Exploring the impact on performance of general practice-based pharmacists: a multiple Case Study

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Abstract

Introduction

In General Medical Practice, pharmacists are being employed to perform tasks previously undertaken by General Practitioners (GPs). While there is evidence of the benefit of pharmacists in different settings and performing specific tasks within a General Medical Practice setting, the impact of pharmacists in these new roles is not clear. The aims of this thesis are to evaluate the impact of pharmacists working in General Medical Practice and identify and explore factors that enhance their positive impact.

Methods

The thesis consists of two studies. First, a Systematic Review of controlled studies evaluating pharmacists completing one specific task (medication reconciliation) in the community after hospital discharge was undertaken. The effectiveness of this approach on the identification, resolution and clinical relevance of discrepancies was evaluated as was the impact on healthcare utilisation.

Next, four Case Studies set in General Medical Practices where pharmacists had been introduced were conducted. A mixed methods approach was used that involved analysis of case notes, observation of pharmacist work and interview of pharmacists and other members of the primary care team. Systems-based approaches directed data collection and analysis.

Evidence of impact on each of the Institute for Healthcare Improvement's domains of quality was sought. The system was modelled and explored using the Functional Resonance Analysis Method to identify important context and mechanisms that supported positive outcomes.

Results

Pharmacists identified more discrepancies than when medication reconciliation was completed by GPs, but there was no statistically significant impact on patient outcomes or healthcare use.

Pharmacists increased safety and effectiveness of prescribing and overall, reduced GP workload; however, actions performed by pharmacists to increase safety and effectiveness increased workload in secondary care and within the practice for GPs and administrative staff.

Five mechanisms were identified across the four Case Studies to optimise the positive impact of pharmacist: team integration; pharmacists' professional development; taking responsibility for assigned tasks; balancing thoroughness and efficiency and anticipating risks and preventing increased work. From this, thirteen recommendations were generated to support the effective implementation of pharmacists into General Medical Practice.

Conclusions

Although further research is required to provide evidence of the impact of implementing the recommendations and to support pharmacists' development, these recommendations should be considered by all involved in the recruitment and management of pharmacists in General Medical Practice. This includes the pharmacists themselves, the practice, the employer, those with governance roles, regulators and politicians.

Table of Contents

List of Tables

List of Figures

List of accompanying material

Appendix 1 – Ethical approval letter

Appendix 2 – Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist

Appendix 3 – Medline search syntax with results from 1.9.17

Appendix 4 - Documents included in guidance document analysis

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Author's Declaration

I declare that, except where explicit reference is made to the contribution of others, that this dissertation is the result of my own work and has not been submitted for any other degree at the University of Glasgow or any other institution."

Printed Name: ___Duncan Stuart McNab____

Signature: ____ _____

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Systematic Review

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Case Studies

Case note analysis, observations and interviews were all undertaken by me. Interviews were transcribed by Liz Cook, Jacqui Dillon and Catrina Gordon who all work for NES.

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Publications and Presentations

Publications arising from this project

McNab D, Bowie P, Ross A, *et al* Systematic review and meta-analysis of the effectiveness of pharmacist-led medication reconciliation in the community after hospital discharge *BMJ Quality & Safety* 2018;**27:**308-320.

McNab D, McKay J, Shorrock S, *et al* Development and application of 'systems thinking' principles for quality improvement *BMJ Open Quality* 2020;**9:**e000714. doi: 10.1136/bmjoq-2019-000714

McNab, D., Freestone, J., Black, C. *et al*. Participatory design of an improvement intervention for the primary care management of possible sepsis using the Functional Resonance Analysis Method. *BMC Med* **16,** 174 (2018). https://doi.org/10.1186/s12916-018-1164-x

McNab, D., Bowie, P., Morrison, J., & Ross A. (2016) Understanding patient safety performance and educational needs using the 'Safety-II' approach for complex systems, Education for Primary Care, 27:6, 443-450, DOI: 10.1080/14739879.2016.1246068

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McNab D., Rutherford G. (2020) System Thinking. In: Rutherford, G. Human Factors in Paramedic Practice. Class Publishing. Bridgwater

Selected presentations and workshops arising from this project

McNab D, Ross A. The Functional Resonance Analysis Method for understanding work in Complex Systems Complexity and Quality Improvement Masterclass workshop. Edinburgh, UK; March 2018.

McNab D, Ross A. The Functional Resonance Analysis Method for understanding work in Complex Systems Complexity and Quality Improvement Masterclass workshop. Glasgow, UK; October 2018.

McNab D. Journey into Complexity Centre for Applied Resilience in Healthcare Masterclass presentation. Birmingham, UK; August 2017

McNab D. Using FRAM to design change in Quality Improvement projects. 12th Annual FRAMily meeting. Cardiff, UK; June 2018

McNab D, Luty S and Blakeman T. Adopting a 'systems approach' to QI and safety work in frontline general practice. Royal College of General Practitioners annual conference. Glasgow, UK; October 2018

McNab D and Luty S. Meet STEW: Systems Principles for Everyday Work. National GP Academic Clinical Fellow and Early Career Medical Researchers Conference. Manchester, UK; March 2019

Bruce, R., Zlotos L., and McNab D. Clinical Decision Making. SP3A Annual Conference 2021 19.11.21

Abbreviations

ACE	Angiotensin Converting Enzyme
AMED	Allied and Complementary Medicine Database
CASP	Critical Appraisal Skills Programme
CCG	Clinical Commissioning Group
CI	Confidence Intervals
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CN review	Case Note review
CPN	Community Psychiatric Nurse
CR	Critical Realism
DMARDS	Disease Modifying Anti Rheumatoid Drugs
DOACs	Direct Oral Anticoagulants
ERIC	Education Resources Information Center
ETTO	Efficiency Thoroughness Trade-Off
FMV	FRAM Model Visualiser
FRAM	Functional Resonance Analysis Method
GMC	General Medical Council
GP	General Practitioner
GST	General Systems Theory
HRO	High Reliability Organisations
IQ range	Interquartile range
KPI	Key Performance Indicators
MeSH	Medical Subject Heading
NAT	Normal Accident Theory
NES	NHS Education for Scotland
NHS	National Health Service
NRLS	National Reporting and Learning System
P	Represents 'Practice' used to identify practices involved in study
PDSA	Plan, Do, Study, Act
Ph	Represents 'pharmacist' used to identify pharmacists involved in study
PINCER	Pharmacist-led IT based Intervention
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QI	Quality Improvement
RCA	Root Cause Analysis

RCGP	Royal College of General Practitioners
RCT	Randomised controlled trials
RE	Resilience Engineering
RPS	Royal Pharmaceutical Society
RR	Risk Ratio
SEA	Significant Event Analysis
SEIPS	Systems Engineering Initiative for Patient Safety
STAMP	System-Theoretic Accident Model and Processes
STEW	Systems Thinking for Everyday Work
STPA	Systems-Theoretic Process Analysis

Glossary

Complex systems consist of many interacting components. Outcomes emerge from the varying interactions between components and the external environment. This means they are difficult to understand by breaking them down into components parts

Context – in this thesis refers to the circumstances that influence people's decisions and actions. Contextual factors do not occur from within the individual but from elsewhere and the physical setting, other people, available equipment and information and the expectations and demands on the person. In this thesis it includes situational factors which are a type of contextual factor that are only present at a specific time and place.

Context-Mechanism-Outcome (CMO) is a heuristic used in realist research to generate causative explanations of events from the data. A CMO explains the relationship of context, mechanism, and outcome of interest.

Instantiation is a specific real or imagined event that takes place under specific conditions. When using the Functional Resonance Analysis Method instantiations are considered to identify the particular subset of functions that interact during that event.

Mechanisms - are the things that people do that generate outcomes. In realist research they refer to underlying processes that operate in particular contexts to generate outcomes of interest.

Medication Reconciliation -"the process of identifying the most accurate list of a patient's current medicines including the name dosage frequency and route – and comparing them to the current list in use, recognising and documenting any discrepancies, thus resulting in a complete list of medications." (35)

Safety-II – is the popular name given to adopting a Resilience Engineering approach when considering safety – in essence to ensuring as many things as

possible go right under varying conditions. This is different to Safety-I which generally attempts to make as few things as possible go wrong.

Realism - refers to a philosophy of science that sits between positivism ('there is a real world which we can see and understand directly through observation') and constructivism ('we cannot know for sure what the nature of reality is, because all knowledge has been interpreted through human senses, language and culture').

Resilience of a system - has been defined as the ability of the system, to "adjust its functioning prior to, during, or following events (changes, disturbances, and opportunities), and thereby sustain required operations under both expected and unexpected conditions." (Hollnagel, 2016a)

Resilience Engineering - involves designing systems to behave in a resilient manner.

Theory – there are varying definitions of the word theory. In this thesis it refers to a coherent set of ideas used to explain facts and events.

Chapter 1 Introduction to the Thesis

An ageing population with increasing multimorbidity and polypharmacy has increased demand on General Medical Practices (henceforth called General Practices) in the United Kingdom. Coupled with increased financial pressure on the National Health Service (NHS), this has led to changes in the delivery of General Practice services. General Practitioners (GPs) were traditionally regarded as 'gatekeepers' to other services in both primary care, such as physiotherapy and podiatry, and secondary care. To reduce demand on GPs, this way of working has been changing with patients being encouraged to refer themselves directly to appropriate primary care professionals such as podiatrists and optometrists.

The role of pharmacist has been developed to further reduce General Practice demand. Pharmacists employed in community, commercial properties ('high street pharmacies') traditionally dispensed medication prescribed by another professional (such as a GP) or offered advice to patients and recommended medication that could be purchased over the counter. The services they offer have expanded to include treatment of medical conditions (such as urinary tract infections) for which a prescription would usually be required. Pharmacists have also developed roles within the General Practice team. It is thought that many of the prescribing tasks completed by GPs could be completed by pharmacists.

The impact of these new ways of working needs to be evaluated. Similarly, the best ways to maximise the impact on safety, effectiveness and workload reduction is not understood.

This thesis will focus on the role of pharmacists in General Practices and study the impact they have, the different systems used and how these influence impact. From this, recommendations to improve the impact of pharmacists working in General Practices will be developed.

1.1 Structure of thesis

The introduction to the thesis will describe how pharmacists working in General Practices is being promoted. Next a Systematic Review will explore published evidence of the benefit of pharmacists performing one specific task (medication reconciliation) after hospital discharge of patients into the community.

The remainder of the thesis consists of four Case Studies that explore the impact of pharmacists working in General Practice and how their positive impact can be maximised. First, the philosophical approach, methodology and theoretical framework that influence the thesis will be discussed. Next, the way in which these factors directed the methods employed in the Case Study will be described. Following this, the results section will contain one chapter for each Case Study and one chapter that details the cross-case analysis of results.

The discussion chapter will explore the findings of the thesis and compare to existing evidence and the strengths and limitations of the thesis. Finally, recommendations for policy and future research are outlined along with the conclusions of the thesis.

1.2 Research Motivation

I am a partner in a General Medical Practice where I work two days per week. The practice list size increased substantially between 2014 and 2018 and there was a large turnover in staff due to retirement and relocation. Recruitment of GPs was difficult which resulted in an increased workload for the remaining GPs and reduced access to GPs for patients. Many practices across Scotland were in similar positions.

In Scotland, a new General Medical Services contract was agreed in 2018. (Scottish Government, 2017a) One of the main aims was to increase capacity in General Practice by introducing other health care professionals who would be employed by local health boards. These included mental health practitioners, physiotherapists, community link workers and general practice-based pharmacists.

In my health board area, the development of the pharmacists' role had begun prior to the 2018 contract and several had been assigned to my practice. Through informal discussion within my own team and with other practices, it was clear that the impact pharmacists had on demand and capacity was variable and the reasons were not clear. Many colleagues suggested that this was due to the personal qualities of individual pharmacists, for example, "They just fit in with our team" or "They just get on with the job". The health board employed pharmacists were often moved between practices and from speaking to colleagues in other practices, some pharmacists seemed to 'fit in' and have a positive impact on workload reduction when in one practice but not when they worked in other practices.

I also work for a special health board (NHS Education for Scotland (NES)). NES are responsible for developing and delivering training to health and care staff to support specialty training and workforce development. (NHS Education for Scotland, 2021) When I started my PhD, I was an Associate Adviser in Patient Safety and Quality Improvement. As part of this role, I

had developed an interest in ‘Systems Thinking’ and how this can be applied to safety and improvement work. Within systems thinking, I was particularly interested in the field of Safety-II. In simple terms, this is a way of thinking about how we create safety by studying all types of work (successful work as well as work that results in unwanted outcomes) rather than focussing on things that go wrong. It seeks to explore, explain and enhance how people adapt the way they work to get the best results.

