour by others without feedback "addressed MRPs during intervention" 3.1 Social support (unspecified) "weekly dispensing aid for medicines management" "provision of medication plan" **12.5 Adding objects to the environment** "weekly dispensing aid for medicines management" "provision of medication plan"	Role expansion or task shifting "pharmacists changed a patient's care plan, adjusted therapy or substituted a therapy"
Nabergoj Makovec 2021 [207]	2.5 Monitoring of outcomes of behaviour by others without feedback "identify ADRs" **12.5 Adding objects to the environment** "patients provides with medicines card"	Educational meetings "pharmacist training"
Östbring 2021, 2018 [208,253]	**1.1 Goal setting (behaviour)** "goal was that patients should feel safe and secure with their medication, and any problems affecting adherence or quality of life would be found and solved together" **3.1 Social support (unspecified)** motivational interviewing 2.5 Monitoring of outcomes of behaviour by others without feedback "identify MRPs" **5.1 Information about health consequences** useful information about health and medicines; information about medicines and risk factors Usual care 5.1 Information about health consequences information about medicines and risk factors	NR
Ravn-Nielsen 2018, Rasmussen 2019 [209,254]	2.1 Monitoring of behaviour by others without feedback "medication review"	Referral systems

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
	Extended intervention **3.1 Social support (unspecified**) “Motivation interviewing to ensure adequate patient behaviour to prevent MRPs”	"Summary note…sent to primary care physician (and care home). Follow up telephone calls to care giver/ care home and physician” Educational meetings “Pharmacists completed 3 day course before entering the study”
Roughead 2022 [235]	2.5 Monitoring of outcomes of behaviour by others without feedback “identify MRPs”	Educational materials "Detection of Medicine Induced Deterioration Training Program"
Sellors 2003 [229]	1.2 Problem solving “recommended actions to resolve problems” 2.5 Monitoring of outcomes of behaviour by others without feedback “identify MRPs”	Communication between providers " Physician and pharmacist met to discuss MRPS and recommended actions” Environment “Pharmacists taken out of community pharmacy and placed on-site with physicians”
Shim 2018 [223]	1.2 Problem solving “identifying and resolving MRPs” **2.1 Monitoring of behaviour by others without feedback** “medication review and reconciliation” 2.5 Monitoring of outcomes of behaviour by others without feedback “identify MRPs” 3.1 Social support (unspecified) “counselling on medicines and how to use them”	Communication between providers “Discussion with doctor about drug-related problems.”
	Usual care 3.1 Social care (unspecified) “instructions on method of administration”	
Tuttle 2018 [230]	1.1 Goal setting (behaviour) "patient discuss solutions with prescriber to encourage patient medication self-management" 1.2 Problem solving “discussed solutions” “identify and resolve medication problems” 1.4 Action planning "Patient interview developing medication action plan to improve patient medication management" 2.1 Monitoring of behaviour by others without feedback "comprehensive medication review" 3.2 Social support (practical) “ patient discuss solutions with prescriber to encourage patient medication self management” 4.1 Instructions on how to perform the behaviour "advised about proper medicine use and avoidance of contraindicated drugs"	NR
	Usual care **12.5 Adding objects to the environment** “received a …. medication list and discharge prescriptions"	

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
van der Heijden 2019, Ahmad 2010 [210,255]	**1.1 Goal setting (behaviour)** "establishing achievable goals for problem resolution" 1.4 Action planning "collaboration with pharmacist in planning treatment" **2.1 Monitoring of behaviour by others without feedback** "interviewed about non-adherence" 2.5 Monitoring of outcomes of behaviour by others without feedback “identify MRPs” **3.1 Social support unspecified** " Motivational interviewing …informed about use, SE and effect of medicines" 11.1 pharmacological support "adaptation of drug regimen" [in response to MRP] 12.5 adding objects to environment "hand written outline of drug regimen"	NR
Verdoorn 2019, Verdoorn 2018, Verdoorn 2021 [211,256,257]	**1.1 Goal setting (behaviour)** "goals related to patients' health problems or medication" 1.2 Problem solving "resolving MRPs" **1.4 Action planning** "recommendations were proposed to attain goals and to solve MRPs" **1.5 review behaviour goals** **"g**oals proposed during interview and evaluated using goal attainment scoring” **2.1 Monitoring of behaviour by others without feedback** "extensive discussion of patients medicines, practical problems with medication" 2.5 Monitoring of outcomes of behaviour by others without feedback "discussion about side effects"	Educational meetings "one day training… communication skills and goal setting in older persons during CMR" Communication between providers “Face-to-face meetings with pharmacist and GP to discuss health-related goals and other identified MRPs. Develop a pharmaceutical care plan”
Zermansky 2006 [212]	2.1 Monitoring of behaviour by others without feedback "medication review"	NR
Zillich 2014 [231]	**1.1 Goal setting (behaviour)** ”Action plan served as a patient centred document to assist the patient and pharmacist in resolution of MRPs” **1.2 Problem solving** “assist … the resolution of MRPs” “follow up- continued to resolve problems” **1.4 Action planning** **“**Action plan served as a patient centred document to assist the patient and pharmacist in resolution of MRPs” “follow up- continue to solve problems” 2.1 Monitoring of behaviour by others without feedback "therapy review to identify any problems"	NR

Author (year)	BCTs (patients taking medications as directed)	Implementation strategies
Key	**BCT present beyond all reasonable doubt;** BCT present in all probability	NR= not reported
	MRPs= medicines related problems GP= general practitioner ADR= adverse drug reaction	

4.3.6 Medication review implementation as described in the studies

The description of the implementation of medication reviews was poorly reported. In 34 studies there was sufficient detail about the intervention to identify the Effective Practice and Organisation of Care (EPOC) taxonomy domains and subcategories. Details of the EPOC taxonomy subcategories identified in each study can be found in **Table 3.2**. The most reported EPOC subcategory was communication between providers, where a system or strategy for improving the communication between the pharmacist and other health care providers was reported [191,194,199,203,214,216,218–221,223–225,234,244,258]. Other EPOC taxonomy domains were identified in fewer studies.

Planned adaptations to the intervention were reported in eight studies [192,193,195,204,208,216,220,236]. Adaptations during the intervention were reported in eight studies; examples include adapting care plans according to patient needs and modifying the intervention based upon pharmacists' professional judgment [190,198,202,203,224,228,235,250]. Fidelity of the intervention was assessed in five studies [192,200,204,236,250]. Kempen et al. reported that 15% of control patients received unintended intervention components [200]. Graabaek et al. reported that the staff were unaccustomed to working with the pharmacist, and the physician did not make use of the pharmacist at the start of the study [190]. The implementation rates of pharmacist recommendations were between 28.6% [216] to 86% [195].

4.3.7 Description of reported outcomes

A mixture of economic, clinical, and patient-orientated outcomes was reported. Economic and clinical outcomes were most frequently reported. Healthcare utilisation was reported in 25 studies [190–192,194–196,198,200,201,203,205,206,208–212,221,227,229,230,233,234,236,238],

medicines-related problems/ adverse drug events/ medication appropriateness in 23 [190,197,199,201,203,207,210,211,213,216,218–223,225,228,231,232,235,237,244], and clinical monitoring parameters in 17 [193,197,204–206,208,211,212,214,221,224,230,232,235–237,244]. Patient-orientated were reported least often with 17 studies reporting quality of life [191,192,194,196,198,205,207,211,214,216,217,220,222,226,229,232,235], and 14 adherence [203,206–208,213,216,220–223,236–239]. **Appendix 5** details all reported outcomes.

Of the eight studies that were assessed to be of low risk of bias, fourteen results were statistically significant. Two of these studies reported improvements in blood pressure in the intervention groups; mean reduction in systolic blood pressure (8.64 mm Hg; 95% CI −12.8 to −4.49) [224], achievement of hypertension treatment goals, (OR 4.37; 95% CI 2.54 to 7.51) [236]. Reduction in the number of medicines prescribed in the intervention group was observed in two studies (mean difference-0.86; 95% CI-1.14 to -0.58 [236], mean difference of -0.87; 95% CI −1.66 to −0.08, [191]. Lim et al. and Martinez-Mardones et al. stated that medication reviews improved compliance/adherence (OR 2.52, 90% CI 1.09-5.83 [213], OR 6.60; 95% CI 1.36 to 31.9 [236]. Statistically significant results are reported in **Table 4.3**.

Table 4.3 Statistically significant outcomes, BCTs and implementation strategies

Author (Year)	Statistically significant results	BCTs (patients taking medications as directed)	Implementation strategies	Risk of Bias
Alalawneh 2022 [259]	Improvement in adherence in intervention group Improvement on knowledge of medicines in intervention group	2.5 Monitoring of outcomes of behaviour by others without feedback, 2.7 Feedback on outcome of behaviour 5.1 Information about health consequences	NR	Low
Anderegg 2018 [224]	Reduction in SBP in intervention group; much smaller reduction of SBP in the control group. Increase in the number of medication changes in intervention group	1.3 Goal setting (outcome), 2.1 Monitoring of behaviour by others without feedback, **5.1 information about health consequences** 11.1 Pharmacological support, **12.5 Adding objects to the environment**	Communication between providers	Low
Lenaghan 2007 [191]	Reduction of medicines prescribed in intervention group compared to control	1.7 Review outcome goal(s), 2.5 Monitoring of outcomes of behaviour by others without feedback, 5.1 Information about health consequences 12.5 Adding objects to the environment	Communication between providers	Low
Lim 2004 [213]	Improved compliance in intervention group	2.5 Monitoring of outcomes of behaviour by others without feedback **4.1 Instruction on how to perform a behaviour, 3.2 Social support (practical)** 5.1 Information on health consequences, 12.5 Adding objects to the environment	NR	Low
Lin 2018 [214]	Improvement in quality of life in intervention group Improvement in performance in activities of daily living in intervention group Estimates reduction in medical expenditure in intervention group (3,758 TWD)	2.5 monitoring of outcomes of behaviour without feedback	Role expansion or task shifting Environment, Teams Communication between providers	Low
Maritnez-Mardones (2023) Ahumada-Canale 2021a, 2021b [236,240,241]	Higher number of patients with hypertension, diabetes and high cholesterol achieving therapy goals in intervention group compared to control. Reduced cardiovascular risk score for those in intervention group compared to control. Reduced number of medicines prescribed in intervention group compared to control. Improvement in adherence in intervention group compared to control.	2.5 monitoring of outcomes of behaviour without feedback 2.7 Feedback on outcome of behaviour	Educational meetings Educational outreach	Low
Schulz 2019 Schulz 2020 Laufs 2018 [192,242,243]	Improvement in quality of life in intervention group Increased adherence after 365 days in intervention group	1.5 review behaviour goal, 2.1 Monitoring of behaviour by others without feedback, 2.5 monitoring of outcomes of behaviour, 3.1 Social support (unspecified), 5.1 Information on health consequences, **12.5 Adding objects to the environment**	Educational material	Low
Aguiar 2018 [237]	Improvement in adherence in intervention group Improved chance of achieving HbA1c goal in intervention group compared to control	1.1 Goal setting (behaviour), **2.4 Self-monitoring the outcome(s) of behaviour** **5.1 Information about health consequences, 12.5 Add objects to the environment**	Environment Role expansion or task shifting	Some
Basheti 2016 [244]	Higher resolution of MRPs in intervention group than control. Improvements in blood pressure, blood glucose, triglycerides in intervention group compared to control	2.5 monitoring of outcomes of behaviour without feedback	Communication between providers Role expansion or task shifting	Some
Basheti 2018 [216]	Improvement in adherence in intervention group compared to control Improvement in self-care in intervention group	2.5 monitoring of outcomes of behaviour without feedback 5.1 Information on health consequences	Communication between providers	Some
Garcia 2015 [193]	Improvement in adherence in intervention group compared to control	**1.2 problem solving,** 2.5 Monitoring of outcomes of behaviour without feedback, **3.1 Social support (unspecified),** 5.1 Information about health consequences	NR	Some
Jameson 1995 [225]	Change in number of medicines at follow up in intervention group compared to control. Evidence of a 24% reduction of healthcare costs in intervention group	2.5 monitoring of outcomes of behaviour without feedback 5.1 Information about health consequences	Communication between providers	Some
Lisby 2018 [194]	Improvement in usual activities in intervention group	2.5 monitoring of outcomes of behaviour without feedback	Communication between providers	Some
Sakthong 2018 [217]	Improvement in post intervention quality of life in intervention group	1.1 Goal setting (behaviour), **1.2 Problem solving,** 2.5 monitoring of outcomes of behaviour without feedback, 2.7 Feedback on outcome of behaviour	NR	Some
Williams 2004 [226]	Reduction in the number of medicines prescribed; on average 2.1 fewer drugs prescribed in the intervention group Reduction in medication costs at 6 weeks; mean $38 saving in intervention group	**1.4 Action planning,** 2.1 Monitoring of behaviour by others without feedback 3.1 Social support (unspecified, 5.1 Information about health consequences 12.5 Adding objects to the environment	Teams	Some
Zermansky 2002 [195]	Smaller rise in number of medicines prescribed in the intervention group (number of medicines prescribed increased in both groups); Smaller rise in mean cost of medicines in intervention group (Cost of medicines increased in both groups)	**1.1 Goal setting (behaviour), 1.4 Action planning** 3.1 social support (unspecified), 5.1 Information about health consequences 11.1 Pharmacological support	Environment Role expansion or task shifting Communication between providers	Some

Aburuz 2020 [218]	Reduction of MRPs at discharge in intervention group; twice as many MRPs at discharge in control group	2.5 monitoring of outcomes of behaviour without feedback, 5.1 Information about health consequences, **2.1 Monitoring of behaviour by others without feedback**	Environment Communication between providers	High
Al alawneh 2019 [219]	Reduction in MRPs at follow up in intervention group, no significant change in control	3.1 social support (unspecified)	Communication between providers Outreach services	High
Al-Qudah 2018, Basheti 2016 [215,220]	Significantly higher number of MRPs corrected at the end of the study in the intervention group compared to control; Improvement in medication adherence at follow up in intervention group; Improvement in self-care activity scores at follow up in intervention group	**2.1 Monitoring of behaviour by others without feedback** 2.5 monitoring of outcomes of behaviour without feedback **5.1 Information about health consequences**	Communication between providers	High
Briggs 2015 [233]	Reduction in admission rates in intervention group	**2.1 Monitoring of behaviour by others without feedback** 2.5 Monitoring of outcomes of behaviour by others without feedback	NR	High
El-Refae 2017 [221]	Reduction in hospital visits in intervention group; Reduction Total cholesterol in intervention group; Improvement in self-care activities in intervention group	**3.2 Social support (practical),** 5.1 Information about health consequences 12.5 Adding objects to the environment	Communication between providers	High
Erku 2017 [238]	Reduction in hospitalisation visits; number of visits in control group more than double those in intervention; Improvement in medication adherence in intervention group; 51.8% change in intervention v 17% in control	2.1 Monitoring of behaviour by others without feedback	NR	High
Freeman 2021, Foot 2017 [234,245]	Reduction in hospital re-admission/ ED presentation in intervention group Estimated incremental cost per patient of the intervention = $164, benefit– cost ratio, 31:1	2.1 Monitoring of behaviour by others without feedback 2.5 Monitoring of outcomes of behaviour by others without feedback	Teams; Environment; Payment methods for health workers; Educational meetings; Communication between providers	High
Holland 2005, 2010, Pacini 2007 [198,246,247]	Increase in hospital readmission rate and GP home visits in intervention group Reduction in medication hoarding in intervention group	2.1 Monitoring of behaviour by others without feedback, 3.2 Social support (practical), 12.5 Adding objects to the environment, 5.1 Information about health consequences	Educational meetings; Referral systems; Payment methods for health workers	High
Krska 2001 [201]	More MRPs resolved at follow up; double the number of MRPs resolved in intervention compared to control	1.1 Goal setting (behaviour), 1.2 Problem solving, 1.4 Action planning 2.1 Monitoring of behaviour by others without feedback 2.5 Monitoring of outcomes of behaviour by others without feedback	NR	High
Lea 2020 [202]	Increased overall survival in intervention group HR= 0.66, 95% CI 0.48 to 0.90, p=0.008	1.2 Problem solving, 2.5 Monitoring of outcomes of behaviour by others without feedback, **5.1 Information about health consequences** **12.5 Adding objects to the environment**	Teams Environment	High
Lenssen 2018 [203]	Improvement in adherence in the intervention group; 5.7% non-adherent in intervention compared to 14% in control	1.2 Problem solving, 2.5 Monitoring of outcomes of behaviour by others without feedback	Communication between providers Environment	High
Liou 2021 [222]	Reduction of MRPs at follow up; Improvement in medication adherence in intervention group; 10% in intervention compared with 8.7% in control. Participants in intervention group more willing to receive pharmacist visits; (mean, SD) Intervention = 8.9±2.2, Control =7.4±3.1, P=0.04. Improved awareness of medical problems in intervention group; (mean SD) Intervention= 3.0±4.0, Control =0.9±2.7, P=0.035	2.5 Monitoring of outcomes of behaviour by others without feedback **12.5 Adding objects to the environment**	Environment Educational meetings	High
Malet-Larrea 2016 Jodar-Sanchez2015, VarasDoval 2020 [205,250,251]	Improvement in quality of life in intervention group. Reduction in number of hospital admissions; mean number of visits were double in the control than in intervention group. Reduction in health problems over 6 months in intervention group	**1.1 Goal setting (behaviour)** 2.1 Monitoring of behaviour by others without feedback 2.5 Monitoring of outcomes of behaviour by others without feedback	Educational outreach visits Educational meetings	High
Nabergoj Makovec 2021 [207]	Reduction of MRPs at follow up.	2.5 Monitoring of outcomes of behaviour by others without feedback **12.5 Adding objects to the environment**	Educational meetings	High
Ravn-Nielsen 2018 Rasmussen 2019 [209,254]	NNT for readmissions within 180 days Extended intervention =11, Basic intervention = 65	2.1 Monitoring of behaviour by others without feedback, **3.1 Social support (unspecified**)	Referral systems Educational meetings	High
Shim 2018 [223]	Improvement in prescribing (medication appropriateness index) in intervention group, Improvement in adherence in intervention group; more than double the number of participants in intervention group were adherent compared to control	1.2 Problem solving, **2.1 Monitoring of behaviour by others without feedback** 2.5 Monitoring of outcomes of behaviour by others without feedback 3.1 Social support (unspecified)	Communication between providers	High

van der Heijden 2019, Ahmad 2010[210,255]	Reduction in MRPs in intervention group Increase in hospital readmissions in intervention group; double the number of readmissions in intervention than control	**1.1 Goal setting (behaviour),** 1.4 Action planning, **2.1 Monitoring of behaviour by others without feedback,** 2.5 Monitoring of outcomes of behaviour by others without feedback, **3.1 Social support unspecified** 11.1 pharmacological support, 12.5 adding objects to environment	NR	High
Verdoorn 2019, Verdoorn 2018, Verdoorn 2021 [211,256,257]	Improvements in quality of life in intervention group Improvement in health problems in intervention group	**1.1 Goal setting (behaviour),** 1.2 Problem solving, **1.4 Action planning** **1.5 review behaviour goals, 2.1 Monitoring of behaviour by others without feedback,** 2.5 Monitoring of outcomes of behaviour by others without feedback	Educational meetings Communication between providers	High
Zermansky 2006 [212]	Reduction in falls per patient in intervention group; mean 0.5 less per 6 months in intervention compared to control group. Increase in the number of drug changes in 6 months in the intervention group compared to control	2.1 Monitoring of behaviour by others without feedback	NR	High
Zillich 2014 [231]	Reduction in 60-day hospitalisations for low-risk patients in intervention group OR 3.78 (1.35, 10.57) p=0 .01	**1.1 Goal setting (behaviour), 1.2 Problem solving, 1.4 Action planning** 2.1 Monitoring of behaviour by others without feedback	NR	High
Key	SBP = systolic blood pressure DBP= diastolic blood pressure GP= general practitioner ADR= adverse drug reaction MRP= medicines related problem HbA1c= glycated haemoglobin LDL=low density lipoprotein HDL= high density lipoprotein NNT= number needed to treat ADE= adverse drug event ICER= incremental cost-effectiveness ratio QALY= quality adjusted life year SMMESE= standardised mini mental state exam TWD= Taiwanese new dollars NR= not reported BCTs= Behaviour Change Techniques **BCT present beyond all reasonable doubt** BCT present in all probability			

4.3.8 Mechanisms of impact

The potential mechanisms of impact were difficult to identify, as they were largely not reported in most of the studies. When examining participant responses and interactions with the intervention, data could only be extracted from one study [228], which found that many patients declined the intervention. Among the included studies, only two process evaluations provided insights into mediators of the intervention's effect [246,248].

Ten studies reported an unintended pathway or consequence [193,195,198,210,216,218–220,224,244]. Examples include financial or health-related barriers preventing patients attending follow-up appointments [216,219,220] and increased utilisation of healthcare practitioners due to pharmacist referrals, or patients' concern following increased patient knowledge about medication side effects [195,210]. **Appendix 6** provides further information about potential mechanisms of impact.

4.3.9 Description of comparator groups

In many intervention studies, the comparator group receives "usual care," which is often not described in detail. The findings of this systematic review reflect this issue, with the activities of the comparator group being poorly reported. Thirteen studies provided no details about the comparator intervention, while thirty-four studies did describe its content. Sixteen studies [190,194,195,200–202,210,211,216,218–221,231,237,244] sought to identify medicines-related problems, ten studies educated patients about their medicines/ condition(s) [192,193,210,228,230–232,237] and three focused on improving adherence [201,219,238]. Where the healthcare professionals involved in delivering care was identified, pharmacists delivered the care in nine studies [195,201,205,211,216,219–221,244], nursing staff in five [208,222,230–232]and a mixture of

healthcare professionals in the remaining studies [192,202–204,210,218,223,236,237]. Only ten studies reported at least one BCT relating to patients taking their medicines as directed in the comparator groups [192,202–204,210,218,223,236,237]. Where medicines-related problems were explored in the comparator group, the BCT "monitoring of outcomes of behaviour by others without feedback" was present in all probability in six studies [199,202,216,218,239,244]. The BCTs are reported in **Table 3.2.**

4.3.10 Themes and components identified from data synthesis

The themes underpinning medication review implementation and an explanation of how these may influence outcomes is presented in **Table 4.4**. This table also shows how the theme map onto the TIDieR framework for the reporting of interventions [113]. **Figure 4.1** illustrates the themes and components of medication reviews. The way that these themes and components reflect the physical, organisational, social dimensions of the health system context [104] in which the medication review is implemented are described below:

Physical dimension:	Experienced pharmacist, Enhanced clinical skills, Comfortable and professional space
Organisational:	Pharmacists access to and/ or working collaboratively with other healthcare professionals. Access to clinical and medication history Pharmacist autonomy to make medication changes Flexible protocol for medication review delivery
Social:	Set goals to take medicine, Patient education, Develop action plan, Follow up appointment, Adherence aids [where appropriate

Table 4.4 Themes underpinning medication review (MR) implementation.

TIDieR framework	Themes	Explanation
Where	Setting in which medication review is delivered	There is moderate quality evidence from low [191,192,224,236] , some [195,216,225,226,244]and high [205,211,212,220] risk of bias studies that medication reviews undertaken in primary care settings may have a greater impact on some outcomes, such as reduction in clinical biomarkers, number of medicines prescribed, adherence, and quality of life, whereas healthcare utilisation and mortality may not be affected.
		There is low quality evidence from studies with some [195,237] and a high [202,218,234] risk of bias that pharmacists with access to other healthcare professionals, such as physicians, can improve some clinical, economic, and patient-orientated outcomes, such as improved diabetes biomarkers and adherence, and reduced hospital re-admissions and medicines related problems. There is low quality evidence from low risk of bias studies that pharmacists working collaboratively with other healthcare professionals, where their roles and responsibilities are known, may have a positive influence on outcomes [190,224], such as a reduction in prescribed medicines.
		There is very low-quality evidence from studies with some risk of bias [216,244] that a safe, comfortable, not restricted, and professional space to conduct the medication review may improve blood pressure, blood glucose and triglyceride levels, lead to a higher resolution of medicines related problems and improve adherence and self-care activities.
		Three studies reported that medication reviews were only able to be delivered on specific days at specified times [190,196,233] One low risk of bias study suggested that pharmacists lack of availability for all the operational times of the setting influenced the implementation of the intervention [224]. It is unclear how this affected outcomes.
	Regulations and standards guiding medication review	There is low quality evidence from a low risk of bias study that medication reviews cannot be properly implemented without a protocol, and this may result in variation in delivery, which might negatively influence outcomes [224]. Furthermore, low quality evidence from low [224] and some [193] risk of bias studies that pharmacists' ability to adjust the MR content according to the patient's needs may reduce blood pressure, increase the number of medication changes, and improve adherence.
	Recruitment of patients for medication review	Participants are often identified by another individual and referred to the pharmacist for the medication review. There is low quality evidence from low [190–192,224,236], some [225,237] and high [197,198,211,228,229,231,233,238] risk of bias studies that this may influence clinical, economic, and patient-orientated outcomes. However, it is unclear how this occurs.
Who	Pharmacist skills and experience	There is moderate quality evidence from low [224,236], some [195], and high [233,234] risk of bias studies that pharmacists with greater clinical knowledge/ experience may improve blood pressure and reduce medicine costs and healthcare utilisation. There is low quality evidence from low [224] and some [195] risk of bias studies that pharmacists having the autonomy to make some medication changes may positively influence blood pressure control and number of medicines prescribed. Furthermore, it was suggested that improved blood pressure control was likely due to implementing changes to blood pressure goals in line with new [more intensive] guidelines [224].
	Access to patient information	There is moderate quality evidence from low [190–192,213,236,239], some [193–195,217,237,244] and high [199,201–203,209,210,212,218,220,221,239]risk of bias studies that pharmacists having access to clinical and medication history for the medication review may have a positive influence on clinical, economic, and patient-

		orientated outcomes, such as blood pressure, number of medicines prescribed, adherence and quality of life.
How	Setting goals relating to medication taking	There is moderate quality evidence from low [190], some [195,217], and high [201,205,211,230,231] risk of bias studies that setting behaviour goals around taking their medicines, may influence outcomes such as quality of life.
	Information about medicines and health	There is moderate quality evidence from low [191,192,224], some [237,244], and high [221] risk of bias studies that educating the patient/ carer about the reasons for taking the medicines, how medicines work, how they should be taken and the importance of healthy living may have a greater impact on some outcomes, such as improvement in clinical biomarkers, number of medicines prescribed, adherence, and quality of life.
	Action planning for medicines use	There is low quality evidence from some [195,226] and high [201,210,211,231] risk of bias studies that developing an action plan for medicines management/ pharmaceutical care plan can have a greater impact on clinical, economic, and patient-orientated outcomes, such as an improvement in health problems, medicines related problems, number of medicines prescribed, and quality of life.
	Social support from pharmacist and/ or other health and social care providers	There is moderate quality evidence from low [192,213], some[237], and high [204,206,221] risk of bias studies that the use of medication aids may improve adherence. However, patients may need help filling it with the correct medication [198].
How much	Follow up with patient following medication review	There is moderate quality evidence from studies with low [192,224,236,239], some [193,216,225,237,244], and high [201,203,205,207,210,211,218–223,238] risk of bias that at least one follow up appointment after the MR may result in improvements in clinical biomarkers, adherence, quality of life, a reduction of medicines related problems and increased medicine changes.
		Studies with some [216] and high [219,220] risk of bias reported that financial limitations can restrict patients' access to practitioners for follow up appointments. However, this does not appear to have impacted on outcomes.

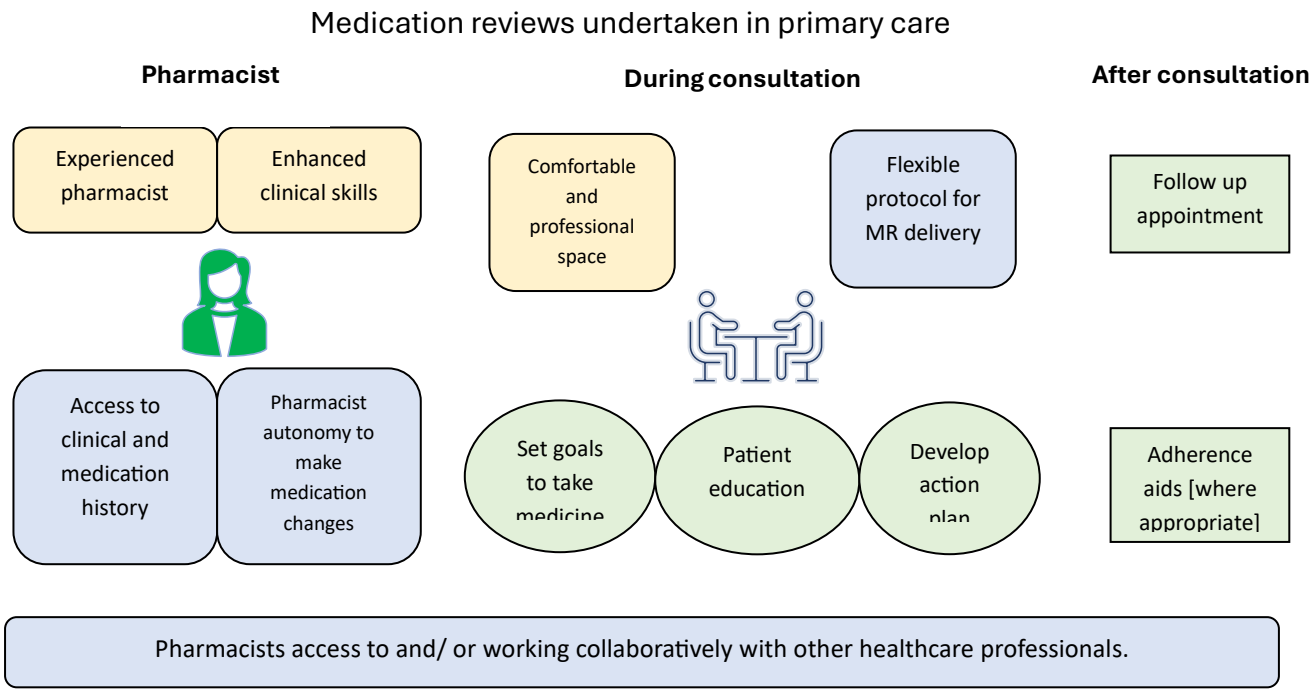

Figure 4.2 Illustration of the components and themes of medication reviews

4.4 Discussion

4.4.1 Statement of key findings and interpretation

My systematic review has highlighted common themes underpinning the implementation of pharmacist-led medication reviews and the components that may positively impact outcomes. Identified themes and components relate to the pharmacist conducting the reviews and the activities occurring during and after the patient consultation. Medication reviews conducted by experienced pharmacists or those with advanced clinical skills, supported by access to patients' clinical and medication histories and the autonomy to make medication changes, are more likely to improve patient outcomes. Pharmacists also need a comfortable, professional space to conduct reviews and a flexible protocol to guide the consultation. During the consultation, opportunities for patient education, goal setting for medication adherence, and the development of an action plan

could influence outcomes. Follow-up appointments after the review may further influence a range of patient outcomes.

I identified evidence of role expansion and task shifting by pharmacists as they delivered medication reviews. Hikaka et al. highlighted that pharmacists are poorly embedded in the healthcare framework and suggested that leveraging their expertise in medicines could free up other healthcare professionals [260]. Additionally, there was evidence of pharmacists being integrated into workplace environments and participating in team-based discussions around patient care. Communication between providers emerged as the most frequently reported EPOC subcategory in my data extraction. Effective communication between pharmacists and physicians, in any form, is essential for implementing medication reviews; a finding also reported by Luetsch et al [119]. Graabaek et al. observed that the method of communication between pharmacists and physicians evolved after the first third of patients were recruited [190]. Initially, the patient's discharge medical report was printed and provided to the physician in charge, allowing the pharmacist and physician to discuss the report verbally. However, to simplify delivery of the intervention, the report was later documented directly in the patient's electronic record instead. These modifications may have reduced the intervention's effect size on reported outcomes. Additionally, the rate at which pharmacists' recommendations were implemented by physicians may have further influenced the observed results.

My findings indicate that pharmacists' experience and clinical skills are key components of effective medication reviews. NHS England's Network Contract Directed Enhanced Service requires clinical pharmacists to either be enrolled in or have completed an approved training pathway, enabling them to become prescribers and work collaboratively within the general practice team [93]. The General Pharmaceutical Council's standards for pharmacist independent prescriber training outlines

four key domains for training providers, one of which is collaboration. This domain requires pharmacists to work effectively with other healthcare professionals and to demonstrate competence in consultation and communication skills. Such additional training may influence the outcomes of medication reviews by enhancing pharmacists' ability to engage patients and collaborate within multidisciplinary teams.

In the UK, several training resources are available to support pharmacists in delivering effective medication reviews. These include courses, webinars, and workshops provided by PrescQIPP [261], NHS Scotland's Polypharmacy Guidance [44], polypharmacy action learning developed by the Health Innovation Network [262]; and medication review training materials from the Centre of Pharmacy Postgraduate education [263].

Luetsch et al. [119] reported that the recognition of pharmacists' competence and skills in conducting medication reviews, along with their access to comprehensive clinical information, can influence intervention outcomes. This supports the conclusion that pharmacists' access to patients' full clinical and medical histories may enhance clinical, economic, and patient-reported outcomes. McCahon et al. developed a simple and pragmatic medication review model to be used by professionals across healthcare setting [264]. This Bristol medication review model [264] describes the need to establish what medicines the patient is taking, how they are taking them, whether they understand why they are prescribed and whether the medicines prescribed are suitable for the patient. These examples are consistent with our findings, which show that educating the patient/ carer about the medicines can benefit some outcomes. The Bristol medication review model also emphasises the importance of patients' values and preferences [264]. Setting individual goals and planning with the patient demonstrates a commitment to considering patient preferences. My review takes this a step further, suggesting that setting specific goals related to medication-taking may improve patient outcomes. However, it is important to note that data extraction did not allow

for a more in-depth exploration of patients' values and preferences, as this was outside the scope of the BCT extraction defined in the method.

Due to underreporting in the literature, I was unable to extract sufficient data to identify the intermediate mechanisms through which medication review activities lead to outcomes. However, patient preference was identified as a potential mechanism of impact. This was demonstrated by acceptability (patients declining intervention) and accessibility (financial or health barriers to follow up). Patient preference (accessibility, acceptability and convenience of location and time for the medication review and who performs it) was identified as a mechanism influencing outcomes in a realist synthesis of pharmacist-conducted medication reviews in primary care after leaving hospital [119].

The findings from this research have implications at both the micro and macro levels. At the micro level, pharmacists can use the guidance to reflect on their own knowledge, skills, and consultation processes, and to consider incorporating key components such as goal setting, action planning, and patient education into medication review practice. At the macro level, commissioners and policymakers could use these findings to inform the development of frameworks that standardise the delivery of medication reviews. Such frameworks might specify minimum requirements for pharmacists' clinical knowledge and training, as well as provide guidance on the issues to be discussed and documented during reviews.

Although a narrative rather than realist approach was chosen for the synthesis of my data, several realist syntheses are highly relevant to this work, offering complementary insights into the contextual and mechanistic factors that influence the success of medication review and deprescribing interventions. **Table 4.5** summarises the key points from these studies and compares them with my work.

Table 4.5 Comparison of key realist studies with my work

Study	Focus/ Aim	Methodology	Setting & Population	Key Findings	Relevance / Comparison to Your Work
MEMORABLE realist synthesis Medication Management in Older People [101]	To understand how medication management works for older people with multimorbidity, and how professionals and patients share responsibility.	Realist synthesis based on literature, stakeholder consultation, and case studies.	Older adults with multimorbidity and polypharmacy, across primary and community care.	Identified a five-stage, four-step, three-loop medication management process. Analysis revealed five key burdens experienced by older people and carers: • Ambiguity • Concealment • Unfamiliarity • Fragmentation • Exclusion	Broader systems focus on medicines management overall. My work narrows in on pharmacist-led medication reviews.
TAILOR evidence synthesis (Deprescribing in Multimorbidity and Polypharmacy [102]	To identify what influences deprescribing decisions in older adults with multimorbidity and polypharmacy.	Mixed-methods evidence synthesis (realist-informed).	Older adults with polypharmacy, multiple conditions, and complex care needs.	Structured deprescribing can be safe and clinically acceptable, but outcomes vary and patient perspectives are often underreported. Medicines carry personal meaning beyond their clinical function, influencing how patients perceive and respond to deprescribing. Effective deprescribing requires: • Permission and support for clinicians to engage in shared decision-making. • Resources and time to build trust and develop a shared understanding of the value of medicines.	Focused specifically on deprescribing rather than general medication review. My work is broader addressing the entire review process, not just medicine withdrawal.

Study	Focus/ Aim	Methodology	Setting & Population	Key Findings	Relevance / Comparison to Your Work
				Deprescribing decisions are deeply personal, affecting not just disease management but also patients' sense of health, identity, and autonomy.	
MODIFY intervention for Structured Medication Review (SMR) and deprescribing [103]	To explore how, why, and in what contexts multidisciplinary medication review and deprescribing interventions succeed in primary care.	Realist review and synthesis.	Older people with polypharmacy in primary care.	Four key themes emerged from 33 Context-Mechanism-Outcome (CMO) configurations: • Roles & Relationships • Training & Education • Review Process • Patient & Carer Involvement Mechanisms for success include: • Integration of pharmacists and other specialists (e.g., nurses, frailty practitioners). • Shared decision-making supported by time, resources, and trust-building. • Person-centred approaches that acknowledge individual needs and preferences	Aligns closely with my work. However, my work narrows in on pharmacist-led medication reviews and is broader, not focussing on deprescribing.

4.4.2 Strengths and Limitations

I used robust and transparent methods to review the international medication review literature, thereby enhancing the reliability and validity of the findings. The review provides a broad overview of pharmacist-led medication reviews and offers a comprehensive understanding of the field. However, only studies published in English were included, introducing the potential for language bias, as relevant studies published in other languages may have been missed. Furthermore, the inclusion of studies across all patient populations and disease areas may have influenced the conclusions. Certain components of medication reviews may vary in importance depending on the patient group or clinical condition, potentially limiting the nuance of findings for specific subpopulations. Given the diversity and heterogeneity of the included studies, narrative synthesis was selected as the most appropriate method for analysing and presenting the data. This qualitative approach allowed for systematic interpretation and integration of findings across studies that were not directly comparable in methodology or outcome measures [123].

Identifying Behaviour Change Techniques (BCTs) used in the medication reviews advances the field by making the behaviour change components of medication reviews explicit. This identification provides a foundation for further discussion within the medication review community.

In this research, the TIDieR framework served not only as a reporting tool but also as a methodological scaffold for systematically extracting detailed intervention characteristics across included studies. This facilitated structured comparison of how pharmacist-led medication reviews were implemented and reported, helping to identify effective components as well as areas of inconsistency or underreporting. The use of the TIDieR checklist ensured methodological rigour and enhanced the potential for replication and practical application of the findings in subsequent phases of this research.

Similarly, the BCT Taxonomy provided a theoretically informed and systematic approach to identifying and categorising the active ingredients of interventions. Each included study was reviewed to determine which BCTs were present, regardless of whether they were explicitly labelled as such by study authors. Coding was conducted using the published taxonomy and guidance, allowing for consistent classification and comparison across studies. Where possible, BCTs were also mapped to the actors involved (e.g. professional- or patient-directed) and to the context and mode of delivery (e.g. during face-to-face consultations or via written communication).

The robustness of the synthesis was further supported through structured quality assessment, which clarified the definition of the intervention and ensured that sufficient detail was available to determine study suitability for inclusion. While many studies were deemed to have a high risk of bias, this was considered in the interpretation of findings, as such studies may overestimate intervention effects. The narrative synthesis identified key themes but represents a thematic summary rather than a quantitative meta-analysis.

To enhance consistency and clarity in comparing outcomes across studies, extracted outcomes were mapped to established classifications, specifically, the Beuscart core outcome set and the Kersting scoping review [59,176]. The Beuscart set provides a concise framework primarily for older populations, while the Kersting scoping review was applied to broaden the classification to encompass all patient populations represented in the included studies.

It is also important to note the existence of another core outcome set developed for clinical trials of interventions aimed at improving adherence to appropriate polypharmacy in older adults [177]. These core outcomes include medication adherence across multiple medications, treatment burden, health-related quality of life, healthcare utilisation, adverse events and side effects, and cost-effectiveness. With the exception of treatment burden, data relating to these outcomes were also

reported, as they aligned with either the Beuscart or Kersting classifications. Although the data extraction form allowed for the inclusion of additional outcomes, no data were available on treatment burden.

Most studies primarily reported clinical or economic outcomes, with relatively limited attention to patient-reported outcomes. Future studies should prioritise patient-reported measures to provide a richer understanding of the impact of pharmacist-led medication reviews on patients' lived experiences and wellbeing, extending beyond economic and clinical indicators [150].

4.5 Conclusions and next steps

This systematic review examined pharmacist-led medication reviews and identified common themes in their design, delivery, and implementation that may influence outcomes. Further studies exploring the impact of pharmacist-led medication reviews, with published protocols and process evaluations will help to determine how different components influence outcomes; measured outcomes should also include those which are patient-reported. My data synthesis has proposed themes and components most likely to improve patient outcomes. These themes and components are linked to activities that occur during and after the patient consultation. Consideration should also be given to the pharmacist conducting the review and the environment in which it occurs:

- Pharmacists need a comfortable, professional space to deliver medication reviews, along with a flexible protocol to guide the consultation.
- During the consultation, there should be opportunities for patient education, goal-setting related to medication adherence, and developing an action plan.
- Follow-up appointments after the medication review may influence a variety of patient outcomes.

The MRC NIHR framework for complex interventions identifies engaging with stakeholders as a core component of developing and evaluating complex interventions [104]. Therefore, the next step in my research was to engage stakeholders and explore the current provision of pharmacist-led medication reviews. The themes and components identified in this systematic review were presented to these stakeholders to determine whether they agreed with my conclusions and how these themes and components could be used to optimise pharmacist-led medication reviews. **Table 4.6** summarises the contribution to research alongside conclusions from previous chapters.

Table 4.6 Contribution to research alongside conclusions from previous chapters

	Introduction	Scoping review	Systematic review
Aim	**Overall aim of this thesis** Investigate how pharmacist -led medication reviews in primary care can be optimised to improve patient outcomes for those with long-term conditions.	Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction.	Identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts.
Results	Background information about long-term conditions and medication reviews. • Increasing prevalence of long-term conditions which adds to individual and health system burden. • Long-term conditions primary managed by medicines. • Some challenges associated with medication use include poor adherence, adverse drug reactions (ADRs), and inappropriate prescribing. • Medicines issues can potentially lead to poor patient outcomes, including hospitalisations and a reduced quality of life • Medication reviews aim to improve medication use and reduce adverse outcomes • UK government policies advocate for expanding pharmacists' roles in medication reviews.	• Significant variation in outcomes associated with pharmacist-led medication reviews. • Many reviews did not report the nature of the intervention; we cannot ascertain what a high-quality medication review looks like and what leads to good outcomes. • An additional literature search was necessary to identify the core components of pharmacist-led medication reviews and how these link to outcomes.	• Identification of themes and components of pharmacist-led medication reviews that are most likely to result in improved outcomes for patients. • Themes and components relate to the activities that occur during and after the patient consultation. Consideration should also be given to the pharmacist undertaking the review and the environment in which it takes place: • Medication reviews delivered by experienced pharmacists or those with enhanced clinical skills, having access to patients' clinical and medication history, and autonomy to make medication changes may improve patient outcomes. • Pharmacists require a comfortable and professional space to deliver medication reviews and a flexible protocol to guide the consultation. • During the consultation, there should be opportunities for patient education, setting goals to take medication and developing an action plan. • Follow-up appointments after the medication review may influence a variety of patient outcomes. • Stakeholders to comment on how the results can be used to optimise pharmacist-led medication reviews.

5.0 Chapter 5 Exploring stakeholders' opinions of pharmacist-led medication review in primary care.

5.1 Introduction

Building on the conclusions of the scoping review in Chapter Three, the systematic review in Chapter Four identified themes and components important to the delivery of effective medication reviews. Key components of a medication review include both the activities undertaken during and after the patient consultation. Additionally, factors related to the pharmacist conducting the review and the environment in which it takes place are also important considerations. My systematic review identified that medication reviews undertaken in primary care were more likely to positively influence outcomes. Pharmacist having full access to patient information was also an identified component of medication reviews. Given that community pharmacies currently do not have full access to patient records, the remainder of this research will focus on medication reviews conducted in general practice.

To optimise pharmacist-led medication reviews, stakeholder input is essential -stakeholder engagement is one of the core elements of the MRC NIHR framework for complex interventions [104]. This chapter details how I engaged with key stakeholders—including patients, pharmacists, and general practitioners (GPs)—to examine how medication reviews are currently implemented in primary care and to identify key uncertainties in their delivery.

5.1.1 Aim and objectives

The overall aim of the final research project in my PhD was to design, and user test an optimised pharmacist-led medication review (PLMR) in primary care, which I named the Optimising Pharmacist-lEd medicatioN reviews (OPen) study. The OPen study was undertaken in two phases: phase one is exploring stakeholders' opinions of pharmacist-led medication review in primary care

and phase two is co-designing and testing an optimised intervention. Phase one is described in this chapter, and phase two the next (Chapter Six).

The aim of this chapter (phase one) is to explore the current provision of medication reviews by pharmacists in primary care with stakeholders.

The objectives of this chapter are to:

1. To explore the thoughts and experiences of patients who have recently undergone a pharmacist-led medication review.
2. To understand the perspectives of healthcare professionals regarding the delivery, effectiveness, and limitations of pharmacist-led medication reviews.

5.2 Method

Co-design and experience based co-design were both considered appropriate methodology for this Optimising Pharmacist-lEd medicatioN reviews (OPen) study. Both approaches require assembly of a team of service users to help guide the development of the intervention and provide opportunities for patients and staff to work together in designing the intervention, paying careful attention to their own experiences. Whilst EBCD is preferred when looking to improve one intervention (pharmacist-led medication reviews) in one setting (primary care), it is resource intensive. The time and funding available for intervention development were dictated by the duration of the PhD and its associated funding. These constraints made it unfeasible to implement Experience-Based Co-Design (EBCD) or its accelerated version. Instead, this study adopted a co-design approach informed by the principles of EBCD. Interviews and discussions with stakeholders were conducted to identify key aspects of the medication review process requiring evaluation. Chapter Six describes how stakeholder feedback, combined with evidence from my systematic review, was used to outline areas for improvement in pharmacist-led medication reviews. Multiple stakeholder workshops were then held to refine and enhance the intervention based on these insights.

5.2.1 Methods for data collection

I took a qualitative approach to data collection in this study as it is concerned with the 'what', 'why' and 'how' of pharmacist-led medication reviews [127]. Qualitative approaches facilitate the gathering of rich, detailed data. The qualitative approaches chosen for this study were focus groups and semi-structured interviews. These methods are described in Chapter Two.

There are several data analysis techniques that can be used to analyse data from focus groups and interviews. I decided to use **thematic analysis** (TA) [139], as it is flexible and widely used approach in qualitative research analysis and is useful for participants' experiences, views and opinions. The six steps of thematic analysis are as follows:

1. Familiarising yourself with the data.
2. Generating initial codes.
3. Generating initial themes.
4. Reviewing themes.
5. Defining and naming the themes.
6. Writing up.

Figure 5.1 illustrates the process for the Optimising Pharmacist-lEd medicatioN reviews (OPen) study and how it maps to the co-design process. My literature reviews reported in Chapters Three and Four identified the problem. This chapter describes the focus groups, interviews and the subsequent data analysis of the lived experiences of stakeholders. This figure also outlines the co-design workshops and early testing of the optimised medication review described in Chapter Six.

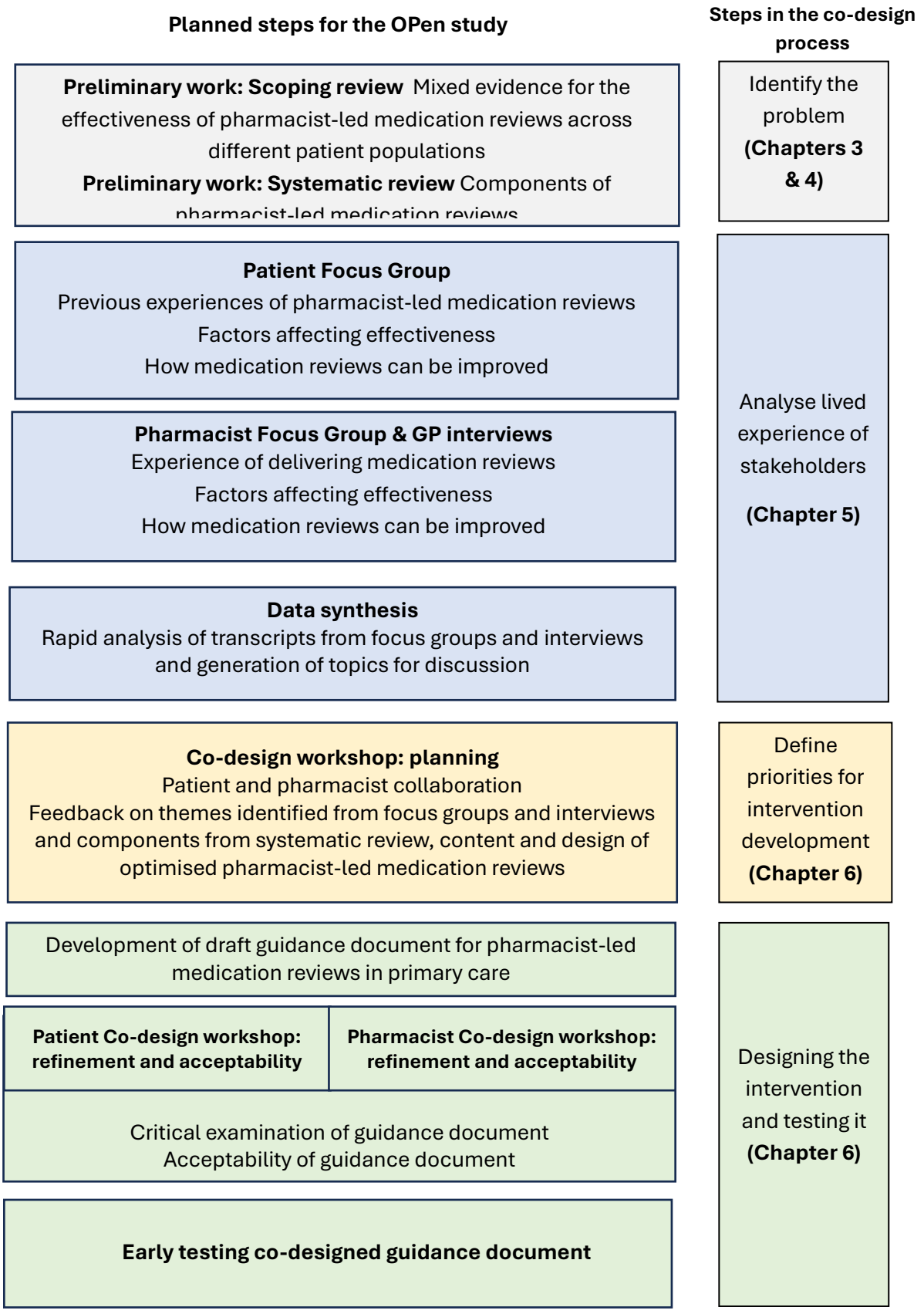

Figure 5.1 Description of the plan for the OPen study and how it aligns to the co-design process

5.2.2 Ethical considerations

Permission and approval from this study was sought from NHS Research Ethics Committees through the Integrated Research Application System (IRAS) (application number 313644). It was given a favourable ethical opinion by the NHS health research authority and was registered and posted on the ClinicalTrials.gov public website (ClinicalTrials.gov Identifier: NCT05928104). Informed consent was obtained by participants at each stage of the study; electronically via the expression of interest forms and verbally at the start of the focus group/ interview/ workshop. This dual approach to consent balanced the need to capture informed consent appropriately whilst ensuring the digital accessibility of the study. Participant personal information was stored securely and only accessed by me and members of the supervisory team. Participant information was collected using JISC© online surveys, a platform that conforms to General Data Protection Regulation (GDPR). Only data that was relevant and necessary to the study was collected. All data was reported confidentially; participant data is not associated with their names.