I thought this was an interesting and appropriate approach to apply in order to study the impact of pharmacists working in General Practice. I was keen to explore if and how pharmacists adapt their approaches, if this aids success and if successful adaptation can be supported by systems within practices and wider organisations to enhance the positive impact of introducing pharmacists to GP.

1.3 Aims and research questions

The aims of this thesis were to explore the impact of pharmacist working in general practice, understand the factors that influence their impact and generate recommendations to increase positive impact. In order to meet these aims, the following research questions were developed:

1.3.1 Research questions

1. When pharmacists complete medication reconciliation in the community after hospital discharge:
    a. What approaches have been used, including who employs the pharmacists, how long do pharmacists take to complete the task and how do pharmacists interact with patients and General Practitioners?
    b. What is the effect on discrepancy identification and resolution?
    c. What is the clinical relevance of resolved discrepancies?
    d. What is the effect of healthcare utilisation in terms of readmission rates, emergency department attendance and primary care workload?
2. What is the impact of pharmacists working in general practices on:
    a. Quality of care?
    b. Workload and wellbeing of staff?
3. What mechanisms influence the impact of pharmacists working in General Practice on quality of care, workload and wellbeing?
4. How do identified mechanisms influence the impact of pharmacists working in General Practice on quality of care, workload and wellbeing?
5. What contextual factors influence the identified mechanisms that impact on quality of care, workload and wellbeing?

1.4 Overview of the thesis

The content of each chapter is briefly described below.

Chapter 2 provides background information on how the role of GPs and pharmacists have been changing. Drivers for the development of the role of pharmacists to work in General Practice premises are summarised.

Chapter 3 systematically reviews the published literature to explore the impact of pharmacists in the community completing one specific task that is part of their new role: medication reconciliation after discharge from hospital.

Chapter 4 details the philosophical approach used in this thesis. It explores why this is important, why Critical Realism was chosen and how this will be applied in the thesis.

Chapter 5 describes why and how Case Study methodology was used. Other approaches are considered and the links to the philosophical approach of Critical Realism is explored.

Chapter 6 explores the theoretical perspective adopted that directs data collection and analysis within the Case Study approach. Systems approaches in general are described with the focus on those used in complex systems. The reasons for using Resilience Engineering are explored and the existing evidence of the application of this approach in health and care are summarised. Finally, the links between a complex systems approach, Case Study methodology and a Critical Realism philosophical approach are identified and described.

Chapter 7 describes, in detail, the methods used to collect and analyse data and links these to the theoretical perspective, methodology and philosophical approach.

Chapter 8, 9, 10 and 11 are results chapter. Each chapter describes the findings from one Case Study.

Chapter 12 is a cross case analysis where findings from the four cases are compared.

Chapter 13 is a discussion of the findings in light of previously published evidence and the strengths and limitations of the thesis.

Chapter 14 provides recommendations for future GP practice policy, those employing pharmacist, national policy and future research. The chapter ends with conclusions from the thesis.

Chapter 2 Background

2.1 Overview

This chapter will set the scene for this thesis. It will describe the traditional roles held by General Practitioners (GPs) and pharmacists in the community and the main drivers for extending pharmacists' roles. Examples of expanded pharmacist roles and existing evidence of benefits in various settings will be explored.

2.2 Pharmacists in General Practice

2.2.1 Traditional pharmacist and General Practitioner roles

Prior to the foundation of the NHS in 1948, both pharmacists and doctors had a role in diagnosis and advising on medication (Anderson, S., 2007). Those unable to afford a doctor, could consult with a pharmacist who would offer advice and sell medicines, often that they had made themselves. Following the foundation of the NHS, one of the main roles of pharmacists became to dispense medication that was prescribed by doctors. Doctors diagnosed problems and advised on treatment. They wrote prescriptions that would be conveyed to a commercial pharmacist where the medication would be prepared and dispensed by a qualified pharmacist and their team (Royal Pharmaceutical Society, 2021). A minority of GP practices performed a dispensing role, especially in rural communities where income from dispensing can help offset the effect of reduced income due to low patient numbers (Dispensing Doctors' Association, 2021).

The 'normal' system of a GP writing a prescription that is later dispensed by a pharmacist requires GPs and pharmacists to work together in different parts of the system to ensure the safe transfer of information (Royal College of General Practitioners and Royal Pharmaceutical Society, 2016). This ensures that patients receive the correct medication and know how to take it. Problems such as GPs and pharmacists working in different locations with little sharing of information may affect the process (Royal College of General Practitioners and Royal Pharmaceutical Society, 2016). For

example, the pharmacist may be aware of other 'over the counter' medication that would interact with a medication proposed by a GP or the GP may be aware of medical problems that necessitate an unusual medication or dose.

2.2.2 Drivers for change of pharmacists' roles

Drivers for changing the role of pharmacists in primary care include to increase capacity within general practice and to improve the quality of prescribing (Primary Care Foundation and NHS Alliance, 2015; NHS England, Royal College of General Practitioners, British Medical Association, 2015; Royal College of General Practitioners and Royal Pharmaceutical Society, 2016).

Increase capacity in General Practice

The workload pressures within UK GP have been well documented and indeed GP has been described as being 'in crisis' (The King's Fund, 2016). Workload has increased due to an aging population with multimorbidity (the coexistence of two or more long-term conditions within an individual) (Violan *et al.*, 2014) and polypharmacy (the use of five or more medications) (Masnoon *et al.*, 2017). In addition, there has been a focus on providing care closer to patients' homes and services have been transferred to community settings to be managed within primary care. This has caused increased demand for GP appointments, prescriptions and other services such as long-term conditions reviews (The King's Fund, 2016).

In addition to an increased demand for appointments, the complexity of care has increased (The King's Fund, 2016). With multimorbidity there is a need to be aware and be able to consider multiple sources of evidence and guidance and patient's care often involves many different health and care professionals (Barnett *et al.*, 2012).

Despite total numbers of qualified GPs increasing, clinical capacity may not have increased. An analysis of GP workload by the Kings Fund found that

between 2011/12 and 2014/15, the number of contacts with General Practices increased by 13% (The King's Fund, 2016). During this time the GP workforce grew by 4.75%. They reported a reduction in the number of GPs undertaking fulltime clinical duties. The 'intensity of clinical work' was one of the main reasons reported by GPs for wanting to work less than full time.

While levels of patient satisfaction with General Practice services is traditionally high (and higher than other areas of the NHS), it has been falling due to problems especially with access and continuity of care (Appleby and Robertson, 2016).

Improving prescribing safety, effectiveness and efficiency

A second reason for developing the role of pharmacists in General Practice is to reduce the risk of harm to patients from medications (Scottish Government, 2013a). Patients can and do experience harm due to medications that are prescribed, issued by a pharmacist or bought over the counter (Avery, Barber *et al.*, 2012). Harm may be from:

- known adverse effects of the correct drug (for example, developing a cough with an angiotensin converting enzyme (ACE) inhibitor)
- the prescription or supply of the wrong medication or wrong dose (for example, receiving liquid morphine strength 100mg/5ml rather than 10mg/5ml causing overdose)
- the right medication taken in the wrong manner (for example, inhaled medication may be ineffective due to poor technique)
- interactions between medications (for example, ACE inhibitor with a diuretic and non-steroidal anti-inflammatory drug can increase the risk of acute kidney injury)
- failure to prescribe a medication (for example, increased risk of myocardial infarction in certain at-risk patients if a statin medication is not prescribed)

- lack of monitoring of medication (for example, inadequate monitoring of warfarin may result in fatal haemorrhage).

Some of these mechanisms of causing harm are preventable and it is thought that prevention may be enhanced by the introduction of pharmacists to General Practice (Scottish Government, 2013).

Incidence of prescribing problems in General Practice

Most of the time prescriptions are written and dispensed appropriately but 'error rates' for prescriptions have been calculated in many settings. Results within community healthcare settings have varied widely from 1% (Quinlan, Ashcroft, Blenkinsopp, 2002) to 40% (Claesoon *et al.*, 1995) of prescriptions containing an 'error' (prescribing error). The problem is that the calculation of error rate depends on the definition of an error. The figure of a 40% error rate came from a study in Sweden where a prescription was said to contain an error if it did not include the indication for the medication (Claesoon *et al.*, 1995). This would not be classed as an error in other countries.

The PRACTICe study led by Avery for the General Medical Council (GMC) in 2012 calculated 'error rate' for prescriptions in English general practice (Avery *et al.*, 2012). Six thousand prescription items were reviewed from 15 General Practices. This was undertaken by a pharmacist followed by agreement by a panel of one GP, a clinical pharmacologist and three pharmacists. A second panel which consisted of two GPs, two pharmacists and one clinical pharmacologist judged the severity of the errors.

The PRACTICe study included errors relating to the wrong medication, wrong information on the prescription, medication recommended by guidelines not being prescribed and monitoring that did not take place that would be considered ‘acceptable or routine practice’ (Leape, 1994).

On reviewing 6048 prescription items from 15 general practices an error rate of 4.9% was reported of which 1 in 550 was deemed serious. If these findings are consistent with prescriptions issued by GPs in Scotland, in

2014/15 five million prescribing errors and 900 serious prescribing errors may have occurred over this time period (ISD Scotland, 2015).

The percentage of these errors that reach the patient and actually cause harm is not clear. Errors may be identified and rectified by a community pharmacist; indeed pharmacists are seen as an error defence mechanism (Brown *et al.*, 2006; Knudsen *et al.*, 2007). Even if the patient receives the medication, it is not clear how often patients suffer harm due to medication errors. In a study of over 18,000 admissions to two large English hospitals, 6.5% were judged to be due to adverse drug reactions (Pirmohamed *et al.*, 2004). Of these, 72% were thought to have been preventable. Additionally, of the half a million medication error incidents reported to the National Reporting and Learning System (NRLS) between 2005 and 2010, 16% caused harm to the patients (Cousins, Gerrett, Warner, 2012). It is unlikely that this is reflective of the potential of all errors to cause harm as reported errors are a small proportion of the total number of prescription errors and most errors are reported in secondary care rather than primary care (Cousins, Gerrett, Warner, 2012).

Irrespective of how 'errors' are defined or reported, it is clear that there is potential to reduce error rates and therefore harm to patients. This is one of the reasons for the promotion of pharmacists working in General Practice.

2.2.3 Policy support for change

The development of the role of pharmacists in General Practice has been promoted by the Scottish Government and the Academic colleges (Royal College of General Practitioners and Royal Pharmaceutical Society, 2016; Scottish Government, 2017b). The Scottish Government report *A Prescription for Excellence - A Vision and Action Plan for the right pharmaceutical care through integrated partnerships and innovation,* sets out their vision for the development of the role of pharmacists (Scottish Government, 2013). It stresses the importance of closer working between health professionals

including GPs and pharmacists. The traditional model of care is challenged and the colocation of GPs and pharmacists is promoted. It states that all community pharmacists shall be independent prescribers by 2023 and that they shall be called 'general practice clinical pharmacists' regardless of where they work within the community. It also calls for the role of pharmacists to be extended by developing their clinical role and states:

> *"All patients, regardless of their age and setting of care, receive high quality pharmaceutical care from clinical pharmacist independent prescribers. This will be delivered through collaborative partnerships with the patient, carer, GP and the other relevant health, social care, third and independent sector professionals so that every patient gets the best possible outcomes from their medicines, and avoiding waste and harm".*

Although the definition of 'pharmaceutical care' is not explicit within *A prescription for excellence*, a definition is included in the previous government document *The Right Medicine – pharmaceutical care in Scotland* (Scottish Executive, 2006):

> *"Pharmaceutical care reflects a systematic approach that makes sure that the patient gets the right medicines, in the right dose, at the right time and for the right reasons. It is about a patient-centred partnership approach with the team accepting responsibility for ensuring that the patient's medicines are as effective as possible and as safe as possible".*

It has been suggested that extending the role of pharmacists and increasing their integration with other health professionals has the potential to improve safety (by reducing the harm caused by medication) and increase the quality of prescribing (by, for example, following local and national guidelines) (Scottish Government, 2013). It is also expected that closer working will reduce the workload pressure currently experienced by GPs by transferring some of the tasks they complete to pharmacists (Mathers, 2016). Due to an

oversupply of qualified pharmacists and a shortage of GPs, pharmacists have been described as the "hidden army" that can help reduce GP workload (Primary Care Foundation and NHS Alliance, 2015).

The Royal College of General Practitioners (RCGP) and the Royal Pharmaceutical Society (RPS) have promoted this extension of the role of pharmacists and their integration with GPs (Royal Pharmaceutical Society, 2014). Guidance produced jointly by the RCGP and RPS has emphasised the advantages for both professionals and for patients in closer working.

Locating pharmacists within GP surgeries has been promoted as a necessary step to improve collaborative working. In Scotland this is being achieved by Health Board employed pharmacists being assigned to GP practices. This contrasts with the system being piloted in England (Mathers, 2016). The Clinical Pharmacist in General Practice pilot is a scheme where GP practices in England directly employ pharmacists (Royal College of General Practitioners, British Medical Association, NHS England, 2015). Funding is provided to cover part of their income amounting to 60% in year one, 40% in year two and 20% in year three.

2.2.4 Comparison different international models for integrating pharmacists

Pharmacists' roles in Primary Health Care are being expanded internationally, including in Australia, USA and Canada, to include tasks such as medication reviews and immunisation work (Benrimoj and Fernandez-Llimos, 2020). They have been integrated into primary care teams in North America where their roles include (Slazak *et al.*, 2020; Khaira *et al.*, 2020; McCullough *et al.*, 2021):

- Direct patient care - managing medication and completing medication reviews
- Clinician and patient education
- Implementing improvements to service design

- Members of Multi-disciplinary teams with specific tasks such as facilitating effective hospital discharge.

While success has been reported in these roles, healthcare is organised and funded differently than in the UK. In addition, the introduction of pharmacists in the UK aims to transfer a variety of prescribing tasks traditionally completed by GPs to pharmacists, rather than for pharmacists to have specific roles to augment existing systems (such as a Multi-disciplinary team to facilitate safe discharge). This means that while there may be lessons to be learned from international experience regarding ability of pharmacists to complete specific tasks, these may not be directly transferable to the situation in the UK and more specifically in Scotland.

2.2.5 The Scottish General Medical Services contract 2018

In 2018, a new contract was agreed between Scottish Government and GPs in Scotland (Scottish Government, 2017). Under this contract, many tasks currently undertaken by GPs were to be transferred to other professionals. One example was the transfer of pharmacotherapy services to health board employed pharmacists based in GP practices. The aim was to reduce GP workload (thus increasing GP capacity to allow the adoption of the role of 'Expert Generalist') and to increase the quality and cost effectiveness of prescribing. Further funding was announced to allow health boards to employ 140 more whole time equivalent pharmacists in Scotland with extended clinical skills to work with GPs and deliver 'patient facing care' (Scottish Government, 2016a).

The 2018 GMS contract divided pharmacotherapy services into three levels as described in Box 1.1 (Scottish Government, 2017). The expectation was that as the pharmaceutical service developed and expanded, by April 2021 all core services would be completed by pharmacists in every GP practice.

Box 1.1 – core and additional pharmaceutical services in the 2018 GMS contract (Scottish Government, 2017)		
Level	**Pharmacists' roles**	**Pharmacy Technicians' roles**
Level one (core)	• Authorising/actioning all acute prescribing requests • Authorising/actioning all repeat prescribing requests • Authorising/actioning hospital Immediate Discharge Letters • Medicines reconciliation • Medicine safety reviews/recalls • Monitoring high risk medicines • Non-clinical medication review Acute and repeat prescribing requests includes/ authorising/actioning: • Hospital outpatient requests • Non-medicine prescriptions • Instalment requests • Serial prescriptions • Pharmaceutical queries • Medicine shortages • Review of use of 'specials' and 'off-licence' requests	• Monitoring clinics • Medication compliance reviews (patient's own home) • Medication management advice and reviews (care homes) • Formulary adherence • Prescribing indicators and audits
Level two (additional - advanced)	• Medication review (more than 5 medicines) • Resolving high risk medicine problems	• Non-clinical medication review • Medicines shortages • Pharmaceutical queries
Level three (additional - specialist)	• Polypharmacy reviews: pharmacy contribution to complex care • Specialist clinics (e.g. chronic pain, heart failure)	• Medicines reconciliation • Telephone triage

2.2.6 Pharmacists as prescribers

For pharmacists to fulfil the pharmacotherapy requirement of the 2018 GMS contract, it is essential that they become independent prescribers (Scottish Government, 2017). Two types of 'appropriate practitioners' are able to

write a prescription: independent prescribers and supplementary prescribers (The British National Formulary, 2022). Independent prescribers include doctors, dentists and allied professionals who have completed extra training such as nurses, pharmacists and optometrists. These professionals can start medications based on knowledge of the patient's history and/or examination findings. Supplementary prescribers are able to continue medication that has been commenced by an independent prescriber and include nurses, pharmacists, physiotherapists, podiatrists and radiographers.

2.2.7 Benefits of developing the role of pharmacists

The main areas of expansion of pharmacist work as detailed in the new contract consist of (Scottish Government, 2017):

1. Medicines reconciliation after discharge
2. Authorising and actioning prescription requests
3. Medication reviews including poly-pharmacy reviews
4. Monitoring high risk medications
5. Specialist clinics - adopting clinical duties in management of long-term conditions.

There have been previous studies that evaluated the benefits of GP and pharmacist collaboration in community care that have focused on these areas.

<u>Medicines reconciliation after discharge</u>

Medicines reconciliation has been defined as:

> "*The process of identifying the most accurate list of a patient's current medicines including the name dosage frequency and route – and comparing them to the current list in use, recognising and documenting any discrepancies, thus resulting in a complete list of medications*." (Institute for Healthcare Improvement, 2022)

When a patient is admitted to hospital their medication is reconciled. Recommended practice is to use two sources of information including the patient or carer's reported medication list, the admission letter or existing electronic medication lists (Scottish Government, 2013b). When a patient is discharged from hospital a discharge document is completed to communicate the most up to date list of medications that reflect the patient's medication before admission and changes made during their inpatient stay. This document is either given to the patient to hand into the GP surgery or sent electronically or by mail to the GP surgery.

At the GP surgery, the GP, or a member of their team, reconciles the medication by comparing the information contained in the discharge document to the medications recorded in the patient's electronic record. The changes, if felt appropriate by the GP, are incorporated into the electronic prescribing record. The process involves professionals from different physical locations communicating using different methods such as electronic transfer of a document, email, telephone conversations and so accurate medicines reconciliation can be challenging.

Pharmacist involvement in improvement efforts

Pharmacist-led medication reconciliation interventions have been found to be beneficial to reduce the number of discrepancies on discharge documents (Farley *et al.*, 2014) , reduce reattendance at Emergency Departments (Dudas *et al.*, 2002) and lower readmission rate (Tuso *et al.*, 2013; Hawes *et al.*, 2014; Phatak *et al.*, 2016).

Not all studies have shown a positive effect of the involvement of community pharmacists in medicines reconciliation. Setter in 2009 assessed the effectiveness of a nurse and pharmacist resolving medication discrepancies following discharge and found that although the number of discrepancies was reduced there was a trend towards increased planned and unplanned physician visits (Setter *et al.*, 2009). Additionally, Holland showed that medicines reconciliation by community pharmacists resulted in

increased primary care use (Holland *et al.*, 2005). It was postulated that this unintended consequence was due to the involvement of a pharmacist increasing the complexity of the patient's care thus increasing health care utilisation.

Several systematic reviews assessing the impact of pharmacist led interventions to improve transitions are summarised in Table 2.1. [Table 2.1] Many of the included studies were of low quality. A wide range of discrepancy rates on discharge documents (14.1% and 98.2%) were reported, although the clinical relevance of many of these may have been low (0.3% thought to be clinically relevant in one study (Varkey, Cunningham, Bisping, 2007)). These studies conclude that although medicines reconciliation can identify discrepancies and so reduce the potential for harm, the effect of the process on clinical outcomes is not clear (Lehnbom *et al.*, 2014).

Studies of hospital-based, pharmacist-led medication reconciliation interventions showed decreased composite readmission and emergency department visits and readmissions (Kwan *et al.*, 2013). Most successful interventions included several components and improvements could not be put down to medication reconciliation alone. Further systematic review evaluating different methods aimed at reducing 30-day readmission rates failed to show that any one intervention component was successful (Hansen *et al.*, 2011; Hesselink *et al.*, 2012)

A systematic review of the role of community pharmacist in improving transition from secondary to primary care was published in 2015 (Nazar *et al.*, 2015). This reviewed a wide variety of studies with differing study designs. It determined that there was evidence that involving pharmacists in medicines reconciliation at discharge can reduce drug related problems but the impact on hospital admission, mortality, medication adherence and patient satisfaction was not clear. It was not always possible to ensure that the control group in experimental studies did not receive at least part of the intervention that was being evaluated.

Patient understanding and involvement

While many of these studies report a reduction in discrepancy rate, it is important to remember that this is perhaps not the most important measure. It is more important to assess what the patient is actually taking (Eggink *et al.*, 2010). Around half of discrepancies between medication lists and the medication the patient takes, are thought to be patient associated including use of additional over the counter medication or poor adherence due to lack of understanding (Coleman *et al.*, 2005; Setter *et al.*, 2009). Patient participation has been under studied but in one study 81.6% of patients had no understanding that their medication had been stopped, 69.3% were unaware that the medication dosage had been changed and 62% were not aware of newly prescribed medication (Ziaeian *et al.*, 2012). Physicians overestimate patient understanding and successful improvement strategies need to attempt to improve patient understanding (Calkins *et al.*, 1997). There is a need for both accurate information at transitions and for patients to be aware of and act upon this information.

Research gap

There have been many studies and systematic reviews of pharmacists performing medication reconciliation in hospital or following discharge, but few have studied community-based pharmacists (as opposed to hospital-based pharmacists) performing medication reconciliation in the community. Those that have looked at community-based pharmacist interventions have included tasks comprising of more than medication reconciliation. Evaluation of impact of pharmacists completing medication reconciliation in the community after hospital discharge is required as is exploration of the optimal ways of working (such as pharmacist employment model and ways of collaborating with other primary care team members). Published reports of medication reconciliation interventions have several components and are often designed to suit local settings. Medication reconciliation has been described as complex as it contains numerous interactions between professionals and can be influenced by many factors (Pevnick, Shane,

Schnipper, 2016). These factors make it difficult to understand how and why results were achieved and therefore recommendation for future policy on collaborative working are not clear.

As Medication Reconciliation is one of the main tasks being asked of pharmacists within their new roles, a systematic review of the literature is needed to evaluate the impact. The optimal models for completion of this task also need to be explored.

Authorising and actioning prescription requests

Another role proposed for pharmacists in general practice is to process prescription requests. In GP electronic health records, medications can either be 'repeat' medications (Petty, Zermansky, Alldred, 2014) or 'special requests' medications (Maskrey *et al.*, 2018). 'Repeat' medications are those that are included on the patient's medication list and can be ordered at a specified frequency for a set time without further review. These include medications, such as blood pressure medication, that may be authorised to be issued at the patient's request each month. These medications may be authorised for a set number of re-issues, for example, 12 prescriptions until the annual blood pressure review, or they may have no limit to the number of re-issues. 'Special request' medications (also sometimes called 'acute requests') are not added to the 'repeat' medication list. Instead these are issued as a one-off prescription that requires clinical review before re-issue. Such requests are dealt with by prescribers by reviewing the request and the patient record to decide on whether to prescribe, decline to prescribe and/or arrange further review.

The expansion of the role of pharmacists includes processing both types of medication requests. It is thought that pharmacists completing these tasks could free GP time to undertake clinical tasks and identify prescribing problems.

Pharmacists involvement in improvement interventions

Evidence of the impact of pharmacists in this area is limited, indeed the terms 'special requests' and 'acute prescriptions' rarely appear in the literature. Pharmacists have been shown to reduce GP workload and implement cost saving changes when managing repeat prescribing systems (Bush *et al.*, 2018). In another study, the largest time saving effect of the introduction of pharmacists into General Practice was achieved through pharmacist completion of 'special requests' (Maskrey *et al.*, 2018). Potential improvements in prescribing safety through investigation of potentially inappropriate prescribing was also reported (Hayhoe *et al.*, 2019).

Research gaps

Due the paucity of published research in this area, there is opportunity to evaluate the impact of pharmacists prescribing both repeat prescriptions and 'special requests'. Impact on safety, effectiveness of treatment, time saved, health care utilisation and cost needs to be assessed.

Medication reviews including poly-pharmacy reviews

Medication reviews provide an opportunity to optimise prescribed medication. This is defined by the National Institute for Health and Care Excellence (NICE) as 'a structured, 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 medicine-related problems and reducing waste' (National Institute for Health and Care Excellence, 2015).

Pharmacist review of prescribed medication has been used to identify and rectify inappropriate prescribing and optimise current prescribed medications (Huiskes *et al.*, 2017). Inappropriate prescribing includes prescribing medications that interact, over prescribing (medications that are not clinically indicated) and under prescribing (medications that should be prescribed but are not). Reviews can also identify medication regime

adherence issues and ensure doses of medication and follow up are optimised.