Appendix 7 contains the protocol for the Optimising Pharmacist-lEd medicatioN reviews in primary care (OPen) study. The study protocol contains the method and the associated documents, including participant information sheets, expression of interest and consent forms, and topic guides.

5.2.3 Patient focus group and practitioner focus group/interviews

This section describes recruitment and sampling, data collection, and data analysis and from patient and pharmacist focus groups/ GP interviews.

5.2.3.1 Recruitment and sampling: patients

I aimed to recruit eight patient representatives for patient focus groups. A sample size of eight participants aligns with the recommended size for focus groups [129]. To recruit participants, I

emailed several patient societies (such as the Patients' Association, British Heart Foundation, Diabetes UK, Asthma UK, and Arthritis Research UK) requesting that they circulate the participant information sheet (**Appendix 7**; sub-Appendix 13) to their members. Additionally, I advertised the study on social media platforms (Facebook®, Twitter®, LinkedIn®), tagging the aforementioned patient organisations in the posts. The emails and social media posts included links to the online expression of interest forms and participant information sheets.

The inclusion and exclusion criteria for patient participants are described below:

Inclusion criteria:

- Aged ≥ 18 years
- Prescribed at least five medicines
- Patient has received a medication review conducted by a pharmacist in community pharmacy or GP surgery in the last three months
- Resident in England
- Effectively communicate in English
- Provide informed consent

Exclusion criteria:

- Have no access to the internet
- Lack capacity to consent
- Currently (or recently) involved in another research project

Prospective participants completed an online expression of interest form which also captured data relating to ethnicity, gender, age, and geography to facilitate purposive sampling. Purposive sampling helps to provide a diverse sample so that differences in perspectives can be explored [238]. The online expression of interest also contained the consent form to participate in the study. Participants selected for the study were re-sent a participant information sheet with a confirmation email. People who expressed an interest and were not included in the study received an email thanking them for their response.

5.2.3.2 Recruitment and sampling: practitioners

I aimed to recruit eight primary care practitioners for practitioner focus groups/interviews. Primary care practitioners included pharmacists from community settings, general practice, primary care networks, as well as GPs. To recruit participants, I emailed pharmacy organisations (including the Primary Care Pharmacists Association (PCPA), Royal Pharmaceutical Society (RPS), Pharmacy Research UK (PRUK), and Pharmaceutical Services Negotiating Committee (PSNC)), requesting that they circulate the participant information sheet (**Appendix 7**; sub-Appendix 8) to their members. Additionally, I advertised the study on social media platforms (Facebook®, Twitter®, LinkedIn®), tagging the previously stated pharmacy organisations in the posts. The emails and social media posts included links to the online expression of interest forms and participant information sheets. GPs were recruited via word of mouth through existing connections within the research team.

The inclusion and exclusion criteria for practitioner participants are described below:

Inclusion criteria

- A qualified healthcare professional registered with the appropriate body (General Medical Council, General Pharmaceutical Council, for doctors and pharmacists.)
- Works in primary care in England
- Review medicines as part of their practice
- Effectively communicate in English
- Provide informed consent

Exclusion criteria

Potential participants will be excluded if they

- Have no access to the internet
- Lack capacity to consent
- Currently (or recently) involved in another research project

Prospective participants completed an online expression of interest form which also captured data relating to ethnicity, gender, age, and geography to facilitate purposive sampling. The online expression of interest also contained the consent form to participate in the study. Participants selected for the study were re-sent a participant information sheet with a confirmation email. People who expressed an interest and were not included in the study received an email thanking them for their response.

5.2.3.3 Data collection

Focus groups and interviews were conducted via Microsoft® Teams and recorded using the Teams® software, with an audio recording device serving as a backup. Each focus group session was planned to last no longer than two hours [128], while interviews were scheduled for one hour. Patient and practitioner participants were informed about confidentiality arrangements and the ground rules at the start of the sessions. Discussions centred on the content and perceptions of medication reviews, factors affecting their effectiveness, and ways to improve medication reviews. Topic guides for the focus groups were reviewed by members of the supervisory team and Patient and Public Involvement (PPI) contributors prior to the sessions to ensure their suitability and clarity. Three Patient and Public Involvement (PPI) members were recruited through the School of Pharmacy administration team, which maintains a repository of individuals available to assist in research or teaching. These members provided feedback on several study materials, including the patient participation information sheets, expression of interest form, consent statements, and guides for focus groups, workshops, and interviews. Their input was incorporated before the research protocol was submitted for ethical approval.

Obtaining consent

Prior to the focus groups and interviews, participants received a consent survey via email along with their confirmation details. I asked participants to complete the survey electronically at least 24 hours

before the session. At the start of each session, I confirmed that verbal consent had been obtained from all participants. Participants were reminded of the confidentiality arrangements and informed that the session would be recorded (both visual and audio) for research purposes. Ground rules for the session were outlined, including avoiding talking over one another and minimising background noise to ensure a productive and respectful environment for discussion.

5.2.3.4 Data analysis

Data collection and analysis in qualitative research can be time-consuming, leading to the development of rapid research methods to expedite the process [265]. Gale et al. described a method for the rapid analysis of interview transcripts [266]. Given the time constraints during the co-design phase, I employed rapid analysis on the transcripts from both the patient and practitioner focus groups/ interviews to generate data for discussion during the co-design workshops. I broadly followed their method in that I summarised individual transcripts and consolidated these summaries by participant type. However, I did not use a pre-designed template for data extraction as I took an inductive approach to analysis. Identification of exemplar quotes was postponed until the in-depth analysis. The aim of the rapid analysis was not to identify themes but to highlight topics for further discussion on medication reviews. For the rapid analysis, I summarised key points from the transcripts using Microsoft Excel®, categorising responses based on the relevant focus group topic guide. Identification of illustrative quotes was reserved for the in-depth analysis.

Transcripts of the focus groups and interviews were automatically generated using Microsoft® Teams. To ensure accuracy and reliability, I carefully reviewed each transcript, cross-checking them against the original audio recordings and making necessary corrections where required. The transcripts were fairly accurate, with most corrections required for technical phrases, colloquial speech and strong accents. Once the transcripts were verified, I utilised the NVivo® software

program to facilitate the data analysis process. NVivo® enabled the systematic organisation, coding, and retrieval of data, allowing for a more structured and efficient thematic analysis.

The patient and practitioner focus groups and interviews were analysed together as one data set. I reviewed the transcripts multiple times before coding the data inductively and grouping it into conceptual themes. I undertook the initial coding and theme generation, which were then reviewed and refined in discussions with my supervisory team.

5.2.4 Data synthesis of focus groups and interviews

The individual transcripts of the patient focus group and practitioner focus group/interviews, were summarised and consolidated by participant type. This process resulted in a single dataset where the key points from the transcripts were organised using Microsoft Excel®. The identification of illustrative quotes was reserved for the in-depth thematic analysis, which was conducted at the conclusion of the co-design phase to allow for a break and a fresh perspective on the responses. The topics identified during the rapid analysis of the focus groups and interviews were grouped alongside the key findings from the systematic review. This information was synthesised into a two-page written summary (**Appendix 8**) and a six-minute video summarising "what is more likely to make a medication review work?" and "what do patients and practitioners think?" (Summary of results from literature and participant discussions) These materials were shared with participants before the co-design planning workshop (described in Chapter Six).

5.3 Results

This results section describes the uptake and attendance for the focus groups and interviews. It also describes the topics identified from the rapid analysis and the themes from focus group/ interviews and workshops. Finally, the key uncertainties to take forward to the next phase were identified.

5.3.1 Uptake and attendance for focus group/ interviews

Twelve patients expressed an interest in being involved in the focus group. A sample of eight patient participants purposively sampled to participate in the patient focus group, and seven participants joined. Prospective participants that were not selected were informed by email and thanked for their interest. Five pharmacists (one community pharmacy, two primary care network (PCN) and two general practice) expressed an interest in participating in the practitioner focus group, however, one PCN pharmacist did not attend. Two GPs expressed an interest in the study, but they were unable to attend the focus group, therefore, I interviewed them separately. Characteristics of the participants in the focus groups/ interviews are reported in **Table 5.1**.

Table 5.1 Characteristics of participants in focus groups/ interviews

	Patient focus group	Practitioner focus group/ interviews
	N (%)	N (%)
Sample	Patient n=7	Pharmacist n=4 GP n=2
Gender		
Female	3 (43)	3 (50)
Male	4 (57)	3 (50)
Age group (years)		
20-30	1 (14)	1 (17)
31-40	2 (29)	2 (33)
41-50	1 (14)	1 (17)
51-60	1 (14)	2 (33)
61 years and older	2 (29)	
Ethnic group		
Black, African, Black British or Caribbean	2 (29)	1 (17)
Mixed or multiple ethnic groups		1 (17)
White	5 (71)	4 (67)
Index of multiple deprivation (IMD)	**(home)**	**(work)**
2		2 (33)
3	2 (29)	1 (17)
4	1 (14)	
5	1 (14)	
6	1 (14)	1 (17)
7	1 (14)	1 (17)
8	1 (14)	1 (17)

5.3.2 Rapid analysis of patient focus group and practitioner focus group/ interviews

The rapid analysis of the patient focus group and practitioner focus group/interviews identified five topics that were commonly discussed across both the patient focus group and the pharmacist focus group/GP interviews:

1. **Medication reviews vary for different patients**

Our participants told us that different patients often have varying needs in their medication reviews. Some patients with complex medication regimes usually benefit from longer face-to-face appointments, whereas other patients who are happy with their medicines may be content with a telephone or online review.

2. **Access to and familiarity with patient information**

Our participants told us that pharmacists should review and be familiar with the patients' medicines and medical history before the appointment. This may reduce the time the patient needs to spend updating the pharmacist during the consultation.

3. **Patient focussed review**

Our participants told us that medication reviews should be patient-led and a take a holistic approach, with patients having opportunities to ask questions and raise concerns. Our patient participants told us that they need to feel that they have been listened to during the consultation.

4. **Time**

Our participants told us that they often feel that there is not enough time in the consultations to address all the issues that need to be discussed.

5. **Communication**

Our pharmacist and patient participants reported issues around the communication between hospital specialities and doctors' surgeries. Our patient participants felt that surgeries could communicate better about when patients would be having medication reviews. This is particularly problematic when patients receive opportunistic telephone reviews. After the medication review, patients should be notified and kept updated about any referrals or follow up appointments.

5.3.3 Thematic analysis of focus groups and interviews

This section identifies the themes that were synthesised through reflexive thematic analysis of the transcripts for the patient and pharmacist focus groups and GP interviews. The six steps of thematic analysis are described in Section 5.2.1.2. Themes identified include the role of healthcare professionals, patients' expectations, engaging patients, and the process of delivering the medication review.

Theme 1: The importance of acknowledging the role of different healthcare professionals in the management of patients' medicines

The responses indicated that participants recognised the importance of different roles within the practice team necessary for medication reviews. Participants reported that support staff manage appointments, nurses review long-term conditions like diabetes and asthma, pharmacists conduct reviews ranging from acute requests to structured assessments, and GPs handle ad hoc or complex reviews.

> "We are very grateful to be able to tap into the pharmacists, who will take a little bit longer and go a little bit more in depth with every medication." **(GP 1 Part-time GP, PCN research lead)**
>
> "Pharmacists have different knowledge than GPs, and sometimes they can help… they (GPs) never tell the interaction with other medicines. They don't tell this at all, and that's what I learned from the pharmacist, who, who knows more." **(Patient 2)**
>
> "Over the last few years, people recognise that pharmacists are in practice more, so, they've become more comfortable with speaking to or directly seeking input from a pharmacist rather than worrying the GP. So, I certainly find in my practice, or in in the practices that I've worked in, that that patients would actively want to speak to the pharmacist…Sometimes

…if it's something that's really clinical or complicated and you have to pass it on again."

(**Pharmacist 3 Partner in GP surgery >10 years**)

Practitioner responses reflected that pharmacists tend to want to work within a system and are more risk averse than GPs:

"Pharmacists by our very protocolised …nature…, as a risk adverse kind of profession, … we're perhaps less likely to be a bit maverick and go off piste." **(Pharmacist 3 Partner in GP surgery >10 years**)

"And they're [pharmacists] very, very good at switching, … very good at optimising. So, if somebody's on simvastatin, they're very good at saying the best evidence now is atorvastatin, whereas a GP would probably go, yes, fine carry on. But I think they're less bold at look at helicoptering back and looking at that bigger picture because they're risk averse." **(GP 2 GP partner 25 years)**

One GP noted that since pharmacists have been undertaking medication reviews, it has increased the number of queries that they have to respond to. However, they reported that these queries are more relevant and are improving patient safety.

Through their responses, practitioners identified that GPs and pharmacists have different strengths when conducting medication reviews; clear roles within the team help to make the multidisciplinary team work more effectively. One pharmacist explained that they spent a lot of time with the support staff at their practice explaining their role and what they can and cannot do, and how they approach their medication reviews.

Theme 2: Resources required to deliver medication reviews

Participants reflected on the different resources required to deliver medication reviews. These subtheme A identifies the importance of adequate space and time, and subtheme B highlights the

need for a systematic, flexible approach to a medication review to meet patients' needs. have been influence of time, space, and resources to deliver medication reviews.

Subtheme 2A: The importance of adequate space and time

Pharmacists identified that not having access to a consultation room in practices posed a barrier to delivering medication reviews, especially face-to-face.

> "PCN pharmacists … don't have a room, so a lot of pharmacists can't fit in practices because of the massively expanding MDT [multidisciplinary team]. And they don't have either an appropriate clinic room, some of them having to share with admin staff, which means … their telephone consultation … the other person can hear what's being said. But they [the pharmacists] haven't got anywhere to offer a face-to-face appointment." (**Pharmacist 5 PCN pharmacist >5 years)**

Participants acknowledged that lack of time to prepare for and deliver the quality and number of medication reviews required in primary care is problematic:

> "I'm the only pharmacist so I can only cover so many in X level of quality. So, you have to pick the ones that get a 20-minute face to face 'cause they're on 10 or more or high frailty or multiple high-risk medicines, to those that get a 5- or 10-minute telephone consultation booked in, or those that you just get sent on the day to call." (**Pharmacist 5 PCN pharmacist >5 years)**
>
> "We're under immense pressure in primary care and we just don't have the time to do lovely half an hour chats with everybody." **(Pharmacist 3 Partner in GP surgery >10 years**)

Lack of time was a strong theme that was reflected by all participants. As pharmacist 5 identified, practitioners must decide which patients have time allocated for a more in-depth review. An additional challenge is when patients attend for a standard appointment, and present with a complex issue or problem, meaning that there is insufficient time to address it.

Patients reported that would like time to prepare for the medication review and felt that pharmacists should be familiar with the patient and their history before the review:

> "I was called, you know, out of the sudden and wasn't prepared at all. I didn't have my list of my medication. I didn't have any questions in my mind to ask. So, I would like to be prepared." (**Patient 2**)
>
> "They should automatically read your notes before they see you, which they don't." (**Patient 5**)

Several patients shared that their medication reviews were carried out via an unexpected telephone call. Patients reported that in most cases, when presenting for a medication review, the clinicians are unfamiliar with the patient and their medical problems. Patient felt that explaining the medical history wasted valuable consultation time.

Subtheme 2B: A systematic, flexible approach to a medication review to meet patients' needs

Practitioners identified a variety of tools/ prompts that are used when delivering medication reviews. Regardless of the approach used, participants felt a systematic approach is required to ensure all key elements are included:

> "Having a more of a systematic approach to the medication review …would make a difference to what I say. Systematic not to say that you're using a tool necessarily…I know colleagues use the Ardens templates and things like that, which sometimes I can do if there's a lot and if it's a bit complex. But I say systematic in the way that the patient themselves understand the process and they know we're going to look at these tablets, we're going to look at side effects…once they've done it once or twice, they do understand what you're looking for, and what they will be looking for. In fact, sometimes a patient will trigger the medication review if they have that full understanding." **(GP 1 Part-time GP, PCN research lead)**

> "Often, even after the review has been completed and the templates filled in, you have no idea really or understanding of where, what the, what the point of the medication review was. So, we tend to tailor it and actually, we tend to get a good response." (**Pharmacist 3 Partner in GP surgery >10 years**)

Patients recognised the importance of a flexible approach to a medication review. The activities undertaken during the medication review will vary depending on the aim of the review:

> "I've been asked every medicine, one by one when I am taking it, if I take it separately or with anything else, how long I wait before taking another one? … and I've been asked why I didn't order repeat prescription for one of my medications and I've been sent for blood tests by the pharmacist." (**Patient 2)**

Patients reported a disparity in the content of their medication reviews. For example, Patient 2 had a thorough discussion about their medications and medication-taking behaviour, while other participants experienced brief conversations simply confirming that everything was satisfactory. The focus of the review often seemed to be driven by the pharmacist rather than the patient, though there were occasional instances where both the pharmacist and patient shared the same objective.

Participants identified that there are several different elements involved in the medication review process; some activities should be completed before the medication review, e.g., reviewing blood test results and some after, e.g., arranging follow up appointments.

Theme 3: Understanding and responding to patients' expectations of pharmacist-led medication reviews

Participants described the need to understand patients' expectations of medication reviews. Practitioners report that some patients present for medication reviews having been influenced by

trends in the media; others are seeking information about the indication if their medicines. Practitioners acknowledged that patient expectations will be based on their previous experiences and others from their own understanding:

> "it's more the patient's frame of mind as well as what they want to get out of the conversation. It will determine how well the interview will go and then the sort of intervention that we could make." (**Pharmacist 2 Community Pharmacist >10 years**)

> "Patients can get on the defence straight away … some of them almost pre-empt that they're gonna be challenged on something like high dose opiates, … overuse of their salbutamol, … maybe not ordering their statin, because, you know, they feel defensive." (**Pharmacist 4 PCN pharmacist recently qualified**)

Participants identified that patients' concerns about being challenged about medication use was identified as a barrier to the delivery of medication reviews. In addition, responses indicated that patients sometimes do not know that they need to have medication reviews.

Patients reported that they are not usually asked what they would like from the medication review and suggested that if patients self-referred for a medication review, they would have better outcomes. Patients identified the importance of knowing why they are having the medication review:

> "We are all in the situation where they do the review without us asking so, it's for them, not for us. So we should ask [them] why they are doing it." (**Patient 2**)

None of the patients in the group recalled being asked what they wanted to achieve in the medication review. In general, patients reported that they wanted to feel as though they are listened to. Patients also require more information about their medicines, particularly at the point of prescribing:

> "They let me talk. They just didn't listen" **(Patient 3)**

"But that just makes you, you know, you're just given the tablets, and you're just shoved away and you gotta deal with your own problems like." (**Patient 5**)

"I know GP time is critical, and pharmacist's time is critical, as you say, sometimes a little bit of communication doesn't hurt...and it sort of, gives people a bit more confidence if they can just express what it does and ask a few questions. There doesn't seem to be the time." (**Patient 4**)

Patients' desire to be heard was a strong theme. This was reflected in the fact that patients felt that a medication review had been successful if pharmacists had listened to and acted upon a patient's concerns. Patients reported that information about medicines at the point of prescribing is often lacking, and they report it makes them feel neglected. Participants indicated that more information about medicines, especially side effects and drug interactions, is required during the medication review.

Practitioners made several suggestions to facilitate a patient-centred review. These suggestions include starting the consultation with an open question, allowing the patient to lead the consultation and identify any issues, and pharmacists approaching the medication review with an open mind and not a target-driven narrow agenda:

"I think that the saying is that you know, like guidelines, not tram lines. You know, you don't have to stick to the guidelines; you find that GPs are very good at working around guidelines and actually applying them when they're appropriate, whereas pharmacists, …want to only have people that fit guidelines and not people that don't fit guidelines, if that makes sense." (**Pharmacist 3 Partner in GP surgery >10 years**)

"My view is that putting the patient at the centre of it all, in showing that they have as much understanding as possible of the review and the purpose of medication and how it helps them means that they can actually take the lead on it and you end up having them triggering

these support system rather than you having to call them, pull them in once a year." **(GP 1 Part-time GP, PCN research lead)**

Practitioners suggested that patients should be allowed to lead the consultation; this may lead to them being invested in the medication review.

Theme 4: Different approaches for engaging patients and delivering medication reviews

Participants identified the need for different approaches for engaging patients and delivering medication reviews. Pharmacists highlighted that there isn't a "one size fits all" approach to identifying patients for medication reviews. Participants reflected on the mode of delivery for medication reviews:

> "Elderly people, if you have a face-to-face review with them, it is better for them because sometimes, they can't hear very well and they just … need to sit with you and go through stuff." (**Pharmacist 1 GP Clinical Pharmacist >15 years**)
>
> "Sometimes you get people in for a face-to-face, they engage more, they kind of build that relationship. Yes, it takes longer. Maybe the quality is better, don't know. It depends on the situation. But I seem to find it the ones that come in face to face are more open to change or deprescribing opportunities." (**Pharmacist 5 PCN pharmacist >5 years)**
>
> "Yeah, I prefer face-to-face. Ohh yeah, but at some point, maybe if I'm busy, I could just do a phone or teleclinic, I think. But for me personally, I prefer face-to-face where I could see my GP/ my pharmacist which could have to see me, talk to me and then assess me as well." (**Patient 6**)

Among the patient participants, many medication reviews had been undertaken over the telephone, often without prior notice. Overall, participants expressed a preference for ace-to-face reviews; one participant suggested video consultations as a preference to telephone calls. Responses indicated that patients who are well managed or have a simple medication review were content to have a

medication review over the telephone. Practitioners recognised that telephone reviews are more time efficient, but it is more difficult to build rapport and you lose the ability to interpret non-verbal behaviour. Practitioners suggested that face-to-face appointments may be appropriate for patients who require a chaperone or have a particularly complex medication regime. Practitioners also recognised that not all patients require the same intensity of medication reviews; patients who are well managed and stable will not require medication reviews as often as patients with complex polypharmacy.

Practitioners acknowledged the challenges faced by patients when trying to arrange appointments for medication reviews. Different practices will have their own procedures, e.g. booking for a review in the patient's birthday month, or when their medicines need to be re-authorised. Some surgeries utilise on-line questionnaires where patients can choose whether they would prefer face-to-face or telephone consult, and others use text messages to inform patients that are due for a medication review.

5.3.4 Comparison of results from rapid and in-depth analyses.

Table 5.2 presents a comparison of the themes identified from the in-depth analysis of the patient and practitioner focus groups/ interviews alongside the topics identified in the rapid analysis. In some instances, the topics identified in the rapid review feature in more than one theme. For simplicity, the topics are only mapped to one theme to demonstrate triangulation of data. Triangulation of the data enhances the validity and reliability of my findings. There was only one theme from the in depth analysis that was not reflected in the topics identified in the rapid analysis.

Table 5.2 Comparison of themes in-depth analysis of focus groups/ interviews with topics from rapid analysis

Topics identified in rapid analysis	**Themes identified in focus groups/ interviews**
	The importance of acknowledging the role of different healthcare professionals in the management of patients' medicines
Time Access to and familiarity with patient information Patient focussed review	Resources required to deliver medication reviews • Subtheme 2A The importance of adequate space and time • Subtheme 2B systematic, flexible approach to a medication review to meet patients' needs
Medication reviews vary for different patients	Understanding and responding to patients' expectations of pharmacist-led medication reviews
Communication	Different approaches for engaging patients and delivering medication reviews

5.4 Discussion

5.4.1 Summary of main findings

Participants' focus groups and interviews demonstrated that the participating practitioners generally embraced the role of pharmacists in delivering medication reviews. However, concerns were raised about how well patients and practice staff understand the pharmacist's role and responsibilities. These concerns were echoed in the patient responses. While some patients expressed confidence in pharmacists' abilities, others expressed doubt. There was considerable variation in how pharmacist-led medication reviews were delivered across practices. This variation stemmed not only from different policies and procedures within each practice but also from the quality of existing guidance.

Participants suggested that a flexible guidance document could be helpful in standardising and optimising medication reviews.

Patients noted that they are typically not asked what they would like from their medication review. Some suggested that if patients had the option to self-refer for a medication review, the outcomes might be better. Additionally, during the discussions, some patients shared their experiences with ordering repeat medication, which revealed confusion about what constitutes a medication review. Both patient and practitioner participants highlighted the diversity of potential outcomes from pharmacist-led medication reviews. Patients described a range of outcomes resulting from medication reviews, many of which involved medication changes. These changes included discontinuation of certain medications or switching to alternative medicines within the same drug class, which patients often assumed were cost-related. While some medication changes were favourable, being well-tolerated and effective, others led to side effects that patients either managed to tolerate or reported back to their GP.

Practitioners outlined a wide variety of potential outcomes from pharmacist-led medication reviews. These outcomes included patient satisfaction with medication changes, effective management of patients' conditions following medication adjustments, reductions in opiate prescribing, decreases in hospital readmissions, and referrals to other healthcare professionals. Practitioners also noted the challenges in measuring these outcomes due to the varied reasons for conducting medication reviews. Follow-up was deemed necessary to assess the impact of medication reviews on patient outcomes. However, practitioners acknowledged that the numerous confounding factors make it difficult to undertake meaningful or standardised outcome measures.

5.4.2 Comparison with existing literature

Participants in my study highlighted the need for further education for patients and other staff members regarding pharmacist-led medication reviews. This is corroborated by the findings from McCahon et al. where participants in their qualitative study exploring patient perceptions and experiences of medication reviews in general practice requested clearer information about the intended purpose of the medication review and a better understanding of the pharmacist's role within general practice [267]. Furthermore, a realist review by Luetsch et al. identified trust in healthcare professionals and recognition of pharmacists' clinical and professional role as mechanisms influencing outcomes of medication reviews [119].

Preparation for the medication review emerged as part of the "resources to deliver medication reviews" theme. Participants expressed a preference for face-to-face consultations, although participants acknowledged that there are situations where telephone or other forms of consultation might be necessary. McCahon's study [267] also described preferences for the organisation and delivery of medication reviews; face-to-face consultations were preferred over telephone reviews.

The importance of a patient-centred review emerged as a prominent theme in the patient and practitioner focus groups. The integration of patient values and preferences is a key component of the Bristol medication review model published by McCahon et al. in 2021 [264]. Luetsch et al. also identified patient preference, i.e., accessibility, acceptability and convenience of location and time for medication review and who performs the review, and prioritisation of health and social care needs (balancing the benefit of MR against other priorities and commitments) as mechanisms influencing pharmacist-led medication review outcomes [119].

Participants in my study, both patients and practitioners, expressed concerns about whether pharmacists would have sufficient time to deliver the required number of medication reviews. Duncan et al. conducted qualitative interviews on medication reviews in primary care and found that while pharmacists were considered more thorough, they were also perceived as less time-efficient compared to GPs [268]. This finding supports the concerns raised in my study regarding the time required to deliver medication reviews.

My study reinforces key findings from previous research while adding valuable insights into pharmacist-led medication reviews:

- The need for further education for both patients and staff
- Patient and pharmacist preparation for medication reviews
- Face-to-face consultations are preferred where practical
- Medication reviews should take a patient-centred approach.

5.4.3 Strengths and limitations

Stakeholder engagement was instrumental in understanding how pharmacist-led medication reviews are currently implemented, providing valuable insights into existing challenges and opportunities for improvement. Their lived experiences were essential for the next phase of this study, co-designing an optimised pharmacist-led medication review in primary care.

Recruitment for the study was challenging. Only the patients' association was prepared to share information with their members. None of the pharmacist professional groups were able to share information with their members. Social media and personal networks were more effective at recruiting practitioners, but I still struggled to recruit enough participants to facilitate purposive sampling. I was unable to recruit any GPs for the practitioner focus group, therefore interviews were undertaken with GPs at times convenient to them. My study coincided with the start of the COVID/

flu vaccination season; this could have contributed to the challenges with recruitment. If I had stared recruitment earlier and planned my study for a different time of year, recruitment may have been more successful. However, despite the challenges with recruitment, the participant demographics demonstrate that I was able to provide a diverse sample of participants from mixed geography, age, gender and ethnicity.

5.5 Conclusions and next steps

This phase of my project allowed me to engage with key stakeholders—patients, pharmacists, and GPs—gaining valuable insights into how pharmacist-led medication reviews are currently implemented in practice. Their responses highlighted the variation in patients' experiences of pharmacist-led medication review and their understanding of the process and how pharmacists' skills, and policies and procedures in different practices influence implementation.

Several key uncertainties in relation to the current delivery of pharmacist-led medication reviews emerged from the patient and practitioner focus groups/interviews, including:

- The roles of other healthcare professionals in the medication review process,
- Patients' expectations of medication reviews,
- Varied approaches to engaging patients and delivering medication reviews,
- The need for a systematic and flexible approach to delivering medication reviews,
- The importance of recognising and responding to individual patient needs.

Table 5.3 summarises the research undertaken in this and previous chapters, demonstrating how it has progressed as it endeavours to answer the overall research question for this thesis.

Table 5.3 Contribution to research alongside conclusions from previous chapters

	Scoping review	**Systematic review**	**OPen study Phase One Stakeholders opinions**
Aim	Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction.	Identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts.	Explore the current provision of medication reviews by pharmacists in primary care with stakeholders.
Results	• Significant variation in outcomes associated with pharmacist-led medication reviews. • Many reviews did not report the nature of the intervention, therefore, we cannot ascertain what a high-quality medication review looks like and what leads to good outcomes. • An additional literature search was necessary to identify the core components of pharmacist-led medication reviews and how these link to outcomes.	• Identification of themes and components of pharmacist-led medication reviews that are most likely to result in improved outcomes for patients. • Themes and components relate to the activities that occur during and after the patient consultation. Consideration should also be given to the pharmacist undertaking the review and the environment in which it takes place: • Medication reviews delivered by experienced pharmacists or those with enhanced clinical skills, having access to patients' clinical and medication history, and autonomy to make medication changes may improve patient outcomes. • Pharmacists require a comfortable and professional space to deliver medication reviews and a flexible protocol to guide the consultation. • During the consultation, there should be opportunities for patient education, setting goals to take medication and developing an action plan. • Follow-up appointments after the medication review may influence a variety of patient outcomes. • This evidence-base was used to co-design the guidance document to optimise pharmacist-led medication reviews.	• Variation in patients' experiences of pharmacist-led medication review and their understanding of the process. • Variation in pharmacists' skills and policies and procedures in different practices influencing implementation. • Key uncertainties in relation to the current delivery of pharmacist-led medication reviews: i. The roles of other healthcare professionals in the medication review process, ii. Patients' expectations of medication reviews, iii. Varied approaches to engaging patients and delivering medication reviews, iv. The need for a systematic and flexible approach to delivering medication reviews, v. The importance of recognising and responding to individual patient needs.

6.0 Chapter 6 Co-designing an optimised pharmacist-led medication review in primary care

6.1 Introduction

Chapters Three and Four involved data synthesis through literature reviews, and Chapter Five described the collection and analysis of data from stakeholder engagement. The focus groups and interviews were instrumental in understanding how pharmacist-led medication reviews were being implemented. Data from literature and participants lived experiences were essential to the next step in this project, co-designing and testing an optimised pharmacist-led medication review.

6.1.2 Aim and objectives

The overall aim of the final research project in my PhD was to design, and user test an optimised pharmacist-led medication review (PLMR) in primary care. The final project was undertaken in two phases: phase one explored stakeholders' opinions of pharmacist-led medication review in primary care and is reported in Chapter Five. The aim of phase two, described in this chapter, was to co-design and conduct early testing of an optimised pharmacist-led medication reviews in primary care. The objectives were to:

- Engage stakeholders (e.g., pharmacists, patients) in the co-design of a document to optimise pharmacist-led medication review
- Refine the content and processes within the document, following feedback from pharmacists and patients.
- Determine the acceptability and relevance of the draft document among a small number of key stakeholders in primary care.

6.2 Method

This method section describes the methods for designing and testing an optimised pharmacist-led medication review, including recruitment and sampling, and study procedures. **Figure 5.1** illustrates the process for this study and how it maps to the co-design process.

6.2.1 Co-design workshops

I conducted one "planning workshop" with both pharmacists and patients, followed by two parallel "refinement and acceptability" workshops: one with pharmacists and the other with patients.

6.2.1.1 Recruitment and sampling

I aimed to recruit eight primary care practitioners and two patients for planning co-design workshop and four patients and six practitioners for the refinement and acceptability workshops. The ideal number of participants for a focus group is six to ten [269].

While the number of patient participants in this study fell outside this range, a protocol change—separating pharmacists and patients in the refinement and acceptability workshops—limited my ability to recruit additional patients. A key constraint was financial limitations, as this study did not receive external funding and was conducted within the budget available through my school. In my original protocol, I had allocated funding for a total of ten participants in the co-design workshops. Given these financial restrictions, I was unable to expand the sample size.

I emailed several patient societies (the Patients' Association, British Heart Foundation, Diabetes UK, Asthma UK, Arthritis Research UK) and pharmacy organisations (Primary Care Pharmacists Association (PCPA), Royal Pharmaceutical Society (RPS), Pharmacy Research UK (PRUK), Pharmaceutical Services Negotiating Committee (PSNC)) requesting them to circulate the participant information sheet (**Appendix 7**: sub-appendices 8 and 13) among their members. I advertised the study on social media (Facebook®, Twitter®, LinkedIn®), tagging the stated patient and pharmacy

organisations in the posts. The emails and social media posts included links to the online expression of interest forms and participant information sheets.

The inclusion and exclusion criteria for participants are described below:

Inclusion criteria

Practitioner participant

- A qualified pharmacist registered with the General Pharmaceutical Council
- Works in primary care in England
- Review medicines as part of their practice

Patient participant

- Aged ≥ 18 years
- Prescribed at least five medicines
- Patient has received a medication review in by a pharmacist in community pharmacy or GP surgery in the last three months
- Resident in England

All participants needed to

- Effectively communicate in English
- Provide informed consent

Exclusion criteria

Potential participants were excluded if they

- Had no access to the internet
- Lacked capacity to consent
- Were currently (or recently) involved in another research project

Prospective participants completed an online expression of interest form which included the consent statements, and captured data relating to ethnicity, gender, age, and geography to facilitate

purposive sampling. Participants selected for the study were re-sent a participant information sheet with a confirmation email.

6.2.1.2 Data collection and process for workshops

Workshops took place on Microsoft® Teams and were recorded via the Teams® software with an audio recording device used as a backup. Where participants could not access Microsoft® Teams they were asked to join by telephone. Workshops were planned to not exceed ninety minutes. Topic guides (**Appendix 7**: sub-appendices 2 and 3) were reviewed by members of the supervisory team and patient and public involvement (PPI) members before the sessions.

Obtaining consent

In advance of the workshops, participants were sent a consent survey electronically with their confirmation email and were asked to complete it at least 24 hours before the session. At the start of each workshop, I ensured verbal consent was obtained from all participants. Additionally, participants were reminded of the confidentiality arrangements and the ground rules for the sessions.

Planning co-design workshop

One week before the planning co-design workshop, I emailed all participants a two-page written summary of the topics identified through the rapid analysis of the focus groups and interviews, as well as the results of the systematic review (see Section 5.2.4). A link to a video summary was also provided. During the workshop, we reviewed and discussed the findings from the systematic review and the insights from the patient and practitioner focus groups and interviews. Participants contributed verbally or in the chat. Together, participants identified and agreed the priorities for optimising pharmacist-led medication reviews and explored strategies to address and implement these priorities effectively in a primary care setting.

Development of the guidance document

During the planning co-design workshop, participants agreed that the priorities for optimising pharmacist-led medication reviews could be addressed through the development of a document to support how they are delivered in primary care. In my protocol I had expected to develop a service specification, however, participants explained that this would not be useful due to the existing frameworks. Between the planning workshop and the refinement and acceptability workshops, I drafted a guidance document, which was reviewed by my supervisors before being circulated to participants.

Refinement and acceptability workshops

One week before the refinement and acceptability workshops, I sent participants the draft guidance document along with a summary of key themes from the systematic review, focus groups, interviews, *and* workshops. This new summary document was circulated to provide context for the guidance document. Participants were asked to review the draft, make notes of any queries, and prepare to discuss these during the workshop.

During the refinement and acceptability workshops, participants were invited to share their overall opinions on the guidance document, including its acceptability, practicality, and perceived effectiveness. Feedback from both pharmacists and patients was used to refine the guidance document further.

6.2.1.3 Data analysis

I analysed the workshop transcripts using thematic analysis methods as described in Section 5.2.1 After familiarising myself with the data, I assigned labels to key concepts related to the characteristics of an optimised pharmacist-led medication review. These labels were then systematically grouped into broader themes, and I cross-checked them against the original data,

refining and adjusting as necessary. Once finalised, each theme was given a clear, descriptive name, and supporting statements were extracted from the transcripts to illustrate and substantiate the findings.

Data from the planning co-design workshop were analysed as a single dataset, and data from the parallel patient and pharmacist refinement and acceptability workshops were combined and analysed as one dataset. This approach helped identify key uncertainties in the delivery of pharmacist-led medication reviews and allowed integration of these findings with results from the systematic review, focus groups, and interviews. The synthesis informed the development of a draft guidance document outlining the proposed structure and implementation of an optimised medication review. This draft was then presented in the refinement and acceptability workshops, where participants provided feedback and suggested modifications. These discussions generated a new dataset, which was subsequently analysed to further refine and enhance the guidance document.

6.2.2 Procedures for acceptability testing of the guidance document

Acceptability testing of the guidance document followed this order:

- Delivery of medication reviews by pharmacist using the guidance document.
- Semi-structured interviews with patients to collect their thoughts following their optimised medication review.
- Semi-structured interviews with pharmacists at the end of the study period to review the acceptability and perceived effectiveness of the guidance document in optimising medication reviews.
- Revision of the guidance document following participant feedback.

6.2.2.1 Recruitment and sampling

Pharmacist recruitment

I aimed to recruit ten primary care network/ GP practice pharmacists across Norfolk and Suffolk to conduct early acceptability testing of the guidance document. This sample size was determined by time and financial limitations of the PhD. Geographical restrictions were imposed to limit the amount of time I would spend travelling to participating sites.

I emailed an expression of interest form to all pharmacists from the focus group (Chapter Four) and co-design workshops who had expressed an interest in testing the guidance document. In addition, the study was advertised on social media (Facebook®, Twitter/X®, Linked In®) and the research team used existing contacts in pharmacy networks to generate interest in the study. The inclusion criteria for pharmacists were that they were:

- Registered with the General Pharmaceutical Council.
- *Have a prescribing qualification and advanced assessment and history taking skills or were enrolled in a current training pathway to develop this qualification and skills.
- Had consented to utilise the guidance document for optimised pharmacist-led medication reviews during the study period.
- Regularly undertook medication reviews as part of their practice.
- Provided informed consent.

*I spoke to one local pharmacist who said that the inclusion criteria of being a prescriber was restrictive as many local pharmacists were still undertaking their prescriber training. An amendment was submitted through IRAS to include pharmacists who were undergoing prescribing training.

Prospective pharmacist participants completed an online expression of interest form, which assessed the inclusion criteria for the study. Participants were asked to provide their work postcode to give an indication as to the geography and degree of social deprivation. I used the index of

multiple deprivation (IMD) as a measure of the area in which participants worked [270]. Through the online expression of interest form I was able to collect data about participants' gender, age, and ethnic origin. This data was captured to facilitate selection of a diverse sample through purposive sampling. Data was collected using JISC© online surveys, the UEA's recommended platform to facilitate conformation to General Data Protection Regulation (GDPR).

Patient recruitment

Pharmacists were asked to recruit five patients from their practice. Potential patient participants were provided with a participant information sheet at least one day prior to their scheduled medication review. Convenience sampling was employed to recruit two out of the five patients from each site who consented to be interviewed. Convenience sampling refers to a method where participants are selected based solely on their availability [127]. The maximum patient recruitment target was twenty participants across the ten sites. Limited resources, including time and financial constraints, restricted the number of interviews conducted.

When pharmacists identified patients in their practice who were due for a medication review, they assessed the patients' eligibility for inclusion in the study. The inclusion and exclusion criteria for patient participants were as follows:

Inclusion

- Aged 18 years or older.
- Due for a medication review by the practice pharmacist.
- Ability to effectively communicate in English.
- Ability to provide informed consent.

Exclusion

- Had no access to telephone or internet.

6.2.2.2 Data collection and process for acceptability testing of the guidance document

Semi-structured interviews with patients and pharmacists were conducted following medication reviews to explore participants' attitudes and responses in greater depth. This approach provided detailed insights into their thoughts, feelings, and experiences, generating rich qualitative data to inform the study's objectives.

The APEASE criteria, as defined in the Behaviour Change Wheel, were used to frame the interview questions, with a focus on acceptability, practicability, and effectiveness[271]. Although the guidance document was not explicitly structured around Behaviour Change Techniques (BCTs), its development was informed by systematically coded BCTs from the systematic review in Chapter Four. Applying the APEASE criteria ensured that the evaluation of the guidance document was grounded in behaviour change principles while also assessing its acceptability and practical value in primary care.

Pharmacists selected for participation were provided with the Organisation Information Document (OID) (**Appendix 7, sub-appendix 28**) and asked to complete the consent form. The OID outlined how the study would be delivered, the activities required of participating organisations, the level of investigator oversight, and the agreed financial arrangements. As a non-commercial, non-interventional study, the OID served as the contract between the sponsor and the participating organisation [272]. Once pharmacists completed recruitment, I contacted them by email to arrange interviews.

For patient recruitment, pharmacists confirmed at the start of the medication review whether patients had read the study information and were interested in participating. Patients who declined were reassured that their care would not be affected. Those who agreed signed a consent form, and

those willing to be interviewed also consented to their contact details being shared with the researcher (see **Appendix 10** for participant information sheets and consent forms).

Signed consent forms were stored securely at the GP practice for up to four weeks. Pharmacists then uploaded patient details (name, email, and telephone number) to a secure, individualised OneDrive folder. Each pharmacist had a dedicated folder, ensuring patient information was visible only to the pharmacist responsible for their care and the researcher.

I contacted consenting patients within 24–48 hours to confirm participation, ensure they had received the information sheet, and arrange a suitable time for the follow-up interview.

6.2.2.3. Data analysis

Transcripts of the workshop and interviews were generated using Microsoft® Teams and subsequently checked for accuracy. NVivo® software was used to assist with the analysis, which was conducted using thematic analysis methods, as described in Section 5.2.1. [273].

Following this approach, I familiarised myself with the data before assigning labels to the acceptability, practicability, and effectiveness of the guidance document to deliver the pharmacist-led medication review. These labels were then systematically grouped into broader themes, which were cross-checked against the original data, refined, and adjusted as necessary. Each finalised theme was given a clear, descriptive name, and supporting statements from the transcripts were extracted to illustrate and substantiate the findings.

An inductive approach was adopted to allow themes to emerge directly from the data, ensuring that the analysis remained grounded in participant perspectives rather than predefined theoretical

frameworks. Given the distinct roles of pharmacists and patients in the medication review process, their interviews were analysed separately to capture their unique expectations and experiences as those delivering and receiving reviews, respectively.

6.2.3 Ethical considerations

Permission and approval from this study was sought from NHS Research Ethics Committees through the Integrated Research Application System (IRAS) (application number 313644). It was given a favourable ethical opinion by the NHS Health Research Authority (see **Appendix 10** for letter of approval) and was registered and posted on the ClinicalTrials.gov public website (ClinicalTrials.gov Identifier: NCT05928104).

Pharmacists and management representatives from participating practices provided consent for the study and confirmed their capability and capacity to participate. The NHS Norfolk and Waveney Integrated Care Board granted access to the primary care sites for the study (see **Appendix 11** for the letter of access). Pharmacist informed consent was obtained electronically via expression of interest forms and verbally at the start of their interviews at the conclusion of the testing period.

Participants' personal information was securely stored and accessible only to the researcher and the supervisory team. Pharmacist participant information was collected using the JISC© online survey platform, which conforms to General Data Protection Regulation (GDPR) standards. Patient data was uploaded to a secure OneDrive folder, accessible only to the submitting pharmacist and the researcher. The study adhered to the principle of data minimization, collecting only information that was relevant and necessary. Importantly, the researcher did not access patient medical records, or any other information held at the GP surgery. All data were reported confidentially, with participant responses anonymised.

The patient participant information sheet, consent form, and interview topic guide were reviewed by Patient and Public Involvement (PPI) members before being submitted as part of the integrated research application form. Interview topic guides were also piloted with the supervisory team before interviews with pharmacists and patients commenced.

Once participation was confirmed, pharmacists received an electronic version of the guidance document. Meetings were scheduled at the pharmacists' workplaces (GP surgeries) to allow the researcher to address any questions from the pharmacists and their colleagues. During these visits, hard copies of the guidance document, patient participant information sheets, and consent forms were provided.

Pharmacists were asked to recruit patients over a maximum period of four weeks. Eligible patients were contacted by their pharmacist by phone, email or letter in advance of their medication review and provided with an explanation of the study. Patients were given participant information sheets and consent forms to review.

6.3 Results

6.3.1 Co-design workshops

6.3.1.1 Uptake and attendance

Three pharmacists, one GP and two patients expressed an interest in participating in the planning co-design workshop. However, on the day of the workshop, unexpected events meant that the GP was not able to participate. As a result, the planning co-design workshop had only five participants. The patient refinement and acceptability workshop had four participants. Six pharmacists expressed an interest in attending their refinement and acceptability workshop; only three pharmacists were

able to attend the workshop. The characteristics of the participants of the co-design workshops are reported in **Table 6.1**.

Table 6.1 Characteristics of participants in co-design workshops

		Parallel workshops	
	Planning co-design workshop	Patient refinement and acceptability co-design workshop	Pharmacist refinement and acceptability co-design workshop
	N (%)	N (%)	N (%)
Sample size	Patient n=2 Pharmacist n=3 Total n=5	Patient n=4	Pharmacist n=3
Gender			
Female	2 (40)	1 (25)	2 (67)
Male	3 (60)	3 (75)	1 (33)
Age group (years)			
20-30	2 (40)	2 (50)	
31-40	1 (20)		1 (33)
41-50	1 (20)	1 (25)	1 (33)
51-60	1 (20)		1 (33)
61 years and older		1 (25)	
Ethnic group			
Asian or Asian British	1 (20)	1 (25)	1 (33)
Black, African, Black British or Caribbean	1 (20)	1 (25)	
White	3 (60)	2 (50)	2 (67)
Index of multiple deprivation (IMD)			
1		1 (25)	
2	1 (20)	1 (25)	
3	2 (40)	1 (25)	1 (33)
4	1 (20)		1 (33)
7		1 (25)	
9	1 (20)		1 (33)

6.3.1.2 Planning Co-design Workshop

The aim of the planning workshop was to engage stakeholders in co-designing an optimised pharmacist-led medication review. At the commencement of the workshop, all participants confirmed that they had read/ watched the information that had been sent to them in advance of the session. However, I provided a brief precis of this information so it would be fresh in the minds of the participants. I started the workshop by asking participants if they agreed with the topics identified in the rapid analysis of stakeholder feedback and the conclusions from the systematic review (Chapter Four). Participants agreed with the topics that had been synthesised from the rapid analysis of the focus groups/ interviews (what patients and practitioners think) and the components that had been identified from the literature in the systematic review (what is more likely to make a medication review work).

I explored with the participants what they thought an optimised pharmacist-led medication review should entail. Five themes emerged from the analysis of the discussions in this workshop: defining medication reviews, pharmacist support, preparing for the medication review, patient-centred medication reviews, content of the medication review. No new uncertainties relating to the implementation of pharmacist-led medication reviews were identified in this workshop. The emergent themes, illustrative quotes and the ways the theme informed the co-design process are reported in **Table 6.2**.

Table 6.2 Description of themes from the planning workshop including illustrative quotes and the ways the theme informed the co-design process

Overarching theme	Brief description of theme	Illustrative quotes/ excerpts from workshop discussions	Impact on co-design process
Defining medication reviews	Participants discussed the different healthcare professionals involved in the medication review process. Participants described that the administration team are primarily responsible for identifying patients for medication reviews. A pharmacy technician may be responsible for reviewing hospital discharge letters and adding new repeat medications to a patient's record. Pharmacists suggested that the document could be used by all members of the practice team, and not just pharmacists, as all medication reviews should be delivered to the same standard and the whole practice team should be aware of what happens in a medication review.	"I think it's useful having information for the support workers… We have such a high turnover and they just haven't got a clue what the medication review is, what it's meant to do….So I put together some guidance so they could understand it. So when the patients asked, they knew what to say to the patient." (**Pharmacist 2 Part-time GP pharmacist**) "The whole structured medication review versus medication review causes a lot of confusion … in my practise, if it's a full structure medication view, it's between 20 and 30 minutes. Whereas if it's just a standard one, it will be 10…But sometimes you get people booked in the wrong slots. (**Pharmacist 1 Part-time GP pharmacist**)	Document should define pharmacist-led medication reviews and what happens in them and the roles of different healthcare professionals in the process.
Pharmacist support	Participants discussed the results of the literature review which suggests that medication reviews with more experienced pharmacists are more likely to improve outcomes. The discussion evolved to how pharmacists can gain experience and confidence. Pharmacists strongly agreed that pharmacist support was important in their role. Pharmacists often work in isolation; therefore, it is important that there is a support network	"I think … gaining their confidence in a particular area really helps 'cause then they can then move on and develop to do something else and things like that." (**Pharmacist 2 Part-time GP pharmacist**) "The SMR (structured medication review) guidance, it's look at 10 or more [medicines], which is fine, but that takes a long time. But if you're newly qualified, that would absolutely terrify you … That's maybe where the one condition fewer meds might work nicely as a starting point." (**Pharmacist 1 Part-time GP pharmacist**)	Discussions suggest that the document should signpost to support and encourage pharmacists to undertake medication reviews in areas where they have the necessary skills and experience.

	in place where pharmacists can go to for advice. Where pharmacists are not yet prescribers, participants highlighted that it needs to be clear who at the practice will following through on action points.	"There's a number of different elements in terms of what I think experience actually is… [its] quite difficult to build and get and it's important to gain feedback... having read different pharmacist medication reviews is quite variable in terms of what's documented, what's been done, how that's being done and things like that. And there's no real standardisation in terms of what's to be done." (**Pharmacist 2 Part-time GP pharmacist**) "When I was first starting out in primary care, if I didn't have access to a GP mentor or a senior pharmacist, it was more difficult to do, or confidently do a thorough medication review because you didn't have those people to go to. Whereas, when, you know, in previous roles and current roles, there are people that who are more senior that I've been to and have helped me. And then you've got GP mentors, and I think that's quite important … as you develop as a pharmacist, in terms of who you work with locally." (**Pharmacist 1 Part-time GP pharmacist**) "…in some ways you need… those dreaded protocols and what your [GP] is happy for you as a pharmacist…to change … you do need that written down somewhere." **(Pharmacist 3 Full-time GP pharmacist)**	Document should signpost to existing protocols within the GP surgery.
Preparing for the medication review	Participants reiterated that advance notice of the medication review helps pharmacists and patients better prepare. Participants highlighted that booking the right type of appointment is essential; a full structured medication review can take between 20 and 30 minutes, whereas a	"We have some receptionists who get what I do. So, patients will come with their medicines in a bag, if they're on loads, and we want to have a look. And that works really well. And others… turn up and don't know why they're there …It is much better when they know. And the short letter or something or even a video… that might help people." (**Pharmacist 1 Part-time GP pharmacist**)	Discussions suggest that the document should highlight the activities that should/ could be undertaken in advance of patient consultation. It should

	simpler review will have a standard ten-minute appointment time. Pharmacists identified that clinically assessing the patients' medicines and clinical monitoring results is an activity that should be done before the consultation with the patient.	"The SMR (structured medication review) guidance, it's to look at 10 or more [medicines], which is fine, but that takes a long time… because you've gotta go through each one's indication, side effect, blood monitoring, you know." (**Pharmacist 1 Part-time GP pharmacist)**	also contain directions as how to inform patients of their medication review in advance.
A patient-centred medication review	Participants made suggestions to facilitate a patient-centred medication review. It was suggested that the first step is for patients to understand the purpose of the medication review; this will help the patient to decide their agenda. When the pharmacist has ascertained the patient's agenda, this can be built upon to explore their ideas, concerns, and expectations; the content of the medication review should reflect this. Building rapport with the patient helps facilitate a patient-centred review by creating an environment where patients feel they can expression their questions or concerns. Follow-up appointments help with rapport building and are useful to ascertain whether the patient agreed actions have been appropriate and if any problems have arisen since the medication review.	"I think patient involvement is very necessary because all of goals achieved at the end and also communication between Pharmacists, GP and nurses is very important to improve quality of care of the patient or client." (**Patient 1 Male**) "[as] the end decision maker… you can make the decision, you can prescribe, you can do it. And sometimes that is going against guidelines because it's more important to the patient." (**Pharmacist 1 Part-time GP pharmacist**) "You then start talking to the patient … sometimes what they struggle with … is that I've got this long list of drugs but can't work out how to work out things… Communication skills should be covered in school training as [patients] really would like the open questions and things like that." (**Pharmacist 2 Part-time GP pharmacist**) "There may be some [patients] who definitely come in with an agenda which is really helpful at times cause you can guide it around. And so I think it's an important sub point to include explore the patients as we always say their ideas, their concerns etcetera, but it's then you are trying to look at the whole lot if you're gonna try reauthorize them for the next 6 to 12 months or three months depending on what it is." (**Pharmacist 1 Part-time GP pharmacist**)	The document should provide guidance on how to facilitate a patient-centred review. This will include prompts for pharmacists to evaluate their communication skills, reminders to negotiate a shared agenda and to involve patients in setting goals. Plans to follow up with the patient should be part of the medication review process.