Pharmacist involvement in improvement interventions

There is evidence that medication reviews improve medication related problems, reduce the number of medications prescribed (Huiskes *et al.*, 2017) and can reduce prescribing costs (Sorensen *et al.*, 2004), but there is limited effect on clinical outcomes such as mortality (Huiskes *et al.*, 2017) and conflicting evidence that pharmacist-led medication reviews are effective at reducing hospital admission (Royal *et al.*, 2006; Christensen and Lundh, 2016). In a systematic review of the impact of pharmacists working in a GP setting, most interventions involved a medication review and targeted patients with specific medical conditions (Tan *et al.*, 2014). Nineteen of the 38 studies included demonstrated beneficial clinical effects (for example on disease control), there were mixed effects in six studies and no effect in the remaining 13. Positive impact was more likely when a multifaceted intervention was used rather than completion of an isolated task.

Research gaps

While there is evidence of benefit in some outcome measures of pharmacists performing medication reviews, variability on impact of healthcare utilisation is reported. Future research should explore why this variability was found and how pharmacists can perform this task as part of a new role consisting of multiple interlinking prescribing tasks within General Practice.

<u>Monitoring high-risk medications</u>

Some medications are considered to be higher risk of causing adverse drug events. The most common medications to contribute to acute hospital admissions are Non-Steroid Anti-Inflammatory Drugs (Pirmohamed *et al.*, 2004). Other drugs are considered high-risk by clinicians, for example methotrexate, for which there is strict monitoring guidance (Dreischulte and

Guthrie, 2012; Health Improvement Scotland, 2021; National Institute of Clinical Excellence, 2021).

In addition to high-risk drugs, high-risk prescribing has also been defined. Guthrie and Dreischulte define this as, “medication prescription by professionals, for which there is evidence of significant risk of harm to patients, and which should therefore either be avoided or (if avoidance is not possible) closely monitored and regularly reviewed for continued appropriateness.” (Dreischulte and Guthrie, 2012).

Pharmacist involvement in improvement interventions

The role of pharmacists in reducing the risk of harm from high risk medication and prescribing has been demonstrated in large primary care studies (Avery, Rodgers *et al.*, 2012). In the PINCER trial a pharmacist-led intervention, that utilised an Information Technology intervention that included feedback, education and additional support, reduced high risk prescribing in general practice.

Research gaps

The evidence is clear that pharmacists have a valuable role in this area. Future research should explore how this task can be integrated into other roles expected of pharmacists as part of the Primary Care team.

<u>Specialist clinics - adopting clinical duties in management of long-term conditions.</u>

Patients who have long-term medical conditions, such as diabetes or ischaemic heart disease, are invited for regular reviews by the general practice. Traditionally these reviews are undertaken by general practice nurses. Optimisation of medication based on guidelines and advice on medication use are included in reviews. Nurses with advanced training may make medication decisions or information may be passed to GPs for them to make these decisions. One of the drivers for introducing pharmacists into General Practices is to utilise their pharmaceutical knowledge within long

term condition management to improve patient care by ensuring it is evidence based and safe (Scottish Government, 2017).

Pharmacist involvement in improvement interventions

Pharmacists have been utilised in GP to provide clinical care as part of long-term condition management. Benefits have been demonstrated in the management of blood pressure, diabetes and cholesterol management as well as improvements in overall cardiovascular risk (Lowrie *et al.*, 2012; Lowrie *et al.*, 2014; Tan *et al.*, 2014; Hayhoe *et al.*, 2019).

Research gaps

Pharmacists have a positive impact in these specialised roles. It is important, therefore, to explore if this impact can be maintained when pharmacist undertake the wide variety of duties expected of them as part of the Primary Care team.

Reduction in quantity of work

An additional proposed benefit of pharmacist working in GP is to reduce the demand for GP appointments (Scottish Government, 2017); however, the published evidence is inconclusive. A systematic review of studies evaluating the impact of pharmacists integrating into primary care teams showed that in four of the nine studies that reported demand for GP appointments, there was a reduction in demand (Hayhoe *et al.*, 2019). Four of the 10 included studies that looked at overall primary care usage reported that this increased (the others showed no statistical difference). In one study, four times as many follow up appointments were arranged by pharmacists than by GPs (Okamoto and Nakahiro, 2001). The majority of these encounters were arranged to follow guidance for medication and disease follow up. Three studies assessed overall healthcare contacts and, in these studies, this outcome measure increased, although it was only statistically significant in one study. Three studies showed a reduction in Emergency Department attendance. The costs of prescribed medication and overall healthcare costs (including cost of primary care attendance, primary

care workload such as medication reviews, laboratory tests and secondary care clinic attendance) showed varied results with some studies showing increases and others decreases.

Research gaps

Due to the reported variability of impact of pharmacist interventions, future research should consider why impact is variable and how positive impact can be promoted.

2.2.7 Discussion

National policy is promoting the adoption of new roles by pharmacists, one of which is in General Practice. Increasing demand and limited capacity are causing workload pressures and the potential for patient harm from primary care prescribing has been clearly stated. It is thought that locating pharmacists in General Practices in order to perform prescribing tasks traditionally undertaken by GPs will increase capacity, increase the safety and effectiveness of prescribing and increase appointment capacity in GP. There is evidence that, when pharmacists perform specific tasks in GP, they can improve certain aspects of care, such as control of blood pressure, but there is variable evidence on the impact on workload.

The next chapter will systematically review the evidence for community-based pharmacists completing Medication Reconciliation after discharge from hospital. This is because, of the main tasks being promoted for pharmacists working in GP, Medication Reconciliation has been studied more extensively than tasks such as completion of ‘special requests’. Results appear variable compared to other recommended tasks such as improving high-risk prescribing or involvement in specialist clinics and reasons for this are not clear. The systematic review will evaluate impact in terms of identification and reconciliation of discrepancies and healthcare utilisation. In addition, it will review the different ways of working described to determine if they influence outcomes.

As this introduction chapter has described, research is needed to explore pharmacists completing the multiple and varied tasks required in their new roles in GP and how a positive impact can be achieved. This will be the focus of Case Studies included in this thesis.

Chapter 3 Systematic Review

3.1 Introduction to chapter

In this chapter the published literature is systematically reviewed to determine the effectiveness of medication reconciliation performed by community-based pharmacists after hospital discharge. Although there is evidence of pharmacists successfully completing medication reconciliation in other settings, definitive evidence of their impact when based in the community is required. Impact on discrepancy identification and reconciliation and health care utilisation will be measured. The influence of different intervention characteristics will be evaluated.

3.2 Background

One of the roles that has been promoted for pharmacists to undertake in General Practice is medication reconciliation. Multiple definitions of medication reconciliation exist, but all involve defining the list of medications the patient should be taking, altering records to reflect changes and ensuring patients and/or carers are aware of the changes (World Health Organisation, 2013; Almanasreh, Moles, Chen, 2016; Health Improvement Scotland, 2021).

Medication reconciliation can be carried out at any point in time, but it is said to be crucial to patient safety when patients transition from one area of healthcare to another (Michaelsen *et al.*, 2015). Transitions include admission to hospital from the community, transfers within secondary care and discharge back to the community. Safe transitions often require coordinating care with healthcare professionals in both primary and secondary care. (Jack *et al.*, 2009)

At the transition from hospital to community, medication reconciliation is necessary for hospital-initiated medication changes to be maintained. The medication taken by patients in the community, and prescribed by their General Practitioner, is often changed during hospital admissions to optimise care (for example, starting medication to prevent future cardiac

events following admission with a Myocardial Infarction), treat patient symptoms (for examples prescribe analgesics) or to reduce the risk of harm (for example reducing diuretic medication in a patient admitted with Acute Kidney Injury) (Michaelsen *et al.*, 2015). On discharge, a document is sent to the patient's GP, and sometimes their community pharmacist, detailing medication regime changes implemented during their in-patient stay. Medication reconciliation ensures the list held by the GP or community pharmacist (pre-admission medication) is updated to reflect hospital-initiated changes. Following this process, discrepancies that exist between the primary care list of medications and the discharge medication list are either intentional discrepancies (a conscious decision has been made not to implement changes) or unintentional.

Medication errors have been found to be more prevalent after transitions and the World Health Organisation identified that these errors could lead to increased morbidity at times of transition (World Health Organisation, 2013; Lehnbom *et al.*, 2014; Mekonnen, McLachlan, Brien, 2016). A prospective study found that 11% of patients suffered an adverse drug event within 24 days of discharge, 60% of which were thought to be preventable or ameliorable (Forster *et al.*, 2005). Medicines reconciliation during transitions has been deemed a national patient safety goal and the focus of a multitude of improvement efforts including the Scottish Patient Safety Programme (Health Improvement Scotland, 2021).

Medication reconciliation after hospital discharge has been promoted as one task that could be completed by GP based pharmacists (Scottish Government, 2017; Scottish Government, 2017). As well as increasing GP capacity, it is assumed this will increase the safety of care after discharge and improve outcomes such as readmission rate. While improvements in patient outcomes of this type of intervention have been reported in secondary care, effectiveness in the community has not been established (Mekonnen, McLachlan, Brien, 2016).

A previous systematic review that examined all interventions to improve medication reconciliation in primary care found two studies that evaluated medication reconciliation after hospital discharge by pharmacists (Bayoumi *et al.*, 2009). These were of low quality and evidence of benefit was not found. A further systematic review evaluated all interventions (including medication reconciliation) undertaken by pharmacists in the community after hospital discharge (Nazar *et al.*, 2015). This showed that pharmacists can identify potential drug related problems but the impact on outcomes, such as healthcare utilisation, was inconsistent.

3.2.1 Medication reconciliation improvement measures

Studies have assessed the rate of discrepancies in the discharge document or in the patient's electronic record held at the GP surgery after reconciliation. Other measures have included health service usage after discharge and patient satisfaction.

Discrepancies can be intentional – for example if a medication has been stopped, or unintentional – where a medication is not included on the list that should be present. It has been reported that half of all medication errors that occur at transitions of care are due to unintentional discrepancies in the medication prescribed (Rozich *et al.*, 2004). In a recent systematic review of discrepancies in discharge documents, the included studies reported that between 20% and 87% of patients had unintentional discrepancies on their discharge documents with patients having a mean number of 1.2 to 5.3 discrepancies during discharge from hospital (Michaelsen *et al.*, 2015).

Identification and reconciliation of discrepancies is an important process measure of the effective medication reconciliation; they evaluate a specific step in the process. They do not, however, demonstrate the impact of effective medication reconciliation which requires measurement of outcomes such as readmission rate, mortality and health care utilisation.

3.2.3 Aims

We aimed to focus, in depth, on medication reconciliation performed by community and GP-based pharmacists after hospital discharge, by systematically reviewing published studies that compared this process to usual care. The aim was to identify the characteristics of different interventions and determine the effectiveness of this intervention on: overall discrepancy identification and resolution; the clinical relevance of resolved discrepancies and healthcare utilisation in terms of readmission rates, emergency department attendance and primary care workload.

3.3 Methods

The study was conducted using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) group guidelines (Moher *et al.*, 2009). The completed PRISMA checklist is included as appendix 2.

3.3.1 Scope of the review

Studies were included that compared community and primary care-based pharmacist-led medication reconciliation to usual practice. We defined medication reconciliation as the reconciliation of pre-admission and post-admission lists of medication. Many studies evaluated interventions that included medication reconciliation combined with other actions. Studies where drug related problems (such as drug interactions) were identified and corrected were included, (Holland *et al.*, 2005) but studies focused on medication review (for example, recommendations to optimize medication regimes) were not (Barker *et al.*, 2012). Randomised Controlled trials (RCTs), cohort studies and pre-post intervention studies reported in English were included.

3.3.2 Information sources

We searched the Medline (Ovid), CINHAL (EBSCOhost), EMBASE (Ovid), AMED (Ovid), ERIC (Ovid), NHS evidence, Cochrane electronic databases and SCOPUS databases from inception until 1st September 2017. This was updated in December 2020. The reference lists of selected studies were

hand searched to identify any additional relevant studies. Citations were imported into Refworks and all versions of citations lists were kept (Proquest, 2018).

3.3.3 Search strategy

To identify studies pertaining to our definition of medication reconciliation, a combination of Medical Subject Heading (MeSH) terms and free text search terms was developed by the review team in collaboration with a knowledge manager, a qualified librarian whose role includes searching and accessing published healthcare evidence. To identify studies describing medication reconciliation the search terms “medication reconciliation”, “medicines reconciliation”, “medication discrepancy”, “medication error”, “medication adherence” and “medication counselling” were combined. Search terms to identify studies at discharge from hospital included, “discharge”, “transition” and “patient transfer” and terms to identify pharmacists included “pharmacist”, “pharmacy” and “community pharmacy”. To identify studies set in the community rather than in hospital, several terms were combined, including, “primary health care”, “ambulatory care”, “family practice”, general practitioner”, “home care services”. No limit was placed on date of publication or language and the search was adapted for each database. The final search syntax for Medline is included in appendix 3.

3.3.4 Eligibility criteria

For inclusion, studies had to fulfil the criteria in Table 3.1. Following removal of duplicates, two reviewers independently screened titles and abstracts of all citations from the 2017 search (DM and MR, a medical education research fellow working for NES). Full texts of all articles considered to be relevant were obtained and screened by two reviewers independently (DM and MR). These tasks were completed by DM for the additional studies identified in 2020. Disagreements were resolved by discussion of full article content by DM and the supervising team.

Table 3.1 –Systematic review criteria for study inclusion

Characteristic	**Criteria for inclusion**
Population	Patients discharged from hospital to their permanent residence (home, residential unit or nursing home)
Intervention of interest	Medicines reconciliation completed by a pharmacist based in the community.
Comparator	Both controlled and uncontrolled studies were included.
Outcome measure	Discrepancy identification. Discrepancy categorization. Health care usage (re-admission, Emergency department attendance, GP attendance) Workload/efficiency measures – time to complete medicines reconciliation, effect on number of primary and secondary care appointments needed and economic outcomes.
Study design	Randomised controlled trials (RCTs), cluster RCTs, quasi-RCTs, cluster quasi-RCTs, controlled pre-post intervention studies, interrupted-time-series, cohort studies (prospective or retrospective), case-control studies, uncontrolled pre-post intervention studies
Language	No limitation
Publication date	No limitation

3.3.5 Data extraction

Once the final set of studies was agreed, the lead reviewer (DM) extracted data from all studies. A second data extraction was completed independently by another member of the review team (MR and thesis supervisors). This was performed by DM alone for the 2020 search. A template was created to allow extraction of data relevant to the study

questions. This was piloted with two studies and adapted following discussion of extracted data by the review team. The data extracted comprised details of the authors, publication, funding, aims, study design, inclusion and exclusion criteria, method of allocation to intervention or control group, sample sizes, participant characteristics, setting and details of the intervention, statistical techniques used, outcome data and reported strengths, weaknesses and conclusions.

Study details were tabulated to codify the study design, type of pharmacists, setting of intervention, number, timing and duration of contacts and the description of collaboration with other team members. The outcome data which were extracted from each paper were: rates of identification and resolution of discrepancies; rates of resolution of clinically relevant discrepancies; and measures of healthcare utilisation (rates of readmission, emergency department attendance, GP attendance and measures of healthcare team member workload).

3.3.6 Risk of Bias

The quality of each study and risk of bias were assessed independently by the two reviewers who performed the data extraction using the relevant Critical Appraisal Skills Programme (CASP) tools (CASP UK, 2016). These checklists facilitate a systematic approach to considering the presence or absence of certain elements within the study that may cause bias. Following completion of the CASP tool, the two reviewers discussed their findings for each study and graded the risk of bias as low, moderate or high. For example, one section asks, “Were controls recruited in an acceptable way?” Selection bias may be introduced if participants are not randomised but could at recruitment, participants could select their allocation to the intervention or control group. Studies that recruited control groups in this manner would be deemed to have a higher risk of bias.

3.3.7 Data synthesis and analysis

Studies were grouped into randomised controlled trials (RCTs), cohort studies and pre-post intervention studies. Other than for readmission rate, meta-analysis of outcome data could not be performed due to lack of data, heterogeneity of data and method of reporting outcome. To synthesise discrepancy rate resolution and healthcare utilisation data, the positive and negative outcomes were compared narratively with the appraised risk of bias of each study defining the weight given to findings

Meta-analysis of readmission data was performed by calculating the Mantel-Haenszel risk ratio (RR) and 95% confidence intervals (CI). As interventions in the included studies varied, it was thought that there would not be one "true" effect size, therefore a random effects model was used within the Cochrane Review Manager (RevMan) V.5.3 software to synthesise results by constructing a Forest plot. (Cochrane Collaborations, 2014) For studies that reported outcomes over different durations, the longest follow-up period for which all data was presented was used for analysis. Statistical heterogeneity was assessed by calculating τ^2, x^2, I^2 and p values. Publication bias was evaluated by construction and inspection of a funnel plot.

3.4 Results

The 2017 electronic database search identified 2104 citations with four more identified from the reference lists of included studies. After removal of duplicates, 1610 citations remained. Following title and abstract review, 157 publications underwent full text review. Fourteen studies met the inclusion criteria. [Figure 3.1]

The 2020 search identified an additional 1170 citations. Follow removal of duplicates, title and abstract screening and full text review, one further study was included in the systematic review. [Figure 3.2] This meant a total of 15 studies were included.

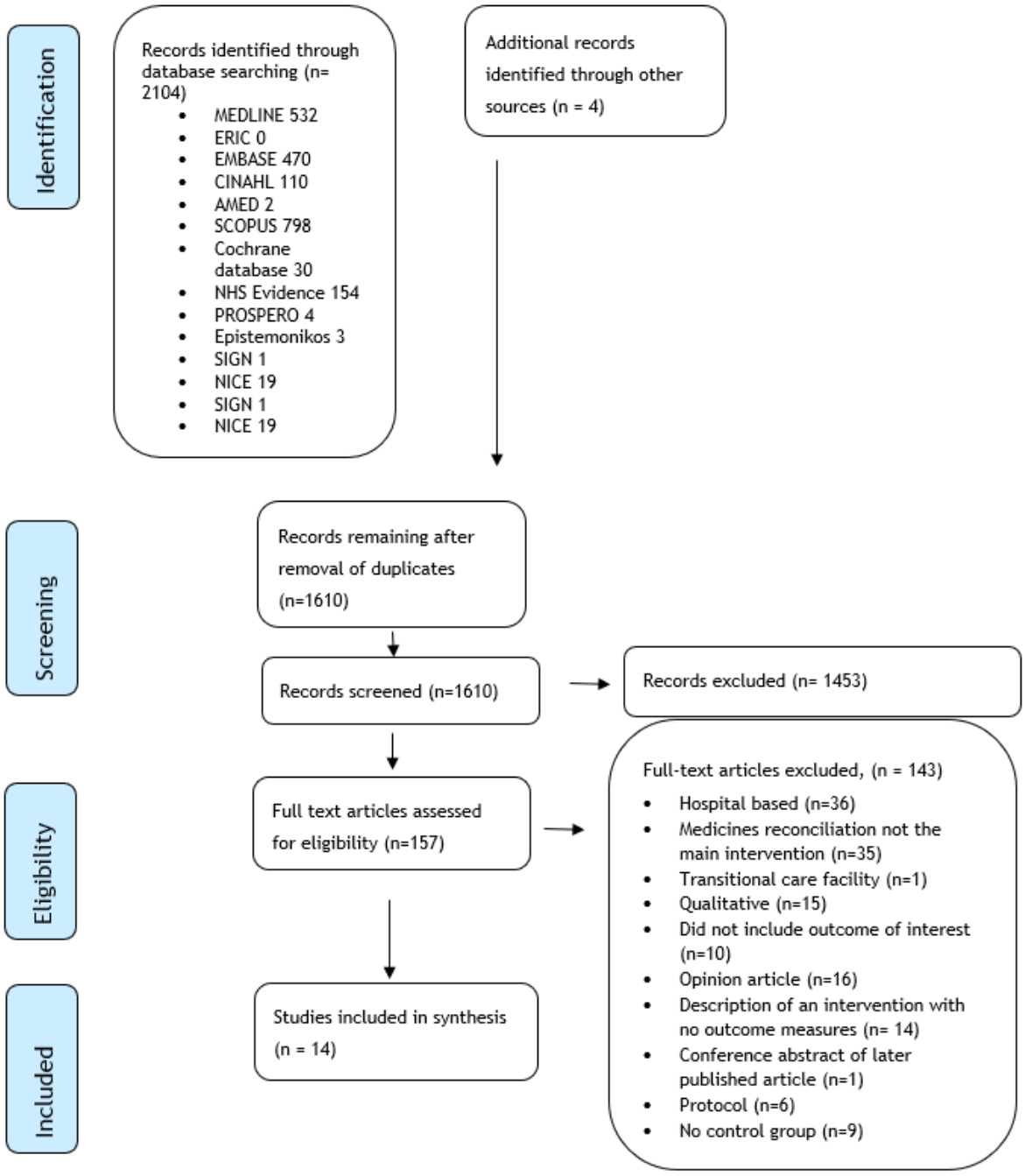

Figure 3.1 – PRISMA flow diagram of selection of eligible studies for Systematic Review – original search 1/9/17. NICE, National Institute for Health and Care Excellence; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; AMED, Allied and Complementary Medicine Database; ERIC, Education Resources Information Center; CINAHL, Cumulative Index to Nursing and Allied Health Literature

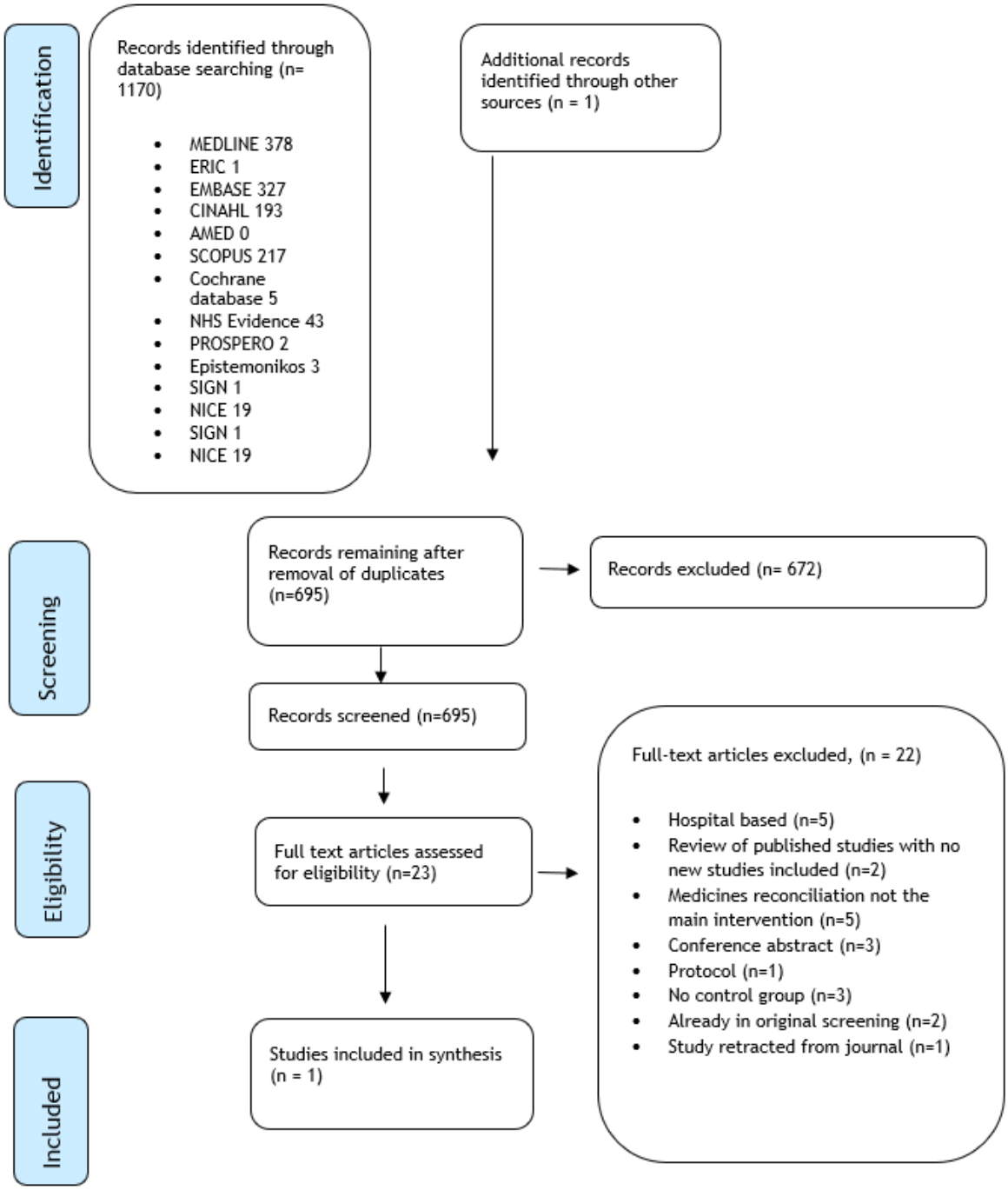

Figure 3.2 – PRISMA flow diagram of selection of eligible studies for Systematic Review – updated search 5/12/20. NICE, National Institute for Health and Care Excellence; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; AMED, Allied and Complementary Medicine Database; ERIC, Education Resources Information Center; CINAHL, Cumulative Index to Nursing and Allied Health Literature

3.4.1 Characteristics of included studies

Five of the included studies were Randomised Controlled Trials (RCTs), seven were cohort studies, two were pre-post intervention studies and one was a quality improvement project that presented a run-chart detailing pre-post intervention data.[Table 3.2] The study added after the 2020 search was a retrospective cohort study (Lapointe-Shaw *et al.*, 2020). Two studies (Nazareth *et al.*, 2001; Holland *et al.*, 2005) were deemed to have a low risk of bias. Although they were not blinded, both studies were RCTs and described robust randomisation techniques to intervention or control group who otherwise received similar care. All significant results were presented and treatment effects were reported in a precise manner. Nine studies were deemed to be of moderate risk of bias (Duggan *et al.*, 1998; Boockvar *et al.*, 2006; Setter *et al.*, 2009; Kilcup *et al.*, 2013; Ho *et al.*, 2014; Hawes *et al.*, 2014; Shcherbakova and Tereso, 2016; Tedesco *et al.*, 2016; Lapointe-Shaw *et al.*, 2020). RCTs in this group had less robust randomisation (Duggan *et al.*, 1998; Hawes *et al.*, 2014), had low numbers (Hawes *et al.*, 2014) and were unable to account for all patients who entered the study (one (Duggan *et al.*, 1998) reported a large dropout rate and another (Hawes *et al.*, 2014) had several patients who were unable to be reached by telephone for follow up). Cohort studies in this group had robust methods to select controls and presented relevant data in a precise manner (Boockvar *et al.*, 2006; Setter *et al.*, 2009; Kilcup *et al.*, 2013; Shcherbakova and Tereso, 2016). Four studies had a high risk of bias (Gray, S. *et al.*, 2008; Zeitouni *et al.*, 2014; Polinski *et al.*, 2016; Vuong *et al.*, 2017). These studies had less robust methods for assigning patients to intervention or control groups (Gray *et al.*, 2008; Polinski *et al.*, 2016) or did not present all information on group allocation (Zeitouni *et al.*, 2014; Vuong *et al.*, 2017).