		“When I did my prescribing, it was all about deprescribing ‘cause it was all in care homes. And basically if there's no follow up, you soon saw how it all just failed... the follow up does then help you identify problems and … the follow up just helps then with the rapport, so that doesn't have to be at the half an hour or the 20 minutes, it might just be a 5 or a 10 minute follow up call but it's a good way to catch problems and avoid problems.” (**Pharmacist 1 Part-time GP pharmacist**)	
Content of the medication review	Participants discussed what they thought an “optimised pharmacist-led medication review” should look like. Pharmacists identified that there are existing templates that identify what should done in a medication review and suggested that the document focussed on how they should be done, allowing flexibility for the presenting patient. Due to variability within each practice, it was proposed that the guidance document should not explicitly specify what should be done, before, during or after the patient consultation, but should pose reflective questions that patients, practitioners, and practices can consider whilst implementing medication reviews.	“There are medication review templates that say ‘consider these things’, tick it when you've done them, they have their benefits, they have their cons. You … get to know which of it you want to use and which you don't. But if it's more about the education and training bit, then probably a document that describes how you do it, that you can read. If this is your first time doing it and process it, but then maybe as shorter summarised version that you might just have it in your clinic … so you can look out quickly if you need to.” (**Pharmacist 1 Part-time GP pharmacist**) “I think as a … new pharmacist going into primary care … what would be useful would be the things that you need to get put in place before you start doing the med[ication] reviews, you know like how are you gonna deal with queries… And I think it's difficult to know what to put into what you should be doing in a medication review in a document, because … it's really dependent on what drugs they're on ... teach them [pharmacists new to the practice] how to structure it in terms of how to look at things, you know, like how to match up your drugs with the conditions have to then work out whether they're not optimised therapies and things like that.” (**Pharmacist 2 Part-time GP pharmacist**)	The discussion confirmed that pharmacists did not want a prescriptive guide of what to cover in a medication review, rather a guidance document of how to do a “good” medication review

		“I definitely think having some type of … questions to ask before you start doing this is useful, cause otherwise you can… start doing stuff and then it's hard to pull back on what you're doing, if it's not quite right.” (**Pharmacist 2 Part-time GP pharmacist**)	

6.3.1.3 First version of guidance document

Following the planning workshop, I drafted a guidance document to support the implementation of pharmacist-led medication reviews in primary care (**Appendix 9**). The document outlines its origins, defines medication reviews, poses reflective questions for pharmacists about their skills, knowledge and experience, and provides guidance on the content and processes that should take place before, during, and after the medication review patient consultation.

6.3.1.4 Refinement and acceptability co-design workshops

The aim of the refinement and acceptability workshops was to further develop the content and processes within the guidance document, drawing on feedback from both pharmacists and patients. At the start of each session, participants confirmed they had reviewed the draft guidance document and the accompanying summary of key findings from the literature, focus groups, and planning workshop. I introduced the workshops by outlining the structure of the guidance (activities to be considered before, during, and after the consultation) and explaining the rationale for this format, before inviting participants' feedback.

Both patients and pharmacists agreed that the guidance reflected existing knowledge and addressed previously identified uncertainties. Patient participants welcomed the emphasis on patient involvement and highlighted the value of receiving advance notice of reviews to prepare questions, noting this would not be burdensome; on participant asked if the document would be available to patients to help them better prepare. Patients did express concern about the potential added workload for pharmacists. Pharmacists felt the guidance provided clear instructions on how to conduct medication reviews and useful signposting to resources, though they also identified some practical challenges in implementation.

While much of the discussion echoed points raised in the planning workshop, analysis of the transcripts revealed three additional themes. These themes, with illustrative quotes and their influence on the co-design process, are presented in **Table 6.3.**

Table 6.3 Themes from acceptability and feasibility workshops including illustrative quotes and the ways the theme informed the co-design process

Overarching theme	**Brief description of theme**	**Illustrative quotes/ excerpts from workshop discussions**	**Impact on co-design process**
Challenges with existing medication review processes	Pharmacists acknowledged the challenges with the existing processes. Participants affirmed the importance of booking the right appointment for the right patient and described some of the challenges with the current process.	"…the SMR [structured medication review] stuff is so wishy washy…the guidance doesn't give you how long you should be given for a time for an SMR…what you should really be doing… you see such a different practice; …some pharmacists getting 45 minutes… some pharmacists … get 10 minutes and that's it. And I think having that guidance will help those as well that and say well look hang on a sec, this is what I'm expected to do, and this is how I'm expected to do it." (**Pharmacist 1 part-time GP pharmacist >5years FG 1D 1E**) "… if they gave me a one-hour slot, I could ping it in as a meeting and say, right, I'm not gonna be available for that hour... But just to say, sometime this afternoon somebody's going to call you. It's really tough to fit that in when you're working." (**Patient 2 1E**)	Use of guidance document may help to standardise practice. patients requiring a more defined appointment time, it was suggested that patients be given a choice of a telephone or face-to-face review.
Positive impressions of the guidance document	Participants felt that the guidance document had a good balance of knowledge and signposting.	"I think … it's got a good mixture of explanation and of what to do, how to do it and also some additional resources to refer to which I thought	Use of the guidance document could help to establish a standard of practice that is transferable across sites.

	Participants appreciated that the document was patient orientated and approved of its focus on preparing patients for the review, commenting that better preparation will lead to more detailed patient responses.	was quite a nice kind of combination of the two." (**Pharmacist 1 part-time GP pharmacist >5years FG 1D 1E**) "I think it just gives people a better understanding of what a medication review is about …a rough explanation or what is expected … and what the outcome of that would be and how that …benefits the patient and practice going forward." (**Pharmacist 2 part-time GP pharmacist >5years 1D 1E)** "I thought they were lovely questions, and I'd like to print them out and put them up on the walls of my surgery because I thought they were great questions to get a conversation going." (**Pharmacist 3 full-time GP pharmacist >10 years FG 1D 1E**) "I like the patient preparation; we're talking about involving the patients, the policies and the procedure communication and the follow up. That was quite interesting to see." **(Patient 1 FG, 1E)** "Is it possible for patients to see the guidelines?... if you let us know	Guidance document should include information about the medication review that can be accessed by patients. Key questions to be highlighted and signposted for use as a prompt.

		more about what what's going on in the medication review, we can come better prepared and give you more fuller answers." **(Patient 3 FG, 1D, 1E)**	
Areas of improvement	Participants indicated that the document needed more clarity around the role of the pharmacist and definitions of medication reviews.	"Just it's the bit about the role of pharmacists and GP surgery is not well understood. … I have come across a lot of patients like 'I don't want to speak to you. You can't do anything for me' sort of thing… But I think it's (the guidance document) quite good for the person who, at the point of booking to kind of like briefly to explain the role pharmacists as well." (**Pharmacist 2 part-time GP pharmacist >5years 1D 1E**) "I think that's quite useful to have, and I know that we spoke about not putting anything clinical in it in terms of … what you should be doing as part of the…medication [review] but it might be useful as part of the resources … linking to things like the anticholinergic stuff … so that if they did want to do further learning,… there is that kind of linkage to potential places to look at." (**Pharmacist 1 part-time GP pharmacist >5years FG 1D 1E**)	Reinforce the guidance document as a tool to educate other staff members about the pharmacist's role and process of a medication review. Additional resources added to guidance document as suggested by participants.
Key: FG= participated in focus group discussion 1D= participated in planning workshop 1E= participated in refinement and acceptability workshop			

6.3.1.5 Second version of guidance document

Following the patient and pharmacist refinement and acceptability workshops, I re-drafted the guidance document in anticipation of its testing in phase two (Chapter Five); this revision is found in **Appendix 12.** Following feedback from the workshops, I made the document more concise whilst ensuring I did not omit any important details. In addition, I improved the clarity and flow by integrating the reflective questions into the relevant sections to enhance readability and enhanced its usability by including a more accessible list of prompts to guide the patient consultation. The revision to the guidance document reinforces the structured approach to medication reviews (content and processes that should take place before, during, and after), while maintaining its role as a reflective and educational tool.

6.3.2 Testing of guidance document to support the delivery of pharmacist-led medication reviews in primary care

6.3.2.1 Uptake and attendance

Four pharmacists initially agreed to test the guidance document in practice, although one later withdrew due to unexpected workplace changes. The characteristics of the participating pharmacists are shown in **Table 6.4.**

Across the three participating practices, thirteen patients (five female and eight male) consented to receive a medication review using the guidance document and to be contacted for a follow-up interview. No patients declined participation. One pharmacist, who worked part-time and had annual leave, was unable to recruit five patients within the study period; however, I was still able to select

two patients from their site for interview. In total, six patients (three female and three male) were conveniently sampled for interviews, with two participants recruited from each practice.

Table 6.4 Characteristics of pharmacists recruited to test the guidance document

	Pharmacist
	N (%)
Gender	
Female	1 (33)
Male	2 (67)
Age group (years)	
20-30	1 (33)
41-50	1 (33)
51-60	1 (33)
Ethnic group	
White	3 (100)
Index of multiple deprivation (IMD)	(work)
3	1 (33)
6	1 (33)
7	1 (33)

6.3.2.2 Themes from pharmacist interviews

The pharmacist interviews aimed to assess the acceptability and relevance of the guidance document in supporting pharmacist-led medication reviews in primary care. Interviews began by asking pharmacists how they had used the guidance document in preparation for reviews, followed by questions about its perceived strengths and weaknesses. Transcripts were analysed thematically [273].

Pharmacists' feedback often echoed points raised in the co-design workshops: the guidance was viewed as a useful educational tool, clearly outlining the structure of a medication review and reinforcing the importance of scheduling appropriate appointments. They also reiterated challenges such as limitations of current software and insufficient time. However, the analysis also revealed three new themes, which are presented in **Table 6.5** alongside illustrative quotes and their implications for the co-design process.

Table 6.5 Themes from pharmacist interviews including illustrative quotes and the ways the theme informed the co-design process

Overarching theme	**Brief description of theme**	**Illustrative quotes/ excerpts from workshop discussions**	**Impact on co-design process**
Aspects of the guidance document that pharmacists found acceptable and practical	Pharmacists appreciated the concise nature of the guidance document and its easy-to-navigate layout. They recognised that key steps in the medication review consultation and valued the inclusion of prompts to guide the process. Pharmacists also emphasised that contacting patients in advance enabled them to prepare more effectively, which in turn supported more meaningful and productive consultations.	"I really liked the length. I thought it was something that you were able to zip through." **(Pharmacist 1 Full-time GP pharmacist > 10 years**) "I think that is good that it's nice and it's pretty brief." **(Pharmacist 2 Full-time GP pharmacist <5 years)** "It's kind of laid out in a way you can just quickly flick through it, which was, yeah, worked pretty, pretty well, I'd say." **(Pharmacist 2 Full-time GP pharmacist <5 years)** "I think because I spoke to these people over the phone and booked them in for a medication review, they were thinking about it [the review]. By the time I spoke to them the next week and it made it meaningful from my point of view and their point of view and that kind of thought about it and saved up their questions for me… so I think that advance notice made it better." **(Pharmacist 1 Full-time GP pharmacist > 10 years**)	The guidance document should maintain a concise structure and remain easy to navigate, with the use of clear headings and bullet points to enhance readability.

		"Most of the people I actually spoke to, we came up with problems that really needed sorting, but they hadn't mentioned them at all before. Then you think how long would this have gone on for if we didn't have this opportunity to do it now?" **(Pharmacist 2 Full-time GP pharmacist <5 years)**	
Supports better practice	Pharmacists acknowledged that their clinical training and communication skills enabled them to conduct medication reviews effectively. However, they reported that certain elements highlighted in the guidance document were not routinely incorporated into practice. Specifically, goal setting and action planning were often overlooked, and the guidance document provided useful prompts to ensure these steps were consistently included.	"I think generally we do things, or certainly… once you've got experience… you hope you do things fairly well. But there's always … one bit you miss out…whether it's organizing follow up…or you know … goal setting at the start, ...So it definitely gives you a good reminder of all those things." **(Pharmacist 2 Full-time GP pharmacist <5 years)** "Action planning and goal setting… goal setting that isn't something that I do very often… that's something I'm going to do more of." **(Pharmacist 1 Full-time GP pharmacist > 10 years**)	
Suggestions to improve the effectiveness of the guidance document	Overall, the guidance document was well received. Pharmacists requested that the prompts for the medication review, that is, aim of the medication review, Involve and engage the patient, process for undertaking medication review, action plan and goal setting, be presented in a	"The guidance document is quite useful. I think it would …be good at the beginning, maybe to have some kind of a circular overview just only communicating that you're gonna end up coming into this medication review situation from different angles… because when you get the document, it looks like it's a kind of a (linear) process thing."	Update the prompts for the patient consultation into a cyclical process. Include in the guidance document a concise overview of the medication review process. Make these accessible for display in the consultation room to be used as a prompt.

	separate cyclical not linear format, without the explanations, to be displayed in the clinic room as an aide memoir.	**(Pharmacist 1 Full-time GP pharmacist > 10 years**) “When you're in a Med(ication) review with limited time, a summary version, maybe like one- sided prompt… you can have on the wall that's big enough to just think…like a memory jog.” **(Pharmacist 3 Part-time GP pharmacist >5 years)**	

6.3.2.3 Themes from patient interviews

The patient interviews aimed to explore their experiences of a pharmacist-led medication review conducted using the guidance document. Interviews began by asking patients to reflect on their recent consultation with the pharmacist. They were invited to comment on their preparation for the review, the opportunities they had to contribute during the consultation, and their confidence in managing their medicines afterwards. Transcripts were analysed thematically [273]. Three themes were generated: expectations and content of medication reviews, the importance of preparing for the review, and patients' feedback on pharmacists during medication review.

Theme 1: Expectations and content of the medication review

Each of the participants attended their medication review with a different expectation. Some patients had never had a pharmacist-led medication review and did not know what to expect:

> "I spoke to request a telephone appointment from the doctor… they scrapped it the day before. So I rang the next week, which is what they asked me to do and I said I just need to speak to somebody about these meds and they said, oh, the pharmacist can do that." (**Patient 1)**
>
> "I didn't really know what to expect (from the medication review). I mean, I had it done … where I get my medication from, but I've never had one down at the doctor's before." (**Patient 3)**
>
> "Whether I need to keep taking them (medicines)… I have been taking them a long while." (**Patient 5)**
>
> "All my life, I've been having that medication for asthma, eczema. It was always a doctor for all these medications… they (the surgery) wanted me to have a review… they phoned and I had to go and see somebody. So I saw the lady there and she explained what I needed to take." (**Patient 6)**

Some patients requested a medication review, and others were identified by the practice. In many cases patients were not aware that the pharmacist could review their medication and consequently this may have altered their expectations of the medication review.

Patients provided insights into how their expectations shaped the review process:

> "Oh it's just that I take two lots (of medicines), but one of them, I've been taking quite a long while and the other one not long. So she … took my blood pressure." (**Patient 5)**
>
> "We really did just discuss the dosage and… when I take them… also side effects; that was quite important because one of the meds is causing me side effects I wanted to look at dosage." (**Patient 1)**

In both instances, the pharmacists tailored the content of the medication review to meet the specific needs and concerns of the patients. Patient 5 expressed a concern about the efficacy of one of their medications, which prompted the pharmacist to measure their blood pressure, while Patient 1, experiencing side effects, asked the pharmacist to review the dosage of their medication. These examples highlight the responsiveness of the pharmacist to individual patient expectations, emphasising the importance of patient-centred care.

Theme 2: Advance notice of medication review

The following quotes illustrate the positive impact that advance notice had on patient engagement and preparation for the medication review:

> "Because I had (questions) in my head, I asked them straight away. I'm a fairly straightforward person when I've a got a concern, and I knew what I wanted to know." (**Patient 1)**

> "I was contacted by (the pharmacist) …he rang me and said he would like to make an appointment to have a medication review … (later, it was) him going through my medication

and making sure that, you know, I was OK with them and but asking, you know, are they helping with my pain? And to do my best to try and lower the dose which I did, we did try to lower the dose once, but I was in more pain. So I'd like to go back." (**Patient 2)**

Both patients demonstrate the importance of being contacted in advance, as it allowed them to reflect on their medications, prepare any questions or concerns they had, and actively engage in the review process. For Patient 1, this resulted in a focused conversation where concerns were directly addressed. Patient 2 reflected on the process of lowering medication dosage, indicating a partnership in decision-making with the pharmacist.

Theme 3: Patients' feedback on pharmacists during medication review

The following quotes demonstrate the positive impact of a friendly and approachable manner in the medication review process. By creating a relaxed and non-judgmental environment, pharmacists made patients feel comfortable, encouraging them to discuss their concerns freely. **Patient 3** specifically contrasts this with previous experiences, noting that the pharmacist's friendly and attentive approach stood out, leading to a feeling of being genuinely listened to.

Patients' willingness to return for reviews, as mentioned by **Patient 2**, further emphasises the importance of a good rapport and thorough communication in building trust and fostering an ongoing relationship with the pharmacist:

Patients described pharmacists as friendly, pleasant and thorough, and the responses indicated that pharmacists had built rapport with the patients, facilitating ease of discussion and an ability to raise questions or concerns.:

"I came away feeling quite pleased that he was so nice and friendly because I have had them done in certain places and they've been a bit talk down to you, but it was it was just a friendly chat, which I found really nice, actually. I did feel that I've been listened to." (**Patient 3)**

"It was very relaxed and chatty, so it was very nice. He did say if I had any thoughts about something afterwards, just to give him a ring." (**Patient 1)**

"I think I might have a review with (the pharmacist) before. I think this one was more thorough." (**Patient 2)**

"I could have discussed anything with him" (**Patient 2)**

"I think (the pharmacist was) very thorough and very pleasant." (**Patient 5)**

The patients' responses highlight the significant role that rapport-building plays in the success of pharmacist-led medication reviews.

In addition to the three themes that emerged, I also noted that patients reported a variety of outcomes from the medication reviews, from reassurance that their medication is working to control their long-term condition, to medication changes and referrals to other healthcare professionals.

6.3.3 Third and final version of guidance document

Following analysis of the pharmacist and patient interviews, I refined the guidance document. The final co-designed guidance document can be found in **Appendix 13** and pages 200-204. The content has been edited for clarity. The prompts for the patient consultation have updated to represent a cyclical process (**Figure 1 in the guidance document**), and I have included a concise overview of the medication review process (**Figure 2 in the guidance document**). These figures have been developed in a more accessible format suitable for display in the consultation room to be used as a prompt. It is important to note that the guidance is not intended to function as a standalone document. Instead, it has been purposefully designed, based on stakeholder feedback, to act as a practical signposting tool that directs users to relevant existing resources, frameworks, and training materials. This approach ensures that pharmacists can access additional support and detailed information as needed, without being overwhelmed by excessive content within a single document. The development of the guidance is an ongoing and iterative process, informed by continued feedback

from users and emerging evidence in clinical practice. As such, it is expected to evolve over time to remain relevant, user-friendly, and responsive to the changing needs of pharmacists and primary care teams.

Document to support the implementation of pharmacist-led medication reviews in primary care

Background

Who is this document for?

This document is primarily intended for **pharmacists delivering medication reviews** in general practice. It may also be useful for other healthcare professionals involved in the delivery of medication reviews.

What is this document for?

To ensure patients gain the most benefit from their medicines, pharmacists need the skills and confidence to conduct high-quality medication reviews [1]. The likelihood of patients experiencing harmful effects increases with the number of medicines they take [2]. Recognising this, the UK government has emphasised the importance of medication reviews, leading to the integration of pharmacists into general practice to increase their availability [2,3].

Despite the volume of reviews undertaken, up to 7% of hospital admissions in the UK are attributed to harmful effects from medicines [4]. Research suggests that medication reviews achieve high-quality outcomes only under specific circumstances [1].

This document has been developed using evidence from literature and discussions with patients and healthcare professionals. It outlines the circumstances under which medication reviews yield the best outcomes, aiming to benefit both patients and health systems. Additionally, it seeks to enhance pharmacists' skills and confidence, enabling them to deliver more effective medication reviews.

What is a medication review?

Discussions with patients and practitioners have highlighted confusion about what constitutes a medication review and its purpose.

For the purposes of this document, a medication review is defined as:

"A consultation between a pharmacist and a patient to review the patient's total medicines use with the aim of improving health outcomes and minimising medicines-related problems."

This definition aligns broadly with those from The National Institute for Health and Care Excellence (NICE) and the Pharmaceutical Care Network Europe (PCNE) [5,6] but has been adapted to better reflect current practice.

For further clarity:

- **Medicines reconciliation** is defined by NICE as *"the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated."* [7]

How should I use this document?

This document comprises two main parts:

Part One
Part One identifies key prompts to guide the medication review process. These prompts are summarised in **Figure 1**, which outlines the steps involved in the patient consultation. **Figure 1** is intended as a quick reference that can be printed and displayed in consultation rooms; it is also a reminder that medication reviews are not strictly linear.

Patients may begin the review by presenting their agenda, which can shift the review's focus. Similarly, action planning and goal setting may alter the consultation's direction. The review process – what you do and how you do it – will depend on the patient and the specific goals of the review.

Figure 2 is a concise overview of the medication review process. This could also be displayed in consultation rooms as concise practical summary.

Part Two
Part Two is designed for **reflection, reference**, and **education**.

- It includes questions that pharmacists can use to reflect on their practice and identify learning needs.
- Signposting sections and appendices provide resources relevant to the medication review process.
- It also offers educational material for practice staff, highlighting the pharmacist's role, the various types of medication reviews, and the importance of scheduling appropriate appointments for suitable patients.

This document is practical, adaptable, and educational for both new and experienced team members while supporting role evolution.

Figure 1. Process for patient consultation element of medication review

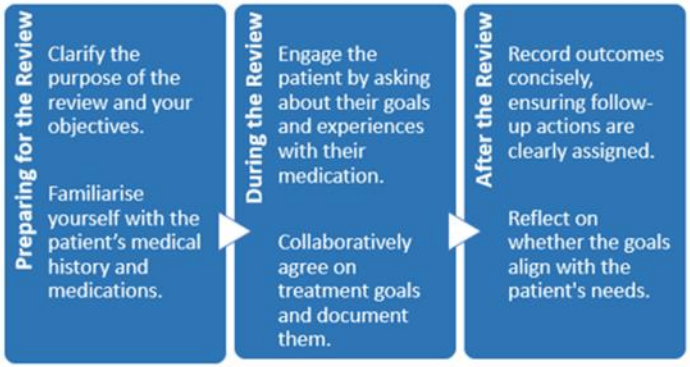

Figure 2. Concise overview of medication review process

Part One Prompts for Medication Review

Be clear on the aim of the medication review

At the start of the medication review, the pharmacist should have a clear understanding of what they aim to achieve. Defining the purpose of the review helps to guide its direction and identify measurable outcomes that both patients and pharmacists can use to assess its impact.

Example aims of medication reviews	**Potential outcomes**
Improve adherence	Patient is taking medicines as prescribed Patient is regularly ordering medicines
Minimise side effects from medication	Patient is well managed with fewer side effects
Reduce the number of medicines prescribed	Patient is well managed on reduced medicines

Involve and engage the patient in the review process

Actively engaging patients is crucial for a successful medication review. Allow patients time to prepare beforehand. Guidance on how to support patients in preparing for their review can be found in **Part Two**.

Understanding the patient's expectations at the outset is essential. Patients should have opportunities to:

- Ask questions
- Raise concerns
- Actively participate in discussions throughout the review.

Have a structured procedure for the medication review

For complex medication reviews, pharmacists often use templates to structure the process, though some develop their own frameworks based on general guidance.

Before the consultation, pharmacists should:

- Verify that all prescribed medicines remain suitable for the patient
- Review the original indications for the prescribed medicines
- Check relevant clinical monitoring parameters, such as blood test results.

Completing this preparatory work helps to evaluate the appropriateness of the medicines and establishes a clearer aim for the review.

Action plan and goal setting

Pharmacists and patients should collaboratively agree on treatment goals. Action plans should be documented in the patient's record to ensure accessibility for all healthcare professionals involved in the patient's care.

The action plan should record:

- Medication problem identified
- Action proposed
- Action by
- Planned outcomes (How do we know this has been achieved?)

Part Two

Before the Patient Consultation

Your Role in the Practice

Each pharmacist brings individual skills, experience, and expertise to their role. Summarising these for practice staff can help them better understand your contributions and effectively explain your role when booking appointments.

It is also helpful to be aware of the different staff members who support the medication review process. Some Primary Care Networks (PCNs) have websites that outline the roles of general practice team members, and the services provided within the PCN.

Space constraints can be a challenge in some practices. To ensure a smooth workflow, pharmacists should coordinate with practice management and support staff to secure consultation rooms for face-to-face reviews on planned days.

> Have all members of the practice team been briefed on medication reviews and their responsibilities in the process?
> Is there information available for patients to know what pharmacists do?

Signposting

- Appendix 2 includes an example description of the pharmacist's role in a GP practice. This can be customised to reflect your specific role and shared with staff or patients.
- The following link provides further details on the roles and responsibilities of pharmacy professionals in general practice: CQC Mythbuster on Pharmacy Professionals in General Practice.

Booking and Planning

Patient populations and priorities for medication reviews vary by practice. Each pharmacist or practice will have their own criteria to determine whether a consultation can be conducted via telephone or requires a face-to-face appointment.

Pharmacists can collaborate with support teams to implement an efficient booking system that clearly indicates:

- Whether the consultation is telephone-based or in-person, and
- Whether the patient requires a standard or extended appointment.

> Has a robust booking system been implemented?

Signposting

- For guidance on identifying patients eligible for structured medication reviews and extended appointments, refer to the Network Contract Directed Enhanced Service Contract for General Practice.

Supporting Patients to Get the Most Out of Their Medication Review

Patients should be given adequate time to prepare for their medication review. Pharmacists can work with the practice to determine how much advance notice is appropriate.

Structured medication reviews require patients to receive information about what to expect [8]. Providing patients with guidance before their review can help them prepare effectively.

Example questions for patients to consider before their review:

- Why am I taking these medicines?
- How do I know they are helping me?
- Do I still need all my medicines?
- Why do I have to take so many medicines?

> Do you have materials that you use to help patients prepare for their review?

Signposting

- The Health Innovation Network has developed patient information materials to help patients prepare for medication reviews: Patient Information Materials.

Medicines Reconciliation

Pharmacists should ensure that medicines prescribed by the practice are up to date and align with the latest hospital recommendations.

> Are there other staff members who support with medicines reconciliation?

Signposting

- Useful guidance on medicines reconciliation can be found at:
  - CQC Guidance on Medicines Reconciliation
  - NICE Recommendations for Medicines Reconciliation
  - CPPE Medicines Reconciliation Programme.

Pharmacist Support

Having access to a mentor in general practice can significantly boost confidence and competence. Experience also plays a key role in building these skills. Pharmacists can discuss with their practice team which patients they feel confident managing independently.

To expand their scope of practice, pharmacists can work with their mentor or line manager to develop a planned strategy. This development can be informed by patient demographics and practice needs.

> Is there a pharmacist support network in place?
> Has the pharmacist/ practice identified future learning needs?

Signposting

- Organisations that provide peer support include:
  - Primary Care Pharmacists Association (PCPA)
  - Royal Pharmaceutical Society (RPS)
  - PrescQIPP Practice Plus
    (Note: Some content may be restricted to members only.)

During the Patient Consultation

Delivering the Medication Review

Part One of this document provides prompts to guide you through the patient consultation process.

Signposting

- Appendix 3 lists useful resources to support the delivery of medication reviews.

Consultation Skills

Building rapport with patients is crucial to the success of a medication review. Patients are more likely to consider medication changes when they:

- Feel listened to
- Believe their experiences and opinions have been taken into account.

Is there a need to review current evidence-based consultation models to refresh skills?

Effective communication and empathy are essential to creating a positive consultation experience.

Signposting

- Appendix 4 provides resources to help develop consultation skills.

Policies and Procedures

To ensure consistency in patient care, all practitioners delivering medication reviews should adhere to the same policies and procedures.

Key actions for pharmacists include:

- Familiarising themselves with the specific procedures in place at each practice.
- Collaborating with the practice management team to discuss and formalise any informal processes.
- Ensuring that all procedures are regularly reviewed and updated to streamline patient care.

- Standardised procedures help ensure that patients receive the same level of care, regardless of who conducts the review.

After the Patient Consultation

Communication

There may be instances where the patient's management requires input from other professionals in the practice or at the hospital.

What systems are in place to minimise miscommunication?

Referrals to secondary care (e.g., hospital specialists) will typically need to be actioned by the patient's GP.

Follow-Up

If all identified issues cannot be addressed during the initial appointment, patients may require additional consultations.

Where referrals (e.g., to a physiotherapist or social prescriber) are necessary, these should ideally be discussed with the patient at the end of the review. Clear instructions should also be provided on how to proceed with these referrals.

In cases where recommended changes following a medication review have not been implemented, pharmacists can collaborate with the practice to develop a follow-up process.

Recording Outcomes

The success of a medication review should be measured against its original aim. For example:

- If the aim was to optimise diabetic control, an appropriate outcome measure might be a reduction in glycated haemoglobin (HbA1c).
- If the goal was to improve opioid or benzodiazepine use, reduced usage of these medications could serve as an outcome.

The Care Quality Commission (CQC) evaluates the quality of medication reviews during inspections, so outcomes should be recorded clearly and accurately.

Signposting

- PrescQIPP: Documenting Outcomes from Medication Review (PrescQIPP membership required).
- CQC Key Lines of Enquiry: Guidance on evaluating patient care quality.
- GP MythBusters: A resource for best practice in general practice.

Additional Signposting

Appendix 1: Resources available to help check the appropriateness of prescribed medicines

- The Specialist Pharmacist Service has compiled a list of tools to support medication review: https://www.sps.nhs.uk/articles/using-tools-to-support-medication-review/
- Anticholinergic Burden Scales: https://www.medichec.com/assessment
- STOPP/START tool: https://link.springer.com/article/10.1007/s41999-023-00777-y
- Improving Medicines and Polypharmacy Appropriateness Clinical Tool (IMPACT): PrescQIPP membership is needed to access this information. https://www.prescqipp.info/our-resources/bulletins/bulletin-268-impact/

Appendix 2: Primary Care Pharmacists Association (PCPA) description of the role of GP pharmacist

"Pharmacists take responsibility for areas of chronic disease management, such as diabetes, asthma, and high blood pressure. Pharmacists undertake clinical medication reviews to help patients who take lots of medicines. Pharmacists also help other members of staff in the practice with prescription and medication queries and help support the repeat prescription system. Pharmacists will check the medicines that have been prescribed when patients are discharged from the hospital, and work with patients and other healthcare professionals to make sure the best (and safest) medicines are prescribed." [9]

Appendix 3: Useful resources for delivery of medication reviews

- The Royal Pharmaceutical guidance for medicines optimisation: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf
- NICE guidance for medicines optimisation: https://www.nice.org.uk/guidance/ng5
- The 7-steps medication review: https://www.polypharmacy.scot.nhs.uk/for-healthcare-professionals/principles/the-7-steps-medication-review/
- Bedfordshire, Luton, and Milton Keynes Integrated Care Board SMR process for pharmacists: https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/wp-content/uploads/2020/10/Structured-Medication-Review-SMR-Process-for-Pharmacists.pdf

Appendix 4: Resources available to support consultation skills

- https://www.cppe.ac.uk/services/consultation-skills
- https://www.rpharms.com/professional-development/foundation/foundation-assessment-tools/consultation-skills-assessment
- https://www.youtube.com/c/Consultations4Health
- https://www.bristol.ac.uk/primaryhealthcare/teaching/cog-connect/

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6.4 Discussion

This chapter has described the co-design and testing of the guidance document, with the testing phase concentrating on its practicality, acceptability, and initial insights into its implementation.

6.4.1 Summary of main findings

Rapid analysis of the focus groups and interviews (Chapter Five) identified key topics to bring forward to the planning co-design workshop. No new uncertainties emerged during the workshop; however, the main surprise was participants' vision of what an optimised medication review should look like. I had assumed that a service specification was required, but participants explained that sufficient information already exists on what should be included in a review. What was lacking was practical guidance on *how* to deliver reviews and where pharmacists could access support.

Initial feedback on the first draft of the guidance document was clear, specific, and constructive. While participants agreed it addressed all previously identified uncertainties, they highlighted several areas for improvement:

- Concise structure: reduce repetition and make key points more prominent.
- Visual hierarchy: increase use of headings, bullet points, and images to improve readability.
- Hyperlinks instead of lengthy explanations: streamline content while maintaining access to supporting resources.

Patients particularly valued the patient-centred approach embedded in the document. The revised version of the guidance document, incorporating these changes, was taken forward for testing by a small number of pharmacists.

The interviews provided insights into the acceptability and effectiveness of the guidance document for pharmacist-led medication reviews and highlighted areas for improvement. Pharmacists considered the content comprehensive, reporting no elements of the review that were insufficiently

explained, indicating that the document met their needs. They found the guidance acceptable, particularly valuing its brevity, layout, and prompts, which supported ease of use during consultations and served as a resource for educating other practice staff. Patients also described positive experiences with pharmacists, reflecting acceptance of pharmacist-led medication reviews, with many noting that this was their first such review at their GP surgery.

Pharmacists valued the document's flexibility, which allowed them to tailor reviews to individual patient needs. Patient feedback confirmed this, with many reporting that their reviews addressed their personal health concerns. Pharmacists also described changes in practice during the testing period, such as incorporating goal setting and action planning, which they intended to continue, suggesting that the guidance had a positive influence on implementation.

No unwanted consequences or side effects were reported. However, pharmacists highlighted persistent challenges around time and capacity, which remain significant barriers to effective delivery.

One design issue was identified: the list format of consultation prompts implied a rigid sequence. Pharmacists suggested that a cyclical version of the prompts displayed in the clinic room would provide a more flexible quick-reference tool. This recommendation was incorporated into the final refined guidance document (**Appendix 13**).

6.4.2 Comparison with existing literature

This chapter aligns with other research in this area. One of the key insights from the planning co-design workshop was that a rigid "service specification" was not necessary, with pharmacists

expressing a preference for a more flexible guidance document. This aligns with the flexible approach taken in the Bristol medication review model [264].

The Bristol medication review model is a figure outlines the four key areas of the medication review process for quick reference. In contrast, the guidance document is eight pages long and contains educational material, signposting to references and reflective questions, in addition to a list of prompts for the process of the patient consultation.

Other studies have also tested the medication review models. Krska et al. tested the feasibility of structured supported medication reviews in care homes [274]; the intervention was developed by an experienced clinical pharmacist. The results were primarily outcomes focussed, recording the number and types of medication problems following the medication review. However, feasibility and acceptability data were collected via surveys among healthcare professionals. This survey facilitated the collection of qualitative data where participants reflected on the intervention and the potential it had to impact on their practice.

Wauters et al. tested the efficacy, feasibility and acceptability of an intervention, designed by a group of academics, to support multidisciplinary medication reviews [275]. This study focussed mostly on outcomes- medicine changes, safety events-, with nurses recording how long the medication review took to assess feasibility and an online survey to check acceptability.
Unlike my study, neither Krska nor Wauters collaborated with stakeholders in the design of the intervention. Without the contribution of the lived experiences of stakeholders, it is difficult to determine whether the intervention meets the need of the population who will be using it [131].

6.4.3 Strengths and limitations

A robust co-design process was employed to address the objectives of this study, ensuring that the guidance document was developed with direct input from key stakeholders. No new uncertainties were identified in the co-design workshops, which may reflect data saturation [276]. However, this is also likely to have been influenced by overlap between focus group and workshop participants, limiting opportunities for new themes to emerge. Initially, a single refinement and acceptability workshop including both patients and pharmacists had been planned. Following the planning workshop, it was evident that pharmacist contributions dominated discussions. The protocol was therefore amended to conduct separate workshops, ensuring that patient perspectives were adequately represented.

Pharmacists (as providers) and patients (as recipients) enriched the findings by offering complementary perspectives on how the guidance document and review process were perceived. The use of remote, face-to-face interviews improved accessibility by enabling participation despite logistical or geographical constraints. Feedback on the document's presentation supported further refinement of the intervention prior to wider dissemination.

A limitation of the workshop design was that participant contributions were restricted to verbal comments and use of the chat box. Interactive features such as polls or digital whiteboards were not employed, as the digital literacy of participants was uncertain, and it was important to avoid excluding those less confident with technology. While this decision may have reduced opportunities for creativity and limited the transparency of priority-setting, it also prioritised inclusivity and ensured that all participants were able to contribute comfortably, regardless of their technical skills.

Interviews with pharmacists or patients could have been subject to the Hawthorne effect [277], which could mean:

- Pharmacists may describe their use of the guidance document or their approach to medication reviews more positively than in practice, wanting to appear competent or supportive of the intervention.
- Patients may report more favourable experiences with pharmacist-led medication reviews because they know the researcher is evaluating the process, rather than sharing negative views.

This can introduce response bias, affecting the authenticity of the data.

Recruitment of pharmacists to test the guidance document proved challenging, limiting the diversity and size of the participant group. Of the 325 individuals who accessed the participant information sheet, only three initially confirmed interest. This suggested that the inclusion criteria may have been too restrictive. A revised recruitment strategy was implemented too late to capitalise on early interest, resulting in a final sample of four pharmacists. Although small, this group included variation in age, gender, and levels of social deprivation, allowing for meaningful, if not fully generalisable, findings.

Recruitment challenges may have been due to the advertising approach, competing demands on pharmacists' time, limited awareness of the study's aims, or the timing of recruitment, which coincided with the winter vaccination programme in primary care.

Of the three pharmacists who tested the guidance document, one was a former undergraduate and another a previous professional colleague. These prior relationships may have introduced bias, for

example through social desirability effects or shared professional perspectives. Although efforts were made to mitigate such effects, including highlighting the voluntary nature of participation and maintaining confidentiality, the potential impact of these relational dynamics on the authenticity and objectivity of the data cannot be overlooked. Morecroft et al. [278] explored the benefits and drawbacks of pharmacist-led peer interviews, noting that shared experiences and mutual understanding between interviewers and interviewees created a more open environment for discussing challenges and shortcomings. This observation aligns with broader literature on peer-led initiatives in healthcare, which suggests that professionals are more willing to disclose weaknesses and less-than-optimal practices when they feel understood and not judged.

6.5 Conclusion

The co-design workshops revealed that pharmacists felt existing templates already provided sufficient guidance on the content of medication reviews. As a result, they did not see the need for a rigid, structured document. Instead, they expressed a preference for a guidance document that signposted *how* to deliver medication reviews, alongside content that provides definitions, signposts to relevant resources, and poses reflective questions for pharmacists to assess their skills and confidence.

Following the insights gathered during the workshops, I refined the draft guidance document in preparation for testing by a small number of pharmacists in GP surgeries. I will refine this document following feedback received from patients and pharmacists following its use by a small number of pharmacists.

The co-designed guidance document to support the delivery of medication reviews in primary care meets several criteria for acceptability and practicability, as it was positively received by both pharmacists and patients and was integrated into the medication review process. This aligns with the broader research aim of developing an evidence-based, user-informed tool to optimise pharmacist-led medication reviews in primary care. However, challenges such as time constraints and capacity limitations remain key barriers to implementation. To address these issues and improve the document's effectiveness in practice, refinements, including the incorporation of a cyclical prompt system, were made following acceptability testing. The final version of this refined guidance document (**Appendix 13**) represents the ultimate output of this thesis, providing a structured, evidence-based resource to support the delivery of pharmacist-led medication reviews.

It is important to note that the guidance document is not intended to be a standalone resource. As directed by stakeholders, it has been designed to signpost users to additional resources, helping to prevent information overload. The development of the guidance is an ongoing process, with future iterations expected to incorporate further feedback and updates. Future studies should explore the scalability of the guidance document across a larger number of settings to assess its broader applicability and long-term impact, while ensuring that all signposted resources remain relevant and up to date.

Table 6.6 provides a summary of the research conducted in this and previous chapters, illustrating its progression in addressing the overarching research question of this thesis.

Table 6.6 Contribution to research alongside conclusions from previous chapters

	Scoping review	**Systematic review**	**OPen study Phase One Stakeholders opinions**	**OPen study Phase Two Co-design and testing**
Aim	Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction.	Identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts.	Explore stakeholders' opinions of pharmacist-led medication review in primary care	Co-design and conduct early testing of an optimised pharmacist-led medication reviews in primary care.
Results	• Significant variation in outcomes associated with pharmacist-led medication reviews. • Many reviews did not report the nature of the intervention, therefore, we cannot ascertain what a high-quality medication review looks like and what leads to good outcomes. • An additional literature search was necessary to identify the core components of pharmacist-led medication reviews and how these link to outcomes.	• Identification of themes and components of pharmacist-led medication reviews that are most likely to result in improved outcomes for patients. • Themes and components relate to the activities that occur during and after the patient consultation. Consideration should also be given to the pharmacist undertaking the review and the environment in which it takes place: • Medication reviews delivered by experienced pharmacists or those with enhanced clinical skills, having access to patients' clinical and medication history, and autonomy to make medication changes may improve patient outcomes. • Pharmacists require a comfortable and professional space to deliver medication reviews and a flexible protocol to guide the consultation. • During the consultation, there should be opportunities for patient education, setting goals to take	• Variation in patients' experiences of pharmacist-led medication review and their understanding of the process. • Variation in pharmacists' skills and policies and procedures in different practices influencing implementation. • Key uncertainties in relation to the current delivery of pharmacist-led medication reviews: i. The roles of other healthcare professionals in the medication review process ii. Patients' expectations of medication reviews iii. Varied approaches to engaging patients and delivering medication reviews iv. The need for a systematic and flexible approach to delivering medication reviews v. The importance of recognising and responding to individual patient needs.	• A guidance document which provided prompts to help address the key uncertainties identified, with signposting to relevant resources was preferred to a substantial, didactic document. • Pharmacists appreciated the brevity and layout of the document. • Identified as a useful tool for educating members of practice staff. • Flexibility of document facilitates tailoring of the review to the individual patient. • Pharmacists reported positive changes in their practice during the testing period, which they intended to continue. • Time and capacity constraints remain significant barriers to implementing medication reviews effectively. • Advance notice of medication reviews was highlighted by both patients and pharmacists as a

		medication and developing an action plan. • Follow-up appointments after the medication review may influence a variety of patient outcomes. • This evidence-base was used to co-design the guidance document to optimise pharmacist-led medication reviews.		key factor that improved patient engagement. • Pharmacists suggested displaying a cyclical version of the prompts in the clinic room, which could serve as a quick reference during consultations.

7.0 Overall discussion

7.1 Summary of findings from thesis

The introduction described the prevalence of people living with long-term conditions, and benefits and challenges of the use of medication in their management. Some challenges with the use of medication include inappropriate prescribing and non-adherence, both of which can lead to adverse outcomes, including hospital admissions and reduced quality of life. Medication reviews aim to improve medication management, and UK policies advocate for expanding pharmacists' roles in this area. However, variations in how medication reviews are conducted may impact their effectiveness, and despite significant investment, poor outcomes persist. The MRC NIHR framework for complex interventions was used as a structured, theory-based approach to evaluate how pharmacist-led medication reviews in primary care can be optimised to improve outcomes for patients with long-term conditions [104].

The first step in this thesis was to describe existing literature on pharmacist-led medication reviews to inform the future research direction; I achieved this by undertaking a scoping review of systematic reviews. The literature identified significant variation in the evidence regarding the effectiveness of pharmacist-led medication reviews. Only two systematic reviews were rated as high-confidence, showing that medication reviews could resolve medicine-related problems and reduce healthcare utilisation. Other moderate- and low-quality reviews reported improvements in clinical outcomes, but their findings were inconsistent across different settings and patient populations. A major limitation was the lack of detailed descriptions of the intervention, making it difficult to identify the key components of a high-quality medication review. This lack of clarity contributes to uncertainty about their overall effectiveness and implementation. The findings emphasise the need for further research to define high-quality medication reviews and determine which elements contribute to positive patient outcomes.

Building on the scoping review results, I conducted a systematic review of randomised controlled trials to identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts, that is, what a high-quality medication review looks like and what leads to good outcomes for patients and the health system. The findings identified several key themes related to the effectiveness of medication reviews, drawing from studies with varying levels of bias. Medication reviews are most effective when conducted in a comfortable, professional setting with structured yet flexible protocols. Reviews led by experienced pharmacists or those with advanced clinical skills are particularly beneficial, especially when they have full access to patients' clinical and medication histories and the autonomy to make necessary changes. Additionally, collaboration with other healthcare providers, goal setting, patient education, and follow-up are important factors that enhance the overall effectiveness of medication reviews.

The results of the systematic literature review equipped me to co-design and test an optimised pharmacist-led medication review in primary care. Co-design and testing required stakeholder engagement, and this was achieved in two phases. In the first, co-design phase, focus groups and interviews helped to determine how pharmacist-led medication reviews are currently implemented. Patients in the focus group emphasised the need for a more patient-centred approach in pharmacist-led medication reviews. They sought more opportunities to express their concerns, greater involvement in decision-making, and better preparation for reviews. While face-to-face appointments were preferred, a flexible approach that incorporates different methods of delivery, such as telephone or video consultations, was also seen as beneficial. Lastly, patients actively sought out information about their medicines, highlighting the importance of providing them with adequate resources and information during reviews.

Pharmacists and GPs in the focus group and interviews recognised that pharmacists were undertaking more review in primary care, but also pointed out significant challenges, such as limited

resources, time constraints, and infrastructure issues, that hinder the effective delivery of medication reviews. They stressed the importance of clear role definitions within the team and a patient-centred approach, which could enhance patient engagement and satisfaction. Pharmacists and GPs noted that a systematic and flexible approach to medication reviews, with consideration of individual patient needs, would lead to more effective outcomes. However, the diversity of patient conditions and expectations, along with logistical barriers, made it difficult to establish uniform outcomes from pharmacist-led reviews.

The co-design workshops generated themes that helped the development of a guidance document to support the delivery of pharmacist-led medication reviews. Participants agreed the guidance document should encourage flexibility of the review in response to patients' needs, fostering collaboration between healthcare professionals and patients, and supporting practitioners at all levels of experience. The co-designed document provides guidance and signposting for activities to be completed before, during and after the patient consultation part of the medication review.

In the second phase, early testing of the guidance document was undertaken by a small number of pharmacists. Pharmacists who delivered medication reviews and a sample of patients who had received a medication review were interviewed for their opinions of the acceptability and practicality of the guidance document. The patient interviews emphasised the importance of clear expectations, preparation, and positive pharmacist-patient interactions in the medication review process. Patients valued having time to prepare questions and appreciated the friendly, thorough approach of pharmacists. These factors may have contributed to more engaging and productive medication reviews, fostering an environment where patients felt heard and supported. Additionally, the tailoring of the review content to meet individual patient needs helps to deliver a review that was more relevant and meaningful.

It is important to recognise that the guidance document does not focus on outcomes directly. However, the components of the medication review were informed by evidence from the literature and stakeholder feedback. The components identified in the literature were those most likely to influence outcomes. Participants in the co-design study acknowledged the importance of selecting appropriate outcomes for measurement and highlighted the challenges in doing so. While the guidance document does not prescribe specific outcomes, its emphasis on goal setting and follow-up should naturally facilitate outcome measurement.

The pharmacist interviews highlighted that the guidance document is a valuable educational tool, particularly for reinforcing good practices and improving the quality of medication reviews. However, ongoing challenges such as time constraints and the lack of integration with practice software remain significant obstacles. By refining the guidance document to include a more accessible, cyclical layout and providing summarised prompts for quick reference, its effectiveness could be further enhanced. These adjustments would help pharmacists better navigate the challenges of medication reviews and ensure more consistent and thorough patient outcomes.

7.2 Final guidance document

By employing a co-design methodology, I identified that pharmacists did not require a new medication review service specification, as existing frameworks already provide sufficient procedural guidance. Instead, participants emphasised the need for a document that supports how medication reviews are delivered in primary care. The initial draft of the guidance document outlined its development process, defined medication reviews, included reflective questions for pharmacists regarding their skills, knowledge, and experience, and provided structured guidance on the key processes before, during, and after the patient consultation.

Feedback from patient and pharmacist refinement and acceptability workshops highlighted the need for a more concise format and improved flow. To address this, reflective questions were integrated into relevant sections of the document. The revised version was subsequently tested by pharmacists and further refined based on findings from pharmacist and patient interviews. The final iteration includes improved clarity and updated patient consultation prompts to reflect a cyclical process. This final co-designed guidance document (**Appendix 13**) is now ready for dissemination among local and national interest groups for further discussion and debate.

7.2.1 Implementing the guidance document into regular practice

The successful implementation of the pharmacist-led medication review (PLMR) guidance document requires consideration of factors operating at individual, organisational, and system levels. Embedding the guidance into routine practice will depend not only on practitioner engagement but also on alignment with existing NHS priorities, local infrastructure, and wider medicines optimisation frameworks.

Implementation frameworks such as the Consolidated Framework for Implementation Research (CFIR) [279], the Promoting Action on Research Implementation in Health Services (PARIHS) framework [280], and Normalisation Process Theory (NPT) [111] all highlight the need to address multiple, interacting dimensions of implementation, including the characteristics of the intervention itself, the people delivering it, the organisational context, and wider policy drivers. In this context, the PLMR guidance should not be viewed as a standalone innovation but as a complementary tool that can be integrated into, and strengthen, existing NHS initiatives on medicines optimisation and polypharmacy.

There are already several well-established programmes and resources across the UK that promote high-quality medication review and safe prescribing. These include the Health Innovation Network's Polypharmacy Programme [262] and Scotland's "7-Steps Medication Review" approach [281]. Both initiatives provide structured, evidence-based frameworks to guide practitioners in conducting patient-centred medication reviews, emphasising shared decision-making, deprescribing where appropriate, and a focus on patient goals. The pharmacist-led medication review guidance builds on these principles, offering a more detailed and pharmacist-specific resource grounded in empirical evidence and co-designed with stakeholders.

Individual Level

At the practitioner level, pharmacists will need targeted training and professional development opportunities to ensure confidence in applying the guidance consistently. Embedding reflective practice, peer discussion, and shared learning within Primary Care Networks (PCNs) can further support integration. The guidance document could also be incorporated into professional revalidation activities, continuing professional development (CPD) frameworks, and independent prescribing training, ensuring that the approach becomes a recognised component of professional competence.

Organisational Level

At the organisational level, practices and PCNs should consider incorporating the guidance within Standard Operating Procedures (SOPs) for Structured Medication Reviews (SMRs) and medicines optimisation activities. Implementation should be supported through multidisciplinary collaboration—ensuring that pharmacists, GPs, nurses, and other members of the care team act on and document recommendations effectively. This approach aligns with ongoing national efforts to

embed pharmacist-led interventions within team-based care models, as outlined in the NHS Long Term Plan and Medicines Optimisation Strategy [49].

System Level

At the system and policy level, implementation should align with national guidance and commissioning frameworks to ensure consistent delivery across regions. The pharmacist-led medication review guidance can inform competency standards, training requirements, and service specifications for medication review delivery. Integration within commissioning frameworks and national quality improvement programmes would help sustain its use and reinforce its value in improving clinical and patient-reported outcomes.