Sample sizes ranged from 61 patients (Hawes *et al.*, 2014) to 134,326 (Lapointe-Shaw *et al.*, 2020). The largest sample size was from the study added after updating the systematic review in 2020. This was a retrospective cohort study comparing outcomes for those who had undergone MedsCheck review. This is a Canadian government funded

scheme that had been running for several years. Although there are multiple components to the MedsCheck scheme, the included study specifically targeted patients discharged for medication reconciliation and this appears to be the main activity undertaken and therefore this study was included.

Interventions varied by the patient group targeted, the setting within which they were completed and the timing and number of contacts. Most studies targeted those considered at higher risk of readmission either through age (Nazareth *et al.*, 2001; Holland *et al.*, 2005; Gray *et al.*, 2008; Tedesco *et al.*, 2016) or presence of a long-term condition (Setter *et al.*, 2009; Hawes *et al.*, 2014). Five studies evaluated medication reconciliation undertaken by the pharmacist in the patient's home (Nazareth *et al.*, 2001; Holland *et al.*, 2005; Setter *et al.*, 2009; Kilcup *et al.*, 2013; Shcherbakova and Tereso, 2016) whereas in three studies medication reconciliation was performed with the patient at a primary care clinic appointment (Ho *et al.*, 2014; Hawes *et al.*, 2014; Tedesco *et al.*, 2016). In one study, medication reconciliation was completed by telephone (Zeitouni *et al.*, 2014) and in another reconciliation was performed either at a home visit for those with high risk of medication related problems, or by telephone for those with moderate risk (Polinski *et al.*, 2016). Two were set in nursing homes (Boockvar *et al.*, 2006; Vuong *et al.*, 2017) and one in a community pharmacy (Duggan *et al.*, 1998). In two studies medication reconciliation was completed in the absence of the patient (Duggan *et al.*, 1998; Gray *et al.*, 2008).

In seven studies patients were contacted once, (Boockvar *et al.*, 2006; Setter *et al.*, 2009; Kilcup *et al.*, 2013; Hawes *et al.*, 2014; Zeitouni *et al.*, 2014; Shcherbakova and Tereso, 2016; Vuong *et al.*, 2017) in two studies twice (Holland *et al.*, 2005; Ho *et al.*, 2014) and in three studies the number of contacts varied dependent on patient preference and perceived need by pharmacists (Nazareth *et al.*, 2001; Tedesco *et al.*, 2016; Polinski *et al.*, 2016). Medication reconciliation was completed two days before hospital discharge to the nursing home in one study (Vuong *et al.*, 2017). Six studies contacted the patient within the first week of discharge (Boockvar

et al., 2006; Kilcup *et al.*, 2013; Hawes *et al.*, 2014; Zeitouni *et al.*, 2014; Tedesco *et al.*, 2016; Polinski *et al.*, 2016) and four in the second week (Nazareth *et al.*, 2001; Holland *et al.*, 2005; Ho *et al.*, 2014; Shcherbakova and Tereso, 2016). In seven studies, pharmacists discussed outcomes of medication reconciliation with other team members such as the GP or nursing staff (Nazareth *et al.*, 2001; Gray *et al.*, 2008; Hawes *et al.*, 2014; Zeitouni *et al.*, 2014; Shcherbakova and Tereso, 2016; Tedesco *et al.*, 2016; Polinski *et al.*, 2016) whereas in four, a written report was produced for other clinical staff (Holland *et al.*, 2005; Setter *et al.*, 2009; Kilcup *et al.*, 2013; Ho *et al.*, 2014).

3.4.2 Effectiveness of identification, resolution and clinical relevance of discrepancies

The identification and resolution of discrepancies by pharmacists completing medication reconciliation was compared to usual care in four studies (Duggan *et al.*, 1998; Gray *et al.*, 2008; Setter *et al.*, 2009; Hawes *et al.*, 2014). In all four studies, rates of identification and resolution were greater in the intervention group although all four had a moderate or high risk of bias. [Table 3.3]

Two studies compared the clinical relevance of resolved discrepancies between intervention and control groups and suggested that there was the potential for fewer adverse drug events after pharmacists had completed medication reconciliation (Duggan *et al.*, 1998; Boockvar *et al.*, 2006). [Table 3.3] Seven studies described the type of discrepancy found when pharmacists perform medication reconciliation (such as drug-drug interaction identified) but did not describe the clinical relevance (Setter *et al.*, 2009; Hawes *et al.*, 2014; Zeitouni *et al.*, 2014; Polinski *et al.*, 2016; Vuong *et al.*, 2017).

3.4.3 Healthcare utilisation

Healthcare utilisation was reported in thirteen of the included studies. The different outcome measures reported included: readmission rate at one,

three, six and 12 months, emergency department attendance and additional GP and secondary care consultations.[Table 3.3] Four studies (three of which were considered to have a moderate risk of bias and one had a high risk of bias) reported a statistically significant reduction in readmission rate (Hawes *et al.*, 2014; Zeitouni *et al.*, 2014; Polinski *et al.*, 2016; Lapointe-Shaw *et al.*, 2020). One study with a low risk of bias reported an increase in readmission rate (Holland *et al.*, 2005). Data from eight studies were included for meta-analysis. One study was excluded as only admissions related to myocardial infarction or coronary re-vascularisation were included, (Ho *et al.*, 2014) another as the number of days hospitalised (rather than readmission rate) was reported (Setter *et al.*, 2009) and three more were excluded as they did not report numbers of patients re-admitted (Boockvar *et al.*, 2006; Zeitouni *et al.*, 2014; Vuong *et al.*, 2017). One of these (Zeitouni *et al.*, 2014) reported a reduced readmission rate whereas the others (Boockvar *et al.*, 2006; Vuong *et al.*, 2017) reported no change. Two studies reported readmission rates over different time scales (Nazareth *et al.*, 2001; Kilcup *et al.*, 2013). In one study the longer time scale was used in the meta-analysis (Kilcup *et al.*, 2013). The shorter time frame was used in the second study as the composite readmission rate over the longer time frame was not clear (Nazareth *et al.*, 2001). The pooled risk ratio across all included studies (total number of patients = 2336) was 0.91 (95%CI 0.66 to 1.25) indicating no clear effect on re-admission rate. [Figure 3.3] There was a high degree of statistical heterogeneity. As few studies were included, I^2 is the most suitable statistic for assessing the impact of heterogeneity. An I^2 value of 71% and p=0.002 was calculated indicating high heterogeneity (Higgins and Thompson, 2002).

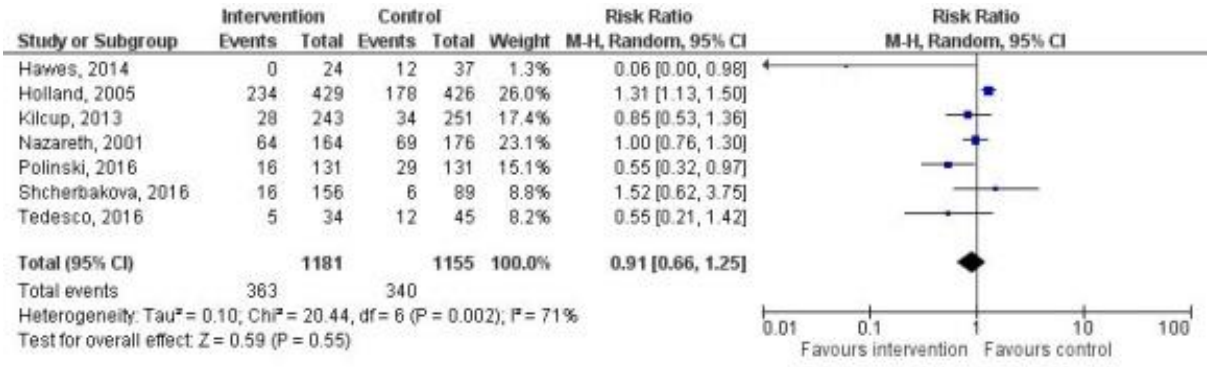

Figure 3.3: Forest plot of intervention effects on the proportion of patients with all cause readmission. Diamond represents pooled estimate of relative risk calculated using Mantel-Haenszel random effects model and 95% confidence intervals. Squares represent study weighting and horizontal bars represent 95% confidence interval.

Emergency department attendance rate was measured in four studies (Hawes *et al.*, 2014; Shcherbakova and Tereso, 2016; Vuong *et al.*, 2017; Lapointe-Shaw *et al.*, 2020). No difference was observed between intervention and control groups in three studies (Shcherbakova and Tereso, 2016; Vuong *et al.*, 2017; Lapointe-Shaw *et al.*, 2020) whereas in one, a large reduction was found, this was a small RCT with a moderate risk of bias. (Hawes *et al.*, 2014) In subgroup analysis, one study found a reduction in emergency department attendance for patients in whom a new high-risk medication had been started (Lapointe-Shaw *et al.*, 2020).

Two studies (Holland *et al.*, 2005; Lapointe-Shaw *et al.*, 2020) reported an increase in outpatient doctor appointments (including GPs) in the intervention group (one study rated as low risk of bias, the other moderate risk), another reported no significant difference in GP attendance (low risk of bias) (Nazareth *et al.*, 2001). Two studies reported that a pharmacist completing medication reconciliation had the potential to free up clinical time for other healthcare team members. One reported that two hours of pharmacist time freed three hours of nursing time and one hour of physician time (Vuong *et al.*, 2017) and the other stated that planned and unplanned physician visits were reduced. (Setter *et al.*, 2009) Three studies reported

the mean time taken to complete medication reconciliation by pharmacist (Nazareth *et al.*, 2001; Ho *et al.*, 2014; Vuong *et al.*, 2017). This varied from 1 hour 27 minutes (Nazareth *et al.*, 2001) to 3 hours 51 minutes (Ho *et al.*, 2014) per patient.

3.5 Discussion

The international scientific literature was systematically reviewed to evaluate the effectiveness of pharmacist-led medication reconciliation performed in the community after hospital discharge. Pharmacists were more effective at identifying and resolving discrepancies compared to the usual care process. Meta-analysis did not demonstrate a statically significant reduction in readmission rates and the effect on emergency department attendance and workload of other healthcare team members was rarely measured and no consistent evidence of related benefit was found.

3.5.1 Comparison with previous literature

Previous systematic reviews also reported the ability of pharmacists to effectively identify and resolve discrepancies in community (Bayoumi *et al.*, 2009) and hospital settings (Mueller, S. K. *et al.*, 2012; Kwan *et al.*, 2013; Lehnbom *et al.*, 2014). The clinical relevance of reduced discrepancy resolution has been questioned in studies set in the community as many discrepancies remained after interventions (Bayoumi *et al.*, 2009) and the effect on patient outcomes was not consistent (Nazar *et al.*, 2015), (Setter *et al.*, 2009; Kilcup *et al.*, 2013; Gray, D., 2013; Hawes *et al.*, 2014; Shcherbakova and Tereso, 2016; Polinski *et al.*, 2016; Vuong *et al.*, 2017). The lowest mean time to complete medication reconciliation reported in our included studies was 1 hour 27 minutes (Nazareth *et al.*, 2001). The time taken in usual care processes was never accurately reported. Having more time to perform this task may be the reason why more discrepancies are identified.

Unlike this study, a systematic review and meta-analysis of pharmacist-led medication reconciliation in hospital performed at care transitions

demonstrated a reduction in healthcare use after discharge (Mekonnen, McLachlan, Brien, 2016). One possible explanation is that they included studies with multiple intervention components, such as patient education; follow up telephone call; home visit; medication review; enhanced communication with primary care and the use of strategies to enhanced adherence. In contrast, in this systematic review we included some of these components but excluded those describing a medication review and, as medication reconciliation was performed in the community, infrequently involved interventions to improve primary/secondary care communication. This may reflect the problem of varying definitions of medication reconciliation. The World Health Organisation (WHO) defines medication reconciliation as: "*The formal process in which healthcare professionals partner with patients to ensure accurate and complete medication information transfer at interfaces of care*" (World Health Organisation, 2013). Such a definition may legitimately include all the aspects of interventions described by Mekonnen *et al*. The Joint Commission definition of, "*The process of comparing a patient's medication orders to all of the medications that the patient has been taking*" is more precise and may not include such diverse activities (Joint Commission on Accreditation of Health Care Organisations, 2006). It may be that these additional components are important to influence health outcomes, however, recent systematic reviews of pharmacist completed medication reviews in various settings have failed to show a benefit to patient outcomes (Christensen and Lundh, 2016; Huiskes *et al.*, 2017).

It is reported that roughly half of all discharge communications have been found to contain unintended medications (Kripalani *et al.*, 2012). Performing an accurate medication reconciliation using such a list is unlikely to improve patient outcomes as unintended medications will continue to be prescribed (Holland *et al.*, 2005). However, even when medication is reconciled before discharge and patients are followed up by pharmacists to improve adherence, clinically important medication errors and harm due to medication is not reduced (Kripalani *et al.*, 2012).

3.5.2 Strengths and limitations

The search strategy included several relevant databases, with no limitation placed on date of publication. Broader terms than medication reconciliation were included in the search to incorporate studies reporting medication reconciliation as part of wider interventions. For example, although Holland *et al* describe their intervention as a medication review, we deemed it to be similar enough to our classification of medication reconciliation to be included. Screening for inclusion, data abstraction and quality appraisal was independently completed by two reviewers to enhance study rigour.

A systematic method using the CASP tools was used to assess bias and quality. Although designed for use in RCTs and cohort studies these were adapted to assess the quality of Quality Improvement (QI) projects and pre-post intervention studies. This led to these studies being treated as having a higher risk of bias. Several of the included studies were described as pilot projects (Gray *et al.*, 2008; Hawes *et al.*, 2014) or QI projects (Kilcup *et al.*, 2013; Zeitouni *et al.*, 2014; Vuong *et al.*, 2017) and require more robust evaluation of their findings to determine if they are replicated at scale or in different settings. Included studies were generally of low to moderate quality and susceptible to bias, which means the positive outcomes reported in this systematic review must be treated with caution.

The study has several limitations. Some studies that would have been valuable in answering our questions may have been excluded as their focus of intervention was not on medication reconciliation *per se* (Crotty, Maria *et al.*, 2004). One study evaluated a community liaison pharmacist intervention but was based in hospital and so was excluded (Bolas *et al.*, 2004). Healthcare settings vary and findings from different countries may not be comparable. For example, studies were set in North American primary care services run by large organisations often with links to hospitals that may blur the lines between primary and secondary care (Ho *et al.*, 2014;

Zeitouni *et al.*, 2014). Others involved home care services that may not be present in other areas (Setter *et al.*, 2009).

The meta-analysis of data from studies reporting readmission rates was limited to studies that reported similar outcomes; however, this approach may still be open to challenge. A high level of heterogeneity was identified with possible reasons including: different study designs, settings, intervention components, outcome definitions and follow-up periods. This means that it is difficult to draw definitive conclusions from the meta-analysis other than to say that there is currently no firm evidence that readmission rate is reduced. Meta-analysis of other outcome measures was not possible due to heterogeneity of reported outcomes. For example, discrepancy identification rates were reported as number of discrepancies per drug prescribed (Duggan *et al.*, 1998); number of patients in a study who had a discrepancy (Hawes *et al.*, 2014); full or partial implementation of the patient plan (Gray *et al.*, 2008) and the number of discrepancies resolved (Setter *et al.*, 2009)). Despite the inclusion of a wide range of study type, publication bias may still influence results as demonstrated by asymmetry of the funnel plot. [Figure 3.4] Of note, the smallest study showed the largest positive effect (Hawes *et al.*, 2014). It may be that smaller projects with less robust methods that did not show a positive effect were not published.

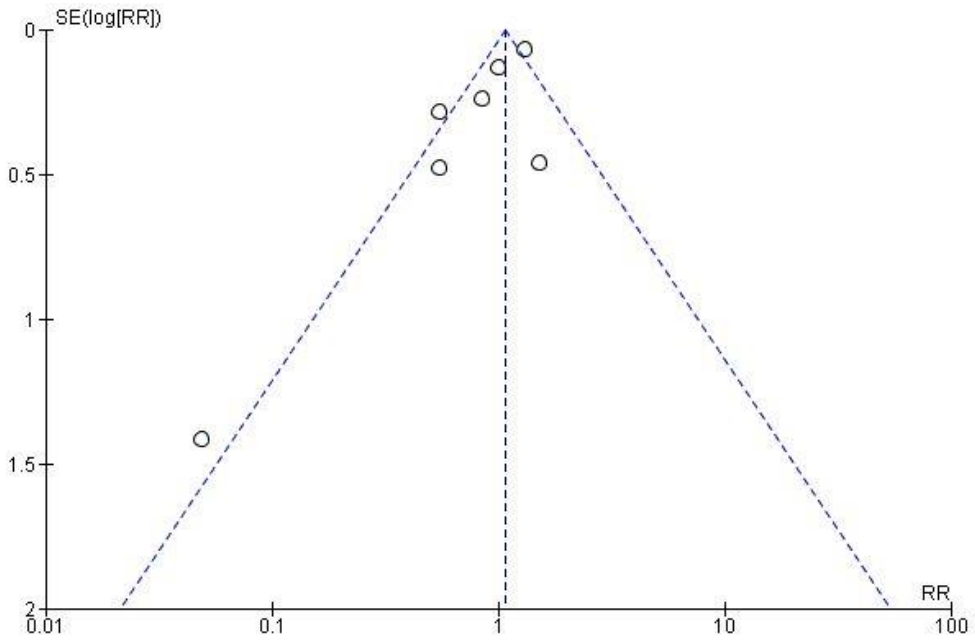

Figure 3.4: Funnel plot of standard error of risk ratio versus risk ratio

3.5.3 Implications for future policy and research

The lack of effect on patient outcomes raises the question of what role the pharmacists should play post-discharge. Patients are at a high risk of harm due to medication following discharge and the involvement of pharmacists seems a logical step to reduce the risk of harm (Forster *et al.*, 2005). Despite this, there is a paucity of high-quality studies investigating pharmacist-led medication reconciliation post-discharge and the few that do exist do not provide conclusive evidence of benefit. At present, pharmacist completed medication reconciliation post-discharge cannot be promoted to reduce harm and improve health outcome. Future research must do more than evaluate process measures such as discrepancy rate detection and focus on evaluating the clinical relevance of resolved discrepancies such as potential or actual adverse drug events. This may be more resource intensive as clinical review of notes is required to make judgments on clinical relevance (Duggan *et al.*, 1998; Boockvar *et al.*, 2006; Kripalani *et al.*, 2012). In addition, the development of an agreed taxonomy of discrepancies would be beneficial to aid process evaluation of such

interventions and understanding of discrepancy relevance and why it occurs (Almanasreh, Moles, Chen, 2016). Of note, the included studies failed to include patient reported outcomes, such as impact on quality of life, as outcome measures. This is something that should be considered in future research.

The lack of improvement in patient outcomes may be less important to policymakers and frontline clinical teams if reduction in workload pressures improves performance in other areas of primary care such as face-to-face clinical care or administrative tasks such as laboratory test results handling. High levels of workload are perceived as a major safety concern in UK general practice and one of the main policy drivers of pharmacist role development is to free clinical and administrative time for GPs (Bell *et al.*, 2016). The effect of pharmacist-led medication reconciliation on these related systems has not been studied previously and further research is clearly needed.

3.6 Conclusions

This systematic review has shown that pharmacists can identify and resolve discrepancies while completing medication reconciliation after hospital discharge; however, the clinical relevance of these discrepancies has rarely been reported. The evidence does not support a reduction in readmission rates and there is not consistent evidence that other measures of healthcare utilisation, such as emergency department attendance and GP appointments are reduced.

3.7 Implications for thesis

While the systematic review demonstrates that pharmacists can safely complete the task of Medication Reconciliation, several questions remain to be answered which will be explored later in the thesis.

Firstly, the systematic review does not demonstrate the impact of pharmacists performing Medication Reconciliation as part of their new roles that consists of numerous, varied tasks.

In addition, the systematic review did not describe the impact on workload either for the pharmacist or within the GP practice. The reported time to complete one medication reconciliation task (from one and a half to nearly four hours) seems unfeasibly long and is unlikely to reflect the time available for this task when performing the numerous pharmacy roles envisaged in the new GP contract.

Due to lack of information in included studies, the factors that influence the impact of pharmacist are not explained by this systematic review. The exact mechanism of GP and pharmacist interaction was rarely explained and so the importance and most effective method for collaborative working is not clear. Many of the included studies suggested that robust methods for communication were needed (Holland *et al.*, 2005; Gray *et al.*, 2008; Shcherbakova and Tereso, 2016). This mirrors findings from qualitative studies of GPs and pharmacists where report writing was considered adequate for simple medicines reconciliations, but face-to-face discussion was required for complex cases (Rathbone *et al.*, 2016). Pharmacists also valued face-to-face feedback on their work when learning new roles and integrating into a primary care team (Dey, de Vries, Bosnic-Anticevich, 2011). The proximity of working was thought to help collaborative working as was a mutual understanding of training and roles, mutual respect and flexible attitudes (Farrell *et al.*, 2008; Bradley *et al.*, 2008; Tan *et al.*, 2014; Rathbone *et al.*, 2016).

The rest of this thesis will explore pharmacists working in GP practices to understand the impact on the quality (for example, safety and effectiveness) and workload of pharmacists completing the multiple tasks required in of their new roles.

A multiple Case Study approach will be used to explore how pharmacists work and why they work in that way to understand how the positive impact of pharmacists working in GP can be optimised.

Chapter 4 Philosophical considerations

4.1 Overview of chapter

The systematic review has demonstrated that pharmacists are capable of successfully completing medication reconciliation, but study reports did not include sufficient contextual detail to determine what factors influenced the impact of pharmacists on quality and workload.

The next four chapters describe the approach used to explore these factors in depth. The way that these Chapters link together is summarised in Figure 4.1. [Figure 4.1]

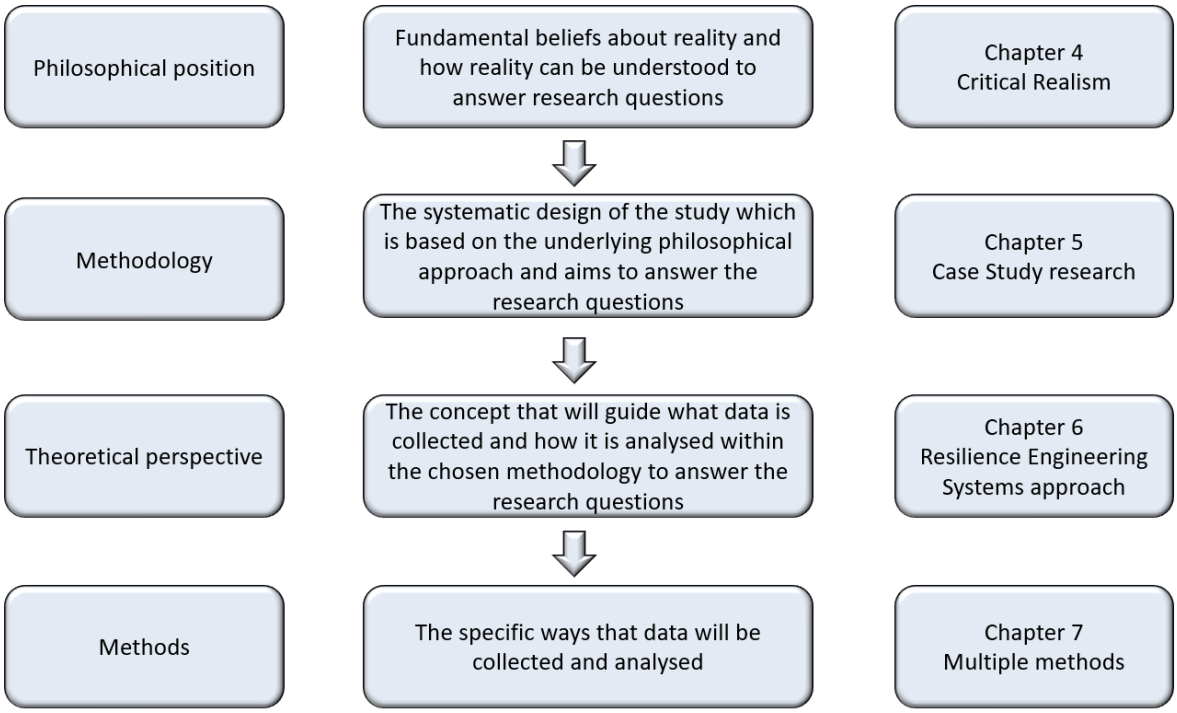

Figure 4.1 - Representation of content of chapters 4-7 and how these are linked to provide research strategy

Researchers' ontological and epistemological positions influence how they conduct their research including choice of methodology (for example the decision to use quantitative, qualitative, or multi methods approaches) and application of theorical perspectives (Crotty, Michael, 1998).