Evaluation and Continuous Learning

Implementation should be accompanied by ongoing evaluation focusing on feasibility, acceptability, and impact at multiple levels. Feedback mechanisms should enable iterative refinement of the guidance based on real-world experience, consistent with the principles of learning health systems and continuous quality improvement.

In summary, the implementation of the pharmacist-led medication review guidance requires a multi-level strategy that aligns with existing NHS priorities and frameworks. Rather than representing a new or separate process, the guidance should be normalised within day-to-day practice as an integral part of delivering safe, effective, and person-centred medicines management.

7.3 Interpretation of results

The results of the literature reviews presented in this thesis demonstrates the extensive nature of the field of research in medication reviews. My systematic review enabled me to identify themes and components of pharmacist-led medication reviews that were associated with positive outcomes

for patients. Stakeholders' opinions about the delivery of pharmacist-led medication reviews in primary care, synthesised with the evidence from the systematic review were essential in co-designing the guidance document. The early testing of this guidance to support pharmacist-led medication reviews demonstrated its acceptability and practical application in general practice.

7.3.1 Comparison with existing literature

Whilst I have been undertaking this PhD, other research teams have undertaken medication review research. In 2021, McCahon et al. published their work on the development of a model of medication review for use in clinical practice (Bristol Medication Review Model) [264]. The Bristol Medication Review Model is a flexible model that can be utilised by any healthcare professional in any setting.

In 2023 Radcliffe et al. published the results of a realist review which details a programme theory for multidisciplinary medication review and deprescribing for older people in primary care [103]. Unlike the Bristol Medication Review model [264] which was designed to be used by different healthcare professionals, the Radcliffe programme theory outlines when, why and how medication reviews and deprescribing involving multidisciplinary teams work for older people. Like my work, the Radcliffe programme theory [103] is based in primary care but focuses its research on a particular population (older people) and a multidisciplinary team (MDT) as opposed to a sole pharmacist. **Table 7.1** compares the similarities between my work and that undertaken by McCahon et al. and Radcliffe et al. [103,264].

Table 7.1 Similarities identified with the final output of my research compared with other recent work in this field

Content	**Final output from this thesis (Document to support the delivery of pharmacist-led medication reviews in primary care)**	**Bristol Medication Review Model** [264]	**Multidisciplinary medication review and deprescribing for older people in primary care** [103]
Roles and responsibilities of practice staff/ team members	Roles and responsibilities of the different members of the practice team are clearly defined in the medication review process. Patient and staff to have knowledge of pharmacist's role and responsibilities. Communication pathways between other members of staff and secondary care.		Clearly defined roles and responsibilities for multidisciplinary team (MDT) members. Good communication and collaboration within the MDT Lead role of pharmacists in medication review
Patient preparation	Patients should have time to prepare for the medication review.	Prepare the patient by explaining the rationale for the upcoming review, helping them prepare any questions they might have.	
Patient engagement	Pharmacist to involve and engage the patient in the review process and to tailor the medication review to the patient you are seeing. They should ask what the patient hopes to achieve from the medication review and negotiate a shared agenda.	The medication review should identify patient values and perspectives from the outset, making it clear which components will be most relevant and valuable to spend time on. Information gathering questions should be patient-centred and open in nature.	MDT should focus on patient's preferences and priorities
Assess clinical appropriateness	Pharmacists should check that all medicines are still suitable for the patient.	Practitioner to explore medication, problems, priorities; specifically look at pharmacological-related aspects of the medication used.	

Face-to-face appointments are ideal for specific patients	Each pharmacist/ practice will prioritise which patients require a telephone or face-to-face consultation.	Face-to-face interactions are ideal but video or telephone consultation can be utilised where needed.	Face to face medication review is preferred but can be tailored to needs of patient
Appropriate training for professionals delivering medication reviews	Pharmacists to see patients that they have the skills, and the confidence to review independently. Planned development should be guided by patient demographics and self-assessed skills.	Training should be provided for health care professionals	De-prescribing training and education for healthcare professionals
Treatment goals	Goals for treatment need to be agreed with the patient. Action plans should be recorded in the patient's record so it can be accessed by all professionals involved in the care of the patient.	Measurement and recording of clinical, patient or process outcomes may be of value, and should be adapted according to clinical context and health service need.	
Structuring the medication review	Templates often used to help structure a complex medication review.		Recommend the use of medication review tools
Repeat appointments/ Follow up	Some patients will require an extended appointment slot. If there are outstanding issues following medication review, a follow up appointment should be scheduled. All referrals should be discussed with the patient at the end of the review.	Medication review should be an ongoing process and undertaken on a regular basis appropriate to clinical and patient need, ensuring dedicated time is allotted for carrying out the review.	Patients should receive a scheduled follow up by a pharmacist

Methodologically, my work shares some similarities with that of McCahon et al. [264], as both conducted systematic reviews updating Huiskes et al. (2015) [156]. However, our aims, objectives, data synthesis methods, and research outcomes differed significantly. McCahon et al.'s original protocol planned to categorise behaviour change techniques (BCTs) that aligned with their thematic framework and descriptions of intervention components. However, this was not reported in the results, suggesting that there was insufficient information for them to do this. In contrast, my systematic review identified BCTs by focusing specifically on adherence behaviours, which have strong links to patient outcomes. Following this, I used co-design workshops to identify what an optimised pharmacist-led medication review should include and how it should be delivered. McCahon et al. also engaged stakeholders, but their model development involved a structured consensus approach with nine experienced stakeholders (researchers, patients, pharmacists, and doctors). My approach differed in its iterative co-production method, enabling pharmacists and patients to directly shape both the content and format of the final guidance document.

The realist review undertaken by Radcliffe et al. identified 33 context, mechanism, outcome (CMO) configurations as part of their work to develop and test a complex multidisciplinary deprescribing intervention in primary care targeting older people. These CMOs were grouped into four key themes:

1. Healthcare professionals' roles, responsibilities, and relationships
2. Healthcare professionals' training and education
3. Format and process of the medication review
4. Involvement and education of patients and informal carers.

These themes are echoed in my guidance document, which emphasises the need for pharmacists to understand team roles and responsibilities, reflect on training and competence, and actively involve patients to elicit expectations and treatment goals. This aligns closely with the work of Joanna Reeve, who has written extensively on person-centred primary care and the importance of

professional identity and context in shaping clinical practice [102]. Similarly, Carmel Hughes has highlighted that medicines optimisation interventions must account for professional boundaries, communication structures, and organisational culture, factors that are central to my framework's recommendations [282].

My guidance document suggests that before the patient consultation of the medication review, pharmacists should:

- Verify that all prescribed medicines remain suitable for the patient
- Review the original indications for the prescribed medicines
- Check relevant clinical monitoring parameters, such as blood test results.

This preparatory work reflects the Bristol Medication Review Model, which advocates that any clinical monitoring should be undertaken in advance so that it does not distract from the patient-centred focus of the consultation. Similarly, Rupert Payne's work on multimorbidity and polypharmacy [283–285] underscores the value of structured pre-consultation review in identifying potential prescribing cascades and ensuring holistic, patient-focused decision-making.

My guidance document provides structured guidance on the key processes before, during, and after the patient consultation of the medication review; this aligns with the principles identified by Luetsch et al. [119], who emphasised that the medication review process begins before direct patient contact and depends on pharmacists having comprehensive access to clinical information. This process-oriented approach resonates with Ian Maidment's research, which has highlighted the practical challenges of conducting safe, effective medication reviews for older adults with dementia or cognitive impairment [286]. His findings stress the need for adaptable, context-sensitive frameworks, an idea my guidance seeks to operationalise for general primary care practice.

Whilst there are some differences between the results of my research and those reported by McCahon et al. and Radcliffe et al. [103,264] in that the guidance document encourages pharmacists to reflect not only on their training needs but also on their confidence in their abilities and the support networks available to them. Luetsch et al. reported that recognition of pharmacists' competence and skill to perform medication reviews and pharmacist access to comprehensive clinical information can influence outcomes [119]. Additionally, while previous work relied on stakeholder opinions and literature to determine the content of medication reviews, my approach extended beyond this by involving stakeholders in shaping the format and presentation of the guidance itself.

Communication between pharmacists and physicians remains a recurring theme across the literature. Luetsch et al. [119] and Barnett [287] both highlight that effective interprofessional communication is fundamental to translating medication review recommendations into practice. My findings support these observations, reinforcing that pharmacist access to clinical records and effective communication with prescribers underpin successful review implementation.

Patient preference, including accessibility, convenience, and choice of reviewer, was also identified by Luetsch et al. [119] as a key mechanism influencing outcomes. This mirrors the emphasis on relational care by Reeve et al. [102].

In summary, the collective evidence from my work and recent studies, including the Radcliffe realist review [103], McCahon review [264], and the research of Maidment, Payne, Alldred, Hughes, Reeve, and Barnett [41,101,155,264,285,286,288], points toward a converging set of principles for effective medication review practice:

- **Targeted Training and Support:** Ongoing, role-specific training and reflective practice should underpin professional development.
- **Collaborative Delivery:** Strong interprofessional communication and shared accountability are essential.
- **Patient-Centred Engagement:** Medication reviews must incorporate patient goals, values, and preferences.
- **Structured, Continuous Process:** Reviews should follow a consistent structure with planned follow-up and evaluation.

Future research and implementation efforts should continue to embed these principles, ensuring that medication reviews evolve from isolated clinical activities into dynamic, collaborative processes central to person-centred primary care.

Mapping this work to the MRC Framework

The MRC NIHR framework for complex intervention research consists of four phases: development or identification of the intervention, feasibility, evaluation, and implementation. Each phase shares core elements, including considering context, developing and refining programme theory, engaging stakeholders, identifying key uncertainties, refining the intervention, and assessing economic considerations [104]. This thesis focused on the 'develop intervention' phase, adapting an existing intervention based on research evidence. Throughout the research, various core elements have been explored. The scoping review provided a broad context for pharmacist-led medication reviews, while the systematic review offered a more detailed insight by examining the settings, modes of delivery, and pharmacist skills and experience involved in delivering these reviews. Meanwhile, the co-design and acceptability testing of a guidance document supported stakeholder engagement and helped identify key uncertainties (areas that required further exploration).

Programme theories associated with the MRC NIHR framework for complex interventions take a broader perspective, aiming to explain the overall functioning of an intervention without necessarily specifying the nuanced context-mechanism-outcome relationships as in realist approaches [94]. While I have started to define components to build a programme theory, this was not a primary focus of the thesis and should form a key part of future steps in line with the approach taken by Radcliffe [103].

The comparative analysis of alternative courses of action in terms of both costs (resource use) and consequences (outcomes, effects), that is, economic consideration, are a core component of each phase of complex intervention research [104]. This element was outside the scope of this study but is an important area for future research.

7.4 Strengths and Limitations

My thesis presents a methodologically rigorous approach to optimising pharmacist-led medication reviews in primary care. I used various research methods to identify and explore opportunities for improving pharmacist-led medication reviews in primary care, which enhances the quality and depth of my research.

Conducting two different evidence syntheses provided a comprehensive overview of the literature on pharmacist-led medication reviews. However, evidence synthesis is inherently time-consuming. To improve efficiency, I repeated a previously utilised search strategy for my systematic review. Despite this, the part-time nature of my PhD and an unavoidable break in study introduced additional time constraints. As a result, I had to repeat literature searches to ensure the inclusion of the most up-to-date studies in my data analysis.

The focus groups facilitated in-depth discussions, allowing me to explore how pharmacist-led medication reviews are currently implemented in practice and identify the key uncertainties that stakeholders wish to address in future reviews. Focus groups proved to be time-efficient for data gathering, as I was able to capture the thoughts and opinions of seven pharmacists in the same amount of time it took to interview two GPs. However, effective facilitation is crucial in focus groups to manage group dynamics and keep discussions focused. This proved to be a challenge for me during the sessions.

The co-design workshops enabled me to actively involve key stakeholders – pharmacists and patients- in identifying what an optimised medication review would look like, and how it could be implemented. Bringing these groups together fostered interactive discussions and collaboration. Brainstorming what pharmacists and patients aimed to achieve through a medication review helped inform the development of a guidance document outlining its essential components and best practices. However, power imbalances can be a limitation of co-design workshops. I observed this after the first workshop, where pharmacist contributions overshadowed those of patients. To address this, I adjusted the approach for the second workshop by running separate parallel sessions for patients and pharmacists, ensuring that both perspectives were equally represented.

Early testing of the guidance document provided additional opportunities to engage with stakeholders through interviews. This allowed me to explore how the guidance document met their expectations. Feedback from the interview provided an opportunity to further refine the guidance document and helped to ensure that the guidance document aligns with real- world needs. However, I encountered additional recruitment challenges during the acceptability testing. While small sample sizes are a known limitation of this method, my sample size (n=3) was particularly limited, which restricts the generalisability of the results.

While the methodological approaches used in my thesis were thorough and pragmatic, their implementation faced certain limitations. Recruitment for the focus groups and workshops proved challenging, with most participating practitioners based in Norfolk or Suffolk. Given that many pharmacists operated under the same Integrated Care Board (ICB), their perspectives may have been influenced by similar ICB guidance on medication review delivery. This geographic concentration potentially limited the diversity and depth of the data. Whilst sampling is instrumental in selecting a representative sample, it does not ensure that those who respond are representative [289]. I know that some participants expressed an interest because they knew me, others because they had specific opinions about pharmacists that they wanted to share. Social desirability bias is also a limitation of this study. In Section 7.6 I have reflected upon how my position as a pharmacist researcher and previous relationships with participants may have influenced their responses to ones which are more socially acceptable [269]. The limited number and diversity of stakeholders in the co-design process is a limitation of this research. A broader range of stakeholders could have contributed additional perspectives, potentially enriching the design of the guidance document.

NHS England has identified several populations that are underrepresented in research, including individuals living in the most deprived 20% of the population, people from ethnic minority communities, and adults with a learning disability or who are autistic [132,291]. In this study, purposive sampling was used to ensure participants were drawn from a range of geographical areas and included varied ethnic representation. However, participants were required to speak English, which limited the inclusion of non-English-speaking individuals from diverse ethnic backgrounds.

Additionally, participants who were unable to provide informed consent were excluded. A person may lack capacity to consent for various reasons, such as dementia, learning disabilities, stroke, or other brain injuries [292]. While individuals are legally presumed to have capacity unless proven

otherwise [292], the process of obtaining informed consent for research participation differs from that for receiving healthcare. This distinction can create additional barriers to inclusion for individuals with cognitive or communication difficulties, even where they routinely engage in care decisions.

Given the small scale of this PhD study and the limited resources and expertise available, it was not feasible to implement enhanced recruitment or supported consent procedures, such as the use of advocates, simplified information materials, or assisted decision-making, to include participants with reduced capacity. Consequently, this study may not fully reflect the perspectives and experiences of these groups.

Future research should therefore examine the transferability and applicability of the pharmacist-led medication review guidance to populations with reduced capacity to consent. Such work should also explore inclusive research methods that enable meaningful participation of individuals with cognitive impairment or communication difficulties, ensuring that the development and implementation of medication review practices are equitable and representative of all patient populations.

7.5 Implications of the research in this thesis

7.5.1 Implications for research

Given the limitations presented in this thesis, additional research is required to engage with a more diverse group of stakeholders on a larger scale. A future research direction could explore how stakeholders perceive the guidance document to support the delivery of pharmacist-led medication reviews and ask what the barriers and facilitators to its effective implementation are. Stakeholders

could include health service commissioners at local and national levels and representatives from the Primary Care Pharmacists Association, in addition to pharmacists and patients.

Future research could take a realist approach to understand how the guidance document operates in different contexts, the mechanisms it triggers, and the outcomes it generates by asking “What are the contextual factors, mechanisms, and outcomes associated with the use of the medication review guidance document among stakeholders in practice?"

Due to time and resource limitations, I was not able to explore how the “follow-up” component of the guidance document was implemented in the testing phase. Therefore, additional research could explore the nature and intensity of follow-up appointments, and the healthcare professionals involved in this process.

Furthermore, early testing did not assess the impact of the medication reviews on patient outcomes. A future longitudinal study could follow-up with patients and pharmacists to assess several outcomes such as health-related quality of life, symptoms of disease and adverse drug events.

A novel contribution from my systematic review was identification of Behaviour Change Techniques (BCTs) in relation to adherence. Participants in the focus groups, interviews and workshops identified additional key uncertainties. There is scope for further evidence syntheses to apply the BCT taxonomy to other behaviours related to these key uncertainties, such as practice staff engaging with patients to attend medication reviews, or pharmacists recognising and responding to the needs of individual patients.

7.5.2 Implications for practice

Alongside the conclusions from the Radcliffe [103] and McCahon [264] reviews, my work has highlighted the importance of pharmacists having the right training to deliver medication reviews, careful selection of the most appropriate mode of delivery, prioritising patient preferences and treatment goals, and scheduling follow-ups to address outstanding issues and review the outcomes of agreed action points. The flexible nature of the guidance document means that it could be used by any pharmacist in any GP surgery in England, as rather that giving explicit content, it encourages self-reflection and identification of processes and procedures within their individual setting.

On a local level, my work is contributing to the advancement of clinical practice and education:

- Ongoing use in practice: Pharmacists who tested the document plan to continue using it as a reference and training tool.
- Wider Recognition: A clinical pharmacist outside the study learned of my work through her Primary Care Network and requested a copy to aid in training and development.
- Educational Resource: The consultation process (**Appendix 13, Figure 1**) from my study has been incorporated into the core consultation skills module of the clinical diploma at the University of East Anglia's School of Pharmacy.
- Personal Implementation: I've applied the insights from my research in my own clinical practice, especially focusing on goal setting and action planning during patient consultations.

7.5.3 Implications for policy

Current UK policy positions pharmacists as key providers of medication reviews within two of the four primary care settings: community pharmacy and general practice. My research supports the effectiveness of pharmacist-led medication reviews, suggesting that they represent a well-founded policy decision for supporting patients to use their medicines. However, there is scope to optimise

the intervention. The final output of this thesis—a guidance document for delivering pharmacist-led medication reviews in primary care—is one avenue for optimisation.

My research has identified a need for enhanced educational support for pharmacists conducting medication reviews. The Centre for Pharmacy Postgraduate Education (CPPE) is the primary provider of medication review training [263], with additional training available through professional bodies such as the Primary Care Pharmacy Association (PCPA) and the Royal Pharmaceutical Society (RPS). Current training largely focuses on the procedural aspects of medication reviews—what should be done—whereas my research highlights that pharmacists also require guidance on how to effectively deliver these reviews in practice. This suggests that the current educational focus for pharmacists in general practice should be critically evaluated. Future training should incorporate a broader perspective, considering factors that influence the medication review process before the patient consultation. Additionally, this training should not be limited to pharmacists but should also seek to educate other members of the practice team and patients. These findings have implications for both undergraduate and postgraduate training pathways, particularly as pharmacists take on greater responsibilities as independent prescribers, which will include conducting structured medication reviews.

A recently published policy document, *How Medicines Optimisation Contributes to Population Health* (2025), suggests expanding the Community Pharmacy Contractual Framework (CPCF) to enable community pharmacies to deliver medication reviews [293]. However, it remains unclear to what extent this proposal considers the key factors identified in my research, and that of McCahon and Radcliffe [103,264], as essential for effective implementation. To ensure value for money and avoid repeating past inefficiencies, such as those seen with Medicines Use Reviews (MURs), it is critical that future policy decisions incorporate evidence-based insights on how medication reviews can be optimally designed and delivered.

7.6 Researcher characteristics and reflexivity

I began my PhD journey as a mature student with nineteen years of experience as a community pharmacist and fourteen years of teaching pharmacy undergraduates. While my career provided numerous opportunities to refine my clinical and teaching skills, my experience in research was limited. Undertaking a PhD offered me the chance to address this gap and develop the essential research skills required for my study.

The qualitative research methods utilised in this thesis were focus group discussion, interviews, and workshops: I utilised Braun and Clarke's thematic analysis to analyse the data from these methods [167]. Researcher reflexivity is a key aspect of Braun and Clarke's approach to thematic analysis and required me to be self-aware and transparent about how my underlying beliefs and perspectives informed my analysis [294].

My role as a pharmacist naturally aligns with a positivist perspective—patients are prescribed medicines and may take them with varying outcomes. As a result, my research approach has been largely linear [127]. My professional background likely influenced my interpretation of the data, as I am aware of the benefits pharmacists bring to practice. This presented a risk of bias when assessing the impact of pharmacist-led medication reviews on outcomes. To mitigate this, my supervisory team provided diverse expertise: while my primary supervisor is also a pharmacist, my other supervisors are a behavioural scientist and a public health specialist. Their varied perspectives helped challenge potential biases in my data interpretation. At one point, I had titled my systematic review *'Components of pharmacist-led medication reviews and how they lead to positive outcomes for patients and health services.'* My supervisory team quickly identified this bias, reminding me that without completing data extraction and synthesis, I could not assume a positive impact. They also questioned whether I was prepared to acknowledge data that suggested otherwise. As a result, I

revised the title to *'Components of pharmacist-led medication reviews and their relationship to outcomes: A systematic review and narrative synthesis.'*

My professional background may have also influenced data collection during focus groups, workshops, and interviews. Effective facilitation required careful management to mitigate the investigator effect—the unintentional influence researchers can have on their results [295]. Additionally, I had to make a paradigm shift from my role as a clinician to that of a researcher, which required adopting a more neutral and observational stance.

My first experience facilitating a focus group was with patients. While the session started well, I found it challenging to consistently maintain my position as a researcher. My primary supervisor, who attended the session as a silent observer, occasionally sent me prompts to help steer the discussion back on track. However, there was one moment during the session where I completely defaulted to my role as a pharmacist, providing advice and guidance that extended beyond my scope as a facilitator. Although this did not directly affect the data collected, I recognise that it may have influenced the direction of the discussion, potentially preventing some participants from expressing their thoughts and opinions fully.

When leading the patient focus group discussion, I was initially unaware of the participants' motivations for agreeing to take part in the study. Upon reflection, I recognise that I experienced a degree of apprehension about the potential responses to the questions. I was particularly concerned about how I would react if the session consisted entirely of negative comments regarding their experiences with pharmacist-led medication reviews. Although my role in the focus group was that of a researcher, my professional identity as a pharmacist—and my empathetic nature—made it challenging to fully detach. I was conscious that I might take such comments personally.

To address this, I was transparent about my dual roles. The participant information sheet and my introduction at the start of the focus group made clear my background as a community pharmacist. While this openness was important for ethical reasons, it may have influenced the responses, as participants might have muted their critiques to reconcile my dual position as both a pharmacist and a researcher. Nevertheless, the nature of the responses suggested that participants were being honest, as they openly shared a range of both positive and negative experiences. This reflection has underscored the importance of managing my emotional responses and maintaining professional boundaries to ensure the integrity of the research process.

I felt more at ease going into the practitioner focus group compared to the patient focus group. However, I remained mindful of the need to exercise caution during discussions to avoid inadvertently influencing participants' responses with my own views and experiences. This was particularly challenging given my empathetic nature, as I tend to naturally align with others' perspectives. Despite this, feedback from my silent-attendee supervisor and my own review of the session recording confirmed that I successfully maintained a neutral stance throughout the discussion.

The practitioner recruitment strategy relied heavily on social media and existing networks amongst the supervisory team. While this method was efficient, it risked introducing bias; participants recruited from a known network may have shared perspectives or feel personally motivated to participate, which could influence the diversity of viewpoints. Some of the participants were former undergraduates that I had taught. The teacher-student relationship or familiarity between the researcher and participants introduces potential power dynamics that could influence responses. Participants may have felt obligated to provide certain answers out of respect, loyalty, or a perceived need to meet expectations. Other participants were known to me having worked alongside me in clinical or academic practice; their motivations, such as feeling obliged to participate because of

their relationship with the me, could have affected the authenticity of their responses. However, a mix of participants who had no prior relationship with me were able to provide a contrasting perspective.

Although I felt generally confident conducting both pharmacist and patient interviews due to my prior experience with semi-structured interviews, I still faced the challenge of maintaining objectivity—particularly given my personal investment in the project. At times, it was difficult to detach emotionally from participants' responses or to avoid unintentionally steering the conversation toward desired outcomes. Reflecting on this struggle has highlighted the importance of self-awareness and reflexivity in the research process, as well as the need to continually refine my interviewing techniques to ensure impartiality and rigor.

Of the three pharmacists who participating in testing the guidance document, one was a former undergraduate whom I had taught, and another was a colleague with whom I had worked closely in a previous role. These historical relationships may have introduced potential biases during data collection. For instance, the teacher-student dynamic might have persisted on a subconscious level, leading the former undergraduate to provide responses they perceived as favourable or aligned with my expectations. Similarly, my prior professional relationship with the other participant might have influenced their willingness to participate or shaped their responses based on shared experiences or a desire to support the research. Despite making every effort to maintain neutrality and encourage honest responses, such as not engaging in conversations that demonstrated familiarity, these factors must be acknowledged as potential influences on the study's findings.

The co-design and user testing phases of this research required me to learn and apply reflexive thematic analysis and I encountered some challenges and insights along the way:

- Training and Learning Process: I engaged with a variety of learning materials to familiarise myself with thematic analysis.
- Initial Coding and Feedback: I found the initial coding of the transcripts to be relatively straightforward but received feedback about ensuring that I highlighted enough context for each statement to be fully understood.
- Challenges of Working in Isolation: I spent a lot of time working alone from home, which made it challenging to refine and review themes without face-to-face discussions. While working in isolation has its benefits, such as focusing on individual interpretation, I realised that collaboration and discussion can be crucial for refining my analysis and for challenging my own interpretive stance.
- Reflexive Stance and Interpretative Lens: Reflexive thematic analysis encourages researchers to acknowledge their own positionality and the lens they apply in interpreting data. I recognised that it was easy to interpret responses from a specific perspective (e.g., as a pharmacist or a patient), but the reflexive process ensures that this bias is acknowledged and incorporated into my analysis.

My experience highlights the importance of a balanced approach—working in isolation can allow for deep focus, but collaboration and ongoing self-reflection are essential for robust and valid interpretations, particularly when using reflexive methods.

7.7 Conclusions from this work

Table 7.2 is a tabular summary of the research undertaken throughout this thesis, describing the aims and objectives of each of the projects (chapters) in this thesis to demonstrate how they have contributed to the final output from this thesis.

The final output of this thesis is an evidence-based, co-designed guidance document to support the implementation of pharmacist-led medication reviews in primary care. Early testing suggests that the guidance document is both acceptable and practical for use in general practice. However, several research directions remain to be explored. Future studies could examine stakeholder perceptions of the guidance document in supporting pharmacist-led medication reviews and identify the barriers and facilitators to its effective implementation. A realist approach could be taken to investigate how the guidance document functions across different contexts, the mechanisms it activates, and the outcomes it generates. Additionally, further research could explore how the "follow-up" component of the guidance document was implemented during acceptability testing, including the nature and intensity of follow-up appointments and the healthcare professionals involved in this process. Longitudinal studies could also assess the impact of follow-up on patient outcomes, including health-related quality of life, disease symptoms, and adverse drug events.

My research has also highlighted key factors necessary for optimising pharmacist-led medication reviews, including ensuring pharmacists receive appropriate training, selecting the most suitable mode of delivery, prioritising patient preferences and treatment goals, and scheduling follow-ups to address outstanding issues and review agreed action points. Current pharmacist training largely focuses on the procedural aspects of medication reviews. Future training should adopt a broader perspective, considering factors that influence the medication review process before the patient consultation to better equip pharmacists for their expanding roles in primary care.

Table 7.2 Description of the research undertaken in this thesis

	Overall thesis question	**Project 1 (Chapter 2) Scoping review**	**Project 2 (Chapter 3) Systematic review**	**Project 3 (Chapters 4 & 5) Co-design and testing an optimised medication review**
Research Question	How can Pharmacist-led medication reviews in primary care be optimized to improve patient outcomes for those with long-term conditions?	What is the current literature surrounding pharmacist-led medication reviews and is there a necessity for undertaking further evidence syntheses in this field?	What are the components of medication reviews performed by pharmacists and how do these link to outcomes in different contexts?	How can Pharmacist-led medication reviews in primary care be optimised to improve outcomes for people with long-term conditions?
Aim	Explore how pharmacist -led medication reviews in primary care can be optimised to improve patient outcomes for those with long-term conditions.	Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction.	Identify the components of pharmacist-led medication reviews and how they link to outcomes in different contexts.	Co-design and user test an optimised pharmacist led medication review (PLMR) in primary care.
Objectives	1. Describe existing systematic review literature on pharmacist-led medication reviews to inform future research direction. 2. Identify the core components of pharmacist-led medication reviews and how they link to outcomes in different contexts. 3. Co-design and user test an optimised pharmacist led	1. To examine the extent and range of systematic reviews on medication reviews 2. To explore reporting of the nature of the medication review intervention in systematic reviews 3. To describe the systematic review evidence for effectiveness of medication reviews	In relation to the literature evidence of medication reviews: 1. Describe their core components 2. Describe their implementation 3. Examine potential mechanisms of impact 4. Describe the reported outcomes	Phase 1 1. Explore the current provision of medication reviews by pharmacists in primary care with stakeholders Phase 2 2. Co-design an optimised approach to medication reviews by pharmacists in primary care

	medication review in primary care.	4. To identify research gaps in the existing systematic review literature		3. Conduct early testing of the optimised approach to medication reviews by pharmacists in primary care
Methodology		Evidence synthesis	Evidence synthesis	Co-design
Methods		Scoping literature review	Systematic literature review	Focus groups Early acceptability testing Semi-structured interviews
Output	Guidance on implementation of pharmacist-led medication reviews (PLMR) in primary care. This guidance: • Identifies key prompts to guide the medication review • Includes questions that pharmacists can use to reflect on their practice and identify learning needs. • Signposting sections and appendices provide resources relevant to the medication review process. • Offers educational material for practice staff, highlighting the pharmacist's role, the various types of medication	Detailed research strategy for PhD thesis Publication; PLoS One	Publication; BMJ Quality and Safety Conference abstract Two-page executive summary (in lay language) for optimising pharmacist-led medication reviews in primary care	Summary of patient and practitioner experiences of MR Conference abstract Guidance document for pharmacist-led medication reviews in primary care

	reviews, and the importance of scheduling appropriate appointments for suitable patients.			

7.8 Publications and conference abstracts arising from the thesis

Peer-reviewed journals

Craske M E, Hardeman W, Steel N, Twigg MJ (2024) Pharmacist-led medication reviews: A scoping review of systematic reviews. *PLOS ONE* Vol 19 No 9: e0309729. https://doi.org/10.1371/journal.pone.0309729

Craske ME, Hardeman W, Steel N*,* Twigg MJ (2024) Components of pharmacist-led medication reviews and their relationship to outcomes: a systematic review and narrative synthesis *BMJ Quality & Safety* Published Online. https://doi.org/10.1136/bmjqs-2024-017283

Published Conference Abstracts

Craske ME, Hardeman W, Steel N, Twigg MJ, Core components of pharmacist-led medication reviews and their relationship to outcomes: a systematic review, International Journal of Pharmacy Practice, Volume 32, Issue Supplement_1, April 2024, Pages i52–i53, https://doi.org/10.1093/ijpp/riae013.066 (Rapid presentation and poster at Health Services Research & Pharmacy Practice (HSRPP) Conference 2024)

Craske ME, Hardeman W, Steel N, Twigg MJ, Exploring stakeholders' views of pharmacist-led medication reviews in general practice, *International Journal of Pharmacy Practice*, Volume 32, Issue Supplement_1, April 2024, Page i51, https://doi.org/10.1093/ijpp/riae013.064 (Poster at HSRPP 2024)

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Optimising pharmacist-led medication reviews in primary care to improve patient outcomes for those with long-term conditions.

By

Miriam Elizabeth Craske

Appendices to support the thesis Submitted to the University of East Anglia for the degree of

Doctor of Philosophy

School of Pharmacy

Appendix 1 Research strategy for Scoping Review

The OVID platform was used to search the Embase and MEDLINE databases. This meant that only one search string was necessary.

The following search terms were used:

pharmac* AND [“medicine review” OR “medication review” OR “medicines review”] AND “systematic review”. The search was restricted to abstracts; these, along with their titles, were reviewed, and full text retrieved of those that met the inclusion criteria. Through forward and backward reference searching, other papers of interest were identified. In addition, the Cochrane database of systematic reviews was searched for relevant systematic reviews published after December 2015 (‘medication review’ and ‘pharmacist’).

A time filter was applied to the results: January 2016 to January 2023 (the time of the search).

Appendix 2 Search strategy for systematic review

The review involved re-running the search undertaken by Huiskes et al.

Huiskes, V.J.B., Burger, D.M., van den Ende, C.H.M. *et al.* Effectiveness of medication review: a systematic review and meta-analysis of randomized controlled trials. *BMC Fam Pract* **18**, 5 (2017). https://doi.org/10.1186/s12875-016-0577-x

The Medline search via PubMed

Full electronic search (MEDLINE)

(((((((((("Drug Utilization Review"[Mesh]) OR "Pharmaceutical Services"[Mesh])) AND (((((("Randomized Controlled Trial"[Publication Type]) OR "randomized controlled trial"[tw]) OR "randomised controlled trial"[tw]) OR "randomised controlled study"[tw]) OR "randomized controlled study"[tw]))))) OR ((("pharmacist review"[TW] OR "pharmacist intervention"[TW] OR "pharmacist program"[TW] OR "pharmacist assessment"[TW] OR "pharmacist management"[TW] OR "pharmacist care"[TW] OR "pharmacist consult"[TW] OR "pharmacist counselling"[TW] OR "pharmacist evaluation"[TW] OR "pharmacist reviews"[TW] OR "pharmacist interventions"[TW] OR "pharmacist programs"[TW] OR "pharmacist assessments"[TW] OR "pharmacist consults"[TW] OR "pharmacist evaluations"[TW] OR "pharmacologist review"[TW] OR "pharmacologist intervention"[TW] OR "pharmacologist program"[TW] OR "pharmacologist assessment"[TW] OR "pharmacologist management"[TW] OR "pharmacologist care"[TW] OR "pharmacologist consult"[TW] OR "pharmacologist 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Web of Science

TS= **Pharmacy** Near/0 (Review$ or intervention$ OR program* OR assessment$ OR management OR care OR consult$ or counselling OR evaluation$)

Polypharmacy, pharmaci*, drug$, medicine$, medication$, pharmaceutic*, prescribing$, prescription$

AND

(randomi?ed controlled study OR randomi?ed controlled trial)

Embase (Ovid)

((Polypharmacy adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (pharmaci* adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (drug? adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (medicine? adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (medication? adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (pharmaceutic* adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (prescribing? adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?)) or (prescription? adj (Review? or intervention? or program* or assessment? or management or care or consult? or counselling or evaluation?))).tw.

OR exp “drug utilization review” OR pharmaceutical services.mp. or exp “pharmacy (shop)”/

AND

("randomi#ed controlled trial" or "randomi#ed controlled study").tw. OR exp randomized controlled trial/ OR exp randomized controlled trial/ or exp controlled study/ or RCT.mp.

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Appendix 3 Data collection form for systematic review

Item	**Question**	**Options**	**Explanation**
1.1	Study title		First five words
1.2	Study population *Free text*		Study inclusion criteria e.g. patients over 65, patients taking 5 or medicines, patients recently discharged from hospital
1.3	Recruitment process *Free text*		How were participants recruited for the intervention? E.g. through primary care registers and invitations sent my physician or pharmacist
1.4.1	No. of control participants		Number of control participants at the start of the study
1.4.2	No. of intervention participants		Number of participants enrolled in the intervention group at the start of the study
1.4.3	Total No. of participants		Total number of participants enrolled at the start of the study
1.5.1	No. of control sites		Number of control sites at the start of the study
1.5.2	No. of intervention sites		Number of intervention sites at the start of the study
1.5.3	Total No. of sites		Total number of sites in the study
1.6	Aim of study *Free text*		Primary aim only
1.7	Companion papers		List references for any companion papers, e.g. protocol, process evaluation
2.1	Aim of the review *Free text*		What is the stated aim of the review e.g. falls reduction. This is not the aim of the paper. If not stated, write "not stated"
2.2.1	Content of the MR	ID of MRPs	Identification of medicines related problems (MRPs) also known as drug-related problems. MRPs are defined by PCNE as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes." [1] Examples include lack of efficacy, adverse reaction, drug interaction, medicine no longer indicated. Discussion or assessment of MRPs as an explicit part of the intervention
	List manually	Adherence	Discussion or assessment of a patient's medicines taking behaviours is an explicit part of the intervention
		Education	Intervention includes either information giving relating to condition, lifestyle or medicines use (includes counselling)
		Social/FH	Intervention includes an assessment or discussion of a patient's social or family history. Family history includes recording family members current and past illnesses. Social history explores aspects of a patient's home, work or social life that could be clinically significant.
		Clinical assessment	Intervention includes one or more clinical assessment, e.g. blood pressure measurement, measurement of blood glucose, measurement of height and weight
		Other	Any other content of the intervention that isn't covered by the definition of a MR or other cited examples. E.g. assessing inhaler/ injection technique
2.2.2	Information availability	Pt interview & medication history	Intervention included a patient interview and review of medication history. This equates to PCNE classification of MR at level 2a [2]. Medication history may not include full access to physician notes. Patient interview enables medicines reconciliation, over the counter medicines use and patient involvement.
		Pt interview, medication history & clinical data	Intervention included a patient interview, review of medication history and clinical data (including access to physician held notes and results from laboratory tests) . This equates to PCNE classification of MR at level 3. [2] Patient interview enables medicines reconciliation, over the counter medicines use and patient involvement.

2.2.3	Pharmacist resolution of MRPs	Yes	Intervention description refers to MRPs that pharmacist will resolve
		No	Intervention does NOT refer to MRPs the pharmacist will resolve
2.2.4	Is the pharmacist capable of making prescription changes following the review?	Yes	The pharmacist is able to make prescription changes following the review. This may be because the pharmacist is an independent or supplementary prescriber, or because there is a pre-arranged agreement with a prescriber that certain suggested changes can be made without prescriber scrutiny.
		No	The pharmacist is unable to make changes to the prescription following the review and these changes must be actioned by another (e.g. physician)
		Uncertain	Description of the intervention isn't detailed enough to ascertain whether the pharmacist is capable to make prescription changes following the review
2.2.5	Referral to physician for resolution of MRPs that pharmacist cannot resolve	Yes	Intervention includes a process for referral to physician for MRPs that pharmacist cannot resolve
		No	Intervention does NOT include a process for referring MRPs to physician
		Uncertain	Description of the intervention does not make it clear about process of the resolution of MRPs
2.2.6	How is the referral to the physician made?	face to face	Following identification of issues identified in MR, these are communicated to the patient's physician face to face.
		Written	Following identification of issues identified in MR, a written referral is made to the patient's physician, e.g. pharmaceutical care plan, specifically formatted referral letter. This can be via delivered letter or fax
		Electronic	Following identification of issues identified in MR, an electronic referral is made to the patient's physician, e.g. via direct email or a platform such as PharmOutcomes
		Telephone	Following identification of issues identified in MR, the patient's physician is contacted via telephone to be informed of these
		Patient	Following identification of issues identified in MR, patients are signposted to their physician to discuss these issues
		Uncertain	Referral to physician is part of the intervention but uncertain/ not documented how these are made
		None	Referral to the physician was not part of the intervention
2.2.7	Follow up with patient after MR	Yes	Follow up with patient by pharmacist or pharmacy team for the purposes of checking MR outcomes or further MR actions. This is not follow-up purely for data collection for the study.
		No	Pharmacist or pharmacy team did not follow up with patient for the purposes of checking MR outcomes or further MR actions. Select "no" if follow-up is purely for study data collection.
2.2.8	Follow up with physician after MR	Yes	Follow up with physician by pharmacist for the purposes of following up on any recommendations or patient care following the MR. This is not follow-up purely for data collection for the study.
		No	Pharmacist did not follow up with physician for the purposes of checking MR outcomes or further MR actions. Select "no" if follow-up is purely for study data collection.
2.3.1	Referral process *Free text*		How is the patient referred for the medication review (MR)? E.g. referral from GP, as part of a routine consultation. The referral process may be identical to the study recruitment process. If so annotate as “recruited and referred at the same time as described in 1.3)"
2.3.2	Mode of delivery	face to face	Patient interview part of intervention takes place face to face
		telephone	Patient interview part of intervention takes place over the telephone

		virtual	Patient interview is undertaken virtually using approved software programmes
		unclear	Unclear how the patient interview takes place
2.3.3	Physical location	Hospital	MR undertaken in hospital as an inpatient
		General Practice	MR undertaken in general practice/ physician's office
		Community Pharmacy	MR undertaken in a community pharmacy
		Domiciliary	MR undertaken in patient's home
		Care	MR undertaken in a care home
		Outpatient	MR undertaken in an outpatient clinic. Outpatient or ambulatory clinics are medical facilities that perform procedures that do not require an overnight stay in a hospital or care facility.
2.3.4	Intensity: Number of times consultations were delivered over a period of time		How many times were consultations delivered over a period of time? E.g if the patient had an initial MR and was then followed up at 1 month, 6 months, 12 months, the intensity would be 4. Also include the time intervals if appropriate. One off intervention (1). May also be less specific, e.g. "daily" or "regular"
2.3.5	Duration: Average length of time for the consultations		What was the reported average length of time for consultation? E.g. 30 mins, 50-60 mins. If times are given for any follow up appointments, record these also. If not reported, state "NR", Not reported
2.3.6	Duration: period of time intervention delivered over		How long was the period of time the intervention was delivered over? E.g. one off, duration of hospital stay, if after initial consultation patient followed up over 3 months (3 months)
2.4	Other relevant details		Any other content relevant details of the intervention that isn't covered elsewhere. E.g. staged review, where pharmacist remotely reviews the medicines then interviews the patient at a different time following this; follow-up conducted by pharmacy technicians
2.5	BCTs		Target Behaviour Change Technique (BCT) behaviour is patients taking medicines in accordance with agreed directions. Record page number, BCT and example
2.6	EPOC subcategory		EPOC taxonomy of health systems interventions. Record page number, EPOC taxonomy and example
3.1.1	Content of control	ID of MRPs	Identification of medicines related problems (MRPs) also known as drug-related problems. MRPs are defined by PCNE as "an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes." Examples include lack of efficacy, adverse reaction, drug interaction, medicine no longer indicated. Discussion or assessment of MRPs as an explicit part of the intervention
	List manually	Adherence	Discussion or assessment of a patient's medicines taking behaviours is an explicit part of the intervention
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		Clinical assessment	Intervention includes one or more clinical assessment, e.g. blood pressure measurement, measurement of blood glucose, measurement of height and weight
		Other	Any other content of the intervention that isn't covered by the definition of a MR or other cited examples. E.g. medicines reconciliation

3.1.2	Information availability	NR	Not reported; content of control group is not described. Unless there is a description of usual care, this is defined as not reported.
	List manually	Patient interview	Is patient interview part of the control?
		Medicines history	Does the control group have access to patients' medicines history?
		Clinical data	Is access to clinical data part of the control?
3.2.1	Professional(s) delivering control *Free text*	Other	Other relevant details e.g. pharmacy held medication records only, summary care record
3.2.2	Mode of delivery		Who delivers the control intervention? E.g. doctors, nurses, control pharmacists, other pharmacy staff
		face to face	Is the control delivered face to face?
		telephone	Is the control delivered by telephone?
3.2.3	Physical location	NR	Delivery of control not reported
		Hospital	Control undertaken in hospital as an inpatient
		General Practice	Control undertaken in general practice/ physician's office
		Community Pharmacy	Control undertaken in a community pharmacy
		Domiciliary	Control undertaken in patient's home
		Care	Control undertaken in a care home
3.2.4	Intensity: Number of times consultations were delivered over a period of time	Outpatient	Control undertaken in an outpatient clinic. Outpatient or ambulatory clinics are medical facilities that perform procedures that do not require an overnight stay in a hospital or care facility.
3.2.5	Duration: Average length of time for the control		How many times were consultations delivered over a period of time? E.g if the patient had an initial MR and was then followed up at 1 month, 6 months, 12 months, the intensity would be 4. Also include the time intervals if appropriate. One off intervention (1). May also be less specific, e.g. "daily" or "regular"
3.2.6	2.3.6 Duration: period of time control delivered over (months)		What was the reported average length of time for control? E.g. 10 mins, 30 mins. If times are given for any follow up appointments, record these also. If not reported, state "NR", Not reported
			How long was the period of time the intervention was delivered over? E.g. one off, duration of hospital stay, if after initial consultation patient followed up over 3 months (3 months)
3.3	BCTs aimed at patient behaviour *Free text*		Target Behaviour Change Technique (BCT) behaviour is patients taking medicines in accordance with agreed directions. Record page number, BCT and example
3.4	Other relevant details *Free text*		Any other content relevant details of the control intervention that isn't covered elsewhere. E.g. support staff provide counselling at prescription collection
4.1	Planned adaptations *Free text*		Adaptations If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. E.g. if the intervention is planned to be delivered in the community pharmacy, but if the patient is unable to visit the pharmacy the pharmacist is able to visit the patient in their home

4.2	Adaptations during intervention *Free text*		Adaptations If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). E.g. pharmacist was supposed to deliver intervention in the GP surgery but space was needed for another clinician so intervention had to take place at the community pharmacy
4.3	Assessment of fidelity *Free text*		Method of assessment of fidelity: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.
4.4	Fidelity outcome *Free text*		What was of the fidelity of the intervention delivered? E.g. 20/30 interventions were delivered
4.5	Pharmacist Reach *Free text*		Reach: proportion of the target population PHARMACISTS that participated in the intervention e.g. how many pharmacists/ pharmacy sites were approached to participate in the study and how many actually participated
4.6	Patient Reach *Free text*		Reach: proportion of the target population PATIENTS that participated in the intervention e.g. how many patients were approached to participate in the study and how many actually participated. Also record the number of "lost to follow up" patients, and the final numbers included for data analysis.
FOR ALL OUTCOMES EXTRACT REPORTED RESULTS FOR INTERVENTION AND CONTROL GROUPS e.g. % of patients using resource [followed by mean (SD)] Control 20.9, [3.4 (9.4)] Intervention 46.4, [7.0 (17.3)] May be necessary to narrow down to the main outcomes, i.e. what the intervention was trying to address			
5.1	Beuscart 2018 Core Outcome Set		
5.1.1	Potentially inappropriate medicines *Free text*		This outcome maps to medication use
5.1.2	Medicines related Problems *Free text*		This outcome maps to medication use
	Beuscart and Kersting outcomes		
5.1.3	Quality of life *Free text*		This outcome maps to Beuscarts Patient-reported outcomes and Kerstings disease-specific quality of life/ health status, quality of life/ generic health
5.1.4	Pain *Free text*		This outcome maps to Beuscart Pain relief and Kersting Pain
5.2.1	Hospitalisations *Free text*		This outcome maps to Beuscarts Adverse events and Kerstings Healthcare utilisation
5.2	Kersting 2020 Patient-relevant outcomes		
5.2.2	Adverse drug events *Free text*		This outcome maps to Adverse effects/ complications
2.2.3	Physician acceptance of pharmacist recommendations *Free text*		This outcome maps to Confidence in therapy
5.2.4	Self care/ Barthel index *Free text*		This outcome maps to Daily activities / participation
5.2.5	Changes to clinical monitoring parameters		This outcome maps to Disease control
5.2.6	Outpatient appointments *Free text*		This outcome maps to Healthcare utilisation

5.2.7	Physician appointments *Free text*		This outcome maps to Healthcare utilisation
5.2.8	Medication changes *Free text*		This outcome maps to Healthcare utilisation
5.2.9	Medication costs *Free text*		This outcome maps to Healthcare utilisation
5.2.10	Cost effectiveness *Free text*		This outcome maps to Healthcare utilisation
5.2.11	Medication Appropriateness Index *Free text*		This outcome maps to Intervention/ therapeutic decision
5.2.12	Patient Medicines Adherence *Free text*		This outcome maps to Optimal support
5.2.13	Satisfaction		This outcome maps to Satisfaction
5.2.14	Mortality *Free text*		This outcome maps to Survival/ Mortality
5.3	Other outcomes of interest		
5.3.1	Other (Specify) *Free text*		Any other outcomes that are
	Process measures		Any measures that help explain the mechanism of effect
6.1	Participant responses to & interaction with intervention *Free text*		This describes how participants interact with a complex intervention. Participants include pharmacists, patients, physicians, and others involved in the intervention. E.g. how the pharmacist is integrated into the wider healthcare team, physician acceptance of pharmacists' recommendations
6.2	Mediators *Free text*		Mediators are intermediate processes which explain subsequent changes in outcomes. They identify why and how interventions have effects (causal links). Mediators occur during an intervention and are often found in process evaluations.
6.3	Moderators of effect *Free text*		These are factors which influence the relationship of the intervention (MR) and the outcome, i.e. on whom and under what circumstances MR effect outcomes. Moderators precede treatment. These can include the development, implementation, and actions of recommendations post-review e.g. pharmacist met with physician and discussed the pharmaceutical care plan
6.4	Unanticipated pathways & consequences		These describe the unexpected effects following an intervention e.g. decreased footfall in the community pharmacy or an increase in professional services
7	RISK OF BIAS	Cochrane risk-of bias tool for randomised trials (RoB2). See Cribsheet for detained explanations. https://drive.google.com/file/d/18Zks7k4kxhbUUlbZ51Ya5xYa3p3ECQV0/view	

Appendix 4 Risk of bias in detail for each study included in systematic review

Author (year)	Domain 1: Risk of bias arising from the randomization process	Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Domain 3: Risk of bias due to missing outcome data	Domain 4: Risk of bias in measurement of the outcome	Domain 5: Risk of bias in selection of the reported result	Overall Risk of Bias
Alalawneh (2022) [239]	Low	Low	Low	Low	Low	Low
Anderegg 2018 [224]	Low	Low	Low	Low	Low	Low
Graabaek 2019 [190]	Low	Low	Low	Low	Low	Low
Lenaghan 2007 [191]	Low	Low	Low	Low	Low	Low
Lim 2004 [213]	Low	Low	Low	Low	Low	Low
Lin 2018 [214]	Low	Low	Low	Low	Low	Low
Maritnez-Mardones (2023) Ahumada-Canale 2021a, 2021b [236,240,241]	Low	Low	Low	Low	Low	Low
Schulz 2019, Schulz 2020, Laufs 2018 [192,242,243]	Low	Low	Low	Low	Low	Low
Aguiar 2018 [237]	Low	Some	Low	Some	Some	Some
Basheti 2016 [244]	Low	Some	Low	Some	Some	Some
Basheti 2018 [216]	Low	Some	Low	Some	Low	Some
Garcia 2015 [193]	Low	Some	Low	Low	Low	Some
Jameson 1995 [225]	Low	Some	Low	Low	Low	Some
Lisby 2018 [194]	Low	Some	Low	Low	Low	Some
Sakthong 2018 [217]	Low	Some	Low	Low	Low	Some
Sellors 2001 [227]	Low	Some	Low	Low	Some	Some
Williams 2004 [226]	Low	Some	Low	Low	Some	Some
Zermansky 2002 [195]	Low	Some	Low	Low	Low	Some
Aburuz 2020 [218]	Low	Some	Low	High	Low	High
Al alawneh 2019 [219]	Low	Some	Low	High	Low	High
Al-Qudah 2018, Basheti 2016 [215,220]	Low	Some	Low	High	Low	High
Basger 2015 [232]	Low	Some	Low	High	Low	High
Bonnerup 2020 [196]	Low	Some	Low	High	Some	High
Briggs 2015 [233]	Low	Some	Low	High	Some	High
El-Refae 2017 [221]	Low	Some	Low	High	Some	High
Erku 2017 [238]	Low	Some	Low	High	Low	High

Freeman 2021, Foot 2017 [234,245]	Low	Low	Low	High	Low	High
Geurts 2016 [197]	Low	Some	Low	High	Low	High
Gurwitz 2021 [228]	Low	Some	Low	High	Low	High
Holland 2005, Holland 2010, Pacini 2007 [198,246,247]	Low	Low	Low	High	Low	High
Huiskes 2020 [199]	Low	Low	Low	High	Low	High
Kempen 2021, Kempen 2020, Kempen 2017 [200,248,249]	Low	High	Low	High	Low	High
Krska 2001 [201]	Low	Low	Low	High	Some	High
Lea 2020 [202]	Low	Low	Low	High	Low	High
Lenssen 2018 [203]	Low	Low	Low	High	Low	High
Liou 2021 [222]	Low	Some	Low	High	Low	High
Lyons 2016 [204]	Low	Low	Low	High	Low	High
Malet-Larrea 2016, Jodar-Sanchez 2015, Varas-Doval 2020 [205,250,251]	Low	Low	Low	High	Low	High
Messerli 2016, Messerli 2018 [206,252]	Low	Low	Low	High	Low	High
Nabergoj Makovec 2021 [207]	Low	Low	Low	High	Low	High
Östbring 2021, 2018 [208,253]	Low	Low	Some	High	Low	High
Ravn-Nielsen 2018, Rasmussen 2019 [209,254]	Low	Low	Low	High	Low	High
Roughead 2022 [235]	Low	Low	Low	High	Low	High
Sellors 2003 [229]	Low	Some	Low	High	Some	High
Shim 2018 [223]	Low	Some	Low	High	Low	High
Tuttle 2018 [230]	Low	Low	Low	High	Low	High
van der Heijden 2019, Ahmad 2010 [210,255]	Low	Low	Low	High	Low	High
Verdoorn 2019, Verdoorn 2018, Verdoorn 2021 [211,256,257]	Low	Some	Some	Some	Low	High
Zermansky 2006 [212]	Low	High	Some	High	Low	High
Zillich 2014 [231]	Low	Some	Some	High	Low	High

Appendix 5 Detailed reported outcomes in systematic review

Risk of Bias	Author (Year)	Medicines Related Problems (MRPs)/ MAI/ ADE	Quality of Life	Healthcare utilisation	Physician acceptance of pharmacist recommendations	Changes to clinical monitoring parameters	Medication changes	Healthcare related costs	Adherence	Satisfaction	Mortality	Other
Low	Alalawneh (2022) [239]	NR	NR	NR	NR	NR	NR	NR	*Intervention 32.1%, Control 9.4% (p=0.01] §*	NR		*Intervention group significant improvement in knowledge of medicines Mean scores 0.054, P < .001 §*
Low	Anderegg 2018 [224]	NR	NR	NR	NR	*SBP reduction in intervention group - 8.64mmHg (-12.8 to -4.49)* §	*Mean changes Intervention 4.9± 5.1, Control 1.1 ± 1.6 (p=0.0003)* §	NR	NR	NR	NR	NR
Low	Graabaek 2019 [190]	Patients with recommendations, n (%) ED= 169 (85), STAY = 176 (88); Recommendations discussed with physicians n(%), ED 66 (33), STAY 55 (28)	NR	Length of stay in days, median (IQR); Control =2.0 (0.7-5.2), ED = 1.9 (0.6-5.0), STAY = 1.3 (0.7-4.2), p=0.404; Patients with medication-related acute readmissions at 30 day follow-up, n (%), Control 11	Overall acceptance rate = 57%	NR	NR	NR	NR	NR	Mortality rate (%); Control= 8.0, ED=5.5, STAY=6.5, p=0.601	NR

				(5.6), ED = 9 (4.5), STAY = 5 (2.6), p=0.331 Number of contacts to general practitioner, median (IQR); Control= 18 (11-34), ED= 17 (10-31), STAY= 18 (10-30), p=0.899								
Low	Lenaghan 2007 [191]	NR	Difference in EQ-5d utility score in 6 months (intervention minus control) 0.09 (CI−0.19 to 0.02 P= 0.10 ; Difference in VAS score over 6 months 4.8 (CI−12.5 to 2.8 p = 0.21	Unplanned admissions, Intervention n=20, Control n=21, RR = 0.92, 95% CI 0.50–1.70, P = 0.80)	85% of recommendations actioned	NR	*Mean difference in the change in the number of items prescribed over 6 months was −0.87 (in favour of the intervention group), 95% CI −1.66 to −0.08, P = 0.03* §	NR	NR	NR	Deaths Intervention n=7, Control n=6 (1.3% difference in proportions, confidence interval −12.1 to 14.7%, P = 0.81)	NR
Low	Lim 2004 [213]	Reported ADRs at Month 2, Intervention=13, Control=6	NR	NR	76% acceptance rate	NR	NR	cost avoidance of S$387.28 over 2 months	*Intervention improved compliance (OR = 2.52; 90% CI, 1.09 to 5.83)*§	NR	NR	NR
Low	Lin 2018 [214]	NR	*Difference/ effect size (standardized mean difference)*	NR	NR	Difference/ effect size (standardized mean difference):	NR	Difference in difference estimate of total	NR	NR	Control= 8.8%, Intervention=	*Difference/ effect size (standardized mean difference)*

			, EQ index, 1.3147 p= 0.0464, EQ-VAS = -0.2244, p= 0.0455 §			HbA1c (%) = 0.0878, p=0.0503, HDL [mg/dL] = 0.2123, p= 0.0592		medical expenditure after 16 months - 3,758,373 TWD (reduction in intervention group)			2.3%, p=0.06	*Barthel index = -0.2092, p=0.0391* §
Low	Maritnez-Mardones (2023) Ahumada-Canale 2021a, 2021b [236,240,241]	NR	NR	Intervention group 43.53% reduction in meds- related hospitalisation costs	GP intervention acceptance rate 92.9% (83.3-97.8%),	*Goal achievement HT OR 4.37, (95% CI 2.54 to 7.51, P = .001) §; LDL C OR 3.67, (95% CI 2.13 to 6.33, P = .001); T2DM OR 6.97, (95% CI 3.69 to 13.2, P = .001) § Intervention CVD risk score -2.27, (95% CI -2.84 to -1.69, P < .001) §*	*Mean No of meds in intervention v control -0.86, (-1.14 to -0.58, P < .001)*	Estimated cost savings Medicines = US$35.73 (95% CI: -11.38–82.84); pathology tests US$9.91 (95% CI -13.01–32.83)	*Intervention adherence OR 6.60, (95% CI 1.36 to 31.9, P = .001) §*	NR	Predicted CVD mortality intervention = 15.5%, Control 20.4%	*ICER of $963 per QALY; Intervention is cost effective compared to control*
Low	Schulz 2019, Schulz 2020, Laufs 2018 [192,242,243]	NR	*Minnesota Living with Heart Failure Questionnaire (MLHFQ) Mean change to baseline and the intervention effect (95% CI) at 365 days, -1.9 (-7.6 to 3.8), at 730 days, -7.8*	Unplanned CV hospitalisations, Intervention n=91, Control n=93.	NR	NR	No. drug intakes/day, median (IQR), Intervention= 3.0 (2–3), Control = 3.0 (2–3)	NR	*Adherence calculated using proportion of days covered (PDC) Mean (SD) after 365 days, Intervention = 91.2 (±11.9), Control = 85.5 (±16.6), p= 0.007*§	NR	NR	NR

			(-14.5 to --1.1), p=0.02 §									
Some	Aguiar 2018 [237]	125/189 MRPs (66.1%) were resolved by the pharmacist	NR	NR	96.9% of pharmacist recommendations were accepted by physician	HbA1C % Change at 12 months Mean, [95% CI] Intervention -0.79[-1.1, -0.5], Control -0.16 [-0.5, 0.2]; Change in SBP (mmHg) at 12 months Mean, [95% CI] Intervention -12.5 [18.5, -6.5], Control -4.4 [-11.0, 2.3]; LDL cholesterol (mg/dL) change at 12 months Intervention -10.2 [-20.1, -0.3], Control -12.2 [-21.2, -3.1]	Change in No. of medications at 12 months, Mean [95% CI], Intervention 0.6 [0.2, 0.9], Control 0.1 [-0.3, 0.5]	NR	*Average score from the Morisky–Green test Intervention 0.9; P<0.001; Control 0.1; P= 0.383* § Improved adherence in intervention	NR	NR	*Logistic regression, model 3 pharmacist interventions increased about 6 times the chance of achieving the individualized goal of HbA1C levels compared with the control (odds ratio = 5.83 [95% CI: 1.16, 29.25], P= 0.032)*.§
Some	Basheti 2016 [244]	MRPs resolved at follow up, Intervention ~70%, Control 2% (p<0.001)§	NR	NR	Physician acceptance rate of pharmacist recommendations = 94%	*BP at follow up [Mean, SD], Intervention 110.36/81.55 ± 9.45/3.91, Control 125.0/88.73 ± 10.34/4.12, p<0.001)§. Blood glucose levels at follow up [Mean, SD], Intervention 99.08 ± 9.66, Control 115.48 ± 17.34,*	NR	NR	NR	NR	NR	NR

						p<0.001) §. *Triglyceride levels at follow up [Mean, SD], Intervention 148.53 ± 15.98, Control 170.74 ± 6.26, p=0.001*§						
Some	Basheti 2018 [216]	Improved or resolved MRPs at follow up, Intervention 76.2%, 0% for control	EQ-5D Mean [SD] scores at study end, Intervention 0.96 ± 0.11, Control 0.91 ± 0.12	NR	Physician acceptance of pharmacist recommendations = 71.4%, 28.6% implemented;	NR	NR	NR	*Mean [SD] Morisky Score at Study End, Intervention 0.43 ± 1.13 p<0.001* §, Control 2.24 ± 2.80 p=0.08	NR	NR	*Mean [SD] self-care score at study end, Intervention 13.9 ±3.9 p<0.001* §, Control 9.38 ±6.6 p=0.16
Some	Garcia 2015 [193]	NR	NR	NR	NR	No significant reduction in clinical measures for the intervention group. Little difference between intervention and control groups at 12 months after discharge.	NR	NR	NR	NR	NR	*Adherence to the MAT-CHDSP criteria at 12 months was higher in intervention group (78.4%) than control 962.0%), with p<0.001*§
Some	Jameson 1995 [225]	Change in side effects score, Control = -1.9, Intervention = -3.7, Net difference 1.8	NR	NR	NR	NR	*Change in number of drugs at follow up, Control =0.5, Intervention = -0.6, Net difference 1.1, p=0.004* §	*6-month cost $, control = 1052, Intervention= 799, Net difference = 293, p=0.008* §	NR	NR	NR	NR

Some	Lisby 2018 [194]	NR	EQ-5D 3 months after discharge= % (95%CI) reporting no problems with the 5 areas. Mobility, Intervention n=24 (6-42), Control n=30 (13-47); Personal care, Intervention n=48 (27-69), Control n=53 (34-72); *Usual activities, Intervention n= 8 (0-20), Control n=43 (25-62)*§ *[p<0.01];* Pain/discomfort, Intervention n=24 (6-42) Control n=30 (13-47); Mental health, Intervention n=67 (45-	Unplanned physician appointments Mean, (95%CI), Intervention = 14.9 days (8.9-21.0), Control = 27.3 days (18.9-35.7)	Physician adhering to one or more recommendation = 46%	NR	NR	NR	NR	NR	NR	NR

			83), Control n=60 (41-79)									
Some	Sakthong 2018 [217]	NR	*Mean change between pre- and post-PROMPT-QoL results, total score; Intervention = 17.7 ± 5.9, Control = 0.9 ± 3.1, p< 0.001* §	NR	NR	NR	NR	NR	NR	NR	NR	NR
Some	Sellors 2001 [227]	NR	NR	Mean no. of visits (SE): All, Intervention = 0.14 (0.02), Control = 0.11 (0.02); Drug related, Intervention = 0.04 (0.01), Control = 0.04 (0.01)	Implementation rate for recommendations =77.8%	NR	NR	Mean daily medication costs Intervention = $5.01, Control = $4.82, p = 0.72	NR	NR	NR	NR
Some	Williams 2004 [226]	NR	RAND 36-item health survey Mean (SD); Baseline Intervention =61.8 (±17.8), Control 63.3 (±16.5), After 6 weeks	NR	NR	NR	*Mean (SD) number prescription drugs at 6 weeks, Intervention = 5.6 (±1.89), Control = 7.7 (±2.67) Difference in Change Score (95% CI), 0.98*	*Mean (SD) at 6 weeks, Intervention = 135.72 (±75.42), Control = 174.12 (±94.56) Difference in Change Score (95% CI) 20.16 (5.78–*	NR	NR	NR	Self-rating anxiety score at 6 weeks Mean (SD), Intervention 13.2 (±6.5), Control 13.1 (±6.8) Cognitive function, Randt memory at

			Intervention =65.5 (±18.9), Control=65.7 (±17.0).				*(1.348–609), p= 0.001* §	*34.54, p=0.006*)§				6 weeks, Mean (SD), Intervention = 9.6 (±3.5), Control= 9.6 (±3.4) Physical function, physical performance tests (seconds), Mean (SD);Baseline, Intervention =57.2(±28.59), Control=57.2 (±28.8). 6 weeks, Intervention= 59.6 (±31.6), Control= 56.3 (±27.5)
Some	Zermansky 2002 [195]	NR	NR	>1 hospital admission Intervention 6%, Control 7% Outpatient appointments Median (IQR), Intervention 1 (0,3), Control 1 (0,3), p=0.41 Physician appointments Median (IQR) Intervention 6 (3, 10), Control	86% of recommendations implemented	NR	*Change in number of medicines Mean (SD), Intervention 0.2 (1.55), Control 0.4 (1.53), p=0.01* §	*change in cost Mean (SD) Intervention £1.80 (17.55), Control £6.53 (21.99) p= 0.00001* §	NR	NR	NR	NR

				6 (3, 10), p=0.69								
High	Aburuz 2020 [218]	*MRPs at discharge; Mean (SD) Intervention 2.34 (±2.1) Control 4.94 (2.44)* § Change in MRPs from baseline to discharge; Mean (SD) Intervention −6.31 (±3.45), Control −3.68 (±2.79)	NR	NR	64.2% of submitted recommendations were accepted by physicians.	NR	NR	NR	NR	NR	NR	NNT pharmaceutical care provided to 1.8 patients (prevention of MRPs) or 4.1 patients (resolution or improvement of MRPs) to achieve benefit in one patient
High	Al alawneh 2019 [219]	Number of MRPs at baseline, Intervention n=600, Control n=541; Number of MRPs at follow up, Intervention n=182, Control n=514 *Number of MRPs per patient intervention = 3.4 ± 1.5 per patient [p<0.001]*§, Control = no significant change	NR	NR	Intervention, 82.9% of recommendations were approved by physicians; 77.1% were implemented	NR	NR	NR	NR	79.2% of patient strongly satisfied/ satisfied with intervention	NR	NR
High	Al-Qudah 2018, Basheti 2016 [215,220]	*MRPs corrected at end of study, Intervention 85%, Control 10%*§ Mean number ± SD of MRP at	P values for differences in QoL [EQ-5D] Interventio	NR	Acceptance rate of pharmacist recommendations among	NR	NR	NR	*Change in medication nonadherence mean score*	NR	NR	*Mean Self-care activity score Interventio*

		follow up, Intervention 0.42 ± 0.79, control 1.33 ± 1.19	n P<0.001, control P<0.001		physicians was 95.1%, 74.6% of accepted recommendations were implemented				*[Morisky MMAS-8] Baseline nonadherence Intervention 81.3%, control 87.8%* §. Follow up nonadherence Intervention 66.7%, Control 85.7%			*n group, Baseline 15.73± 9.00 Follow up 22.44± 8.63 P value for difference P<0.001*§ P value for difference in control group 0.129
High	Basger 2015 [232]	MR identified MRPs in 88/92 patients (8.5 ± 2.7 per patient) Mean difference in medication appropriateness at discharge and follow up; no significant difference in the number of criteria applicable and met in intervention patients, compared to control patients, between follow-up and discharge (0.09 ≤ p ≤ 0.97)	Mean difference in SF-36 scores at discharge and follow up between intervention and control, Positive at follow up, but only statistically significant in 1 domain (vitality, p=0.04)	NR	42.4% of pharmacist recommendations were implemented by physician	Mean difference in pain between control and intervention groups = -0.23 (0.39), p=0.4	NR	NR	NR	NR	NR	NR
High	Bonnerup 2020 [196]	NR	EQ-5D scores mean [95% CI] Difference between baseline and follow-	Mean [95%CI] contacts with GP Intervention 11.8 [10.3-13.3], Control 10.3 [8.9-11.8]	Physician acceptance of recommendations = 65%; this increased to 75% where	NR	NR	NR	NR	NR	Intervention 13.4%, Control 19.2% [p=0.16]	Prescribing errors during hospitalisation, Mean [95% CI], Intervention 0.88

			up, Intervention 0.031 (–0.019 to 0.080), control 0.012 (–0.048 to 0.074), p=0.65. EQ VAS scores mean [95% CI] Difference between baseline and follow-up, Intervention 8.47 (0.98–12.78), Control 6.89 (2.32–14.62), p=0.72		the recommendation concerned a prescribing error							(0.67–1.09), Control 0.84 (0.67–1.01)
High	Briggs 2015 [233]	7.8% of patients in intervention group had been prescribed a Beers criteria medication	NR	*Admission rate, Intervention 53%, Control 62%, adjusted odds ratio =0.67 (p-value =0.0017)* § No effect on Mean [SD] Length of stay, Intervention 6 ± 12, Control 6 ± 11, No effect on Mean [SD] re-presentation to ED, intervention 1	Physician acceptance of pharmacist recommendations= 49%	NR	NR	NR	NR	NR	NR	NR

				± 1, Control 1 ± 1 (p value= 0.43)								
High	El-Refae 2017 [221]	Mean [SD] MRPs at baseline, Intervention 8 ± 3.86, Control 8 ± 3.4 . Mean [SD] MRPs at discharge Intervention 2 ± 2.16, control 3 ± 2.07 (both with significant P values).	NR	Number of hospitalised days Mean [SD] Group 1, Intervention 5.00 ± 1.33, Control versus 4.00 ± 2.36 days (p = 0.001) Group 2 Intervention 4.00 ± 2.06, Control 6.00 ± 3.94 (p = 0.004) *Mean [SD] visits 3 months before and after Intervention Before 2.12 (1) After 0.78 (0.76)* §, Control Before 3 (2) After 2(0.8)	Physician acceptance of pharmacist recommendations, Accepted and implemented = 71%, modification to 12 % of recommendations, Accepted and not implement 10%, Rejected 3%	**HbA1c** Mean [SD] Baseline, follow up; Intervention 10.38 ± 1.68, 7.7 ± 1.68 §, Control 9.98 ± 1.54, 9.7 ± 1.36. **SBP** Mean [SD] Baseline, follow up; Intervention 137 ± 18, 128 ± 5.7, Control 120 ± 14, 128 ± 5.7. **Total cholesterol** *Mean [SD] Baseline, follow up; Intervention 116 ± 5.7, 96.32 ± 8.6*, § Control 120 ± 8.2, 106 ± 8.8	NR	NR	Mean (SD) Adherence scale, Admission Intervention 14.22 ± 4.95, Control 10.42 ±, Follow-up Intervention 6.24 ± 3.89, Control 9.00 ± 5.14	NR	NR	*Mean [SD] number of self-care activities, Initial, Follow-up; Intervention 27.62 ± 6.72, 34.26 ± 7.02*,§ Control 28.62 ± 7.73, 27.4 ± 7.99 Mean [SD] of hospitalisation cost Intervention $260.77 ± 259.21, Control $333.30 ± 269.98
High	Erku 2017 [238]	NR	NR	*Hospitalisation rate Intervention 43%, Control 91%* §	NR	NR	NR	NR	*Patients with Poor Morisky score at baseline vs 6 months later, Intervention 90.8% vs 39%* §, *Control 86.8% vs 69.8%*	NR	NR	NR
High	Freeman 2021, Foot 2017 [234,245]	NR	NR	*12-month Hospital readmission or*	NR	NR	NR	*Estimated incremental cost per*	NR	NR	NR	NR

				ED presentation, No. of events (incidence rate), Intervention n =146 (1.49), Control n= 370 (2.17), Incidence rate ratio (95% CI) Fully adjusted = 0.64 (0.47–0.87) §				*patient of the interventio n = $164, benefit–cost ratio, 31:1*. §				
High	Geurts 2016 [197]	Average potential MRPs and Pharmaceutical care issues identified per patient; Intervention 2.2, Control 0.2. Resolution at 12 months; Intervention 69.2%, Control 91.5%.	NR	NR	NR	DBP reduction in intervention group (79.8–76.8 mmHg; p = 0.008) HDL increase in intervention groups 1.29–1.37 mmol/L; p = 0.021, 1.26–1.37 mmol/L; p = 0.039. LDL decrease Control 2.61–2.58 mmol/L; p = 0.032 No significant effect in other parameters (BMI, HbA1c, BM, CrCl, Na+, K+)	NR	NR	NR	NR	NR	NR
High	Gurwitz 2021 [228]	IR per 100 patient-days of observation; Control IR=0.83, Intervention IR=0.92. Preventable ADEs, IR (incidence rate	NR	NR	35% of recommend ations implemente d	NR	NR	NR	NR	NR	NR	NR

		per 100 patient-days of observation) Control IR=0.47, Intervention IR=0.42. Potential ADEs Control IR= 0.13, Intervention IR=0.18										
High	Holland 2005, Holland 2010, Pacini 2007 [198,246,247]	NR	Difference in change in QoL (intervention minus control) over 6 months, (95% CI) EQ-5D 0.006 (-0.048 to 0.059) p=0.84, VAS −4.12 (−8.09 to −0.15) P=0.042	*30% greater rate of readmission in intervention group (rate ratio =1.30, 95% CI 1.07 to 1.58, P=0.009* § *43% increase in GP home visits in intervention group (rate ratio =1.43, CI 1.14 to 1.80, p=0.002* §	NR	NR	NR	ICER of £53,454 per QALY	NR	NR	Deaths Intervention n=49, control n=63 Hazard ratio =0.75 CI 0.52 to 1.10 p=0.14	*Medication hoarding difference between visit 1 and 2 24.1% (95% CI 17.7 to 30.3 P<0.001* §
High	Huiskes 2020 [199]	Mean number (SD) MRP after 1 month, Intervention= 0.3 (± 0.7), Control = 0.8 (± 0.1). At least 1 MRP resolved after 1 month, Intervention = 47%, Control= 12%	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
High	Kempen 2021, Kempen 2020, Kempen 2017 [200,248,249]	NR	NR	Incidence of unplanned hospitalisations, control = 1.63, Intervention	Implementation rate ranged between 62% and 80%,	NR	NR	NR	NR	NR	NR	NR

				1=1.74 (adjusted rate ratio [RR], 1.04; 95%CI, 0.89-1.22), Intervention 2=1.95 (adjusted RR, 1.15; 95% CI, 0.98-1.34)								
High	Krska 2001 [201]	MRPs resolved at follow up, Intervention= 82.7%, Control=41.2% p=<0.0001§	NR	Decrease in emergency admissions, Intervention= 74%, Control= 27%	Agreement with recommendations =95.8%; 87.3% of these were resolved	NR	NR	Costs increased, Intervention=34.5%, Control= 25%. Costs decreased, Intervention= 44.6%, Control=34.7%	NR	NR	NR	NR
High	Lea 2020 [202]	NR	NR	Time to first readmission, Intervention =184 days, Control= 116 days HR 0.82, 95% CI 0.64 to 1.04, p=0.106	62% of MRPs discussed in MDTs were actioned immediately	NR	NR	NR	NR	NR	Overall survival HR= 0.66, 95% CI 0.48 to 0.90, p=0.008 § [in favour of intervention]	NR
High	Lenssen 2018 [203]	72% of MRPS were partly or fully resolved	NR	Drug related readmission Intervention n=3, Control n=7	NR	NR	Number of changes in medication after discharge during follow-up, Intervention= 16 ± 10 (3–52), Control	NR	Proportion of patients < 90% adherent at 6 months, Intervention=5.7, Control =14.0, p=0.003 §	Satisfaction with the Medicines Advice Service was high, with 91.8% (n=245) agreeing that they were	NR	NR

							= 16 ± 11 (3–47)		(OR 1.54, 95% CI 1.11 to 2.15, p=0.010)	satisfied overall.		
High	Liou 2021 [222]	*Reduction of MRPs in intervention group 1.6±1.4 to 0.3±0.5 (P<0.01)§*	Difference in EQ-5L scores, Mean, SD Intervention =0.1±0.4, Control= 0.2±0.4, p=.670	NR	Acceptance 77.20%	NR	NR	NR	*Taking medicines as instructed Mean, SD Intervention = 10.0±0.0, Control =8.7± 2.1, P=0.00§*	*Willingness to receive further pharmacist visits Mean SD Intervention = 8.9±2.2, Control =7.4±3.1, P=0.04§*	NR	*Awareness of medical problems Mean SD Intervention= 3.0±4.0, Control =0.9±2.7, P=0.035§*
High	Lyons 2016 [204]	NR	NR	NR	NR	**HbA1c** less than 7% (66.7%, n=16) compared with the control group (31.3%, n=5), with this difference approaching statistical significance (p=0.061). **Total cholesterol** levels (<5 mmol/L) at follow up, Intervention =65.3%, Control =55.1%, (p=0.24)	NR	NR	NR	NR	NR	NR
High	Malet-Larrea 2016, Jodar-Sanchez 2015, Varas-Doval 2020 [205,250,251]	NR	*EQ-5D-3L Mean (SD) utility score difference*	*mean number hospitalisations (SD) during 6 months of study*	NR	*Mean (CI) reduction of health problems over 6 months,*	Mean (SD) difference in number of medicines prescribed	Mean (SD) [€/day] difference between 1st and 6th	NR	NR	NR	NR

			1st to 6th month, Intervention= 0.0528 ± 0.20, Control= -0.0022 ± 0.24, p<0.001§. *VAS Mean (SD) difference 1st to 6th month, Intervention =4.97 ± 15.29, Control= -0.90 ± 15.19, p =<0.001*§	*Intervention=0.03 ± 0.19, Control= 0.06 ± 0.31 Adjusted Odds ratio (OR) [95% CI] for hospitalisation in control group OR=3.7 [1..2, 11.3] p=0.021*§		*Intervention= -0.76 (-0.83, -0.69), Control= -0.04 (-0.10, 0.03)* §	between 1st and 6th interview, Intervention= -0.28 ± 1.25, Control= -0.07 ± 0.95, p= 0.001	interview, Intervention= -0.17 ± 2.24, Control= 0.02 ± 1.58, p= 0.079 Mean (SD) total cost Intervention= €977.57 ± 1455.88, Control= €1173.44 ± 3671.65. Mean incremental QALY of 0.0156 ± 0.004 (95 % CI 0.008–0.023)				
High	Messerli 2016, Messerli 2018 [206,252]	NR	NR	Unplanned visits in 2 weeks after initial MR, Intervention n=202, Control n=214 p=0.324	Fully accepted pharmacist recommendations= 64.3%	Incidence of at least 1 FALL until 28 days after interventionT-28, Intervention= 17.7%, Control=15.9%	NR	NR	MMAS-8D Score at 16 weeks Mean (SD), Intervention =6.85 (1.226), Control = 6.82 (1.237). Medication possession ratio, Intervention = 88.3%, Control- 87.5%, p=0.811)	NR	NR	patient knowledge of medicine use at week 1, Mean (SD). Intervention Interviewer =7.99 (1.83), Intervention patient =9.66 (0.80), Control interviewer = 7.63 (2.10), Control

												patient = 9.49 (1.18) Enhanced security in their medicines following MR= 78.0% Improved confidence in medicines following MR (likert scale), = 82.3%
High	Nabergoj Makovec 2021 [207]	*Average 2.87 MRPs per patient 53% of manifested MRP resolved at second visit. P=0.0001 §*	Reduction in Mean LMQ scores Intervention 97.75 (SD=20.31) to 93.56 (SD=18.55) Control 92.88 (SD=19.7) to 91.16 (SD=21.33)	NR	NR	NR	NR	NR	Overall adherence improved by 1.20 points in intervention group compared to control (p=0.025)	NR	NR	understanding of the purpose of their medicines and daily dose improved and deteriorated in equal proportions (5%)
High	Östbring 2021, 2018 [208,253]	NR	NR	Number unplanned healthcare contact, n (%) Intervention= 22 (14.5) Control= 14 (9.0) Risk difference 5.4 % 95% CI (-1.7 to 12.6) p=0.138	NR	Patients reaching target LDL C Intervention= 37%, Control= 44.2%; absolute difference -7.2% (95% CI -19.9% to 5.3%) Patients reaching target BP Intervention = 59.5%, control= 58.3%	NR	NR	Intervention = 87.8%, Control= 77.4%. *Absolute risk difference = 10.4% (95% CI 1.1% to 19.7%*)	NR	NR	Concerns about medicines, Mean SD Intervention= 11.2 (4.6) Control =12.5 (4.8); P = 0.035

						Risk difference 1.1 % (-11.9 to 14.2) p=0.865						
High	Ravn-Nielsen 2018, Rasmussen 2019 [209,254]	NR	NR	Readmission within 180 d after inclusion HR (SD), Basic V control 0.95 (0.79-1.13), Extended V control 0.75 (0.62-0.90)	Implementation rate of recommendations, hospital =61%, Primary Care 66%	NR	NR	Medication costs Mean (CI) Extended = €15 631 (14 120.26;17 141.86) , Basic = €16 748 (15 232.79;18 263.82), Control = €17 288 (15 780.48;18 794.97)	NR	NR	Drug related death within 180 days HR (SD), Basic V Control, 0.60 (0.14-2.52), Extended V Control, 0.83 (0.22-3.11)	*NNT for readmissions within 180 days, Extended= 11, Basic= 65.* § *NNT for readmissions within 30 days, Extended =12, Basic = 41, P<0.05* §
High	Roughead 2022 [235]	Patients in intervention group reporting MRPs/ ADEs reduced from 79% to 64%	change in EQ-5D intervention =−0.199 (0.339), control =−0.159 (0.329), p= 0.566	NR	NR	Change in Frailty index Mean, SD Intervention= 0.08 (0.076) Control= 0.089 (0.082), p=0.320	NR	NR	NR	NR	NR	change in MoCA score Mean SD, Intervention =−1.89 (4.87) Control= −3.16 (5.88) p=0.048
High	Sellors 2003 [229]	NR	SF-36 Mean (95% CI) health rating score at 5 months, Intervention = 3.2 (3.2–3.3), Control = 3.2 (3.2–3.3), p = 0.35	Mean (SE) all hospital admissions, Intervention= 0.14 (0.02), Control= 0.11 (0.02) Physician appointments Mean (SE) Intervention = 5.16 (0.27),	Physicians committed to implementing 76.6% of recommendations. 5 months follow up, 46.3% fully implemented, 9.3% partial	NR	NR	Mean daily medication costs Intervention = $5.01, Control = $4.82, p = 0.72 Mean cost of health care resources per	NR	NR	NR	Physical functioning Mean (95% CI); Enrolment, Intervention = 55.6 (55.5–56.0) control = 54.2 (48.0–54.4), Exit Intervention =55.0

				Control = 4.97 (0.29)	implementation, 16.7% recommendations implemented but not successful.			patient, Intervention = $1281.27, Control = $1299.37, p = 0.45				(54.6–55.3), Control= 55.0 (54.8–55.2), p= 0.93
High	Shim 2018 [223]	*MAI Median (IQR), Intervention = 9.0 (9.0), Control = 20.0 (16.0). MAI Range Intervention = 0.0-26.0, Control = 3.0 - 47.0, p<0.001* §	NR	NR	NR	NR	NR	NR	*Malaysian Medication Adherence Scale (MALMAS) Adherence (Score ≥6), Intervention = 69.9%, control = 31.6 %, p< 0.001* §	NR	NR	NR
High	Tuttle 2018 [230]	Intervention = 92% with MRPs, median MRPs = 3 (IQR, 2–5)	NR	Hospitalisations within 90 days, Intervention =44%, Control = 41%	NR	SBP Proportion at goal <130, mmHg at 90 days post visit, Intervention = 30/62 (48%), Control = 24/58 (41%). Mean (SD) eGFR, ml/min per 1.73 m2 at 90 days post visit, Intervention = 41 ± 17, Control = 43 ± 14	NR	NR	NR	NR	NR	NR
High	van der Heijden 2019, Ahmad 2010 [210,255]	*Mean (SE) effect difference in MRPs -0.2 (-0.4 to 0.0)[favours intervention]* §	NR	*Hospital readmissions in 1st 6 months, Intervention= 46.4%, Control= 20.9%* §	NR	NR	NR	ICER for improvement in MRP = €8270	NR	NR	Mortality rate 1 year following MR, Intervention = 11.7%,	NR

				GP visits in 1st 6 months, Intervention= 85.7%, Control=71.6%							Control= 8.8%	
High	Verdoorn 2019, Verdoorn 2018, Verdoorn 2021 [211,256,257]	Mean MRPs per patient 5.8 (SD 2.1); 67% were resolved. 28% related to health-related goal.	*Adjusted difference (95% CI) in effect between interventio n and control at 3 months, EQ-5D-5L, utility values −0.0011 (−0.012 to 0.010), EQ-VAS 1.7 (0.47 to 2.9), p<0.01* §	Hospitalisation s Mean (SD) Incremental effects and costs over 6 months, Control= €755 (± 1925), Intervention = €700 ± 1997 Physician appointments Mean (SD) Incremental effects and costs over 6 months, Control= €414 (± 558), Intervention = €346 (± 453)	NR	VAS pain scores between intervention and control over 6 months −0.075 95% CI =−0.26 to 0.11, p value = 0.43 *Adjusted difference (95% CI) in effect between intervention and control at 3 months Total health problems, −0.15 (−0.32 to 0.027), Health problems with impact, −0.17, −0.31 to −0.022, p<0.05* §	NR	Total mean (SD) costs per patient, interventio n = €4,008 ± 6,678, Control = €4,189 ± 6,596	NR	NR	NR	NR
High	Zermansky 2006 [212]	NR	NR	Number (SD) patients hospitalised in 6 months Intervention=0. 20, (0.48), Control = 0.26 (0.61), p=0.11	75.6% of recommend ations accepted. Overall implementat ion rate= 58%	*Mean (SD) falls per patient in 6 months, Intervention= 0.8 (1.7), Control= 1.3 (3.1), p=<0.0001*§	*Mean (SD) drug changes in 6 months, Control 2.4 (2.6), Intervention 3.1 (2.7) p=<0.0001*§	Mean (SD) Drug cost per patient, Interventio n= £42.24 (38.33), Control = £42.95 (41.01)	NR	NR	Intervent ion =15.3%, Control= 14.5% p=0.81	Change in mean Barthel score difference (RR 95% CI), 0.46 (−0.02 to 0.94), p=0.06 SMMSE [Mean (SD)], Interventio n = 13.9

												(10.0) [+0.1 change] , Control =13.8 (10.6) [+0.7 change]. Difference [RR 95% CI) = −0.24 (−1.18 to 0.70)p=0.62
High	Zillich 2014 [231]	90% of MRPs resolved by end of study	NR	60 day hospitalisation all patients Control = 23%, Intervention = 20%. Adjusted odds ratio (95% CI) 1.26 (0.89, 1.77), p value= 0.19. *60 day hospitalisation for low risk patients Control = 16%, Intervention =5%, OR 3.78 (1.35, 10.57) p=0.01*§	NR	NR	NR	NR	NR	NR	NR	NR
Key	MRPs= medicine related problems MAI= medication appropriateness index ADE= adverse drug events ADRs= adverse drug reactions NR= not reported IQR=interquartile range SD= standard deviation SE= standard error OR= Odds ratio CI= 95% confidence interval RR= relative risk IR= incident rate HR= hazard ratio NNT= number needed to treat ICER= Incremental cost effectiveness ratio VAS= visual analogue scale BP= blood pressure HT= hypertension SBP= systolic blood pressure DBP= diastolic blood pressure HbA1C= glycated haemoglobin T2DM= type 2 diabetes mellitus eGFR= estimated glomerular filtration rate HDL= high density lipoprotein LDL C= low density lipoprotein cholesterol CVD= cardiovascular disease MR= medication review MDTs= multidisciplinary teams No.= number meds= medicines ED= emergency department QoL= quality of life MAT-CHSSP= The Medication Assessment Tool for Coronary Heart Disease LMQ©= living with medicines questionnaire MoCA= Montreal cognitive assessment test **§ = *statistically significant results*** * Östbring MJ, Eriksson T, Petersson G, *et al*. Motivational Interviewing and Medication Review in Coronary Heart Disease (MIMeRiC): Protocol for a Randomized Controlled Trial Investigating Effects on Clinical Outcomes, Adherence, and Quality of Life. *JMIR Res Protoc*. 2018 Feb 20;7(2):e57. doi: 10.2196/resprot.8659											

Appendix 6 Mechanisms of impact identified in studies included in systematic review

Risk of Bias	Author (year)	Mechanisms of impact			
		Participant responses to & interaction with intervention	Mediators	Moderators of effect	Unanticipated pathways & consequences
Low	Alalawneh (2022) [239]	NR	NR	NR	NR
Low	Anderegg 2018 [224]	NR	NR	NR	Large variance in BP control rate across intervention sites. variability in pharmacist practice styles may have contributed to the differences
Low	Graabaek 2019 [190]	NR	NR	NR	NR
Low	Lenaghan 2007 [191]	NR	NR	NR	NR
Low	Lim 2004 [213]	NR	NR	NR	NR
Low	Lin 2018 [214]	NR	NR	NR	NR
Low	Maritnez-Mardones (2023) Ahumada-Canale 2021a, 2021b [236,240,241]	NR	NR	NR	NR
Low	Schulz 2019, Schulz 2020, Laufs 2018 [192,242,243]	NR	NR	NR	NR
Some	Aguiar 2018 [237]	NR	NR	Intervention needs to be tailored to the patient's needs; active involvement of patients	NR
Some	Basheti 2016 [244]		NR	NR	Restricted time and space in community pharmacy for interviews
Some	Basheti 2018 [216]	NR	NR	NR	Patient problems with insurance (financial) prohibiting additional visits to physician for recommended changes. Challenges with patient and pharmacist safety
Some	Garcia 2015 [193]	NR	NR	NR	Control group were disappointed that they did not receive intervention.
Some	Jameson 1995 [225]	NR	NR	NR	NR
Some	Lisby 2018 [194]	NR	NR	Pharmacist and pharmacologist not part of the team. This impacted on the adherence rate of recommendations	NR

Some	Sakthong 2018 [217]	NR	NR	NR	NR
Some	Sellors 2001 [227]	NR	NR	NR	NR
Some	Williams 2004 [226]	NR	NR	Participants were unwilling to follow suggestions to discontinue drugs, therefore expected improvements were not seen. Patients need to be more involved in the decision-making process when deciding medication regimes.	NR
Some	Zermansky 2002 [195]	NR	NR	NR	Increased referrals to other HCP for clinical monitoring
High	Aburuz 2020 [218]	NR	NR	NR	Some recommendations not enacted as patient had been discharged quicker than planned.
High	Al alawneh 2019 [219]	NR	NR	NR	Financial or health related barriers preventing patients returning to physicians to confirm the recommended treatment changes.
High	Al-Qudah 2018, Basheti 2016 [215,220]	NR	NR	NR	Travel time and length of patient interviews adds to the complexity and cost of health care
High	Basger 2015 [232]	NR	NR	NR	NR
High	Bonnerup 2020 [196]	NR	NR	NR	NR
High	Briggs 2015 [233]	NR	NR	NR	NR
High	El-Refae 2017 [221]	NR	NR	NR	NR
High	Erku 2017 [238]	NR	NR	NR.	NR
High	Freeman 2021, Foot 2017 [234,245]	NR	NR	NR	NR
High	Geurts 2016 [197]	NR	NR	NR	NR
High	Gurwitz 2021 [228]	Many patients refused the intervention	NR	NR	nr
High	Holland 2005, Holland 2010, Pacini 2007 [198,246,247]	NR	NR	NR	Lack of access to clinical notes meant it was not possible for the pharmacists to check whether drugs were being monitored.
High	Huiskes 2020 [199]	NR	NR	NR	NR
High	Kempen 2021, Kempen 2020, Kempen 2017 [200,248,249]	NR	Face-to-face discussions with physicians and patients/carers on how to solve identified problems and full pharmacist access to patient's electronic health record leads to higher rate of implementation of recommendations. Selection of high-risk patients after discharge and individual tailoring of calls could have increased effectiveness	NR	NR
High	Krska 2001 [201]	NR	NR	NR	NR

High	Lea 2020 [202]	NR	NR	NR	NR
High	Lenssen 2018 [203]	NR	NR	NR	NR
High	Liou 2021 [222]	NR	NR	NR	NR
High	Lyons 2016 [204]	NR	NR	NR	NR
High	Malet-Larrea 2016, Jodar-Sanchez 2015, Varas-Doval 2020 [205,250,251]	NR	NR	Greater personal inter-relationships between pharmacists and patients influencing some outcomes.	NR
High	Messerli 2016, Messerli 2018 [206,252]	NR	NR	NR	NR
High	Nabergoj Makovec 2021 [207]	NR	NR	NR	NR
High	Östbring 2021, 2018 [208,253]	NR	NR	NR	NR
High	Ravn-Nielsen 2018, Rasmussen 2019 [209,254]	NR	NR	NR	NR
High	Roughead 2022 [235]	NR	NR	NR	NR
High	Sellors 2003 [229]	NR	NR	NR	NR
High	Shim 2018 [223]	NR	NR	NR	NR
High	Tuttle 2018 [230]	NR	NR	NR	NR
High	van der Heijden 2019, Ahmad 2010 [210,255]	NR	NR	NR	Increased information about side effects etc resulting in increased utilisation of GP
High	Verdoorn 2019, Verdoorn 2018, Verdoorn 2021 [211,256,257]	NR	NR	NR	NR
High	Zermansky 2006 [212]	NR	NR	NR	NR
High	Zillich 2014 [231]	NR	NR	NR	NR

Appendix 7 Protocol for Optimising Pharmacist-lEd medicatioN reviews in primary care (OPen) study

This appendix contains the final approved protocol that was submitted via the Integrated Research Application System. The appendix numbers refer in this protocol refer to the protocol appendices and not the thesis appendices.

Optimising **P**harmacist-l**e**d medicatio**n** reviews in primary care (OPen): a qualitative study to co-design and test an optimised medication review for patients with long-term conditions.

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Project summary

Rationale

An increasing number of people are diagnosed with long term conditions which are primarily managed by medicines. The majority of people living with long term conditions receive treatment in primary care. Medication reviews (MRs) are a widely implemented intervention that seek to optimise medicines, improve health outcomes and decrease medicines related problems. Despite the extensive use of MRs, the proportion of patients who experience poor medicines outcomes such as adverse drug reactions and hospitalisations has not altered significantly in ten years. There is a policy-led drive to involve pharmacists with MRs.

Objectives

1. Examine the current implementation of medication reviews by pharmacists in primary care (phase 1)
2. Co-design a guidance document that defines and describes optimised medication reviews by pharmacists in primary care (phase 1)
3. Conduct early testing of the guidance document for medication reviews by pharmacists in primary care (phase 2)

Methods

Focus groups, co-design workshops, feasibility testing, interviews

Populations

Healthcare professionals: pharmacists, general practitioners (GPs), nurse practitioners

Adult patients prescribed five or more medicines who have previously received a medication review from a pharmacist in their community pharmacy or GP surgery

Time frame

Phase One- April 2023-September 2023

Phase Two- September 2023- July 2024

Phase 1

Inputs

- Current guidance about the delivery of medication reviews in primary care
    - NHS Discharge Medicines Service Toolkit (NHS, 2021)
    - Structured medication reviews and medicines optimisation guidance (NHS and Network Contract Directed Enhanced Service, 2020)
- Programme theory from recent systematic review

Outputs

- Evidence about the key uncertainties in relation to the implementation of pharmacist-led medication reviews
- Evidence about the disconnect between healthcare professionals' practice and the evidence relating to the delivery of medication reviews
- Co-designed draft guidance document for pharmacist-led medication reviews in primary care
- Refined programme theory

Phase 2

Inputs

- Evidence about the key uncertainties in relation to the implementation of pharmacist-led medication reviews
- Evidence about the disconnect between healthcare professionals' practice and the evidence relating to the delivery of medication reviews
- Co-designed draft guidance document for pharmacist-led medication reviews in primary care

- Refined programme theory

Outputs

- Refined and tested programme theory
- Co-designed guidance document for pharmacist-led medication reviews in primary care, which includes a detailed description of the optimised intervention informed by evidence from small scale feasibility testing
- Opinions from pharmacists and patients who have tested the guidance document for optimised medication reviews.

1.0 Rationale and background information

Approximately 15 million people in England have a long-term condition, which accounts for 70% of the health and social care budget (Department of Health, 2012; NICE, 2015). Long-term conditions are primarily managed by medicines with 1.12 billion prescription items dispensed in England in 2019 at a total cost of £9.08 billion (NHSBSA, 2019). Recent government reports have identified overprescribing (Department of Health & Social Care, 2021) and inappropriate prescribing (NHS and Network Contract Directed Enhanced Service, 2020) as significant problems with medicines use to treat long term conditions. This increased, and sometimes inappropriate use, of medicines can lead to more medicines related problems and poor patient outcomes, such as drug interactions, adverse drug reactions, reduced quality of life and hospitalisations (Duerden, Avery and Payne, 2013; Maher, Hanlon and Hajjar, 2014; Khezrian et al., 2020).

Medication reviews are a widely implemented intervention to support patients with their medicines and reduce the risk of overprescribing and inappropriate prescribing. The National Institute of Health and Care Excellence (NICE) and the Pharmaceutical Care Network Europe (PCNE) have published definitions and desired outcomes for medication reviews (NICE, 2016; PCNE, 2016) including optimising medicines, improving health outcomes, and decreasing medicines related problems. However, despite the extensive use of medication reviews in practice, the rate at which patients experience poor medicines outcomes such as adverse drug reactions and hospitalisations as a result of medicines use has not altered significantly in 10 years (Veeren and Weiss, 2017; Harrison and Goldsmith, 2019).

Many organisations advocate for pharmacists to be involved with the delivery of medication reviews given their expertise in this area. Medication reviews at various PCNE levels (Griese-Mammen et al., 2018) are undertaken by pharmacists in general practice (GP) surgeries using medication records or consultations with patients or a combination of both. Primary Care Network (PCN) pharmacists are also providing structured medication reviews (SMRs) in their locality (NHS and Network Contract Directed Enhanced Service, 2020). In addition, the Discharge Medicines Service (DMS) has been implemented as part of the new community pharmacy contractual framework (DoH, NHS England and PSNC, 2019). The increasing role of pharmacists in this area is based upon policy-led rather than evidence-led decisions for them to lead medication reviews in primary care (both in community pharmacy, general practice and primary care networks).

It has been noted that there is a need to better understand how interventions to address issues such as overprescribing (for example medication reviews) are designed and delivered (Department of Health & Social Care, 2021). The Medical Research Council (MRC) recently published guidance on evaluating complex interventions, of which medication reviews are an example. This guidance indicates that where interventions are developed from policy makers or practitioners, they should be investigated to understand how they achieve the desired outcomes, test the assumptions on which they were designed and examine whether they are operating as intended (Skivington et al., 2021). Further MRC guidance on the process evaluation of complex interventions (Moore et al., 2014) states that the key steps in evaluating complex interventions are:

- Understanding how and what is delivered
- Understanding how the intervention produces change
- Understanding how context affects implementation and outcomes

To understand the evidence for pharmacist-led medication reviews, MC undertook a scoping review to describe the existing, extensive literature in this field. This scoping review identified numerous systematic reviews that included a significant quantity of primary research from a wide range of countries. It concluded that overall evidence for effectiveness for MRs is uncertain, i.e., no strong evidence for or against their effect on patient outcomes. In addition, it identified that most reviews did not describe the nature of the intervention in any great depth, i.e., core components or mechanisms of impact. Therefore, there is a lack of evidence about which elements of the medication review might benefit the patient and the health service.

As a follow-up to this scoping review, MC is conducting a systematic to address this evidence gap and explore the core components of pharmacist-led medication reviews, and whether and how they link to outcomes in different contexts. The systematic review will extract data about context, implementation, outcomes and mechanisms of impact, behaviour change techniques used to support patients taking their medicines (Michie et al., 2013), and implementation strategies used(EPOC, 2015). The output from the review will be a draft programme theory (Skivington et al., 2021) for pharmacist-led medication reviews and how they achieve patient and health service outcomes.

Having established the literature evidence for pharmacist-led medication reviews, the next step is to ascertain what is occurring in practice. Current guidance as to the provision of medication reviews in primary care is defined in documents outlining the community pharmacy contractual framework and GP contract (NHS and Network Contract Directed Enhanced Service, 2020; NHS, 2021). These documents take into account the NICE guidance for medication reviews (National Institute for Health and Care Excellence (NICE), 2015). Whilst there is some guidance as to what should happen in medication reviews, these documents lack details on why elements have been included and how they will benefit the patient. By considering the evidence from the systematic review, alongside what is happening in current practice, this study aims to design an optimised, evidence-informed medication review intervention. The programme theory that is being developed in the systematic review will be considered alongside the experiences of key stakeholders to understand what is currently

happening in practice in order to co-design an optimised medication review. This work will address the need to better understand how medication reviews are currently delivered and provide an evidence-based approach to designing an optimised intervention.

This work will be informed by the new MRC framework for developing and evaluating complex interventions (Skivington et al., 2021). It addresses the "intervention development" phase, which includes "adapting an existing intervention for a new context, based on research evidence and theory of the problem".

1.1 Study goals and objectives

Aim:

Co-design and test a guidance document for optimised pharmacist-led medication reviews in primary care to improve outcomes for people with long-term conditions.

Objectives

1. Examine the current implementation of medication reviews by pharmacists in primary care (phase 1)
2. Co-design a guidance document that defines and describes optimised medication reviews by pharmacists in primary care (phase 1)
3. Conduct early testing of the guidance document for medication reviews by pharmacists in primary care (phase 2)

A guidance document is a written document gives broad advice on procedure rather than describing in detail the requirements and standards required for an intervention (Black, 1995). A draft guidance document is included in Appendix 1 with information from the existing policy documents and key results from the systematic review.

2.0 Methodology

This study will consist of two phases:

- Phase one will involve focus groups and workshops with stakeholders to explore the current implementation of medication reviews by pharmacists in primary care and to co-design a guidance document that optimises them.
- Phase two will ask a small number of primary care pharmacists to test the guidance document for medication reviews for acceptability and feasibility.

Participants (pharmacists and patients) will be interviewed about their experiences of the optimised medication review using the guidance document.

The Covid-19 pandemic has impacted on how research is undertaken. To address the challenges of social distancing and self-isolation, some researchers switched to using teleconferencing software to undertake qualitative work. The Public Involvement in Research Group reported their experiences of participation in remote research (Munday et al., 2020). They identified expected issues of reliability of internet connection and unfamiliarity with videoconferencing, however, overall, their experiences were positive. Participants reported that virtual sessions allowed more flexibility, saved travel time, and allowed participants to manage their environment based upon their health conditions or preferences Therefore, having considered this literature, it has been decided that all phases of this study, except for the actual medication reviews undertaken with patients in phase two, will be undertaken virtually.

2.1 Conceptual frameworks used in the study

Stakeholders will be invited to share their experiences on the current implementation of medication reviews by pharmacists in primary care. Focus groups are useful to create debate and discuss differences within the group and facilitate discussion around abstract and conceptual subjects. Focus groups also allow the generation of more detailed data as a result of participant interaction with each other (Ritchie et al., 2014).

Stakeholders will be invited to co-design a guidance document for an optimised pharmacist-led medication review. Co-design is term that is used to describe "collective creativity as it applied across the whole span of a design process" (Sanders and Stappers, 2008). Co-design is a method where services or interventions are designed or redesigned in partnership with patients, healthcare professionals, and other key stakeholders. It involves shared decision making amongst the participants and is an iterative process (Taylor, 2020). Co -design has been used to develop services and reduce the cost of healthcare provision (O'Cathain et al., 2019).

The template for intervention description and replication (TIDieR) checklist and guide (Hoffmann et al., 2014) will be used to frame the development of the guidance document. The TIDieR guide makes it easier to structure the intervention, providing a clear description of what has been delivered by whom, when, where, how much and the extent of tailoring and modifications.

The programme theory that was identified in the systematic review, will be refined following stakeholder feedback. In line with the new MRC framework for developing and evaluating complex interventions (Skivington et al., 2021), responses from the focus groups and workshops will be analysed to identify and address the remaining uncertainties, given what is already known and what the research team and stakeholders identify as being most important to determine. A refined programme theory will then be proposed.

Ten pharmacists will conduct early testing of the guidance document for medication reviews by pharmacists in primary care. Following a short testing period participants (pharmacists and patients) will be interviewed to gather their opinions on the feasibility and acceptability of the guidance document.

Interviews are useful for understanding personal context and generating in depth, detailed accounts. Sekhon et al. developed a comprehensive theoretical framework of acceptability for healthcare interventions, comprising of seven component constructs: affective attitude, burden, ethicality, intervention coherence, opportunity costs, perceived effectiveness and self-efficacy (Sekhon, Cartwright and Francis, 2017).

2.2 Phase One

Aims of phase 1

- Explore the current implementation of medication reviews by pharmacists in primary care with stakeholders
- Co-design a guidance document that defines and describes optimised medication reviews by pharmacists in primary care

Process

Phase One will follow this order:

Phase 1a Patient Focus Group

Patient participants will be asked to reflect on their previous experiences of pharmacist-led medication reviews. This will include questions about:

- The content of medication reviews
- How they perceive medication reviews

- Whether and how they assess whether the review has impacted their health or wellbeing
- How medication reviews can be improved

(See Appendix 2 Phase 1a Patient Focus Group Topic Guide)

This session will be held on a weekday, sometime between 12pm and 6pm.

Phase 1b Practitioner Focus Group

Practitioner participants will be asked to identify the key uncertainties (unknown or incomplete essential details) pertaining to the content and implementation of medication reviews. . The following topics will be explored:

- Content of medication reviews delivered in practice
- Factors perceived to influence the effectiveness of medication reviews
- How participants assess the impact of the review on patient outcomes

(See Appendix 3 Phase 1b Practitioner Focus Group Topic Guide)

This session will be held on a weekday evening, sometime between 5-9 pm.

Phase 1c Data synthesis

Data from focus groups 1a and 1b will be analysed and a 2-page summary of key uncertainties and summary video of these will be produced. These will be considered alongside the data from the systematic review to populate a draft guidance document, highlighting the key uncertainties. An example of what this could look like can be found in Appendix 1. The programme theory will also be refined following analysis of the data from the focus groups.

Phase 1d Co-design workshop

This workshop will involve patient and practitioner collaboration to address the identified areas to optimise pharmacist-led medication reviews. One week before this workshop, the two-page and video summaries of the key uncertainties, and draft guidance document will be sent to participants to reflect upon before the session.

Participants will discuss the identified key uncertainties and agree on which should be prioritised and addressed in the guidance document. Participants will then discuss these key uncertainties and how they can be addressed and implemented in the guidance document.

(See Appendix 4 Phase 1d workshop topic guide)

Following this workshop, the research team will re- draft the guidance document for pharmacist-led medication reviews in primary care following the discussions in Phase 1d workshop. This revised guidance document and/ or programme theory will be circulated to participants one week before workshop 1e.

Phase 1e Refinement and acceptability workshops

These workshops will involve patient and practitioners independently refining the guidance document and exploring its acceptability. Participants will be reminded of the key uncertainties identified in the focus groups and how these have tried to be addressed in the guidance document. Participants will critically examine the document and suggest changes. The first four constructs of the theoretical framework of acceptability cited earlier (Sekhon, Cartwright and Francis, 2017) will be used to explore the perceived acceptability of the guidance document to patients and pharmacists.

(See Appendix 5 Phase 1e workshop topic guide)

social

2.2.1 Recruitment and sampling

The nature and size of the participant samples for each of the phases are outlined below:

Phase 1a focus group

- Eight patient representatives

Phase 1b focus group

- Two PCN pharmacists
- Two GP pharmacists
- Two community pharmacists
- Two GPs or nurse practitioners*
- *If GPs or nurse practitioners are unable to join the focus group, they will be approached to participate in a semi-structured interview, to be arranged a time that is convenient to them.

Phases 1d co-design workshop

- Two PCN pharmacists
- Two GP pharmacists
- Two community pharmacists
- Two GPs or nurse practitioners
- Two patient representatives

Phase 1e Refinement and acceptability workshops

- Four PCN/ GP pharmacists
- Two GPs/ nurse practitioners
- Four patients

It has been suggested that a minimum of two representatives from each stakeholder group should be involved in the co-design process (Taylor, 2020). A sample size of eight is in line with the recommended size for this focus group (Krueger and Casey, 2014).

i) Practitioner participant recruitment strategy

Pharmacists

Pharmacists will be recruited nationally via an advert on social media (Appendix 6). The advert will include a link to the pharmacist expression of interest form (Appendix 7) and participant information sheet (Appendix 8).

In addition, professional societies, and organisations, such as the Primary Care Pharmacists Association (PCPA), Royal Pharmaceutical Society (RPS), Pharmacy Research UK (PRUK) will be emailed (Appendix 9) and asked to forward the study information (Appendix 8) to their members.

General Practitioners and nurse practitioners

General practitioners and nurse practitioners will be recruited via pharmacists who have expressed an interest in the study. Pharmacists who have completed the expression of interest form will be sent an email (Appendix 10) thanking for them for their interest in the study, and they will be asked to identify a general practitioner or nurse practitioners who they think would be interested in the study. They will then be asked to forward on an email (Appendix 10) and the participant information sheet (Appendix 8) to this GP or nurse practitioner.

If general practitioners or nurse practitioners are unable to be recruited in this way, members of the research team will use existing contacts in their professional networks to generate interest in the study.

ii) Patient participant recruitment strategy

Patients will be recruited nationally via an advert on social media (Appendix 11). The advert will include a link to the patient expression of interest form (Appendix 12) and participant information sheet (Appendix 13).

In addition, patient societies and organisations such as British Heart Foundation, Diabetes UK, Asthma UK, Arthritis research UK) will be emailed (Appendix 14) and asked to forward the study information (Appendix 13) to their members.

Inclusion criteria

Practitioner participant

- A qualified healthcare professional registered with the appropriate body (General Medical Council, General Pharmaceutical Council, Nursing and Midwifery Council for doctors, pharmacists and nurses respectively.)
- Works in primary care in England
- Review medicines as part of their practice

Patient participant

- Aged ≥ 18 years
- Prescribed at least five medicines
- Patient has received a medication review in by a pharmacist in community pharmacy or GP surgery in the last three months
- Resident in England

All participants must be able to

- Effectively communicate in English
- Provide informed consent

Exclusion criteria

Potential participants will be excluded if they

- Have no access to the internet
- Lack capacity to consent
- Currently (or recently) involved in another research project

Eligibility screening

Prospective participants will complete an online expression of interest form (Appendix 7 for practitioners, Appendix 12 for patients), which will reflect the inclusion and exclusion criteria for the study. Additional data will be collected for purposive sampling. Purposive sampling helps to provide a diverse sample so that differences in

perspectives can be explored (Ritchie et al., 2014). Participants will be asked to provide their postcode in the expression of interest form. This will give an indication as to their geography and social deprivation, using the index of multiple deprivation (IMD) as a measure, as reported by the UK government's ministry of housing, communities and local government (Ministry of Housing Communities & Local Government, 2019). This data captured will facilitate selection of a sample with a geographical mix and representation from a range of social deprivation. Participants will be asked to identify their ethnicity, gender, and age to facilitate the selection of a diverse sample.

Data will be collected using JISC© online surveys, the UEA's recommended platform to facilitate conformation to General Data Protection Regulation (GDPR).

2.2.2 Data collection

Participants selected for the study will be re-sent a participant information sheet (Appendix 8 practitioners, Appendix 13 patients which contain consent related statements) with a confirmation email (Appendix 15). People who expressed an interest and are not included in the study will receive an email thanking them for their response (Appendix 16).

The supervisory team and patient and public involvement (PPI) members will pilot the topic guides (Appendices 2,3,4,5) used in the focus groups and workshops before participant sessions.

Focus groups and workshops will take place via Microsoft® Teams and will be recorded via the Teams® software with an audio recording device used as a backup. If there is a technical problem with participants' Teams® software, they will be invited to join via telephone. It is anticipated that each focus group/ workshop will not take longer than two hours (Barnett, 2002).

In advance of the discussion, at the same time as the confirmation e-mail (appendix 15) participants will be sent a consent survey to complete electronically (appendix 29). Participants will be asked to complete the electronic consent form at least 24 hours in advance of the discussion. At the start of the sessions, the primary investigator will ensure that verbal consent has been received from the participants and this will be recorded. This dual approach to consent will balance the need to capture informed consent appropriately whilst ensuring the digital accessibility of the study. The

participants will be reminded of the confidentiality arrangements (information discussed in the group is confidential and should not be repeated outside), and that the session will be recorded (visual and audio) for research purposes. The primary investigator will set out the ground rules for the session including ensuring that participants do not talk over one another and reducing background noise. Participants will also be informed that the primary investigator may take field notes during the sessions to assist with data analysis.

2.2.3 Data analysis

Transcripts of the focus groups will be generated by Microsoft® Teams and will be checked for accuracy by the primary investigator. The NVivo software programme will be used to assist with analysis.

Data collected in focus groups 1a and 1b will be analysed using thematic analysis (Braun and Clarke, 2006). Thematic analysis (renamed as reflexive thematic analysis (TA) (Braun and Clarke, 2019) is a flexible and effective approach widely used in the analysis of qualitative research (Kiger and Varpio, 2020).

Key areas to optimise medication reviews will be identified by consensus during workshops 1d and 1e. Transcripts of the workshops will be generated by Microsoft® teams and these will be referred to as necessary to clarify any comments/ feedback.

Phase 1 Inputs

- Current guidance about the delivery of medication reviews in primary care
    - NHS Discharge Medicines Service Toolkit (NHS, 2021)
    - Structured medication reviews and medicines optimisation guidance (NHS and Network Contract Directed Enhanced Service, 2020)
- Programme theory from recent systematic review

Phase 1 Outputs

- Evidence about the key uncertainties in relation to the implementation of pharmacist-led medication reviews
- Evidence about the disconnect between healthcare professionals' practice and the evidence relating to the delivery of medication reviews
- Co-designed draft guidance document for pharmacist-led medication reviews in primary care
- Refined programme theory

2.3 Phase Two

Aim of phase 2

- Conduct early testing of the guidance document for medication reviews by pharmacists in primary care

Process

Phase Two will follow this order:

- Delivery of medication review by pharmacist using the draft guidance document
- Interview with patient to collect their thoughts and feelings about their medication review
- Pharmacist interviews at the end of the study period to explore the feasibility and acceptability of the guidance document

During the four-week pilot period, participating pharmacists will be asked recruit five patients from their practice to be involved in the study. These patients will be due for a medication review as part of their routine care. In addition to the practice's standard method of inviting patients for their medication review, the pharmacist will send the potential study patients an email. This email will be written by the research team (Appendix 17) and a participant information sheet with consent statements (Appendix 18) will be attached. The email briefly explains the study and invites the patient to consider participating.

When the patient attends their medication review, the pharmacist will ask if they have read the study information and if they want to participate. If the patient declines to be involved in the study, their medical care will not be affected. They will still receive a medication review, with the pharmacist using their standard approach.

If a patient consents, the pharmacist will use the new guidance document for the review. The patient will also be given the option to share their thoughts and feelings following the medication review with a researcher. Patients will be asked to sign a consent form (Appendix 19) to indicate they are happy to be involved in the study. Where patients consent to speaking to a researcher about their experience, they also give permission for their contact details to be passed on to the research team for a follow up interview. It is important to note that the research teams will not have access to patients' medical notes, or any information held about them at the GP surgery.

The consent forms will be retained by the GP practice for the duration of the study. The details on the consent form (Patient's name, email address, telephone number) will be uploaded by the pharmacist, as soon as possible after the medication review, to a secure one drive folder. This secure one drive folder can only be accessed by that one pharmacist and the research team. The primary investigator will set up a separate one drive folder for each participating pharmacist. This means that pharmacists will not be able to see the details of patients who are not their own.

When the patient details have been uploaded to one drive, the primary investigator will email the patient, within 24-48 hours, thanking them for agreeing to participate (Appendix 20). The participant information sheet (Appendix 18) will be re-sent, and the patient will be asked to agree a suitable time for an interview. If the patient has not responded within three days, it will be assumed that they have withdrawn their consent to participate.

During the study period, the primary investigator (MC) will send a weekly email to pharmacist participants to offer support and to gauge engagement. Pharmacists can contact MC via telephone or email with queries they may have about the study. MC will document any issues identified, to be later used in data synthesis. Semi-structured interviews will be undertaken with pharmacists at the end of the four-week pilot.

2.3.1 Recruitment and sampling

i) Pharmacist recruitment strategy

The primary investigator will email pharmacists from phase who agreed to be contacted about future medication review research (Appendix 21). This email will be an invitation to be involved in testing the guidance document and link to an expression of interest form (Appendix 22).

In addition, pharmacists will be recruited nationally via an advert on social media (Appendix 23). The advert will include a link to the pharmacist expression of interest form (Appendix 22).

If recruitment is problematic, the research team will use existing contacts in pharmacy networks to generate interest in the study (appendix 24). The expression of interest form

(Appendix 22) will be emailed to pharmacists who show an interest by the primary investigator.

The pharmacist participant sample will consist of:

- Ten Primary Care Network/ GP pharmacists

Previous studies testing primary care pharmacy services recruited 28, 10 and 15 pharmacist participants for studies that lasted a minimum of six months (Urwin et al., 2016; Craske et al., 2018; Khanbhai et al., 2020). Those studies with smaller pharmacist sample sizes collected qualitative in addition to quantitative data. Urwin et al. interviewed eight pharmacists at the end of their study, and Craske et al. held three focus groups, each with five participants from stakeholder groups involved in the study. Data collection for this study will be over a maximum period of five months, so the sample size selected appears appropriate given previous published studies and time restraints.

Inclusion criteria

Practitioner participant

- A qualified pharmacist registered with the General Pharmaceutical Council
- have a prescribing qualification and advanced assessment and history taking skills, or be enrolled in a current training pathway to develop this qualification and skills
- Have consented to utilise the guidance document for optimised pharmacist-led medication reviews during the study period
- Regularly undertake medication reviews as part of their practice
- Provide informed consent

Prospective participants will complete an online expression of interest form (Appendix 22), which will assess the inclusion criteria for the study. Participants will be asked to provide their work postcode. This will give an indication as to the geography and degree of social deprivation, using the index of multiple deprivation (IMD) as a measure of the area in which they work(Ministry of Housing Communities & Local Government, 2019). Data will be collected about participants' gender, age, and ethnic origin. This data is captured to facilitate selection of a diverse sample through purposive sampling. Data will be collected using JISC© online surveys, the UEA's recommended platform to facilitate conformation to General Data Protection Regulation (GDPR).

Pharmacists expressing an interest and selected for participation will be sent the organisation information document (OID) and will be asked to complete the consent form (appendix 28). Those participants who expressed an interest and are not included in the sample will be sent an email thanking them for their response (Appendix 16) and informing them that they are not required to take part in the study.

ii) Patient participant recruitment strategy

Pharmacists who have agreed to pilot the guidance document will be asked to recruit five patients from their practice. Potential participants will be invited for their medication review and pharmacists will send an invitation email written by the research team (Appendix 17) with a participant information sheet (Appendix 18) to them.

Pharmacists will check patients' eligibility for the study. To participate, patients will need to meet the criteria outlined below.

Inclusion criteria

Patient participant

- Aged ≥ 18 years
- Due for a medication review by the practice pharmacist
- Effectively communicate in English
- Provide informed consent

Exclusion criteria

Potential participants will be excluded if they

- Have no access to telephone/ internet
- Recently received a medication review

The research team will use convenience sampling to recruit patients for interviews. Convenience sampling is when selection is based solely on who is available (Ritchie et al., 2014). Data will be collected from the first two patients from each site who consent to the interview, with a maximum recruitment of twenty patients over the ten sites. Limited resources (i.e., primary investigator's time and finances) prohibits more interviews being undertaken.

2.3.2 Data collection

The interview topic guides (Appendix 25 Patient interview guide, Appendix 26 Pharmacist interview guide) will be piloted with the supervisory team and patient and public involvement (PPI) members before sessions with pharmacists and patients are undertaken.

Pharmacist interviews will take place via Microsoft® teams. Pharmacists will be sent a participant information sheet describing the interview and outlining the consent statements to be agreed verbally at the start of the interview (Appendix 27). If teleconferencing is not convenient or is not available at the time of the interview, it will take place via the telephone. The interviews will be recorded via the teleconferencing software and an audio recording device will also be used as a backup, or where the telephone is used, two audio recording devices will be used.

Patient interviews will be undertaken over Microsoft® teams or the telephone, according to patient preference and will take place as soon as is possible following the medication review. Before interviews commence the primary investigator will remind the patient of the consent statements on the consent form (Appendix 19) ensure that the patient continues to consent. The participant will be reminded of the confidentiality arrangements and that the session will be recorded for research purposes on two audio recording devices.

Participants will also be informed during the interview that the primary investigator may take field notes during the interview to assist with data analysis.

Patient and pharmacist interviews will be asked to reflect on how well the key uncertainties identified in phase 1 were addressed in the guidance document. In addition, the interviews will explore the acceptability with the medication review using the theoretical framework of acceptability (Sekhon, Cartwright and Francis, 2017).

It is anticipated that patient interviews take no more than 30 minutes, and pharmacists' not more than 45 minutes.

2.3.3 Data analysis

Where Microsoft ® Teams is used for the interviews, a transcript will be generated and checked for accuracy. Where the telephone has been used, recordings of the interviews will be transcribed verbatim by the primary investigator. The NVivo software programme will be used to assist with analysis. Patient and pharmacist interviews will be analysed separately.

Braun and Clarke guidelines for thematic analysis will be used to analyse the semi-structured interview transcripts (Braun and Clarke, 2006). An inductive approach will be used to analyse the data. The identified themes will then be mapped to the seven concepts of the theoretical framework of acceptability (Sekhon, Cartwright and Francis, 2017). The analysed responses will be summarised to provide an indication of the feasibility and acceptability of the intervention. The programme theory will also be revised following analysis of patient and pharmacist interviews.

Phase Two Inputs

The inputs for this phase include:

- Co-designed draft guidance document for pharmacist-led medication reviews in primary care
- Refined programme theory

Phase Two Outputs

The outputs for this phase include:

- Refined and tested programme theory
- Co-designed guidance document for pharmacist-led medication reviews in primary care, which includes a detailed description of the optimised intervention
- Qualitative feedback from pharmacists and patients who have used the guidance document for optimised medication reviews.

3.0 Data management

All recorded interviews and workshops will be stored on a password protected computer on University of East Anglia's (UEA) secure cloud storage. Transcripts of interviews and workshops will be anonymised to remove identifiable information. Any paper documents relating to the study will be stored in a secure, locked filing cabinet at UEA, with the exception of the signed patient consent forms, which will be stored securely at the participating GP surgeries until the end of the study, where they will be destroyed with other confidential waste. Participants contact details will be retained

until the end of the PhD. Data will be stored for ten years following completion of the PhD (June 2023) in accordance to the UEA's research data management policy (UEA Research data management Team, 2019).

4.0 Expected outcomes of the study

Phase One

- An insight into the key uncertainties relating to the current implementation of medication reviews by pharmacists in primary care
- A two-page written and video summary of these key uncertainties
- A refined programme theory that can be tested
- A co-designed service specification for pharmacist-led medication reviews in primary care.

Phase Two

- A tested programme theory
- A tested guidance document
- Qualitative feedback from pharmacists and patients
- A research question for a future study

5.0 Dissemination of results and publication policy

The results from this study will be shared with participants from phase one and phase two, the patient groups and charities that helped with patient recruitment, Local Pharmaceutical Committees, and local Primary Care Networks. In addition, the results will be shared with the local Clinical Research Network and Medicines Optimisation Group (MOG_EA), of which the primary supervisor is chair. The primary investigator is a member of the Primary Care Pharmacists Association (PCPA) and will share the findings with other members of this group.

The research team plan to publish the results in a peer reviewed journal, such as BMC Health Services Research. In addition, we would like to present the result at conferences such as Health Services Research and Pharmacy Practice (HSRPP).

6.0 Duration of the project

This study is being conducted as part of a part-time PhD. The planned research activities and time scale for each of these is outlined in table 1. The end of the study will be deemed to have occurred when the last participant in phase two has been interviewed.

Table 1: Duration and activities of OPen study

	Apr 23	May 23	Jun 23	Jul 23	Aug 23	Sep 23	Oct 23	Nov 23	Dec 23	Jan 24	Feb 24	Mar - Jul 24
Phase One Co-design of guidance document												
Phase 1a +b Patient and practitioner focus groups												
Participant recruitment												
Focus groups												
Transcription												
Thematic analysis												
Summary documents												
Phase 1c Data synthesis												
Synthesising data to produce draft guidance document												
Phase 1d + 1e Co-design workshops												
Participant recruitment												
Phase 1d Co-design guidance document development												
Redrafting guidance document following stakeholder input												
Phase 1e Practitioner and patient refining guidance document												
Finalise guidance document for testing												
Phase Two Testing of guidance document												
Participant recruitment												
Patient interviews												
Pharmacist interviews												
Data synthesis												
Feedback to stakeholders												

7.0 Problems anticipated

Patient and practitioner participant recruitment can be a challenge. Practitioner recruitment is increasingly problematic due to increasing workplace pressure. Providing tokens of appreciation, such as gift vouchers, may encourage participation. In addition, allowing participants to choose times that are most suited to them will increase the likelihood of participation. The Covid-19 pandemic has provided several challenges across all sectors, including research. Whilst the UK government has ceased all Covid-19 restrictions in England, there are still many people, particularly those who are extremely clinically vulnerable, who choose to exercise caution.

Undertaking virtual as opposed to face-to-face interviews, focus groups and workshops restricts the transmission of any viruses, including Covid-19 and this approach will alleviate concerns of potential participants.

Whilst there are advantages of undertaking virtual interviews and workshops, there are challenges. These include reliability of internet connection, participants' familiarity with the software, background noise, participants talking over each other. In addition, it can be more difficult to build a rapport if not meeting with participants face to face. The participant information sheet will outline the basic requirements of their involvement. In addition, participants will be reminded of these at the start of the focus group or workshop. In order to build rapport, the primary investigator will make regular contact during the participants involvement in the study.

Participants will need to be encouraged to be involved in the study; therefore, it is important that funding for this secured and agreed.

Honorarium is outlined below:

Phase One

Each participant will receive a £50 gift voucher for each focus group/ workshop attended:

Phase 1a Patient focus group 8@£50= £400

Phase 1b Practitioner focus group 8@£50= £400

Phase 1d Co-design workshop 1, 10@ £50 =£500

Phase 1e Co-design workshop 2, 10@ £50 = £500

Total fees for Phase one = £1800

Phase Two

Each participating GP surgery will receive £200 for their pharmacist's participation: 10@£200 = £2000

Patient exit interviews: 20@£10 = £200

Total fees for Phase three = £2200

Overall study cost= £4000

8.0 Project management

Mrs Miriam Craske - Primary Investigator

Dr Michael Twigg - Research supervisor

Prof Wendy Hardeman - Research supervisor

Prof Nick Steel - Research supervisor

8.1 Sponsorship

The University of East Anglia assumes the role of Sponsor for this project.

9.0 Safety and ethical considerations

Permission and approval from this study will be sought from NHS Research Ethics Committees through the Integrated Research Application System (IRAS).

9.1 Ethical considerations

The ongoing Covid-19 pandemic required extra vigilance when conducting research. Patients and practitioners may feel anxious about potential exposure to the virus, therefore the decision has been made to undertake the research remotely. As remote methods can alter the dynamics of rapport building, participants will be contacted in advance of the planned sessions by email/ telephone in an effort to get to know them and address any questions or concerns that they may have.

The primary investigator is a registered pharmacist who works part-time in primary care. There will need to be careful management of focus groups, workshops and interviews to manage the investigator effect, that is the unintentional effect that researchers can have on their results (Lewis-Beck, Bryman and Futing Liao, 2012).

The names and contact details of participants will need to be stored during this study. This information will be kept strictly confidential. Only information that is relevant to and necessary for the study will be collected. All data will be stored on a password protected computer. The contact details will be held by the research team only. Participants will only be contacted about the study and their details will not be shared with any other organisations.

All data will be reported confidentially. Participants' data will have a code number and will not be associated with partipants' names. Participant data will be kept safe and secure.

9.2 Informed consent

Phase One

Participants will receive a participant information sheet which contains consent related statements. If the patient reads the participant information sheet, which includes the consent related statements, and continues to complete the expression of interest form, it is presumed that they have read and understood these statements. In addition, these statements will be read at the start of the focus group/ workshops and participants will be asked to verbally verify their informed consent for this study. The consent statements are listed below:

- I confirm that I have read and understood the information for the study.
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I agree to the recording of the group discussions for the purposes of research analysis and possible publication
- I understand that data collected will be anonymised and stored securely
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
- I agree to take part in the study.

Having already notified participants of the day, date, and time of the focus group/ workshop, one week before the planned session, the primary investigator will follow up with a reminder email with the details of the session. A test call will be offered to those participants who are unfamiliar with the software or want to test their computer/ tablet/ phone. It is the responsibility of the primary investigator to ensure that all participants have consented. Participants will be reminded that they can withdraw from the study at any time without it affecting their medical care or legal rights.

Phase Two

Participants will receive a participant information sheet and a consent form. Pharmacists will complete a consent form online. Patients will sign a consent form to be retained by their surgery until the end of the study. In addition, verbal consent will be obtained at the start of the interviews.

9.3 Researcher and participant safety

The study poses a low risk to the primary investigator and the participants. Focus groups, workshops and interviews will be conducted remotely. If the researcher or participant becomes uncomfortable, the interview may be paused or prematurely concluded. The supervisory team will be notified and reasons for termination will be documented. If a participant discloses information that is of concern, this will be raised with the participant in the first instance, then highlighted to the supervisory team and a decision will be made about what action, if any, should be undertaken.

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University of East Anglia

Service Specification
Optimised Pharmacist-led Medication Reviews in Primary Care (OPen)

February 2023

This is just an example of what the service specification could look like. The structure is mapped to the template for intervention description and replication (TIDieR) checklist (appendix 1) and is populated with information that is known from existing documents relating to the discharge medication service (DMS), Structured Medication Reviews (SMR) and results of a systematic review exploring the core components of medication reviews and how they link to outcomes (SR).

Any sections where there is missing or conflicting information is a key uncertainty and will need to be discussed in the stakeholder co-design workshops.

Service Specification	Optimised Pharmacist-led Medication Reviews in Primary Care (OPen)
Period	February 2023- May 2023

1.0 Background

- Long-term conditions (LTCs) or chronic diseases are those for which there is currently no cure, and which are managed with medicines and other treatments.(The Kings Fund, 2013) Approximately 15 million people in England have a LTC, which accounts for 70% of the health and social care budget (Department of Health, 2012; NICE, 2015).
- Alongside the growth of LTCs, is the rise of multimorbidity, which is the presence of two or more long-term conditions. The average number of medicines dispensed per person increased from 14.8 in 2006 to 20.0 in 2016 (Ewbank *et al.*, 2018).
- Recent government reports have identified overprescribing (Department of Health & Social Care, 2021) and inappropriate prescribing (NHS and Network Contract Directed Enhanced Service, 2020) as significant problems with medicines use to treat long term conditions.
- Increased, and sometimes inappropriate use, of medicines can lead to more medicines related problems and poor patient outcomes, such as drug interactions, adverse drug reactions, reduced quality of life and hospitalisations (Duerden, Avery and Payne, 2013; Maher, Hanlon and Hajjar, 2014; Khezrian *et al.*, 2020).
- Medication reviews are a tool that are widely utilised to support patients with their medicines and many organisations advocate for pharmacist to be involved in their delivery given their expertise in the area (GPhC, 2020; NHS and Network Contract Directed Enhanced Service, 2020; Department of Health & Social Care, 2021), although this decision seems to be policy-led rather than evidence-led.
- A recent scoping review identified a significant quantity of primary research around the effectiveness of medication reviews. It concluded that the overall evidence of effectiveness of medication reviews is uncertain (no strong evidence for or against their effect on patient outcomes). In addition, it identified that most reviews did not describe the nature of the intervention in any great depth, i.e., core components or mechanisms of impact.
- A follow-up systematic review was undertaken to explore the core components of pharmacist-led medication reviews and whether and how they link to outcomes in different contexts. It is the conclusions from this systematic review, alongside the resultant programme theory, that provided the evidence that was considered in the development of this service specification.

2.0 Scope

An optimised pharmacist-led medication review service will be provided to patients with long-term conditions in primary care. This service specification has been designed using three sources of information:

- existing guidance for the Discharge Medication Service [DMS] and Structured Medication Reviews [SMR]) (NHS and Network Contract Directed Enhanced Service, 2020; NHS, 2021),
- evidence from a recent systematic review exploring the core components of pharmacist-led medication reviews and how these link to outcomes, and
- feedback from stakeholders in co-design workshops.

2.1 Aims and outcomes for the service *(to be determined)*

DMS

- Optimise use of medicines, whilst facilitating shared decision making
- Reduce harm from medicines (at the transfer of care)
- Improve patients understanding of medicines and how to take them
- Reduce hospital readmissions

SMR (implied)

- Reduce inappropriate prescribing
- The safe and effective use of medicines, facilitated by shared decision making, to enable the best possible outcomes for the patient

SR

- As yet unknown

Note: *Want to ensure the outcomes for this service reflect patient relevant outcomes and not just the standard adverse drug reactions, hospitalisations etc*

3.0 Service specification

3.1 Staffing of the service

DMS

- Pharmacist/ pharmacy technician

SMR

- Pharmacists with a prescribing qualification and advanced assessment and history taking skills.

SR

- As yet unknown

Note: May require additional details about staffing for identifying patients, organising appointments, any follow up

3.2 Premises providing the service

DMS

- Community pharmacies

SMR

- GP surgeries

SR

- As yet unknown

3.3 Service description

Describe each of the procedures, activities, and/or processes used in the intervention

DMS

- Pharmacist undertakes a clinical review following receipt of NHS trust referral
- Pharmacist/ pharmacy technician checks that the first prescription received following discharge takes into account the changes made in hospital. GP surgery notified of any discrepancies
- Pharmacist/ pharmacy technician holds a discussion with the patient to check their understanding of their post-discharge medicines regime. This will include checking adherence, clinical issues or for any outstanding questions or needs the patient may have regarding their medicines.

SMR

- Safety of the medicines; risk benefit for the patient

- Effectiveness: are medicines still indicated? Are they working? Is the long-term condition controlled? Is the patient taking the medicine?
- Prescribing/ de-prescribing decisions to be made with patient

SR

- As yet unknown

Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery

DMS

- Unknown

SMR

- Patients advised to bring their medicines with them to their review

SR

- As yet unknown

Describe the modes of delivery

DMS

- Face to face, telephone, video consultation

SMR

- Face to face, remote consultations

SR

- As yet unknown

Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.

DMS

- One discussion with the patient is required
- All other details are unknown

SMR

- exact length of SMR should vary in line with the needs of the individual. PCNs should allow for flexibility in appointment length for SMRs, depending on the complexity of individual cases.
- SMRs should be an ongoing process in which an individual appointment or discussion constitutes an episode of care. Regular review and management should be undertaken and SMRs should not be treated as a one-off exercise. The clinician should always ensure any appropriate follow-up SMR appointments are arranged to ensure the safety and effectiveness of any interventions. The clinician undertaking the SMR will determine the number of follow-ups needed in partnership with the patient; this will depend on complexity. **It may be that other professionals could follow up the patient**

SR

- As yet known

If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.

DMS

- Unknown

SMR

- SMRs should be personalised. clinicians should consider the patient when planning the location and mode of delivery for the SMR, including consideration of equitable access for housebound patients.

- Personalised – tailored to the patient. How would the patient like their medicines to impact on their quality of life? What would the patient like to get from a SMR? What medicines is the patient taking/not taking and why?
- Shared decision-making principles should underpin the conversation.

SR

- As yet unknown

3.4 Population covered

DMS

- High risk medicines

They include but are not limited to: anticoagulants (eg warfarin, dabigatran), antiepileptics, digoxin, opioids, methotrexate, antipsychotics, cardiovascular drugs (eg beta-blockers, diuretics),
controlled drugs, valproate, amiodarone, lithium, insulin, methotrexate, non-steroidal anti-inflammatory drugs (NSAIDs) and aspirin among others

- High risk patients

*People taking more than five medications, where the risk of harmful effects and drug interactions is increased.
• Those who have had new medicines prescribed while in hospital.
• Those who have had medication change(s) while in hospital.
• Those who have experienced myocardial infarction or a stroke due to likelihood of new medicines being prescribed.

- Those who appear confused about their medicines on admission/when getting ready for

discharge, and have already needed additional support from a healthcare professional.

- Those who have help at home to take their medications.
- Those patients who have a learning disability

SMR

- Patients in care homes
- with complex and problematic polypharmacy, specifically those on 10 or more medications
- on medicines commonly associated with medication errors
- with severe frailty, who are particularly isolated or housebound or who have had recent hospital admissions and/or falls

SR

- As yet unknown

3.5 Relationships with other service providers/ health care professionals

DMS

- Information shared to community pharmacy from referring NHS trust
- Information to be shared with GP/PCN pharmacy team to support care if clinically appropriate

SMR

- Work with community pharmacists to connect patients for the New Medicines Service

SR

- As yet unknown

What level of communication/ collaboration is needed between pharmacist and GP (and community pharmacist)? (Extracted from literature review, focus groups/ workshops)
How should they communicate? Why is it important

Where information is being shared between other service providers/ health care professionals, need to outline a dataset and means for sharing (See Appendix A of DMS Toolkit for an example).

4.0 Data collection and reporting

Include necessary infrastructure for service delivery

DMS

- Record to made on patient medication record
- Capture dataset and report at the end of each month

SMR

- Details and outcomes from the medication review will be recorded and coded in accordance with the GP contract Network Contract DES Specification [Network Contract DES related Business Rules are published by NHS Digital under the relevant years 'Enhanced Services, Vaccinations and Immunisations and Core Contract components' page https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/quality-and-outcomes-framework-qof]

SR

- As yet unknown

5.0 Location of Provider Premises

This will populated following participant recruitment

Appendix 1 *The TIDieR (Template for Intervention Description and Replication) Checklist (Hoffmann et al., 2014)*

Items from TIDieR checklist	**Where reported in the service specification**
BRIEF NAME Provide the name or a phrase that describes the intervention.	Title page
WHY Describe any rationale, theory, or goal of the elements essential to the intervention.	1.0 Background 2.0 Scope 2.1 Aims and outcomes of service
WHAT Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL). Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	3.3 Service description 3.5 Relationship with other service providers/ health care professionals
WHO PROVIDED For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	3.1 Staffing of the service 5.0 Location of provider premises
HOW Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	3.3 Service description 3.4 Population covered
WHERE Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	3.2 Premises providing the service 4.0 Data collection and reporting
WHEN and HOW MUCH Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	3.3 Service description
TAILORING If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	3.3 Service description
MODIFICATIONS If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	Not applicable to this service specification
HOW WELL Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Not applicable to this service specification

Appendix 2 Phase 1a Patient Focus Group Topic Guide

Welcome and Introductions (start recording and transcription)

Hello and welcome. Michael and I are members of the research team from the University of East Anglia who are seeking to understand and improve the delivery of medication reviews at your GP practice or community pharmacy. We are here today to explore your experiences of pharmacist medication reviews.

What will happen in the session

Today we intend to have a good discussion, with a chance for everyone to have a say.

i. There are no right or wrong answers – this is a chance to talk about what **you** think.
ii. My role is to pose questions to the group, then remain largely quiet whilst you discuss your responses.
iii. We will try to make sure that everyone gets a say as we are interested in the views of each of you.
iv. Whilst there are advantages to virtual discussion groups, there are some challenges. Microphones are very efficient and pick up lots of background noise, so we would ask you to mute your microphone when you are not speaking. To comment you can unmute yourself, and you can also use the chat box. Please do not deliberately speak over another participant.
v. We will make an accurate audio record of what is said. Only members of the research team will see or hear any of what is recorded. It is important to note that you will not be identifiable from the transcripts. As soon as we type up the notes, we will anonymise you and will only refer to you as a number. This is to encourage you to be as open and honest as possible.
vi. Later when the research is written up, we may want to quote some of **your** words as this can often be the best way to show the issues that matter. But this will not be done in a way that would allow anyone to be individually identified.

Consent

Before we proceed, we need to have your individual verbal consent to be involved in the study.

- I confirm that I have read and understand the information for the study.

- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I agree to the recording of the group discussions for the purposes of research analysis and possible publication in a peer reviewed journal
- I understand that data collected will be anonymised and stored securely.
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
- I agree to participate in the study.

Do you () agree to these statements?

Ground Rules

To help ensure everyone is comfortable with the discussion we would like to ask everyone to agree these ground rules:

i) Confidentiality – please treat this discussion as confidential

ii) Respect everyone else's contribution – even if you disagree with it

iii) Everybody will be given time/space to contribute.

Is everyone happy to agree to these?

We hope we will have an enjoyable and interesting time

We will start with introductions; Michael and I will begin and then you can take it turns to *tell us a bit about yourself and why you chose to be involved in this study*

Topic	Stem Question	Prompts
Contextual background	Can you tell me a bit about yourself and why you chose to be involved in this study	Information about self (work and hobbies) Did you look for more information about medication reviews- where did you look?

Identification of key uncertainties	Think back to your last medication review, what kind of things were discussed?	Was there anything that you wanted to talk about in your medication review that you did not get the opportunity to address? What were your expectations for the medication review? Where have you had your medication review? (Pharmacy, surgery, phone)
	What are your thoughts and feelings about attending medication reviews with the pharmacist?	Do you make an appointment for your medication reviews as soon as you are notified it is due? What encourages you to attend medication reviews? What may get in the way of you attending medication reviews?
	Do you know why you are asked to have medication reviews? If yes, tell me why you have medication reviews. If no, medication reviews are used to make sure you are prescribed the right medication for you and to help you get the most out of your medicines. How do you know if the medication review has made a difference to you?	Following your medication review, did you have a better understanding of what your medicines were for? Did it help you take your medicines as prescribed? Were you invited to follow up appointments with health care assistant/ nurse/ pharmacist/ doctor after your medication review to check e.g. blood pressure, blood sugar, general wellbeing?
Optimising the medication review	What are your thoughts on how pharmacist-led medication reviews can be improved?	What do you think should be in a medication review? How can the medication review process be improved?
Any other comments	Do you have any other comments about medication reviews in your pharmacy or doctor's surgery?	

Appendix 3 Phase 1b Practitioner Focus Group Topic Guide

Welcome and Introductions (start recording)

Hello and welcome. We are members of the research team from the University of East Anglia who are looking at optimising pharmacist-led medication reviews in primary care. We are here this evening to explore your experiences of pharmacist medication reviews.

What will happen in the focus group

This evening we intend to have a good discussion, with a chance for everyone to have a say.

vii. There are no right or wrong answers – this is a chance to talk about what **you** think.
viii. My role is to pose questions to the group, then remain largely quiet whilst you discuss your responses.
ix. We will try to make sure that everyone gets a say as we are interested in the views of each of you.
x. Whilst there are advantages to virtual discussion groups, there are some challenges. Microphones are very efficient and pick up lots of background noise, so we would ask you to mute your microphone when you are not speaking. To comment you can unmute yourself, and you can also use the chat box. Please do not deliberately speak over another participant. It is important that we can see your faces during the sessions, so please ensure you have your camera on. Participants can choose to blur their background.
xi. We will make an accurate audio record of what is said. Only members of the research team will see or hear any of what is recorded. It is important to note that you will not be identifiable from the transcripts. As soon as we type up the notes, we will anonymise you and will only refer to you as a number. This is to encourage you to be as open and honest as possible.
xii. Later when the research is written up, we may want to quote some of **your** words as this can often be the best way to show the issues that matter. But this will not be done in a way that would allow anyone to be individually identified.

Consent

Before we proceed, we need to ensure that you consent to be involved in the study.

- I confirm that I have read and understand the information for the study.
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

- I agree to the recording of the group discussions for the purposes of research analysis and possible publication
- I understand that data collected will be anonymised and stored securely
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
- I agree to participate in the study.

Do you all agree to these statements?

Ground Rules

To help ensure everyone is comfortable with the discussion we would like to ask everyone to agree these ground rules:

i) Confidentiality – please treat this discussion as confidential

ii) Respect everyone else's contribution – even if you disagree with it

iii) Everybody will be given time/space to contribute.

Is everyone happy to agree these?

We hope we will have an enjoyable and interesting time

Topic	Stem Question	Prompts
Contextual background	Can you tell me a bit about yourself and why you chose to be involved in this study	Information about self - Profession - How long qualified - How often do medication reviews
Identification of key uncertainties through consideration of the Programme theory (PT)	What are your thoughts about the programme theory?	What things are routinely discussed and covered in a medication review? - How do you decide what is relevant in the medication review?

(This will be sent out in advance to the participants with a detailed explanation of the context surrounding it. The programme theory represents literature evidence relating to the delivery of pharmacist-led medication reviews (PLMR). It presents the causal pathways and context of PLMR. NB Facilitator to state that the PT is not a reflection on practice.)		- What factors influence the delivery of medication reviews? - How do you adapt the medication review to suit the patient you have in front of you? - How are patients recruited for medication reviews? - What motivates you to deliver medication reviews? - How do you engage with the process? What factors do you think affect the effectiveness of medication reviews? - Are there any aspects of your practice that you think are more likely to produce a change in patients' medication taking behaviour How do you know if medication reviews have improved outcomes for patients? - Are patients followed up after medication reviews? - How do you assess whether recommendations made during the review have been carried out? - Are measures used to assess the impact of the medication review?
Optimising the intervention	How can the medication review process can be improved for patients and practitioners?	What are the barriers and enablers to the delivery of medication reviews?
Any other comments	Do you have any other comments about the delivery of medication reviews in primary care?	

Appendix 4 Phase 1d Workshop Topic guide

Phase 1d Generate a draft guidance for the delivery of pharmacist-led medication reviews in primary care
In advance participants to be sent summary video and two-page summary of data from systematic review and qualitative work.

Agenda
T0
Welcome and Introductions (start recording)

What will happen in the workshop

This evening we intend to have a good discussion, with a chance for everyone to have a say.

xiii. There are no right or wrong answers – this is a chance to talk about what **you** think.
xiv. My role is to pose questions to the group, then remain largely quiet whilst you discuss your responses.
xv. We will try to make sure that everyone gets a say as we are interested in the views of each of you.
xvi. Whilst there are advantages to virtual discussion groups, there are some challenges. Microphones are very efficient and pick up lots of background noise, so we would ask you to mute your microphone when you are not speaking. To comment you can unmute yourself, and you can also use the chat box. Please do not deliberately speak over another participant.
xvii. We will make an accurate audio record of what is said. Only members of the research team will see or hear any of what is recorded. It is important to note that you will not be identifiable from the transcripts. As soon as we type up the notes, we will anonymise you and will only refer to you as a number. This is to encourage you to be as open and honest as possible.
xviii. Later when the research is written up, we may want to quote some of **your** words as this can often be the best way to show the issues that matter. But this will not be done in a way that would allow anyone to be individually identified.

Consent
Before we proceed, we need to ensure that you consent to be involved in the study.

- I confirm that I have read and understand the information for the study.
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I agree to the recording of the group discussions for the purposes of research analysis and possible publication
- I understand that data collected will be anonymised and stored securely

- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
- I agree to participate in the study.

Do you all agree to these statements?

Ground Rules

To help ensure everyone is comfortable with the discussion we would like to ask everyone to agree these ground rules:

i) Confidentiality – please treat this discussion as confidential

ii) Respect everyone else's contribution – even if you disagree with it

iii) Everybody will be given time/space to contribute.

Is everyone happy to agree these?

We hope we will have an enjoyable and interesting time

T5

The previous discussions were to find out about your personal experiences with medication reviews. In this workshop we want to talk about what we have learned from the literature and the discussions, then use what we know to work out how to move pharmacist-led medication reviews forward.

As this is the first time we have met together, can we briefly introduce ourselves?

T12

"Would anyone like to view the video summary again before we begin?"

[check that share sound has been enabled in MS teams]

T18

Participants will discuss the results from the literature review and discussions. Participants will agree on which should be prioritised and discussed in the draft guidance.

Prompt questions

1. What do you think of what was presented?
2. Was there anything missing that you feel should have been included?
3. What do you think was most important out of the information that was presented?
4. From the information that has been presented and the discussion that we have had, what do you think this means for pharmacist-led medication reviews?

T45

Short break

T50

We will go on to discuss how these points can be addressed and implemented in a primary care setting. [aim for SMART objectives]

Given the discussion that we have had, we are aiming to produce guidance to help pharmacists deliver medication reviews in primary and help patients get the best from these medication reviews.

If we are producing guidance, how would this be helpful from patient and practitioner perspective?
What should it cover?
Who should it be aimed at?
What should it look like (formatting)? E.g. poster, leaflet, formal guidance
How should it be accessed?
How do we convey this guidance to patients and practitioners?
When might the guidance be used?

T90 Summary, next steps, conclusion of session
I am going use the information that we found and your comments and think about what you said. I will put together draft guidance to bring to next session for discussion.

Appendix 5 Phase 1e Workshop Topic guide

Phase 1e Refinement of the draft guidance for the delivery of pharmacist-led medication reviews in primary care

In advance participants to be a two-page summary of data from systematic review and qualitative work and the draft guidance document.

Agenda
T0
Welcome and Introductions (start recording)
What will happen in the workshop
This evening we intend to have a good discussion, with a chance for everyone to have a say.
i. There are no right or wrong answers – this is a chance to talk about what you think.
ii. My role is to pose questions to the group, then remain largely quiet whilst you discuss your responses.
iii. We will try to make sure that everyone gets a say as we are interested in the views of each of you.
iv. Whilst there are advantages to virtual discussion groups, there are some challenges. Microphones are very efficient and pick up lots of background noise, so we would ask you to mute your microphone when you are not speaking. To comment you can unmute yourself, and you can also use the chat box. Please do not deliberately speak over another participant.
v. We will make an accurate audio record of what is said. Only members of the research team will see or hear any of what is recorded. It is important to note that you will not be identifiable from the transcripts. As soon as we type up the notes, we will anonymise you and will only refer to you as a number. This is to encourage you to be as open and honest as possible.
vi. Later when the research is written up, we may want to quote some of your words as this can often be the best way to show the issues that matter. But this will not be done in a way that would allow anyone to be individually identified.

Consent
Before we proceed, we need to ensure that you consent to be involved in the study.
- I confirm that I have read and understand the information for the study.
- I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- I agree to the recording of the group discussions for the purposes of research analysis and possible publication
- I understand that data collected will be anonymised and stored securely
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected.
- I agree to participate in the study.

Do you all agree to these statements?

Ground Rules
To help ensure everyone is comfortable with the discussion we would like to ask everyone to agree these ground rules:
i) Confidentiality – please treat this discussion as confidential
ii) Respect everyone else's contribution – even if you disagree with it
iii) Everybody will be given time/space to contribute.
Is everyone happy to agree these?

We hope we will have an enjoyable and interesting time

T8
The previous discussions were to find out about your personal experiences with medication reviews and how we could improve the process of pharmacist-led medication reviews. In this session we want to review the guidance document that was sent out last week. We would like your feedback on its appropriateness based on your experience with medication reviews.
T10
As this is the first time we all have met together, can we briefly introduce ourselves?

T15 [PATIENT]
We have learned that a medication review is more than just what happens in those minutes when talking with the patient/ pharmacist. We have learned that we should consider all the other activities that happen before, during and after the consultation.

1. What did you think of the guidance document that was sent out last week? What did you like about it? How can it be improved? Did it make sense?
2. Some of the things you have been asked to do is to think about what you want from the review and any questions that you would like to ask. How do you feel about this? What would help you to be able to do these things?
3. The other document that we sent out outlined the key issues that had been identified in our previous work, which some of you were part of. How well do you think we covered the things that you talked about?
4. What do you think are the disadvantages of this guidance?
5. How well do you think this guidance meets patients' needs? Do you think it can be used for the different types of medication reviews you have had?

T15 [PHARMACIST]

1. What did you think about the draft document that were circulated? What did you like about it? How can it be improved? Is there anything that seems inappropriate or unnecessary?
2. What do you think of the things you have been asked to do as part of the medication review? what would help you to be able to do those things? [Patients to think about what they want from the review, questions in advance]
3. Thinking about the key issues that were identified from the literature and the discussion groups, how well does this guidance document meet these? How well do you think these things can be implemented in the review?

4. What do you think are the unintended consequences of this guidance? How do you think it is going to impact on your time?
5. How do you think this guidance meets the needs of the different patients and medication reviews that are delivered by pharmacists?

T50 Summary, next steps, conclusion of session

"If you think of anything else after the session, please feel free to email me any other comments"

Appendix 6 Social media advert for pharmacists

The OPen study (Optimising Pharmacist-led medication reviews) is looking for pharmacists to participate in a focus group and co-design workshops. This study aims to establish what is currently happening in practice and to co-design a service specification that defines and describes optimised medication reviews by pharmacists in primary care.

If you

- Work in primary care in England
- Undertake medication reviews as part of your practice (including DMS and SMR)

Please click on the link [insert] for more information

Appendix 7 Phase 1 Practitioner Expression of Interest Form

N.B. This will be completed via JISC online survey. The link for the expression of interest form is embedded in the participant information sheet.

Thank you for your interest in Optimising Pharmacist-led medication reviews in Primary Care (OPen study). As outlined in the participant information sheet, we are recruiting professionals to participate in a focus group and workshops as we examine the current implementation of medication reviews and co-design a service specification for optimised medication reviews by pharmacists in primary care.

This short survey is going to collect information to help the research team select a diverse sample of participants.

1. Please tell us who you are [select one from a drop-down list]:
    A. Pharmacist
    Please tell us where you work
        a. GP surgery
        b. Primary Care Network
        c. Community pharmacy
        d. Other (please specify)
    Do you work with a general practitioner colleague who would be interested in this study?
        a. No
        b. Yes (We will send you a follow-up email about recruiting them to the study)
    B. General Practitioner
    C. Nurse practitioner

    The following information is collected to help us select a diverse group of participants

    What is your sex?
    a. Male
    b. Female
    c. Other

d. Prefer not to say

What is your age?
a. 20-30
b. 31-40
c. 41-50
d. 51-60
e. 61 years and older

What is your ethnic group? [select one from a drop-down list]
a. Asian or Asian British (includes any Asian background, for example, Bangladeshi, Chinese, Indian, Pakistani)
b. Black, African, Black British or Caribbean (Includes any Black background)
c. Mixed or multiple ethnic groups (Includes any Mixed background)
d. White (includes any White background)
e. Another ethnic group (Includes any other ethnic group, for example, Arab)
f. Prefer not to say

2. Do you work in primary care in England?
   A. No ➲ End message 1
   B. Yes

3. Do you regularly deliver medication reviews as part of your practice?
   A. No ➲ End message 1
   B. Yes

4. We plan to undertake online interviews and workshops, which will require the use of a computer and an internet connection. Please confirm that you are happy with this.
   A. No ➲ End message 1
   B. Yes
5. I would like to participate in (select all that apply)
   A. One pharmacist/ GP / Nurse practitioner discussion group (Focus group)
   B. Two Pharmacist/ Patient/ GP / Nurse practitioner discussion groups (Workshops)
   C. All discussion groups

6. Please record the postcode of where you work

Please include your details so that we can contact you to let you know if you have been selected to take part in the study.

Your details will only be used for the purpose of contacting you to arrange a suitable date/time for the focus group or to contact you to see if you are interested in participating in

other activities related to this study. Your personal information will be kept strictly confidential.
I can confirm I am happy for my information to be used in this way

- Name
- Surname
- Email
- Telephone

I am happy to be contacted about future medication review research

A. No
B. Yes

➲ End message 2

End message 1:
Thank you for expressing an interest in the OPen study. Unfortunately, some of the answers you have given means that you are not able to take part in the study.

If you have any questions about the study, then please do contact me via email at m.craske@uea.ac.uk

End message 2:
Thank you for expressing an interest in the OPen study. We will be in touch to confirm whether you have been selected to take part or not. If you have been selected, we will send you a meeting poll to arrange a suitable date and time for the focus group/ workshop.
If you have any questions about the study, then please do contact me via email at m.craske@uea.ac.uk

Appendix 8 Phase 1 Practitioner Participant Information sheet and consent statements

OPen study – Optimising Pharmacist-led medication reviews

Designing a service specification to optimise medication reviews for patients with long-term conditions.

Participant Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to help you understand the study and what it will involve. It is set out as a series of questions and answers. **Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us** (m.craske@uea.ac.uk or telephone 07424 379860). We suggest this should take **no more than 15 minutes**. This study is being conducted by the University of East Anglia (UEA) as part of a PhD by Miriam Craske. Miriam Craske is a pharmacist who registered in 2000. She has experience of working in community pharmacy and teaching undergraduates.

What is the purpose of the study?

A medication review is a discussion a patient has with their GP, pharmacist or nurse about their medicines, with the goal of finding those medicines that need to be stopped or changed for the patient's benefit. Medication reviews are used to improve medicines use and health outcomes, and decrease medicines related problems. Despite the growing use of medication reviews, these are implemented differently in different settings and it is not clear how they impact on patient outcomes such as adverse drug reactions or hospitalisations. The purpose of this study is to understand the current delivery of medication reviews in primary care and to design a service specification that defines and describes a new approach to pharmacist-led medication reviews in primary care.

Do I have to take part?
No. It is up to you to decide whether to take part or not. If you agree to take part, please let us know by completing the expression of interest form. Not everyone who completes the expression of interest form will be selected to take part. We are choosing people based on their characteristics and if chosen to take part you will be contacted via email.

What are the possible benefits of taking part?
The study will not benefit you directly. This is an opportunity to help shape how medication reviews are implemented in practice to improve the health of patients with long-term conditions.

What will I have to do?
If you want to take part in this study, we will ask you to take part in online group discussions (focus group/ workshops) or interview. These discussions will involve people talking about their experiences with pharmacist medication reviews. The group discussions will comprise of 8-12 attendees, including members of the research team from the University of East Anglia.

The **focus group** will include community, GP surgery and Primary Care Network pharmacists, general practitioners and nurse practitioners. **Interviews** will consist of a health care professional and a member of the research team from the University of East Anglia.

The interviews/ focus group aims to explore health care practitioners' experiences, with a view to identifying parts of the medication review that can be improved to enhance patient and pharmacist's experiences of medication reviews.

Workshops will include pharmacists, patients, nurse practitioners and GPs. You will be asked for your opinions and experience to help the research team design a service specification that outlines what pharmacists should do in medication reviews and what should be measured to know if they are working. The research team will build on information from existing documents describing medication reviews (NHS Discharge

Medicines Service Toolkit[1], Structured medication reviews and medicines optimisation guidance[2]), conclusions from a recent review of published papers investigating the core components of medication reviews to explore what an optimised pharmacist-led medication review could look like, and the feedback from patient and practitioner focus groups. We will ask you for your thoughts on the acceptability of a proposed new way for pharmacists to deliver medication reviews, ideas on how to improve it, and whether the service can be delivered in primary care.

The focus group/ workshops will take place online using Microsoft ® Teams and will take up to two hours. You can choose to take part in the focus group, workshops, or both. If you choose to take part in the workshops, you should be able to attend both.
The discussion groups will be audio and video recorded and transcribed verbatim. When the transcripts have been produced and verified, the recording will be destroyed. Any ideas that are contributed to workshop discussions will not be personally identifiable.

Before the discussion you will be sent a link to complete an electronic consent form containing the following statements:

1. I confirm that I have read and understood the information for the study.
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
3. I agree to the recording of the group discussions for the purposes of research analysis and possible publication
4. I understand that data collected will be anonymised and stored securely
5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected.
6. I agree to take part in the study.

We will ask that you complete this 24 hours before the discussion takes place. At the start of the discussion group the following statements will be read again. You will be asked to confirm that you agree with them as a way of providing informed consent.

What happens next?
If you would like to take part, please fill in the online expression of interest form. The link to the expression of interest form is included at the end of this document. If you would like to speak to the researcher before completing the form, please contact them on the details below and they will be happy to talk about the study in more detail.
You will be contacted via email by a researcher to let you know if you have been selected to take part. A researcher will work with you to arrange a suitable date and time for the focus group / workshops.

---

[1] NHS England and Improvement (2021) NHS Discharge Medicines Service- Toolkit for pharmacy staff in community, primary and secondary care.

[2] NHS (2020) Structured medication reviews and medicines optimisation: guidance Network Contract Directed Enhanced Service. (September).

When the date/ time has been agreed the researcher will send you a reminder email one week before the session.

How will we use information about you?
We will need to use information from you for this research project. This information will include your name and contact details. We will only use information that we need for the research study.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Once we have finished the study, we will keep the data generated in the focus group and workshops so we can check the results. Reports will be written in a way that no one can work out that you took part in the study. This will involve publishing direct quotes.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will need to keep any information that we already have about you. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk or by asking the research team by sending an email to m.craske@uea.ac.uk. Alternatively, you can look at how we use your information from online forms here: https://www.uea.ac.uk/about/university-information/statutory-and-legal/data-protection/data-protection-for-webforms and the Health Research Authority has information here: www.hra.nhs.uk/information-about-patients/.

Will my taking part in the study be kept confidential?
Yes. All your personal information will be kept strictly confidential. All recorded information will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored on a password protected computer. Your contact details will be held by the research team only, to arrange the focus groups and workshops, and will not be shared with any other organisations. Your personal and research data will be kept securely online for 10 years in line with the UEA research data policy.

However, where issues emerge during the group discussion(s) that are potentially harmful or dangerous, for example, reports of neglect or dangerous advice given, the researcher might consider the need to break confidentiality. In this circumstance, the primary investigator will discuss the need to disclose the information with you in the first instance. The primary investigator will then discuss with the supervisor and if necessary, the research team prior to deciding what action to take.

Will I be able to withdraw from the study?
You will be free to withdraw from the research at any point, without giving a reason. However, if you decide to leave in the middle of the group discussion(s) due to time

constraints or any other reason, we will not be able to remove your data and it will be included in the final analysis.

What will happen to the results of the research study?
This work is being conducted as part of a PhD research project and therefore we will report the findings in a thesis and publish the findings in a peer reviewed journal or present the results at conferences. Any published information will be reported anonymously. At the end of the study, we will share a short summary of the findings with you.

Are there any disadvantages to taking part in the study?
We do not foresee any disadvantages to taking part in the research other than your time commitment, for which we are grateful. A small incentive will be offered to participants. Those attending the focus group will receive a £50 voucher, and those attending workshops will receive a £50 voucher for each session (£100 in total). Gift vouchers will be received via email at the end of the discussion groups.

Who has reviewed the study?
This research has been reviewed and approved by NHS Health Research Authority to protect your safety, rights, wellbeing and dignity. (https://www.hra.nhs.uk/about-us/what-we-do/)

Who is funding this research?
This research is being funded by the University of East Anglia.

What if I have a complaint?
If you have any questions about any aspect of this study, you should contact the researchers who will do their best to answer your questions [m.craske@uea.ac.uk]. If you remain dissatisfied and wish to complain formally, you can do this by contacting the Acting Head of School of Pharmacy, Professor Anja Mueller via email: Anja.Mueller@uea.ac.uk. The University of East Anglia is sponsoring this study.

For further information please contact:

Mrs Miriam Craske School of Pharmacy University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ Email: m.craske@uea.ac.uk Telephone: 07435449141	**Research supervisor and Chief investigator** Dr Michael Twigg School of Pharmacy, University of East Anglia, Norwich Research Park, Norwich, NR4 7T Email: m.twigg@uea.ac.uk

Please click on this link [Optimising Pharmacist-led medication reviews Phase 1 Expression of interest] to complete the expression of interest form [Appendix 7]

Appendix 9 Invitation email to pharmacy organisations

Title: Invitation to participate in OPen study- **O**ptimising **P**harmacist-l**e**d Medicatio**n** reviews in primary care

Dear [organisation name]

Please could you forward this email and study information to your members.

If we haven't recruited enough participants in four weeks, we will ask you to send the invite email again.

Thank you for your help.

Yours Sincerely,

Miriam Craske

[Attached- Appendix 8 Participant Information Sheet]

Dear colleague

The University of East Anglia (UEA) is conducting a research project to optimise pharmacist-led medication reviews in primary care to improve outcomes for patients with long-term conditions.

We are reaching out to invite you to participate this study. This research aims to

4. Explore the current provision of medication reviews by pharmacists in primary care
5. Co-design a service specification that optimises medication reviews by pharmacists in primary care

We would like to recruit pharmacists to take part in a focus group and/ or workshops, which will be held on a weekday, sometime between 5pm and 9pm.

Focus group (2 hours, online) – with community pharmacists, General Practice pharmacists, Primary Care Network pharmacists and General Practitioners. One focus group is planned.

Workshops (2 hours, online)- with General Practitioners, pharmacists, patients. Two workshops are planned.

If you are willing to participate, please complete the online expression of interest form by clicking the link [insert]. We will review your form and get back to you to arrange a date and time for the focus group and/ or workshops, if you are selected to participate.

If you have any queries, please feel free to contact the primary investigator, Miriam Craske, by emailing m.craske@uea.ac.uk.

Thank you in anticipation for your help.

Yours Sincerely,

Miriam Craske

Appendix 10 Pharmacist email for GP and nurse recruitment

Title: Invitation to participate in OPen study- **O**ptimising **P**harmacist-l**e**d Medicatio**n** reviews in primary care

Dear Pharmacist

Thank you for expressing an interest in participating in the OPen study. We are also looking for GPs and nurse practitioners to participate in the focus group and workshops. If you can identify a GP or nurse practitioner colleague who you think would be interested in participating in this study, please could you forward this email and study information to them.

Yours sincerely

Miriam Craske

[Attached- Appendix 8 Participant Information Sheet]

Dear GP/nurse practitioner colleague

An increasing number of people are diagnosed with long term conditions which are primarily managed by medicines. Medication reviews (MRs) are a widely implemented intervention that seek to optimise medicines, improve health outcomes and decrease medicines related problems. Despite the growing use of medication reviews, particularly in primary care, these are implemented differently in different settings and it is not clear how they impact on patient outcomes such as adverse drug reactions or hospitalisations. There is a policy-led drive to involve pharmacists with MRs.

The University of East Anglia (UEA) is undertaking a project to develop a new approach to pharmacist-led medication reviews in primary care to improve outcomes for patients with long-term conditions.

We are reaching out to invite you to participate in this study. This research aims to:

1. Explore the current provision of medication reviews by pharmacists in primary care
2. Co-design a service specification that optimises medication reviews by pharmacists in primary care

We would like to recruit general practitioners and nurse practitioners to take part in a focus group and/ or workshops, which will be held on a weekday, sometime between 5pm and 9pm.

Focus group (2 hours, online) – with pharmacists, general practitioners and nurse practitioners. One focus group is planned.

Workshops (2 hours, online)- with GPs, pharmacists, nurse practitioners, patients. Two workshops are planned.

If you are willing to participate, please complete the online expression of interest form by clicking the link [insert]. We will review your form and get back to you to arrange a date and time for the focus group and/ or workshops, if you are selected to participate.

If you have any queries, please feel free to contact the primary investigator, Miriam Craske, by emailing m.craske@uea.ac.uk

Yours sincerely

Miriam Craske

Appendix 11 Social media advert for patients

The OPen study is looking for **patients** to share their experiences of pharmacist medication reviews in online discussion groups.
If you
✓Live in England
✓Are prescribed 5 or more medicines
✓Have had a medication review by a pharmacist in a pharmacy or GP surgery in the last 3 months
Please click on the link [insert] for more information

Appendix 12 Phase 1 Patient Expression of Interest Form

N.B. This will be completed via JISC online survey The link for the expression of interest form is embedded in the participant information sheet.

Thank you for your interest in Optimising Pharmacist-led medication reviews in Primary Care (OPen) study. As described in the participant information sheet, we are asking patients to take part in discussion groups. The discussion groups will help us understand the current delivery of medication reviews. Then further discussion groups will be used to design a document that helps pharmacists to review medicines.

This short survey is going to collect information to help the research team choose a mixture of participants.

1. Are you aged 18 years or older?
    a. No ➲ End message 1
    b. Yes
2. How many medicines are you currently prescribed?
    a. Four or less ➲ End message 1
    b. Five or more

3. Have you received a medication review from a pharmacist in your pharmacy or GP surgery within the last three months?
    a. No ➲ End message 1
    b. Yes
4. Are you currently (or recently) taking part in another research project?
    a. No
    b. Yes ➲ End message 1

5. We plan to undertake online discussion groups, which will require the use of a computer, tablet or smartphone, with a reliable internet connection. Please confirm that you are happy with this.
    a. No ➲ End message 1
    b. Yes

6. I would like to participate in:

a. One discussion group with just patients
b. Two discussion groups with patients, pharmacists and doctors
c. All discussion groups

The following information is collected to help us select a diverse group of participants

7. Please record the postcode for where you live

8. What is your ethnic group? [select one from a drop-down list]
a. Asian or Asian British (includes any Asian background, for example, Bangladeshi, Chinese, Indian, Pakistani)
b. Black, African, Black British or Caribbean (Includes any Black background)
c. Mixed or multiple ethnic groups (Includes any Mixed background)
d. White (includes any White background)
e. Another ethnic group (Includes any other ethnic group, for example, Arab)
f. Prefer not to say

Please include your details so that we can contact you to let you know if you have been selected to take part in the study.

Your details will only be used for the purpose of contacting you to arrange a suitable date/time for the discussion groups. We will also use them to contact you to see if you are interested in participating in other activities related to this study. Your personal information will be kept strictly confidential.
I confirm I am happy for my information to be used in this way

- Name
- Surname
- Email
- Telephone

➲ End message 2

End message 1:
Thank you for expressing an interest in the OPen study. Unfortunately, some of the answers you have given means that you are not able to take part in the study.
If you have any questions about the study, then please do contact me via email at m.craske@uea.ac.uk

End message 2:
Thank you for expressing an interest in the OPen study. We will be in touch email you within 4 weeks to confirm whether you have been selected to take part or not. If you have been selected, we will send you a meeting poll to arrange a suitable date and time for the focus group/ workshop.
If you have any questions about the study, then please do contact me via email at m.craske@uea.ac.uk

Appendix 13 Phase 1 Patient Participant Information sheet and consent statements

OPen study – Optimising Pharmacist-led medication reviews

Participant Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to help you understand the study and what it will involve. It is set out as a series of questions and answers. **Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us** (m.craske@uea.ac.uk , telephone 07424 379860). We suggest this should take **no more than 15 minutes**. This study is being conducted by the University of East Anglia as part of a PhD by Miriam Craske. Miriam Craske is a pharmacist who registered in 2000. She has experience of working in community pharmacy and teaching pharmacy students.

What is the purpose of the study?
The purpose of this study is to understand the current delivery of medication reviews at your GP practice or community pharmacy. We will then design a document that helps pharmacists to review medicines. This document will outline what pharmacists should do and what should be measured.

Do I have to take part?
No. It is up to you to decide whether to take part or not. If you would like to take part, please complete the expression of interest form by clicking on the link [insert]. Not everyone who completes the expression of interest form will be selected to take part. We are choosing people based on their characteristics and if chosen to take part you will be contacted via email. These characteristics include where in England you live, your gender, age and race.

What are the possible benefits of taking part?
This is an opportunity to help shape how pharmacists review medicines at the GP surgery or community pharmacy. The study will not benefit you directly.

What will I have to do?
If you want to take part in this study, you will be asked to take part in online group discussions. Group discussions involve people coming together to talk about their experiences of a specific activity. In this case the activity will be pharmacist medication reviews. The group discussions will made up of 8-12 attendees, including members of the research team from the University of East Anglia.

Group discussion 1 **(focus group)** will involve a group of patients talking about their experiences of pharmacists reviewing their medicines. We hope that in this session you will be able to identify parts of the medication review that can be made better to improve your experience of medication reviews.

Groups discussions 2 and 3 **(workshops)** will be a mixture of pharmacists, patients, and doctors and nurses. You will be asked for your thoughts and ideas to help the research team to design a document that outlines what pharmacists should do in medication reviews and what should be measured. The research team will use the information that

is currently available and the feedback from the discussion groups to produce a draft document. In the final group discussion, you will be asked to share your thoughts about the document and whether you think it is acceptable.

All group discussions will take place online using Microsoft ® Teams and last for up to two hours each. You can choose to participate in the patient focus group, or the mixed workshops. If you choose to participate in the mixed workshop, we would like you to be available to attend both.
The discussion groups will be audio and video recorded. These recordings will be written up word for word, then destroyed. Any comments or ideas that are contributed to discussions will be written in a way so individual people cannot be identified. If you are uncomfortable with appearing on the screen, once we have confirmed your identity you can turn your camera off and/or participate solely through the 'chat' function if that is your preferred option. The facilitator will then make sure your comments are discussed by the group.

Before the discussion you will be sent a link to complete an electronic consent form containing the following statements:

1. I confirm that I have read and understand the information for the study.
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
3. I agree to the recording of the group discussions for the purposes of research analysis and possible publication
4. I understand that data collected will be anonymised and stored securely
5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected.
6. I agree to participate in the study.

We will ask that you complete this 24 hours before the discussion takes place. At the start of the discussion group the following statements will be read again. You will be asked to confirm that you agree with them as a way of providing informed consent.

What happens next?
If you would like to take part, please fill in the online expression of interest form. The link to the expression of interest form is included at the end of this document. If you would like to speak to the researcher before completing the form, please contact them on the details below and they will be happy to talk about the study in more detail.
You will be contacted by a researcher to let you know if you have been selected to take part. The researcher will work with you to arrange a suitable date and time for the discussion group(s).
When the date and time has been agreed, the researcher will send you a reminder email one week before the discussion group.

How will we use information about you?
We will need to use information from you for this research project. This information will include your name and contact details. We will only use information that we need for the research study.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. Reports will be written in a way that no-one can work out that you took part in the study. This will involve publishing direct quotes.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will need to keep any information that we already have about you. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk or by asking the research team by sending an email to m.craske@uea.ac.uk. Alternatively, you can look at how we use your information from online forms here: https://www.uea.ac.uk/about/university-information/statutory-and-legal/data-protection/data-protection-for-webforms and the Health Research Authority has information here: www.hra.nhs.uk/information-about-patients/.

Will my taking part in the study be kept confidential?
Yes. All your personal information will be kept strictly confidential. All recorded information will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored on a password protected computer. Your contact details will be held by the research team **only**, to arrange the discussion groups, and will not be shared with any other organisations. Your personal and research data will be kept for 10 years in line with the UEA research data policy.

However, where issues emerge during the group discussion(s) that are potentially harmful or dangerous, for example, reports of neglect or dangerous advice given, the researcher might consider the need to break confidentiality. In this circumstance, the primary investigator will discuss the need to disclose the information with you in the first instance. The primary investigator will then discuss with the supervisor and if necessary, the research team prior to deciding what action to take.

Will I be able to withdraw from the study?
You will be free to withdraw from the research at any point, without giving a reason. However, if you decide to leave in the middle of the group discussion(s) due to time constraints or any other reason, we will not be able to remove your data and it will be included in the final analysis.

What will happen to the results of the research study?
This work is being conducted as part of a PhD research project and therefore we will report the findings in a thesis and publish the findings in a peer reviewed journal or

present the results at conferences. Any published information will be reported anonymously. At the end of the study, we will share a brief summary of the findings with you.

Are there any disadvantages to taking part in the study?
We do not see any disadvantages to taking part in the research other than your time commitment, for which we are grateful. To show our appreciation to those who choose to take part, participants will receive a £50 voucher for each group discussion that they attend. Participants will have a choice of gift voucher. Gift vouchers will be emailed to participants at the end of the discussion groups.

Who has reviewed the study?
This research has been reviewed and approved by NHS Health Research Authority to protect your safety, rights, wellbeing, and dignity. (https://www.hra.nhs.uk/about-us/what-we-do/)

Who is funding this research?
This research is being funded by the University of East Anglia.

What if I have a complaint?
If you have any questions about any aspect of this study, you should contact the researchers who will do their best to answer your questions [m.craske@uea.ac.uk]. If you remain dissatisfied and wish to complain formally, you can do this by contacting the Acting Head of School of Pharmacy, Professor Anja Mueller via email: Anja.Mueller@uea.ac.uk. The University of East Anglia is sponsoring this study.

For further information please contact:

Mrs Miriam Craske School of Pharmacy University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ Email: m.craske@uea.ac.uk Telephone: 07424 379860	**Research supervisor and chief investigator** Dr Michael Twigg School of Pharmacy, University of East Anglia, Norwich Research Park, Norwich, NR4 7T Email: m.twigg@uea.ac.uk

Appendix 14 Invitation email to patient organisations

Title: Invitation to participate in the OPen study- developing a new way for pharmacists to deliver Medication reviews in primary care

Dear [organisation name]

Please could you forward this email and study information to your members.

If recruitment is proving to be challenging, we will re-send this email in four weeks, inviting you to forward to your members again.

Yours sincerely

Miriam Craske

[Attached- Appendix 13 Participant Information Sheet]

The University of East Anglia (UEA) is working on a project looking to improve medication reviews by pharmacists in GP surgeries.

We are reaching out to invite you to participate this study. This study aims to

1. Explore how medication reviews are currently delivered by pharmacists
2. Design a document that helps pharmacists to review medicines. This document will outline what pharmacists should do and what should be measured.

We would like to recruit patient representatives to take part in group discussions.

Patients only discussion group (2 hours, online) – with eight to ten participants. This will take place on a weekday, sometime between 12pm and 6pm.

Mixed discussion groups with patients, pharmacists, and doctors (2 hours, online). These groups will have ten to twelve participants. These will take place on a weekday, sometime between 5pm and 9pm. Two mixed discussion groups are planned, and we would like you to attend both.

If you would like to take part, please complete the online expression of interest form by clicking the link https://uea.onlinesurveys.ac.uk/patient-expression-of-interest. Not everyone who completes the form will be able to take part. We will look at your form and let you know if you have been selected to participate. If you are selected to participate, we will email you to arrange a date and time for discussion groups.

If you have any queries, please feel free to contact the primary investigator, Miriam Craske, by emailing m.craske@uea.ac.uk

Yours sincerely

Miriam Craske

Appendix 16 Regret email

Thank you for expressing an interest in the OPen study (Optimising pharmacist-led medication reviews in primary care).

Unfortunately, you have not been selected to participate in this study at this time.

The results of this study will be disseminated among patient and pharmacist groups and shared on social media when the study is completed (June 2024).

Thank you for your support

Miriam Craske

Appendix 17 Pharmacist email to patients

Dear pharmacist

Please send this email to the patients you have selected to participate in the OPen study.

Yours Sincerely,

Miriam Craske

Title: Invitation to participate in testing a new way of delivering medication reviews (The OPen study)

Dear [Patient]

The University of East Anglia (UEA) is working on a project to improve the way pharmacists deliver medication reviews in GP surgeries.

The pharmacist at your GP surgery has agreed to take part in this study. This involves testing a new way of delivering medication reviews. This means that they will use a document to guide them in what they do and say in the medication review. Please consider whether you would be willing for the pharmacist to use this new approach during your medication review.

As part of this study, we would like to speak to patients after their medication review. We will ask you about your thoughts and feelings of your experience. This conversation will take place via a video or telephone call, depending on what you prefer. This should not take longer than 30 minutes. You will receive a £10 voucher for your participation.

Please read the attached participant information sheet and if you have any queries, feel free to contact Miriam Craske, by emailing m.craske@uea.ac.uk

Thank you in anticipation for your help.

Yours Sincerely,

Miriam Craske

[Attached- Appendix 25 Participant Information Sheet]

Appendix 18 Phase 2 Patient Participant Information sheet

OPen study – Optimising Pharmacist-led medication reviews

Participant Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to help you understand the study and what it will involve. It is set out as a series of questions and answers. **Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us** (m.craske@uea.ac.uk, telephone 07435449141). We suggest this should take **no more than 15 minutes**. This study is being conducted by the University of East Anglia as part of a PhD by Miriam Craske. Miriam Craske is a pharmacist who registered in 2000. She has experience of working in community pharmacy and teaching pharmacy students.

What is the purpose of the study?
A group of pharmacists, patients and GPs came together to design a new way of delivering medication reviews. They produced a document (called a service specification) which outlines what pharmacists in general practice should do in a medication review.
This study wants to test this new way of delivering medication reviews. We are also interested in knowing how patients felt after the medication review.

Do I have to take part?
No. It is up to you to decide whether you take part or not. If you decide to take part, you will receive a "new" medication review. After your medication review you can choose whether you want to talk to a researcher about your experience. The pharmacist will remind you of these options at the start of the medication review. If you choose not to be involved in the study, your care will not be affected. You will receive a medication review as normal.

What are the possible benefits of taking part?
This is an opportunity to help shape how pharmacists review medicines at the GP surgery. Besides the general possible benefits associated with medication reviews, the study will not benefit you directly.

What will I have to do?
If you want to take part in this study, the pharmacist will ask you to complete a consent form at the start of your medication review which contains the following statements:
1. I confirm that I have read and understand the participant information sheet for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I agree to take part in the study, by allowing the pharmacist to use the service specification to conduct my medication review
*3. I agree to the pharmacist securely sharing my personal details to the research team at the University of East Anglia so I can be contacted for a follow up interview to discuss my experience.

*4. I am willing to allow the interview to be recorded for the purposes of research analysis and possible publication of findings
*5. I understand that data will be anonymised and will be stored securely at the University of East Anglia (More information about how we handle your data can be found on the university's web site: https://www.uea.ac.uk/about/university-information/statutory-and-legal/data-protection/data-protection-for-webforms)
6. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical and legal rights being affected.
*7. I agree to take part in the above study

* Only applicable if also undertaking the interview

This consent form gives permission for the pharmacist to conduct the medication review using the service specification. If you choose to share your thoughts and feelings with a researcher, your contact details will be captured on the consent form and shared securely with the research team. You can choose whether you speak to a researcher using Microsoft® Teams or by the telephone. If you are uncomfortable with appearing on the screen, once we have confirmed your identity you can turn your camera off and/or participate solely through the 'chat' function if that is your preferred option. This conversation (interview) should not take longer than twenty to thirty minutes. Interviews will be recorded (audio and video (if using Teams)) and written up word for word. When interviews have been transcribed, recordings will be destroyed. Your comments will be written in a way that others cannot identify who made them.

What happens next?
If you agree to take part in this study, you will not have to do anything other than attend your review. The pharmacist will then undertake a medication review using the new approach that has been designed in the previous phase of the research. This is in place of your normal medication review. It could involve changes to your treatment that you currently receive.

If you also agree to be interviewed, the pharmacist will give your name, telephone number and email to the research team after your medication review. A researcher will contact you to arrange a convenient time for your interview. If you would like to speak to the researcher before the interview, please contact them on the details below and they will be happy to talk about the study in more detail.

How will we use information about you?
We will need to use information from you for this research project. This information will include your name and contact details. We will only use information that we need for the research study. The research team **will not** have any access to your medical notes or other information held at about you at your GP surgery.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. Reports will be written in a way that no-one can work out that you took part in the study. This will involve publishing direct quotes.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will need to keep any information that we already have about you. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk or by asking the research team by sending an email to m.craske@uea.ac.uk. Alternatively, you can look at how we use your information from online forms here: https://www.uea.ac.uk/about/university-information/statutory-and-legal/data-protection/data-protection-for-webforms and the Health Research Authority has information here: www.hra.nhs.uk/information-about-patients/.

Will my taking part in the study be kept confidential?
Yes. All your personal information will be kept strictly confidential. Your signed consent form will be kept at your GP surgery until the end of the study and will then be destroyed with the confidential waste. All recorded information will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored on a password protected computer. Your contact details will be held by the research team only to make contact regarding this study and will not be shared with any other organisations. Your personal and research data will be kept for 10 years in line with the UEA research data policy.

However, where issues emerge during the group discussion(s) that are potentially harmful or dangerous, for example, reports of neglect or dangerous advice given, the researcher might consider the need to break confidentiality. In this circumstance, the primary investigator will discuss the need to disclose the information with you in the first instance. The primary investigator will then discuss with the supervisor and if necessary, the research team prior to deciding what action to take.

Will I be able to withdraw from the study?
You will be free to withdraw from the research at any point, without giving a reason. You can withdraw your data from the analysis up to the point of anonymisation, one week after the interview. After this point it will not be possible to withdraw your interview data.

What will happen to the results of the research study?
This work is being conducted as part of a PhD research project and therefore we will report the findings in a thesis and publish the findings in a peer reviewed journal or present the results at conferences. Any published information will be reported anonymously. At the end of the study, we will share a brief summary of the findings with you. You will be asked at the end of the interview if you wish this to happen.

Are there any disadvantages to taking part in the study?

We do not foresee any disadvantages to taking part in the research other than your time commitment, for which we are grateful. Participants who choose to speak to a researcher about their new medication review experience will receive a £10 gift voucher as a token of our appreciation. There will be a small selection of gift vouchers that you can choose from. This gift voucher will be emailed to you after you have talked with a researcher.

Who has reviewed the study?
This research has been reviewed and approved by NHS Health Research Authority to protect your safety, rights, wellbeing, and dignity. (https://www.hra.nhs.uk/about-us/)

Who is funding this research?
This research is being funded by the University of East Anglia.

What if I have a complaint?
If you have any questions about any aspect of this study, you should contact the researchers who will do their best to answer your questions [m.craske@uea.ac.uk]. If you remain dissatisfied and wish to complain formally, you can do this by contacting the Acting Head of School of Pharmacy, Professor Anja Mueller via email: Anja.Mueller@uea.ac.uk. The University of East Anglia is sponsoring this study.

For further information please contact:

Mrs Miriam Craske School of Pharmacy University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ Email: m.craske@uea.ac.uk Telephone: 074535449141	**Research supervisor and Chief investigator.** Dr Michael Twigg School of Pharmacy, University of East Anglia, Norwich Research Park, Norwich, NR4 7T Email: m.twigg@uea.ac.uk

Appendix 19 Phase 2 patient consent form

OPen Study: Patient Consent Form

This surgery has agreed to participate in a study testing a new way of delivering medication reviews. This means that the pharmacist will be using a document to guide them in what to do and say in your medication review.

If you would like to take part in the study, please read and initial the following statements and sign below.

☐ I agree to take part in the study, by allowing the pharmacist to use the service specification to conduct my medication review

☐ I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical and legal rights being affected.

Signature: _____ Date: _____

If you have had a "new" medication review a researcher would like to speak to you about your experience. This conversation will take place via a video or telephone call, depending on what you prefer. This should not take longer than 30 minutes.

If you are happy to speak to a researcher, please tick the following statements

☐ I agree to the pharmacist securely sharing my personal details to the research team at the University of East Anglia so I can be contacted for a follow- up interview to discuss my experience.

☐ I am willing to allow the interview to be recorded for the purposes of research analysis and possible publication of findings

☐ I understand that data will be anonymised and will be stored securely at the University of East Anglia

☐ I confirm that I will read the participant information sheet for this study. I will email the primary investigator (m.craske@uea.ac.uk) if I have any questions.

☐ I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical and legal rights being affected.

☐ I agree to take part the study that is described

Name: _____ Email address:_____

Telephone number: _____

Signature of participant: _____ Date: _____

Name of person taking consent: _____ Email address:_____

Signature of person taking consent: _____ Date: _____

Appendix 20 Email to patient for interview availability

Subject Title: Interview following medication review

Dear [Patient]

Thank you for agreeing to participate in the OPen study, testing a new way for pharmacists to deliver medication reviews at GP surgeries.

During your medication review you agreed to your contact details being shared with the research team. You also agreed to speak to a researcher about your experience.

If you are still willing to participate, please click on the following link [insert] so that we can arrange a convenient time for this conversation.

Yours sincerely

Miriam Craske

[Data to be captured on the scheduling link]

Please indicate which day you would like your interview:

- Monday
- Tuesday
- Wednesday
- Thursday
- Friday
- Saturday

What time slot would you prefer?

- 10am-1pm
- 1pm-4pm
- 4pm-7pm

How would you prefer to speak to the researcher?

- Telephone
- Videocall (Microsoft (R) Teams)

Thank you. You will receive an email confirming your choice.

Appendix 21 Pharmacist email for Phase 2 recruitment

Title: Invitation to participate in service specification testing for the OPen study **O**ptimising **P**harmacist-l**e**d Medicatio**n** reviews in primary care

Dear Pharmacist

Thank you for previously expressing an interest in participating in the OPen study. In the first phase of the study, we wanted to understand the current delivery of medication reviews in primary care and design a service specification for pharmacist-led medication review in primary care. Having completed phase one, we have co-designed a draft service specification. This service specification defines and describes an optimised pharmacist-led medication review. It is based upon existing guidance for medication reviews, literature evidence from a systematic review, and feedback from stakeholders (pharmacists, patients, GPs).

In this next phase, we are inviting pharmacists to test this service specification for feasibility and acceptability. We would like to recruit a small number of pharmacists and the practices where they work to test this service specification. This would require pharmacists to use this service specification whilst conducting five medication reviews over a period of four weeks. The study information is attached.

If you are willing to participate, please complete the online expression of interest form by clicking the link [insert]. We will review your form and if you are selected to participate, we will be in contact to discuss the next steps.

If you have any queries, please feel free to contact Miriam Craske, by emailing m.craske@uea.ac.uk

Yours sincerely
Miriam Craske

Appendix 22 Phase 2 Pharmacist Participant Information sheet and consent form

OPen study – Optimising Pharmacist-led medication reviews

Participant Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to help you understand the study and what it will involve. It is set out as a series of questions and answers. **Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us** (m.craske@uea.ac.uk). We suggest this should take **no more than 15 minutes**. This study is being conducted by the University of East Anglia as part of a PhD by the Primary Investigator, Miriam Craske.

What is the purpose of the study?
The purpose of this study is to test a service specification for a new way to deliver pharmacist-led medication review in primary care. A service specification is a written document that describes in detail the requirements and objectives necessary to deliver an intervention. It also describes the standards that should be demonstrated by individuals providing a service with the aim of providing excellent care for patients.

This service specification has been developed by pharmacists, patients and GPs during discussion groups. The service specification is based upon existing guidance for medication reviews, literature evidence from a systematic review, and feedback from stakeholders (pharmacists, patients, GPs).

Do I have to take part?
No. It is up to you to decide to whether to take part or not. If you agree to take part, please let us know by completing the expression of interest form [insert link]. It is important to note that a pharmacist is unable to participate if their surgery has not agreed, and vice versa.

What are the possible benefits of taking part?
The study will not benefit you directly. This is an opportunity to help shape how medication reviews are implemented in practice to improve the health of patients with long-term conditions.
The practice will receive a £200 payment to cover the administrative costs of being involved in the study.

What will I have to do?
Participation in this study will involve three stages:
Patient recruitment
Using the service specification during medication reviews
End of pilot interview

Patient recruitment

During the four-week pilot period, we would like you to recruit five patients to be involved in the study. These will be patients aged 18 or older who are due for a medication review. In addition to your surgery's standard method of contacting patients who are due for a medication review, we would like you to send an additional email to the five patients you have chosen. This email will be written by the research team and will have the study information attached. The email will briefly explain the study and invites the patient to participate.

When the patient comes for their medication review, we would like you to ask them if they would like to participate in the study. If the patient says no, you can do a medication review in the way you normally would.

If the patient agrees to be part of the study, we ask you to get them to sign a consent form. Patients who agree to be part of the study also have the option to speak to a researcher about their experience: this is an additional option in the consent form. Where patients consent to be interviewed, they also agree to their contact details being shared with the research team.

We would ask you to keep the patient consent forms at the GP surgery for the duration of the study, after which they can be destroyed. You will be notified via email when it is safe to destroy these. As soon as possible after the medication review, we would like you to upload the patient's contact details to a secure one drive folder so the research team can contact them to arrange an interview.

Using the service specification during medication reviews
To take part in the study, we would like you to become familiar with the service specification in advance of using it with patients. During the four-week pilot period, the primary investigator (MC) will send a weekly email to provide support and inviting you to ask questions or raise concerns about the process.

We are only looking to interview two patients per pharmacist, so you will receive a phone call or email from the primary investigator when your two patients have been interviewed. You will not be required to recruit any more patients after you have received this communication.

End of pilot interview
We would like pharmacists to be interviewed by the primary investigator at the end of the four-week pilot period to describe their experience and provide feedback on the feasibility and acceptability of the service specification. These interviews should not take longer than 45 minutes. Interviews will take place using Microsoft® Teams. If Teams is not available or not convenient at the time of the interview, it will take place over the telephone. Interviews will be recorded and transcribed verbatim. When interviews have been transcribed, recordings will be destroyed. Comments made during the interviews will not be personally identifiable.

What happens next?

If you would like to take part, please fill in the online expression of interest form. The expression of interest form also allows the capture the name and contact details of a representative at your GP practice. This representative must be able to give permission for you to be involved in this study. You will be contacted by a researcher to let you know if you have been selected to take part. They will send you further information to be shared with your practice, including arrangements for payment.

Upon selection to participate, you will be sent a consent form, which we would like to be returned within one week of being sent. If your consent has not been received within one week, a reminder email will be sent. If your consent is not received within one week of this reminder email, it will be assumed that you have not granted consent and will not be eligible to participate in the study.

How will we use information about you?
We will need to use information from you for this research project. This information will include your name and contact details. We will only use information that we need for the research study.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. Reports will be written in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will need to keep any information that we already have about you. We need to manage your information in specific ways for the research to be reliable.

Where can you find out more about how your information is used?
You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk or by asking the research team by sending an email to m.craske@uea.ac.uk Alternatively, you can look at how we use your information from online forms here: https://www.uea.ac.uk/about/legalstatements/data-protection-for-webforms

Will my taking part in the study be kept confidential?
Yes. All your personal information will be kept strictly confidential. All recorded information will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored on a password protected computer. Your contact details will be held by the research team only, to make contact regarding this study, and will not be shared with any other organisations. Your personal data will be destroyed after 3 years or at the end of the PhD and all the research data will be kept for 10 years in line with the UEA Data Protection policy.

Will I be able to withdraw from the study?

You will be free to withdraw from the research at any point, without giving a reason. However, if you decide to leave in the middle of the study, and any data gathered will not be removed and it will be included in the final analysis.

What will happen to the results of the research study?
This work is being conducted as part of a PhD research project and therefore we intend to report the findings in a thesis and publish the findings in a peer reviewed journal or present the results at conferences. Any published information will be reported anonymously. At the end of the study, we will share a short summary of the findings with you.

Are there any disadvantages to taking part in the study?
We do not foresee any disadvantages to taking part in the research other than your time commitment.

Who has reviewed the study?
This research has been reviewed and approved by NHS Health Research Authority to protect your safety, rights, wellbeing, and dignity.

Who is funding this research?
This research is being funded by the University of East Anglia.

What if I have a complaint?
If you have any questions about any aspect of this study, you should contact the researchers who will do their best to answer your questions [m.craske@uea.ac.uk]. If you remain unhappy and wish to complain formally, you can do this by contacting the Head of School of Pharmacy, Professor Simon Gibbons via email: s.gibbons@uea.ac.uk

For further information please contact:

Primary Investigator Mrs Miriam Craske School of Pharmacy University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ Email: m.craske@uea.ac.uk Telephone: 07435449141	**Research supervisor** Dr Michael Twigg School of Pharmacy, University of East Anglia, Norwich Research Park, Norwich, NR4 7T Email: m.twigg@uea.ac.uk

Please click on this link [Optimising Pharmacist-led medication reviews Phase 2 study] to complete the expression of interest form
[Appendix 19]

Appendix 23 Social media advert recruiting pharmacists for testing

The OPen study (**O**ptimising **P**harmacist-l**e**d medicatio**n** reviews) is looking for **pharmacists** to test a co-designed service specification for optimised pharmacist-led medication reviews in primary care.
If you
✓Are an independent prescriber working in England
✓Work as a GP or PCN pharmacist
✓Regularly undertake medication reviews
Please click on the link [insert] for more information

Appendix 24 Recruitment email to pharmacy contacts

Title: Invitation to participate in guidance document testing for the OPen study **O**ptimising **P**harmacist-l**e**d Medicatio**n** reviews in primary care

Dear [Name]

Please could you forward this email to any of your colleagues who may be interested in participating in this study.

If recruitment is proving to be challenging, we will re-send this email in four weeks, inviting you to forward to possible participants again.

Yours sincerely

Miriam Craske

Dear colleague

We are reaching out to invite you to participate in a study that seeks test a co-designed service specification for medication reviews by pharmacists in primary care for feasibility and acceptability using a theoretical framework of acceptability (Sekhon, Cartwright and Francis, 2017).

We would like to recruit ten pharmacists and the practices where they work to trial this service specification in their practice for a period of four weeks. The study information is attached.

If you are willing to participate, please complete the online expression of interest form by clicking the link https://uea.onlinesurveys.ac.uk/phase-2-expression-of-interest

We will review your form and if you are selected to participate, we will be in contact to discuss the next steps,

If you have any queries, please feel free to contact the primary investigator, Miriam Craske, by emailing m.craske@uea.ac.uk

Yours sincerely

Miriam Craske

Appendix 25 Phase 2a Patient Interview Topic Guide

[Start recording]

Thank you for taking the time to speak with me today. I would like to spend the next 20-30 minutes exploring your thoughts and feelings following the medication review you recently had with the pharmacist at your GP surgery.

Before we begin, I just want to read some statements to confirm that you have given your consent to be interviewed.

1. I confirm that I have read and understand the participant information sheet for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I am willing to allow the interview to be recorded for the purposes of research analysis and possible publication of findings
3. I understand that data will be anonymised and will be stored securely at the University of East Anglia. You can find more information by sending an email to dataprotection@uea.ac.uk
4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical and legal rights being affected. 5. I agree to take part in the above study.

Please confirm you agree to these statements.

Thank you

Topic	Stem Question	Prompts
Before the medication review	Could you tell me about the lead up to your medication review?	What did you expect from your medication review? Was there anything different about how you prepared for your medication review?
During the medication review	Tell me about the medication review you recently had with the pharmacist	What opportunities did you have to ask questions and raise concerns? What didn't you get the chance to talk about in your review that you wanted to? In what way was this this medication review different to your previous experiences?
After the medication review	Tell me about what happened after your medication review?	How has your medication review helped you manage your medicines or your health? What changes have been made to your medicines or the way you take your medicines? How do you feel about this?
Any other comments	Do you have any other comments about the medication review?	

Appendix 26 Phase 2b Pharmacist Interview Topic Guide

[Start recording]
Thank you for your hard work during the past four weeks recruiting patients for the study and using the document to support the implementation of medication reviews in your practice. For the next 30-45 minutes I would like to take the opportunity to explore your thoughts and feelings about this experience. Before we continue, I need to ensure that you have provided informed consent.
1. I confirm that I have read and understand the participant information sheet for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I am willing to allow the interview to be recorded for the purposes of research analysis and possible publication of findings
3. I understand that data will be anonymised and will be stored securely at the University of East Anglia
4. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. I agree to take part in the above study.
Are you able to agree to these statements?
Thank you. We will proceed.

Topic	Stem Question	Prompts
Before the medication review	Can you tell me how you used the guidance in advance of the medication review	What were your expectations of using the guidance document? How did you share the guidance document with the rest of the practice team?
During the medication review	Tell me about your experience of using the guidance document	How did you use the guidance document? How and why was it useful? Was it easy to understand? How can it be improved?
After the medication review	Tell me what happened after the medication review	How do you think this guidance document influenced the delivery of medication reviews in your practice? How do you plan to continue to use this resource in your practice? What feedback (if any) did you receive from colleagues or patients? Tell me why…
Any other comments	Do you have any other comments about the document to support the delivery of pharmacist-led medication reviews in primary care?	

Appendix 27 Phase 2 Pharmacist Participant Information sheet and consent form

OPen study – Optimising Pharmacist-led medication reviews

Participant Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to help you understand the study and what it will involve. It is set out as a series of questions and answers. **Please take time to read the following information carefully and if you wish to discuss it with us, please do not hesitate to contact us** (m.craske@uea.ac.uk , telephone 07435449141). We suggest this should take **no more than 15 minutes**. This study is being conducted by the University of East Anglia as part of a PhD by Miriam Craske. Miriam Craske is a pharmacist who registered in 2000. She has experience of working in community pharmacy and teaching pharmacy students.

What is the purpose of the study?
The purpose of this study is to test a guidance document to support the delivery of pharmacist-led medication reviews in primary care. This guidance document has been developed by pharmacists, patients and GPs during discussion groups, and is based upon literature evidence from a systematic review, and feedback from stakeholders (pharmacists, patients, GPs).

Do I have to take part?
No. It is up to you to decide to whether to take part or not. If you agree to take part, please let us know by completing the expression of interest form.

What are the possible benefits of taking part?
The study will not benefit you directly. This is an opportunity to help shape how medication reviews are implemented in practice to improve the health of patients with long-term conditions.

What will I have to do?
Participation in this study will involve using the guidance document in the medication review process and attending an end-of-study interview with the researcher.

We would like pharmacists to be interviewed by the primary investigator at the end of the four-week pilot period to describe their experience and provide feedback on the feasibility and acceptability of the guidance document. These interviews should not take longer than 45 minutes. Interviews will take place using Microsoft® Teams. If Teams is not available or not convenient at the time of the interview, it will take place over the telephone. Interviews will be recorded (audio and video (if using Teams) and transcribed verbatim. When interviews have been transcribed, recordings will be destroyed. Comments made during the interviews will not be personally identifiable.

At the start of the interview you will be asked to agree to the following consent statements:

1. I confirm that I have read and understand the participant information sheet for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I agree to take part in the above study to testing the service specification for optimised pharmacist-led medication reviews through an end-of-study interview.

3. I am willing to allow the interview to be recorded for the purposes of research analysis and possible publication of findings

4. I understand that data will be anonymised and will be stored securely at the University of East Anglia

5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. I agree to take part in the above study.

What happens next?
If you are happy to take part, please contact the researcher at the bottom of this information sheet. If you would like to speak to the researcher before taking part, please contact them on the details below and they will be happy to talk about the study in more detail.

How will we use information about you?
We will need to use information from you for this research project. This information will include your name and contact details. We will only use information that we need for the research study.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. Reports will be written in a way that no-one can work out that you took part in the study. This will involve publishing direct quotes.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will need to keep any information that we already have about you. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information by sending an email to dataprotection@uea.ac.uk or by asking the research team by sending an email to m.craske@uea.ac.uk Alternatively, you can look at how we use your information from online forms here: https://www.uea.ac.uk/about/university-information/statutory-and-

legal/data-protection/data-protection-for-webforms and the Health Research Authority has information here: www.hra.nhs.uk/information-about-patients/.

Will my taking part in the study be kept confidential?
Yes. All your personal information will be kept strictly confidential. All recorded information will be kept anonymous and will be reported in such a way that you cannot be identified. All data will be stored on a password protected computer. Your contact details will be held by the research team only, to make contact regarding this study, and will not be shared with any other organisations. Your personal and research data will be kept for 10 years in line with the UEA research data policy.

However, where issues emerge during the group discussion(s) that are potentially harmful or dangerous, for example, reports of neglect or dangerous advice given, the researcher might consider the need to break confidentiality. In this circumstance, the primary investigator will discuss the need to disclose the information with you in the first instance. The primary investigator will then discuss with the supervisor and if necessary, the research team prior to deciding what action to take.

Will I be able to withdraw from the study?
You will be free to withdraw from the research at any point, without giving a reason. You can withdraw your data from the analysis up to the point of anonymisation, one week after the interview. After this point it will not be possible to withdraw your interview data.

What will happen to the results of the research study?
This work is being conducted as part of a PhD research project and therefore we intend to report the findings in a thesis and publish the findings in a peer reviewed journal or present the results at conferences. Any published information will be reported anonymously. At the end of the study, we will share a short summary of the findings with you. You will be asked at the end of the interview if you wish this to happen.

Are there any disadvantages to taking part in the study?
We do not foresee any disadvantages to taking part in the research other than your time commitment, for which we are grateful.

Who has reviewed the study?
This research has been reviewed and approved by NHS Health Research Authority to protect your safety, rights, wellbeing, and dignity. (https://www.hra.nhs.uk/about-us/what-we-do/)

Who is funding this research?
This research is being funded by the University of East Anglia.

What if I have a complaint?
If you have any questions about any aspect of this study, you should contact the researchers who will do their best to answer your questions [m.craske@uea.ac.uk]. If you remain dissatisfied and wish to complain formally, you can do this by contacting the

Acting Head of School of Pharmacy, Professor Anja Mueller via email: Anja.Mueller@uea.ac.uk. The University of East Anglia is sponsoring this study.

For further information please contact:

Mrs Miriam Craske School of Pharmacy University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ Email: m.craske@uea.ac.uk Telephone: 07424 379860	**Research supervisor and Chief investigator** Dr Michael Twigg School of Pharmacy, University of East Anglia, Norwich Research Park, Norwich, NR4 7T Email: m.twigg@uea.ac.uk

Appendix 28 Pharmacist/ Practice Consent Form

To be completed via JISC online survey

1. I confirm that I have read and understand the participant information sheet for this study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I agree to take part in the above study to testing the service specification for a new approach to pharmacist-led medication reviews

3. I confirm that my practice has agreed to my participation in this study.
4. I am willing to allow the interview to be recorded for the purposes of research analysis and possible publication of findings

5. I understand that data will be anonymised and will be stored securely at the University of East Anglia

6. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. I agree to take part in the above study.

[Pharmacist name] [Date= date of return]

[Name of GP surgery]

[Management contact at the surgery] [Management email address]

Appendix 29 Participant consent form

OPen Study: Phase 1 Consent Form

This electronic consent form will be sent to participants at the same time as the PIS and confirmation e-mail (appendix 15). Participants will complete it using the JISC platform which is GDPR compliant.

Please complete this electronic consent form in advance of the discussion for the OPen Study. You cannot participate if we have not received your electronic consent 24 hours prior to the discussion.

At the start of the discussion group the following statements will be read again. You will be asked to confirm that you agree with them as a way of providing informed consent.

Please initial each statement below:

1. I confirm that I have read and understand the information for the study.

2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

3. I agree to the recording of the group discussions for the purposes of research analysis and possible publication

4. I understand that data collected will be anonymised and stored securely

5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected.

6. I agree to participate in the study.

Name: _____

Email address: _____

Telephone number: _____

Date: _____

Appendix 8 Summary of results from literature review (chapter three) and patient and practitioner focus groups/ interviews undertaken in the Optimising Pharmacist-lEd medicatioN reviews in primary care (OPen) study (chapter 4)

Literature

A review of the literature published about pharmacist medication reviews was recently undertaken. The medication reviews in these studies were carried out by pharmacists across the world, in different settings, such as hospitals, community pharmacies, general practice and people's homes. The aim of the review was to figure out how medication reviews improve the care of patients. The review looked at what it is that makes the medication review more likely to work in practice.

Access to patient information

Pharmacists having access to the full range of patient information compared to only partial information, may lead to an improvement in a patient's ability to take their medicines as prescribed, their blood pressure, and quality of life.

Pharmacist skills and experience

The evidence suggests that medication reviews delivered by pharmacists with greater clinical knowledge or experience may to lead to an improvement in the patient's management of their blood pressure and a reduction in medicines costs.

Collaborative working

Pharmacists working closely with doctors and other healthcare professionals may lead to a reduction in medicines-related problems and number of medicines prescribed, compared with pharmacists working in isolation.

Patient/ carer education

The evidence suggests that when pharmacists educate the patient/ carer about the reasons for taking the medicines, how they work and how they should be taken, this may lead to better outcomes.

Patient involvement in goal setting and action planning

The evidence suggests that patient involvement in the medication review through goal setting or action planning, may lead to an improvement in patients' ability to take their medicines as prescribed and help them better achieve their treatment goals, for example blood sugar or blood pressure targets.

Additional support and follow up.

Evidence from the literature suggests that patients who have at least one follow up appointment after their medication review may lead to improvements in blood pressure, diabetes control, quality of life and a reduction of medicines-related problems, when compared to patients with no follow up.

Discussions

Patients, pharmacists, and general practitioners provided their thoughts about pharmacist-led medication reviews. Five key themes that emerged from these patient and practitioner discussions.

Medication reviews vary for different patients

Our participants told us that different patients often have varying needs in their medication reviews. Some patients with complex medication regimes usually benefit from longer face-to-face appointments, whereas other patients who are happy with their medicines may be content with a telephone or online review.

Access to and familiarity with patient information

Our participants told us that pharmacists should review and be familiar with the patients' medicines and medical history before the appointment. This may reduce the time the patient needs to spend updating the pharmacist during the consultation.

Patient focussed review

Our participants told us that medication reviews should be patient-led and a take a holistic approach, with patients having opportunities to ask questions and raise concerns.

Our patient participants told us that they need to feel that they have been listened to during the consultation.

Time

Our participants told us that they often feel that there is not enough time in the consultations to address all the issues that need to be discussed.

Communication

Our pharmacist and patient participants reported issues around the communication between hospital specialities and doctors' surgeries. Our patient participants felt that surgeries could communicate better about when patients would be having medication reviews. This is particularly problematic when patients receive opportunistic telephone reviews. After the medication review, patients should be notified and kept updated about any referrals or follow up appointments.

Appendix 9 Guidance document to support the implementation of pharmacist-led medication reviews in primary care (Version 1)

Introduction

This guidance document has been produced as part of a PhD looking at how medication reviews by pharmacists in primary care can improve outcomes for patients with long term conditions. A literature review was undertaken exploring the core outcomes of medication reviews and their relationship to outcomes [1]. In addition, patient, pharmacist, and general practitioners were approached to participate in a series of focus groups and interviews (discussions) to find out what was currently happening in medication reviews and how they felt the process could be improved. Patients and pharmacists discussed the key themes from the discussion groups and literature review to co-design this guidance document. This guidance document is to be predominantly used by pharmacists in general practice. However, it may also be useful for other healthcare professionals who deliver medication reviews.

Background

What will this guidance do?

This document presents the evidence that we have gathered so far about medication reviews. It also contains reflective questions that patients, practitioners and practices can consider in the context of medication reviews. Pharmacists who are experienced in implementing medication reviews may find some reflective questions that resonate with their experience. For practitioners who are new to their role, this document will prompt them to consider their skills, experience, and readiness to undertake medication reviews.

What is the background to medication reviews?

Medication reviews are used to support patients who are prescribed multiple medicines or those with complex medication regimes [2]. The more medicines a patient takes, the higher the chance of them experiencing harmful effects [3]. The UK government has highlighted the importance of medication reviews [3,4]. Clinical pharmacists have been introduced to GP surgeries to help to increase the number of medication reviews received by patients. We know from published papers, and from speaking to pharmacists and GPs, that medication reviews can be carried out in many ways. Some medication reviews are undertaken for specific long-term conditions, others are initiated following a change in prescribing guidance, whilst others are a lengthy, in-depth review of all prescribed medicines. In discussions with practitioners, we identified that there is a lack of guidance around what should happen before, during, and after medication reviews. For some pharmacists, doing medication reviews is a major part of their role, but for others, it is less significant [5]. Some pharmacists are non-medical prescribers and can change medication. Despite how many medication reviews are undertaken, up to 7% of hospital admissions in the UK are due to harmful effects from medicines [6]. Previous research demonstrated that medication reviews undertaken by

any professional in any setting had minimal effects on clinical outcomes and that evidence is lacking about their effect on economic outcomes [7].

Why is this guidance important now?
We know from our literature review and the discussion groups with patients, pharmacists, and general practitioners that a medication review involves activities before and after and not just during those minutes that a pharmacist talks with a patient. We should consider how the medication review is seen by patients, practitioners, and general practice. We should consider how medication reviews are implemented; getting this right should lead to better outcomes for patients.

What is a medication review?
We know from the patient and pharmacist focus groups and workshops that there was some confusion about what a medication review is and what happens in it. For this guidance, we have defined a medication review as "a consultation between a pharmacist and a patient to review the patient's total medicines use with a view to improve patient health outcomes and minimise medicines related problems". The National Institute of Health and Care Excellence (NICE) and Pharmaceutical Care Network Europe (PCNE) have defined medication reviews [8,9], and whilst there is some overlap with the definitions, we felt that neither definition went far enough to reflect current practice.

Patients and practitioners both felt it was important to take a holistic approach to the review, considering the patient's priorities and social circumstance, and not just whether the medicines are being taken or need changing. In 2020, structured medication reviews (SMRs) were introduced to general practice contract. Structured medication reviews use the NICE definition of medication reviews, but with the addition of targeted specific patient groups and the expectation that the main public health risk factors would be addressed in the review. It is expected that patients scheduled for SMRs have longer appointments [10]. Medicines reconciliation is defined by NICE as "is the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated."[11] This guidance will refer to both medicines reconciliation and medication reviews, therefore it is important to distinguish between the two processes.

Rationale for the reflective questions

Pharmacists and medication reviews
In the patient focus group, there was some confusion about what a medication review was. The role of the pharmacist in the GP surgery was not well understood. Patients told us that understanding the skills, knowledge and role of the pharmacist may help them to get more out of the medication review. Pharmacists told us that it was important the practice support team understand what they do. This is useful to help colleagues to explain the pharmacist's role to patients when booking appointments.

Collaborative working

The literature suggested that there were potential benefits of pharmacists working closely with doctors and other healthcare professionals. Patients recognised the support of doctors in the pharmacist medication review process.

Pharmacist skills and support
Pharmacists said that having access to a mentor in general practice can help build confidence and competence. The literature suggests that outcomes may be improved if medication reviews are delivered by pharmacists with greater clinical knowledge or experience.

Current medication
Patients and pharmacists spoke about the importance of ensuring that the medicines prescribed by the practice were up to date with the latest hospital recommendations. Pharmacists and GPs said it was important to check that all medicines are still suitable for the patient.

Planning appointments
Patients, pharmacists, and GPs told us that medication reviews can vary. Patients with complicated or lots of medicines usually benefit from longer face-to-face appointments. But patients who are happy with their medicines may be content to talk about them over the phone. Patients who have hearing or language problems or require a carer may benefit from face-to-face appointments.

Patient preparation
Patients also told us that they needed time to think about questions to ask in the medication review. They also needed time to think about what they want to get out of the medication review.

Patient involvement
Pharmacists and GPs said that it was important to know patient expectations about the medication review at the start of the review so they could better help them. Pharmacists and GPs agreed on the importance of engaging the patient in the medication review process. Our research said that patients should be involved in deciding what they want from the medication review. This may improve how they take their medicines and how well they work. Also, our research suggests that talking to patients about the reasons for taking the medicines, how they work and how they should be taken, could benefit them. Patients told us that they would like more information during their medication review. Patients also said that they wanted more opportunities to ask questions and raise concerns.

Policies and procedures
Pharmacists told us that all practitioner delivering medication reviews should use the same policies and procedures. This means that patients should have the same level of care from whoever does the medication review. Pharmacists told us that each practice has different procedures. It is important to establish what the preferred processes are in their practice.

Communication
Pharmacists felt that patients are more likely to consider medication changes if there is rapport building between the patient and the pharmacist. Patients told us that it was important that they felt they had been listened to in the medication review. They wanted to feel like their experiences and opinions were considered during the review.

Follow up
Pharmacists said it was useful to have an action plan to follow up issues identified in the medication review. Our research suggests that at least one follow up appointment may lead to improvements in patient outcomes. These outcomes include a reduction in medicines related problems and improvements in how patients take their medicines and how well the medicines work. Our research also told us that continued support following the patient consultation may help to improve patients' quality of life. Patients, pharmacists, and GPs told us there are occasions where there is not enough time in the appointment to review all the medicines.

Before the patient consultation

Reflective questions
Your role in the practice

- How can you help your patients understand the role of the pharmacist in your practice and what to expect in a medication review? What would you like your patients to know and think about before their medication review?
- Does your practice support team know what you do? What are their roles and responsibilities in the medication review process?

Explanation
Each pharmacist will have individual skills, experience and expertise. It could be useful for pharmacists to summarise these for the staff they work with so they can better understand the role. We suggest that pharmacists are aware of the different staff members that support the medication review process. Some pharmacists have had support staff observe a medication review, so they had a better understanding of the process. We suggest that pharmacists' biographies and a summary of their role be posted on the practice website. Some primary care networks (PCN) have a website that describes the roles of each member of the general practice team, and describes the different services offered within the PCN.

The Network Contract Directed Enhanced Service Contract for general practice indicates that patients having a structured medication review should receive an invitation that explains the benefits of, and what to expect from the review. [12]

Signposting

- Appendix 1 gives an example description of the role of the pharmacist in a GP practice. This could be amended to better reflect your role and shared with the staff and/ or patients.
- The following link provides a description of the roles and responsibilities of pharmacy professionals in general practice.

- The following link provides a list of resources to support patients having a structure medication review

Planning appointments

- What is your patient population? How do you prioritise patients for medication reviews?
- How do you decide whether a telephone or face-to-face appointment is required?
- What is the process for booking appointments for the appropriate length of time? Whose responsibility is it to arrange the appointment with the patient?
- How long in advance are medication reviews booked?

Explanation

The patient population in each practice will vary, therefore each will prioritise different patients for medication reviews. Each pharmacist/ practice will have their own criteria that helps them assess whether a patient consultation can be conducted over the phone. We suggest working with your support team to implement a system to help book appointments, where it is clear whether the patient requires a telephone or face-to-face consultation and whether they need a standard or extended appointment. We suggest that the practice discusses how far in advance patients should be notified of the need for a medication review.

Signposting

The following link to the Network Contract Directed Enhanced Service Contract for general practice identifies patients that are eligible for a structured medication review and would require an extended appointment.

Medicines reconciliation

- Who is responsible for checking for changes following recent hospital discharge or outpatient appointments?
- Where do the different roles within your practice sit with regards to medicines reconciliation and medication review?

Explanation

"Medicines Management is a system of processes and behaviours that determines how medicines are used by the NHS and patients. Good medicines management means that patients receive better, safer, and more convenient care. It leads to better use of professional time, and enables practitioners to focus their skills where they are most appropriate"[13]. It is important to determine who in the practice is responsible for different medicines management and the roles and responsibilities for those doing medicines reconciliation and medication review.

Signposting

- The following links provide guidance for medicines reconciliation; CQC, NICE, CPPE

Current medication

- How do you assess the appropriateness of the medicines prescribed?

Explanation

Establishing the initial indication of the prescribed medicines and checking clinical monitoring parameters, such as blood test results, can be undertaken before the patient consultation. You can then evaluate the medicines appropriateness and establish your aim of the medication review.

Signposting

- Appendix 2 suggests useful resources for checking the appropriateness of the medicines prescribed

Where is the dedicated space at the practice where you can conduct face-to-face consultations?
Explanation
With additional practitioners being added to primary care teams, space is at a premium in some practices. We suggest working closely with the practice management and other support staff to ensure there is a consultation room available for the days you plan to undertake face-to-face reviews in the practice.

Pharmacist support

- What stage are you at with your confidence with decision making? What support do you need to help to improve your confidence? Do you have contact details for a GP/ pharmacist mentor?

For sole pharmacists in the GP practice/ those working remotely

- How can you address working in isolation? With whom can you collaborate?

Explanation
Experience builds confidence. We suggest discussing with the practice team the patients that you have the skills and the confidence to see independently. We propose that you plan with your mentor/ line manger a strategy to extend your scope of practice. We suggest that your planned development should be guided by your patient demographics.

Signposting

- The Primary Care Pharmacists Association (PCPA) and Royal Pharmaceutical Society (RPS) are examples of organisations that can provide peer support. Please note that some content is available only to members.

During the patient consultation

Reflective questions
Aim of the medication review

- What is the aim of the medication review? Is it to improve adherence? Reduce the number of medicines prescribed? Reduce prescribed opioids?
- Having thought of the aim of the review, think about the outcomes you can measure that will help with follow up.

Explanation
When the medication review is booked, the pharmacist should have an idea of what they want to achieve. The patient may come to the medication review with different

ideas, so the pharmacist will need to negotiate a shared agenda. Some outcomes that can be measured include the number of medicines prescribed, the regularly of repeat prescription requests, frequency of side effects and effectiveness of medicines.

Patient involvement

- How prepared do you want your patient to be for the medication review?
- Have they had the time to prepare and think about what they want to get out of the review?
- Are there other ways you can involve the patient in the medication review?

Explanation

Only patients who are receiving an extended structure medication review are required to receive information about the review and what to expect. However, we suggest that all patients who are invited for any kind of medication review receive some guidance to help them prepare.

Signposting

- Example questions for patients to think about before their review
    - Why am I taking these medicines?
    - How do I know they are helping me?
    - Do I still need all my medicines?
    - Why do I have to take so many pills?
    - I run out my medicines at different times – can you make this the same time for all of them?

Delivering the medication review

- What resources are available to support you during the medication review, e.g., pre-existing templates, professional guidance?
- How can you use the available resources to tailor the medication review to the patient you are seeing?
- Is there any other information about the patient's medicines that would be beneficial?

Explanation

For complex medication reviews, many pharmacists will use a template to help structure the medication reviews. Other pharmacists have just developed their own structure based upon general guidance.

Signposting

- Appendix 3 provides examples of useful resources to help in the delivery of medication reviews

Pharmacist skills

- How confident are you with your consultation skills?
- What resources are available to help you develop or refresh your skills?

Signposting

- Appendix 4 gives examples of resources that are available to support the development of consultation skills.

Policies and procedures

- What is the repeat prescribing policy at the practice?
- What is the medicines management policy at the practice?
- Are pharmacists named in these protocols?
- What blood tests are you authorised to order?
- What is the process for red flag procedures? Who should these be referred to and how should this be done?

For non-prescribing pharmacists

- What protocols are in place for you to make prescription changes, e.g., dose changes? How should these changes be documented and communicated with the accountable prescriber? E.g., weekly, or daily communication, electronically or verbally.

Explanation

We suggest meeting the practice management team to discuss the policies and procedures in the practice. Many practices have informal procedures, but we suggest formalising these to facilitate streamlining the care of patients. We also suggest reviewing them on an annual basis.

After the patient consultation

Reflective questions

Communication

- Have all notes been entered, and actions coded on the patient's records?
- Is there any further communication that needs to be actioned? Who can help you with this?
- Does the patient need a post medication review action plan?
- Has this been completed and documented in the patient's record?
- Who will make any required changes to the patient's medicines?

Explanation

Occasionally a patient's management will require discussion with other professionals in the practice or at the hospital. Referrals to hospital will need to be actioned by the patient's GP. If a patient requires an action plan, it should clearly state what should be done by whom and when. Any action plans should be recorded in the patient's record so it can be accessed by all professionals involved in the care of the patient.

It is suggested that the action plan should record:

- Medication problem identified
- Action proposed
- Action by
- How do we know this has been achieved?

Follow up

- Did you and the patient discuss everything that you needed to in the review?
- Do you need to schedule any follow up appointments?
- Does the patient need to be referred to another practitioner, e.g., social prescriber, physiotherapist?

- What outcomes can you review to measure whether the medication review has had a positive effect?
- What does the Care Quality Commission (CQC) use as a marker of a quality medication review?

Explanation

The patient may have had several questions that they wanted to ask, or the pharmacist may not have been able to check all the medicines prescribed. This may mean that an additional appointment needs to be arranged. We suggest that any referrals e.g., for a follow up review, physiotherapist, social prescriber, should be discussed with the patient at the end of the review and instructions given on how this should be done. There may be occasions where recommended changes following the medication review have not been implemented. We suggest that as a practice you discuss a process in relation to this. The outcomes that you use a measure of the success of the medication review is linked to the aim of the medication review. For example, if the aim of the review was to review a patient's diabetic control or to improve their use of opioids or benzodiazepines, a suitable outcome measure would be reduced glycated haemoglobin (HbA1c) or reduced used of opioids of benzodiazepines. Visits from the Care Quality Commission (CQC) will check the quality of medication reviews as part of their inspections.

Signposting

- This link describes the key lines of enquiry at a CQC inspection. Knowledge of these can help you to evaluate the quality of your patient care.
- GP mythbusters is a useful resource for best practice in general practice

Additional Signposting

Appendix 1: Primary Care Pharmacists Association (PCPA) description of the role of GP pharmacist

"Pharmacists take responsibility for areas of chronic disease management, such as diabetes, asthma, and high blood pressure. Pharmacists undertake clinical medication reviews to help patients who take lots of medicines. Pharmacists also help other members of staff in the practice with prescription and medication queries and help support the repeat prescription system. Pharmacists will check the medicines that have been prescribed when patients are discharged from the hospital, and work with patients and other healthcare professionals to make sure the best (and safest) medicines are prescribed." [14]

Appendix 2: Resources available to help check the appropriateness of prescribed medicines

- The Specialist Pharmacist Service has compiled a list of tools to support medication review https://www.sps.nhs.uk/articles/using-tools-to-support-medication-review/
- Anticholinergic Burden Scales *https://www.medichec.com/assessment*

- STOPP/START tool *https://link.springer.com/article/10.1007/s41999-023-00777-y*

Appendix 3: Useful resources for delivery of medication reviews

- The Royal Pharmaceutical guidance for medicines optimisation https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf
- NICE guidance for medicines optimisation https://www.nice.org.uk/guidance/ng5
- The 7-steps medication review https://www.polypharmacy.scot.nhs.uk/for-healthcare-professionals/principles/the-7-steps-medication-review/
- Bedfordshire, Luton, and Milton Keynes Integrated Care Board SMR process for pharmacists https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/wp-content/uploads/2020/10/Structured-Medication-Review-SMR-Process-for-Pharmacists.pdf

Appendix 4: Resources available to support consultation skills

- https://www.cppe.ac.uk/services/consultation-skills
- https://www.rpharms.com/professional-development/foundation/foundation-assessment-tools/consultation-skills-assessment
- https://www.youtube.com/c/Consultations4Health

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Appendix 10 Health Research Authority letter of approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Michael Twigg

School of Pharmacy

University of East Anglia

Norwich

NR4 7TJ

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

05 October 2022

Dear Dr Twigg

HRA and Health and Care

Study title:	**Optimising Pharmacist-led medication reviews in primary care (OPen): a qualitative study to co-design and test an optimised medication review for patients with long-term conditions.**
IRAS project ID:	**313644**
Protocol number:	**N/A**
REC reference:	**22/EM/0160**
Sponsor	**Research and Innovation Services**

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.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation.

The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **313644**. Please quote this on all correspondence.

Yours sincerely,

Helen Poole

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Polly Harrison*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Phase 1 Pharmacists social media advert]	1	23 May 2022
Copies of materials calling attention of potential participants to the research [Phase 1 e-mail to pharmacy organisations]	1	23 May 2022
Copies of materials calling attention of potential participants to the research [Phase 1 Patient social media advert]	1	23 May 2022
Copies of materials calling attention of potential participants to the research [Phase 1 E-mail to patient organisations]	1	23 May 2022
Copies of materials calling attention of potential participants to the research [Phase 2 EOI]	1	23 May 2022
Copies of materials calling attention of potential participants to the research [Phase 2 Social media advert for pharmacists]	1	23 May 2022
Copies of materials calling attention of potential participants to the research [Phase 1 Practitioner EOI]	2	12 August 2022
Copies of materials calling attention of potential participants to the research [Phase 1 e-mail for GP recruitment]	2	12 August 2022
Copies of materials calling attention of potential participants to the research [Phase 1 Patient EOI]	2	12 August 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UEA insurance]	1	24 June 2022
Interview schedules or topic guides for participants [Phase 1a Patient FG topic guide]	1	23 May 2022
Interview schedules or topic guides for participants [Phase 1b Practitioner FG topic guide]	1	23 May 2022
Interview schedules or topic guides for participants [Phase 1d Workshop topic guide]	1	23 May 2022
Interview schedules or topic guides for participants [Phase 1e Workshop topic guide]	1	23 May 2022
Interview schedules or topic guides for participants [Phase 2 Patient interview topic guide]	1	23 May 2022

Interview schedules or topic guides for participants [Phase 2 Pharmacist interview topic guide]	1	23 May 2022
IRAS Application Form [IRAS_Form_29062022]		29 June 2022
Letter from sponsor [Sponsorship letter]	1	24 June 2022
Letters of invitation to participant [Phase 1 confirmation email]	1	23 May 2022
Letters of invitation to participant [Regret e-mail]	1	23 May 2022
Letters of invitation to participant [Phase 2 Pharmacist e-mail to patients]	1	23 May 2022
Letters of invitation to participant [Phase 2 E-mail for patient interview]	1	23 May 2022
Letters of invitation to participant [Phase 2 pharmacist recruitment email]	1	23 May 2022
Letters of invitation to participant [Phase 2 e-mail to pharmacy contacts]	1	23 May 2022
Organisation Information Document	1-6	04 October 2022
Other [Response document]	1	12 August 2022
Participant consent form [Phase 2 Patient consent form]	2	12 August 2022
Participant consent form [Phase 1 Participant consent survey]	1	30 August 2022
Participant consent form [Pharmacist Consent Form]	1	12 August 2022
Participant information sheet (PIS) [Phase 1 Practitioner PIS]	3	30 September 2022
Participant information sheet (PIS) [Phase 1 Patient PIS]	3	30 September 2022
Participant information sheet (PIS) [Phase 2 Patient PIS]	3	30 September 2022
Participant information sheet (PIS) [Phase 2 Pharmacist PIS]	4	30 September 2022
Research protocol or project proposal [Protocol v2]	2	12 August 2022
Schedule of Events or SoECAT [SoECAT]	3	23 May 2022
Summary CV for student [Miriam Craske CV]	1	27 April 2022
Summary CV for supervisor (student research) [Michael Twigg CV]	1	07 July 2021
Summary CV for supervisor (student research) [CV Prof Hardeman]	1	12 July 2022
Summary CV for supervisor (student research) [CV Prof Steel]	1	01 May 2022
Summary, synopsis or diagram (flowchart) of protocol in non technical language [MR service specification]	1	23 May 2022

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other agreement to be used with participating NHS organisations of this type.	The sponsor has detailed its proposals with respect to whether any study funding will be provided to participating NHS organisations of this type in the relevant Organisational Information Document. This should be read in conjunction with the relevant Schedule of Events/SoECAT which details the cost implications of the study for participating NHS organisations.	In line with HRA/HCRW expectations a Principal Investigator should be appointed at participating NHS organisations of this type.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding preexisting NHS employment contracts should obtain a Letter of Access. This should be issued be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of preengagement checks letter (if NHS employed). These should confirm Occupational Health Clearance. These should confirm enhanced DBS checks and appropriate barred list checks.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio

Appendix 11 Research and development letter of access

Improving lives together
Norfolk and Waveney Integrated Care System

NHS
Norfolk and Waveney
Integrated Care Board

Ref: 2022GP23 (IRAS 313644)

NHS Norfolk and Waveney Integrated Care Board

Norfolk County Hall

Martineau Lane

Norwich

NR1 2DH

Miriam Craske

University of East Anglia

School of Pharmacy

Norwich

NR4 7TJ

30 August 2023

E-mail: nwicb.RandDoffice@nhs.net

Dear Miriam,

Letter of access for research

Re: OPen Study: Optimising Pharmacist-led medication reviews in primary care

This letter confirms that the necessary pre-engagement checks have been undertaken in line with the '*Research in the NHS: HR Good Practice resource Pack*'. Please provide this letter as evidence to **participating practices in CRN East of England (within NHS Norfolk and Waveney ICB, and NHS Suffolk and North-East Essex ICB)** that these checks have been carried out in order for them to grant access to their site for research purposes.

This letter sets out the terms & conditions for access to primary care sites. Please note that you cannot start the research until the Principal Investigator for the research project has received the Health Research Authority (HRA) Approval letter giving permission to conduct the project and each participating practice has confirmed their capacity and capability (if required, as stated in the HRA Approval letter) to undertake this research. In line with the '*Research in the NHS: HR Good Practice resource Pack*', access rights will end on **29 February 2024** unless terminated earlier in accordance with the clauses below.

The information supplied about your role in research has been reviewed and you do not require an honorary research contract at practices in CRN East of England. We are satisfied that such preengagement checks as we consider necessary have been carried out.

You are considered to be a legal visitor to practices in CRN East of England who have given permission for the study. You are not entitled to any form of payment or access to other benefits provided by these practices to employees and this letter does not give rise to any other relationship between you and these practices, in particular that of an employee.

While undertaking research through practices in CRN East of England, you will remain accountable to your employer**, University of East Anglia,** but you are required to follow the reasonable instructions of **the practice manager of each participating practice** or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the practice or the Research and Evaluation Team in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with participating practices policies and procedures, which are available to you upon request, and the UK Policy Framework Framework for Health and Social Care Research.

You are required to co-operate with each participating practice in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on practice premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each participating practice (please inform your nominated manager as named above) prior to commencing your research role at the practice.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 2018. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that participating practices accept no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of participating practices or if you are convicted of any

criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Practices will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 2018. Any breach of the Data Protection Act 2018 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in each participating practice, and the **Research and Evaluation Team** who manage the Research Passport Scheme on behalf of practices in CRN East of England.

Yours sincerely

Clare Symms
Head of Research Management, Finance and PPI
Research and Evaluation Team
NHS Norfolk and Waveney Integrated Care Board

cc: **m.twigg@uea.ac.uk**

Appendix 12 Document to support the implementation of pharmacist-led medication reviews in primary care (Version 2)

Background

Who is this document for?

This document has been designed to be predominantly used by **pharmacists delivering medication reviews** in general practice. It may also be useful for other healthcare professionals who deliver medication reviews.

What is this document for?

For patients to get the most of their medicines, pharmacists need to have the skills and confidence to deliver **high quality medication reviews** [1]. The more medicines a patient takes, the higher the chance of them experiencing harmful effects [2]. The UK government has highlighted the importance of medication reviews and pharmacists have been introduced to general practice to help increase the number of patients receiving them [2,3]. Despite how many medication reviews are undertaken, up to 7% of hospital admissions in the UK are due to harmful effects from medicines [4]. Our research has indicated that medication reviews only yield high quality outcomes in certain circumstances [1]. This document has been designed using the evidence that we have gathered from the literature and from discussions with patients and professionals: it aims to outline what those circumstances are in order to achieve high-quality outcomes for patients and health systems. Alongside this, the hope is that this document will improve pharmacist skills and confidence to enable them to deliver high quality medication reviews.

What is a medication review?

We know from the patient and pharmacist focus groups and workshops that there was some confusion about what a medication review is and what happens in it. For this document, we have defined a medication review as "a consultation between a pharmacist and a patient to review the patient's total medicines use with a view to improve patient health outcomes and minimise medicines related problems". The National Institute of Health and Care Excellence (NICE) and Pharmaceutical Care Network Europe (PCNE) have defined medication reviews [5,6], and whilst there is some overlap with the definitions, we felt that neither definition went far enough to reflect current practice. For clarity, medicines reconciliation is defined by NICE as "the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated."[7]

How should I use this document?

This document has two main parts. Part One identifies **prompts** that should be used during the medication review.

Part Two is useful for reflection, reference, and education. There are a series of questions that pharmacists should use to **reflect** on their practice and identify learning needs. Resources are identified in the signposting sections and the appendices that contain useful **references** for the medication review process. The information

contained in part two can also be used to **educate** practice staff on the role of the pharmacist, different types of medication reviews and the importance of scheduling the right appointments for the right patients.

Part One. Prompts for medication review

Be clear on the aim of the medication review

At the start of the medication review, the pharmacist should have an idea of what they want to achieve. The aim of the review will help to steer its direction and aid the identification of potential outcomes that patients / pharmacists can use to assess the impact of the medication review.

Example aims of medication reviews	Potential outcomes
Improve adherence	Patient is taking medicines as prescribed Patient is regularly ordering medicines
Minimise side effects from medication	Patient is well managed with fewer side effects
Reduce the number of medicines prescribed	Patient is well managed on reduced medicines
Reduce prescribed opioids	Patient is well managed with reduced opioids

Involve and engage your patient in the review process

Engage patients by giving them time to prepare for the medication review. Supporting patients to get the most out of their medication review in Part Two (page three) provides further guidance on how to help patients prepare. It is important to know patient expectations at the start of the review. Patients should have opportunities to ask questions and raise concerns during the review.

Ask the patient what they hope to achieve from the medication review
Negotiate a shared agenda

Have a process for undertaking the medication review

For complex medication reviews, many pharmacists will use a template to help structure the medication reviews. Other pharmacists have just developed their own structure based upon general guidance. It is important to check that all medicines are still suitable for the patient. Establishing the initial indication of the prescribed medicines and checking clinical monitoring parameters, such as blood test results, can be undertaken before the patient consultation. This helps to evaluate the medicines appropriateness and establish the aim of the medication review.

Assess the appropriateness of the medicines prescribed

- Appendix 1 suggests useful resources for checking the appropriateness of the medicines prescribed.

If needed, refer to your support material, (e.g., pre-existing templates, professional guidance), during the medication review.

Action plan and goal setting

Goals for treatment need to be agreed with the patient. Action plans should be recorded in the patient's record so it can be accessed by all professionals involved in the care of the patient.

The action plan should record:

- Medication problem identified
- Action proposed
- Action by
- Planned outcomes (How do we know this has been achieved?)

Part Two

Before the patient consultation

Your role in the practice

Each pharmacist will have individual skills, experience, and expertise. It could be useful for pharmacists to summarise these for the staff they work with so they can better understand their role. This will help them to explain the pharmacist's role when booking appointments. We also suggest that pharmacists are aware of the different staff members that support the medication review process. Some primary care networks (PCN) have a website that describes the roles of each member of the general practice team, and describes the different services offered within the PCN. Space is often at a premium in some practices. We suggest working closely with the practice management and other support staff to ensure there is a consultation room available for the days you plan to undertake face-to-face reviews in the practice.

Reflective questions

How can patients be helped to understand the role of the pharmacist in your practice and what to expect in a medication review?

Does your practice support team know what you do? What are their roles and responsibilities in the medication review process?

Where is the dedicated space at the practice where you can conduct face-to-face consultations?

Signposting

Appendix 2 gives an example description of the role of the pharmacist in a GP practice. This could be amended to better reflect your role and shared with the staff and / or patients.

The following link provides a description of the roles and responsibilities of pharmacy professionals in general practice. https://www.cqc.org.uk/guidance-providers/gps/gp-mythbusters/gp-mythbuster-81-pharmacy-professionals-general-practice

Booking and planning

The patient population in each practice will vary, therefore each will prioritise different patients for medication reviews. Each pharmacist / practice will have their own criteria that helps them assess whether a patient consultation can be conducted over the phone. We suggest working with your support team to implement a system to help book appointments, where it is clear whether the patient requires a telephone or face-to-face consultation and whether they need a standard or extended appointment.

Reflective questions

What is your patient population? How do you prioritise patients for medication reviews?

How do you decide whether a telephone or face-to-face appointment is required?

What is the process for booking appointments for the appropriate length of time? Whose responsibility is it to arrange the appointment with the patient?

How long in advance are medication reviews booked?

Signposting

The following link to the Network Contract Directed Enhanced Service Contract for general practice identifies patients that are eligible for a structured medication review and would require an extended appointment. https://www.england.nhs.uk/wp-content/uploads/2023/03/PRN00157-ncdes-updated-contract-specification-23-24-pcn-requirements-and-entitlements-updated.pdf

Supporting patients to get the most out of their medication review

Patients should have time to prepare for the medication review and we suggest that the practice discusses how much advance notice a patient should have. Patients receiving a structured medication review are required to receive information about the review and what to expect [8]. It would be useful if all patients who are invited for a medication review receive some guidance to help them prepare.

Reflective question

Do you have a standard letter that you use for patients who are invited for a structured

Signposting

The Health Innovation Network have developed a range of patient information materials to support and prepare people who have been invited for a medication review.
Example questions for patients to think about before their review

- Why am I taking these medicines?
- How do I know they are helping me?
- Do I still need all my medicines?
- Why do I have to take so many medicines?

https://thehealthinnovationnetwork.co.uk/programmes/medicines/polypharmacy/patient-information/

Medicines reconciliation

Medicines prescribed by the practice should be up to date with the latest hospital recommendations.

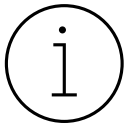
Reflective questions

Who is responsible for checking for changes following recent hospital discharge or outpatient appointments?
Where do the different roles within your practice sit with regards to medicines reconciliation and

Signposting

The following links provide guidance for medicines reconciliation; CQC, NICE, CPPE
https://www.cqc.org.uk/guidance-providers/adult-social-care/medicines-reconciliation-how-check-you-have-right-medicines
https://www.nice.org.uk/guidance/ng5/chapter/1-Recommendations#medicines-reconciliation
https://www.cppe.ac.uk/programmes/l/medsrecon-e-01/

Pharmacist support



Access to a mentor in general practice can help build confidence and competence. Experience also builds confidence. We suggest discussing with the practice team the patients that you have the skills and the confidence to see independently. We propose that you plan a strategy with your mentor/ line manger to extend your scope of practice. We suggest that your planned development should be guided by your patient demographics.

Reflective questions

What stage are you at with your confidence with decision making?
What support do you need to help to improve your confidence, e.g., specific clinical areas, prescribing?
Do you have contact details for a GP / pharmacist mentor?
For sole pharmacists in the GP practice / those working remotely:
How can you address working in isolation? With whom can you collaborate?

Signposting

The Primary Care Pharmacists Association (PCPA), Royal Pharmaceutical Society (RPS) and PrescQIPP Practice Plus are examples of organisations that can provide peer support. Please note that some content is available only to members.
https://www.pcpa.org.uk/clinical-support-network-hub.html ,
https://www.rpharms.com/development/career-support/onetoone-support ,
https://practiceplus.prescqipp.info/

During the patient consultation

Delivering the medication review

Part One contains prompts to guide you through the patient consultation.

Prompts

Be clear on the aim of the medication review
Involve and engage your patient in the review process
Have a process for undertaking the medication review
Action plan and goal setting

Signposting

Appendix 3 provides examples of useful resources to help in the delivery of medication reviews.

Consultation skills

Patients are more likely to consider medication changes if there is rapport building between the patient and the pharmacist. It is important that patients feel they have been listened to in the medication review. Patients want to feel like their experiences and opinions were considered during the review.

Reflective questions

How confident are you with your consultation skills?
What resources are available to help you develop or refresh your skills?

Signposting

Appendix 4 gives examples of resources that are available to support the development of consultation skills.

Policies and procedures

All practitioners delivering medication reviews should use the same policies and procedures. This means that patients should have the same level of care from whoever does the medication review. Every practice has different procedures; therefore, it is important to establish what the preferred processes are in each practice. We suggest meeting the practice management team to discuss the policies and procedures in the practice. Many practices have informal procedures, but we suggest formalising these to facilitate streamlining the care of patients. We also suggest reviewing them on an annual basis.

Reflective questions

What is the repeat prescribing policy at the practice?
What is the medicines management policy at the practice?
Are pharmacists named in these protocols?
What blood tests are you authorised to order?
What is the process for red flag procedures? Who should these be referred to and how should this be done?
For non-prescribing pharmacists:
What protocols are in place for you to make prescription changes, e.g., dose changes?

After the patient consultation

Communication

Occasionally a patient's management will require discussion with other professionals in the practice or at the hospital. Referrals to hospital will need to be actioned by the patient's GP.

Reflective questions

Have all notes been entered, and actions coded on the patient's records?
Is there any further communication that needs to be actioned? Who can help you with this?
Does the patient need a post medication review action plan?
Has this been completed and documented in the patient's record?
Who will make any required changes to the patient's medicines?

Follow up

If there is not enough time in the appointment to address all the issues that were identified, the patient may need an additional appointment. We suggest that any referrals e.g., for a follow up review, physiotherapist, social prescriber, should be discussed with the patient at the end of the review and instructions given on how this should be done. There may be occasions where recommended changes following the medication review have not been implemented. We suggest that as a practice you discuss a process in relation to this.

Reflective questions

Did you and the patient discuss everything that you needed to in the review?
Do you need to schedule any follow up appointments?
Does the patient need to be referred to another practitioner, e.g., social prescriber, physiotherapist?

Recording outcomes

The outcomes that you use a measure of the success of the medication review is linked to the aim of the medication review. For example, if the aim of the review was to optimise a patient's diabetic control or to improve their use of opioids or benzodiazepines, a suitable outcome measure would be reduced glycated haemoglobin (HbA1c) or reduced use of opioids of benzodiazepines. The Care Quality Commission (CQC) will check the quality of medication reviews as part of their inspections.

Reflective questions

What outcomes can you review to measure whether the medication review has had a positive effect?

Signposting

- This link introduces the simple and easy-to-use tool to support the evaluation of the cost-effectiveness of medication reviews. PrescQIPP membership is needed to access this information. https://www.prescqipp.info/our-resources/bulletins/bulletin-326-documenting-outcomes-from-medication-review/
- This link describes the key lines of enquiry at a CQC inspection. Knowledge of these can help you to evaluate the quality of your patient care. https://www.cqc.org.uk/guidance-providers/healthcare/key-lines-enquiry-healthcare-services
- GP MythBusters is a useful resource for best practice in general practice. https://www.cqc.org.uk/guidance-providers/gps/gp-mythbusters

Additional Signposting

Appendix 1: Resources available to help check the appropriateness of prescribed medicines

- The Specialist Pharmacist Service has compiled a list of tools to support medication review: https://www.sps.nhs.uk/articles/using-tools-to-support-medication-review/
- Anticholinergic Burden Scales: https://www.medichec.com/assessment
- STOPP/START tool: https://link.springer.com/article/10.1007/s41999-023-00777-y
- Improving Medicines and Polypharmacy Appropriateness Clinical Tool (IMPACT): PrescQIPP membership is needed to access this information. *https://www.prescqipp.info/our-resources/bulletins/bulletin-268-impact/*

Appendix 2: Primary Care Pharmacists Association (PCPA) description of the role of GP pharmacist

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Appendix 3: Useful resources for delivery of medication reviews

- The Royal Pharmaceutical guidance for medicines optimisation: https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Policy/helping-patients-make-the-most-of-their-medicines.pdf
- NICE guidance for medicines optimisation: https://www.nice.org.uk/guidance/ng5
- The 7-steps medication review: https://www.polypharmacy.scot.nhs.uk/for-healthcare-professionals/principles/the-7-steps-medication-review/
- Bedfordshire, Luton, and Milton Keynes Integrated Care Board SMR process for pharmacists: https://medicines.bedfordshirelutonandmiltonkeynes.icb.nhs.uk/wp-content/uploads/2020/10/Structured-Medication-Review-SMR-Process-for-Pharmacists.pdf

Appendix 4: Resources available to support consultation skills

- https://www.cppe.ac.uk/services/consultation-skills
- https://www.rpharms.com/professional-development/foundation/foundation-assessment-tools/consultation-skills-assessment
- https://www.youtube.com/c/Consultations4Health

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Appendix 13 Final Thesis output: Document to support the implementation of pharmacist-led medication reviews in primary care (Version 3)

Background

Who is this document for?

This document is primarily intended for **pharmacists delivering medication reviews** in general practice. It may also be useful for other healthcare professionals involved in the delivery of medication reviews.

What is this document for?

To ensure patients gain the most benefit from their medicines, pharmacists need the skills and confidence to conduct high-quality medication reviews [1]. The likelihood of patients experiencing harmful effects increases with the number of medicines they take [2]. Recognising this, the UK government has emphasised the importance of medication reviews, leading to the integration of pharmacists into general practice to increase their availability [2,3].

Despite the volume of reviews undertaken, up to 7% of hospital admissions in the UK are attributed to harmful effects from medicines [4]. Research suggests that medication reviews achieve high-quality outcomes only under specific circumstances [1].

This document has been developed using evidence from literature and discussions with patients and healthcare professionals. It outlines the circumstances under which medication reviews yield the best outcomes, aiming to benefit both patients and health systems. Additionally, it seeks to enhance pharmacists' skills and confidence, enabling them to deliver more effective medication reviews.

What is a medication review?

Discussions with patients and practitioners have highlighted confusion about what constitutes a medication review and its purpose.

For the purposes of this document, a medication review is defined as:

"A consultation between a pharmacist and a patient to review the patient's total medicines use with the aim of improving health outcomes and minimising medicines-related problems."

This definition aligns broadly with those from The National Institute for Health and Care Excellence (NICE) and the Pharmaceutical Care Network Europe (PCNE) [5,6] but has been adapted to better reflect current practice.

For further clarity:

- **Medicines reconciliation** is defined by NICE as *"the process of identifying an accurate list of a person's current medicines and comparing them with the current list in use, recognising any discrepancies, and documenting any changes, thereby resulting in a complete list of medicines, accurately communicated."* [7]

How should I use this document?

This document comprises two main parts:

Part One
Part One identifies key prompts to guide the medication review process. These prompts are summarised in **Figure 1**, which outlines the steps involved in the patient consultation. **Figure 1** is intended as a quick reference that can be printed and displayed in consultation rooms; it is also a reminder that medication reviews are not strictly linear.

Patients may begin the review by presenting their agenda, which can shift the review's focus. Similarly, action planning and goal setting may alter the consultation's direction. The review process – what you do and how you do it – will depend on the patient and the specific goals of the review.

Figure 2 is a concise overview of the medication review process. This could also be displayed in consultation rooms as concise practical summary.

Part Two
Part Two is designed for **reflection, reference**, and **education**.


It includes questions that pharmacists can use to reflect on their practice and identify learning needs.


Signposting sections and appendices provide resources relevant to the medication review process.


It also offers educational material for practice staff, highlighting the pharmacist's role, the various types of medication reviews, and the importance of scheduling appropriate appointments for suitable patients.

This document is practical, adaptable, and educational for both new and experienced team members while supporting role evolution.

Figure 1. Process for patient consultation element of medication review

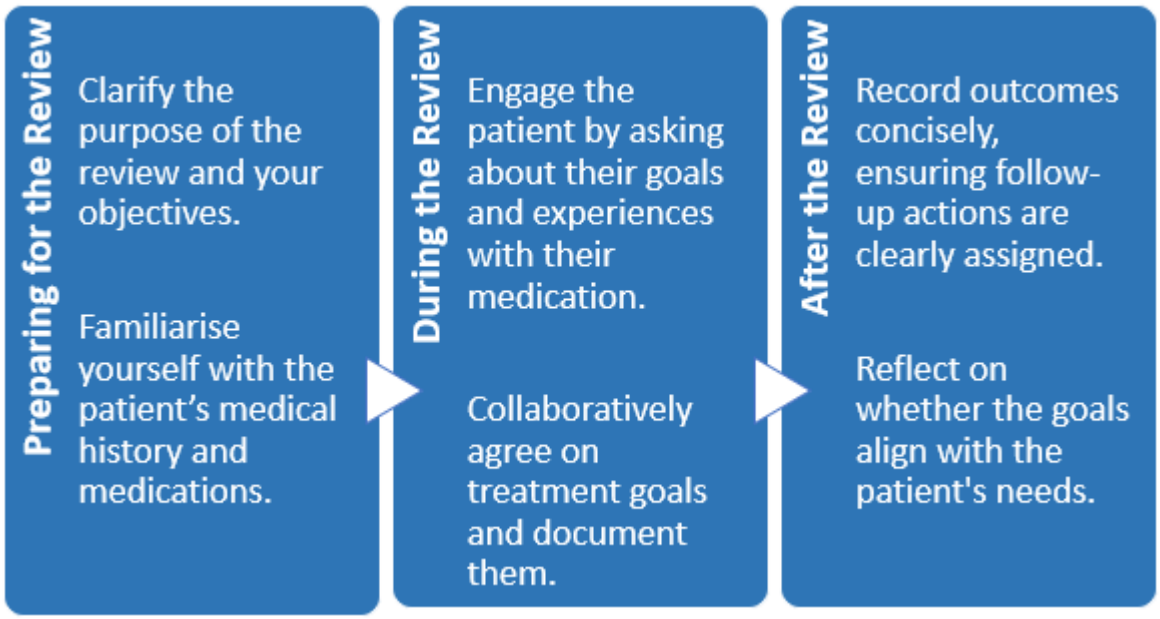

Figure 2. Concise overview of medication review process

Part One Prompts for Medication Review

Be clear on the aim of the medication review

At the start of the medication review, the pharmacist should have a clear understanding of what they aim to achieve. Defining the purpose of the review helps to guide its direction and identify measurable outcomes that both patients and pharmacists can use to assess its impact.

Example aims of medication reviews	**Potential outcomes**
Improve adherence	Patient is taking medicines as prescribed Patient is regularly ordering medicines
Minimise side effects from medication	Patient is well managed with fewer side effects

Involve and engage the patient in the review process

Actively engaging patients is crucial for a successful medication review. Allow patients time to prepare beforehand. Guidance on how to support patients in preparing for their review can be found in **Part Two**.

Understanding the patient's expectations at the outset is essential. Patients should have opportunities to:

- Ask questions
- Raise concerns
- Actively participate in discussions throughout the review.

Have a structured procedure for the medication review

For complex medication reviews, pharmacists often use templates to structure the process, though some develop their own frameworks based on general guidance.

Before the consultation, pharmacists should:

- Verify that all prescribed medicines remain suitable for the patient
- Review the original indications for the prescribed medicines
- Check relevant clinical monitoring parameters, such as blood test results.

Completing this preparatory work helps to evaluate the appropriateness of the medicines and establishes a clearer aim for the review.

Action plan and goal setting

Pharmacists and patients should collaboratively agree on treatment goals. Action plans should be documented in the patient's record to ensure accessibility for all healthcare professionals involved in the patient's care

The action plan should record:

- Medication problem identified
- Action proposed
- Action by
- Planned outcomes (How do we know this has been achieved?)

Part Two

Before the Patient Consultation

Your Role in the Practice

Each pharmacist brings individual skills, experience, and expertise to their role. Summarising these for practice staff can help them better understand your contributions and effectively explain your role when booking appointments.

It is also helpful to be aware of the different staff members who support the medication review process. Some Primary Care Networks (PCNs) have websites that outline the roles of general practice team members, and the services provided within the PCN.

> Have all members of the practice team been briefed on medication reviews and their responsibilities in the process? Is there information available for patients to know what pharmacists do?

Space constraints can be a challenge in some practices. To ensure a smooth workflow, pharmacists should coordinate with practice management and support staff to secure consultation rooms for face-to-face reviews on planned days.

Signposting

- Appendix 2 includes an example description of the pharmacist's role in a GP practice. This can be customised to reflect your specific role and shared with staff or patients.
- The following link provides further details on the roles and responsibilities of pharmacy professionals in general practice: CQC Mythbuster on Pharmacy Professionals in General Practice.

Booking and Planning

Patient populations and priorities for medication reviews vary by practice. Each pharmacist or practice will have their own criteria to determine whether a consultation can be conducted via telephone or requires a face-to-face appointment.

Pharmacists can collaborate with support teams to implement an efficient booking system that clearly indicates:

> Has a robust booking system been implemented?

- Whether the consultation is telephone-based or in-person, and
- Whether the patient requires a standard or extended appointment.

Signposting

- For guidance on identifying patients eligible for structured medication reviews and extended appointments, refer to the Network Contract Directed Enhanced Service Contract for General Practice.

Supporting Patients to Get the Most Out of Their Medication Review

Patients should be given adequate time to prepare for their medication review. Pharmacists can work with the practice to determine how much advance notice is appropriate.

Structured medication reviews require patients to receive information about what to expect [8]. Providing patients with guidance before their review can help them prepare effectively.

Example questions for patients to consider before their review:

- Why am I taking these medicines?
- How do I know they are helping me?
- Do I still need all my medicines?
- Why do I have to take so many medicines?

Do you have materials that you use to help patients prepare for their review?

Signposting

- The Health Innovation Network has developed patient information materials to help patients prepare for medication reviews: Patient Information Materials.

Medicines Reconciliation

Pharmacists should ensure that medicines prescribed by the practice are up to date and align with the latest hospital recommendations.

Are there other staff members who support with medicines reconciliation?

Signposting

- Useful guidance on medicines reconciliation can be found at:
  - CQC Guidance on Medicines Reconciliation
  - NICE Recommendations for Medicines Reconciliation
  - CPPE Medicines Reconciliation Programme.

Pharmacist Support

Having access to a mentor in general practice can significantly boost confidence and competence. Experience also plays a key role in building these skills. Pharmacists can discuss with their practice team which patients they feel confident managing independently.

To expand their scope of practice, pharmacists can work with their mentor or line manager to develop a planned strategy. This development can be informed by patient demographics and practice needs.

Is there a pharmacist support network in place?
Has the pharmacist/ practice identified future learning needs?

Signposting

- Organisations that provide peer support include:
  - Primary Care Pharmacists Association (PCPA)
  - Royal Pharmaceutical Society (RPS)

- PrescQIPP Practice Plus
  (Note: Some content may be restricted to members only.)

During the Patient Consultation

Delivering the Medication Review

Part One of this document provides prompts to guide you through the patient consultation process.

Signposting

- Appendix 3 lists useful resources to support the delivery of medication reviews.

Consultation Skills

Building rapport with patients is crucial to the success of a medication review. Patients are more likely to consider medication changes when they:

- Feel listened to
- Believe their experiences and opinions have been taken into account.

Is there a need to review current evidence-based consultation models to refresh skills?

Effective communication and empathy are essential to creating a positive consultation experience.

Signposting

- Appendix 4 provides resources to help develop consultation skills.

Policies and Procedures

To ensure consistency in patient care, all practitioners delivering medication reviews should adhere to the same policies and procedures.

Key actions for pharmacists include:

- Familiarising themselves with the specific procedures in place at each practice.
- Collaborating with the practice management team to discuss and formalise any informal processes.
- Ensuring that all procedures are regularly reviewed and updated to streamline patient care.
- Standardised procedures help ensure that patients receive the same level of care, regardless of who conducts the review.

After the Patient Consultation

Communication

There may be instances where the patient's management requires input from other professionals in the practice or at the hospital.

> What systems are in place to minimise miscommunication?

Referrals to secondary care (e.g., hospital specialists) will typically need to be actioned by the patient's GP.

Follow-Up

If all identified issues cannot be addressed during the initial appointment, patients may require additional consultations.

Where referrals (e.g., to a physiotherapist or social prescriber) are necessary, these should ideally be discussed with the patient at the end of the review. Clear instructions should also be provided on how to proceed with these referrals.

In cases where recommended changes following a medication review have not been implemented, pharmacists can collaborate with the practice to develop a follow-up process.

Recording Outcomes

The success of a medication review should be measured against its original aim. For example:

- If the aim was to optimise diabetic control, an appropriate outcome measure might be a reduction in glycated haemoglobin (HbA1c).
- If the goal was to improve opioid or benzodiazepine use, reduced usage of these medications could serve as an outcome.

The Care Quality Commission (CQC) evaluates the quality of medication reviews during inspections, so outcomes should be recorded clearly and accurately.

Signposting

- PrescQIPP: Documenting Outcomes from Medication Review (PrescQIPP membership required).
- CQC Key Lines of Enquiry: Guidance on evaluating patient care quality.
- GP MythBusters: A resource for best practice in general practice.

Additional Signposting

Appendix 1: Resources available to help check the appropriateness of prescribed medicines

- The Specialist Pharmacist Service has compiled a list of tools to support medication review: https://www.sps.nhs.uk/articles/using-tools-to-support-medication-review/
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- STOPP/START tool: https://link.springer.com/article/10.1007/s41999-023-00777-y
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- NICE guidance for medicines optimisation: https://www.nice.org.uk/guidance/ng5
- The 7-steps medication review: https://www.polypharmacy.scot.nhs.uk/for-healthcare-professionals/principles/the-7-steps-medication-review/
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- https://www.youtube.com/c/Consultations4Health
- https://www.bristol.ac.uk/primaryhealthcare/teaching/cog-connect/

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2 Department of Health & Social Care. Good for you , good for us , good for everybody. 2021.

3 NHS England. The NHS Long Term Plan – a summary. 2019.

4 NICE. What are the health and financial implications of adverse drug reactions? Clinical Knowledge Summaries (CKS). 2022.

5 NICE. Quality statement 6: Structured medication review. 2016. https://www.nice.org.uk/guidance/qs120/chapter/quality-statement-6-structured-medication-review (accessed 3 March 2021)

6 Griese-Mammen N, Hersberger KE, Messerli M, *et al*. PCNE definition of medication review: reaching agreement. *Int J Clin Pharm*. 2018;40:1199–208. doi: 10.1007/s11096-018-0696-7

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8 NHS England. Network Contract Directed Enhanced Service Contract specification 2023/24- PCN Requirements and Entitlements. 2023.

9 PCPA. Primary Care Networks Clinical Pharmacists Job Descriptions. 2019. https://pcpa.org.uk/assets/documents/PDF-Clinical-Pharmacist-Job-Description.pdf (accessed 23 April 2024)