This chapter will therefore describe the philosophical foundations of this thesis to explain researcher beliefs about reality and how reality can be understood. The Critical Realist approach that was adopted will be described in detail. These beliefs influence the choice of methodology. Case Study methodology builds on the described philosophical approach to help answer the research questions and will be described in Chapter 5. Within Case Study research a 'systems approach' was used to direct data collection and analysis and this will be described in Chapter 6. Finally, Chapter 7 will describe the exact methods for data collection and analysis that were directed by the systems approach within a Case Study methodology.

This chapter will consider the influence of ontology and epistemology on the research and describe the philosophical position, Critical Realism, that guided this thesis. It is set out as follows:

- Description of Ontology and Epistemology and how these influence approaches used by researchers.
- Explanation of common approaches of positivism and interpretivism.
- Realism will be described as an alternative approach
- Critical Realism will be described in depth
    - Description of Critical Realism
    - How a Critical Realist approach influences research
    - Criticisms of Critical Realist approaches
    - How a Critical Realist approach will be applied within this thesis

4.2 Ontology and epistemology

Ontology refers to beliefs about the nature of reality and epistemology refers to beliefs about the nature of knowledge, or how we understand that reality. It is important for researchers to carefully consider and describe the philosophical stance of their work as this influences the research questions asked, the data collection methods used and the way data are analysed. Crotty advocated considering four questions (Crotty, 1998). [Box 4.1]

Box 4.1 – Crotty's four questions for researchers to consider when designing research	
Question	Definition of terms in question
What epistemology informs the research?	*Epistemology* determines what kinds of knowledge are legitimate and adequate and so defines the best ways of inquiring into the nature of the world and establishing 'truth'. This is informed by the ontological position of the research and the researcher. Epistemological perspectives include objectivism (reality exists independently of consciousness) and constructivism (truth and meaning do not exist in some external world but are created by the subject's interactions with the world).(Crotty, 1998)
What theoretical perspective underpins the methodology?	*Theoretical perspectives* define how the philosophical stance informs the methodology chosen.(Gray, 2013) Includes positivism (the world is independent of our knowledge of it), post positivism (there is an independent reality to be studied, but that all observation is inherently fallible – we can only approximate the truth, never explaining it perfectly or completely) and interpretivism ('culturally derived and historically situated interpretations of the social life-world').(Crotty, 1998)
What methodology will be employed?	*Methodology* is the strategy linking the methods employed and the outcomes. Methodologies include experimental research, Case Study research, ethnography and grounded theory.(Gray, 2013)
What methods will be used?	*Methods* are the techniques and procedures such as interview, participant observation and questionnaire. (Gray, 2013)

These four interrelated questions help in the design of the research project: consideration of epistemology helps define a theoretical perspective which in turns defines methodology and methods.

The dominant research paradigm for much of the last century has been positivism (Gray, 2013). In positivism, the ontological position is that reality is static and fixed, and the epistemological position is objectivism (that theory can be developed to describe the world accurately). As such, experimental approaches are used in research to discover 'the truth'. This hypothetico-deductive approach directs research design (such as use of a control group) and methods of data analysis (such as confirmatory statistical tests). Whether made explicit or not, this is the approach used in quantitative research methods and is the standard approach for Randomised Controlled Trials.

In contrast, the ontological position of interpretivism holds that reality is subjective and changing, and truth and meaning are created by subjects' interactions with the world (Gray, 2013). This is based on a constructivist epistemology where knowledge is subjective and there is not a single external 'truth' that can be discovered. With this philosophical positioning, different research methodologies are required that focus on understanding. They often use inductive reasoning and meaning is constructed through the researcher-participant interaction. Methods required for this type of approach are usually qualitative such as participant observation, interview and focus groups.

4.3 Realism

An alternative philosophy is that of Realism which has been described as incorporating some aspects of positivist and interpretivist research paradigms (Bhaskar, 1978). Realism as a philosophy has been defined as "the view that entities exist independently of being perceived, or independently of our theories about them" (Phillips, 1987). However, it is not possible to be certain of this knowledge of the world, and alternative

accounts of any phenomenon may be valid. Theories we may have about reality are based on a particular perspective and worldview, and complete, infallible knowledge is not achievable.

Adopting realist philosophical paradigms in social science and health services research is increasing popular, not least due to the popularity of Realist Evaluation and Realist Synthesis (Pawson, R. and Tilley, 1997; Pawson, Ray *et al.*, 2005). These have been promoted as ways to evaluate complex interventions (Realist Evaluation) and to synthesise literature within systematic review (Realist Synthesis). A key feature of any realist approach is understanding how context and mechanism combine to produce outcomes.

4.4 Critical Realism

One of the most influential applications of realism is Critical Realism (Maxwell, 2012). This emerged in the 1970s through the works of the English philosopher, Roy Bhaskar (Bhaskar, 1978). Critical Realism separates ontology and epistemology. Its ontological position is that there is one true reality that exists which is referred to as the 'intransitive dimension' – this is the object of scientific inquiry (what we want to know). From an epistemological perspective, humans cannot fully understand reality and our knowledge of this reality is constantly evolving as we learn more about the object of study. This is referred to as the 'transitive dimension' (our current understanding - thoughts, beliefs, theories) (Wynn and Williams, 2012).

4.4.1 Stratified domains of reality

Bhaskar describes reality being stratified into the 'real', the 'actual' and the 'empirical' domains (Bhaskar, 1978). [Box 4.2]

- The real domain consists of social and physical structures, their causal powers and generative mechanisms.

- The actual domain is a subset of the real and includes all the events produced through the causal powers of structures regardless of whether these are observed.
- The empirical domain is a subset of the actual domain, consists of experiences and is the only domain which we can observe.

Box 4.2 – Critical Realism stratified domains of reality		
Domain	**Description**	**Example**
Real	The generative mechanisms, causal powers and physical and social structures that produce both events and experiences in the actual and empirical domains	The physical structure of the Earth gives rise to the generative mechanism of the Earth's magnetic field
Actual	Events take place whether or not we observe them	The Earth's magnetic field remains in place whether or not we can observe it. For example, some animals can sense this field to direct their migration
Empirical	Events that we can directly or indirectly observe	We may only become aware of the Earth's magnetic field through its observed effects on a compass needle

As we can only observe the empirical domain, there is no way that the existence or nature of reality can be proved or disproved. This stratified ontology is what separates Critical Realism from positivism and interpretivism. It suggests that both positivism and social constructionism approaches are too superficial and anthropocentric (Alvesson and Sköldberg, 2017).

Positivists describe a flat ontology where Humean constant conjunction explains reality with no consideration of the deeper mechanisms that link cause and effect (Wynn and Williams, 2012). Positivism is focused on determining whether an intervention, such as the introduction of pharmacists into General Practice, is a success or not in summative terms based on rejecting or failing to reject the null hypothesis of no difference. It is less concerned with the mechanism that results in success. To understand causality, in Critical Realism you must explore causal powers and generative mechanism.

Interpretivists view reality as being constructed socially through the actions and meaning assigned by humans (Gray, 2013). In this way pharmacists working in general practice may be perceived to be successful because, for example, their personality 'fits in with the team'. The meaning assigned to this results in more work being assigned to the pharmacist. This theory may be constructed following interviews and observations, whereas in contrast, a Critical Realism approach would hypothesize causal factors and mechanisms that enhance integration into the team. These factors may not be known to those interviewed. Critical Realism holds that most aspects of interest are beyond individuals' conceptions and definitions and therefore a socially constructed view of reality may be incorrect (Wynn and Williams, 2012).

4.4.2 Structures, generative mechanisms, events and experiences

Adopting a Critical Realism approach involves attempting to understand more about reality: structures and generative mechanisms. This is achieved by studying experiences and from these considering the generative mechanisms that may have caused the experiences in order to understand more about the social and physical structures of reality.

Structures refers to a "set of internally related objects or practices" (Sayer, 1992). These are the 'real' entities we wish to investigate. In this study these are both physical and social structures defining the interactions of the components of the socio-technical system of pharmacists working in general

practice (including pharmacists, patients, GPs, administrative staff, secondary care, community pharmacies, discharge letters, electronic health records and their interactions).

Mechanisms are inherent within the social or physical structure and can be described as “nothing other than the ways of acting of things” (Bhaskar, 1978). They consist of causal powers or tendencies. Causal powers are the ability to do certain things but not others. Structures may have a number of powers which may or may not be enacted based on specific contextual features. Causal powers produce all possible outcomes whereas tendencies describe what is likely to happen. In this project the interactions between professionals, such as pharmacists and GPs, may have causal powers that influence outcomes. For example, the interactions between GPs and pharmacists may have the causal power to slow processing of tasks but this may not always happen. Similarly, this mechanism may have a tendency to increase safety of the task due to more than one person considering potential safety issues. Mechanisms may or may not have their intended outcomes and not all are attributable to human actions.

A specific activation of a mechanism is termed an event. There may be multiple events, but we are limited in our ability to observe and measure these. This is especially true for complex events where we may need to abstract what happened from observable effects. For example, a pharmacist discussing a task with a secondary care colleague will cause some events that are observed and others that are not. For example, the delay in issuing a prescription may be observed but the effect in secondary care may not.

Experiences are those events that we are able to directly observe. They are therefore a subset of all the events that have occurred and as such many events occur of which we are not aware and which we cannot observe.

Critical Realism adopts an open system perspective where reality emerges from interactions between the layers of reality; however, individual components are not aware of their role in the emergence of outcomes

(Bhaskar, 1978; Danermark *et al.*, 2002; Wynn and Williams, 2012). The properties of a structure (causal powers and tendencies) emerge from the interaction between components of the structures. As these properties are emergent, structures cannot be defined by the characteristics of the individual components.

4.4.3 Causal mechanisms and retroduction

The aim of Critical Realism is to study what we can experience and theorise about the causal powers and generative mechanisms that led to these outcomes and from this, learn about reality. This allows us to generate mid-range theories that explain causal links between structure and outcomes. Mid-range theory is theory that has limited scope but explains a specific phenomenon (Merton, 1967). These theories are developed by analysing data that includes the experiences observed and the perceptions of participants. Theory is built by specifying and describing what elements of reality are essential in order for these experiences to have occurred. Theory and reality are unlikely to ever match perfectly but with more study are likely to become closer over time.

To identify possible causal links a form of inference termed retroduction is employed (Bhaskar, 1978; Wynn and Williams, 2012; McAvoy and Butler, 2017). This is used to identify what reality must have been like for the observed experience to have occurred and involves hypothesising the causal mechanisms between structures and the observed outcome. It differs from other forms of inference such as deduction, where empirical tests attempt to falsify hypothesised relationships, and induction, where all theory is generated from data collected without considering any entities not included within the empirical data (Wynn and Williams, 2012). Existing theoretical mechanisms can be used and adapted to fit the specifics of the case but if none are available, new theory is generated to attempt to explain the phenomenon. The use of existing theory is more correctly termed retrodiction (Wynn and Williams, 2012; McAvoy and Butler, 2017) whereas the generation of new theory to explain causal mechanism is more correctly

termed retroduction, however many authors use the term retroduction to describe both retroduction and retrodiction as they are considered the same logical process (Wynn and Williams, 2012).

4.4.4 Identifying the correct causal mechanisms

Like other forms of Realism, Critical Realism aims to explain the mechanisms through which context influences outcome. Evidence is sought that supports and refutes mechanisms. Mechanisms should be capable of producing the observed experiences and, if this is not the case, the mechanism may be rejected or adapted.

Although contextual factors within the systems of study may be rapidly changing, the search is for semi-predictable causal mechanisms. The studies in this thesis will look for events that occur in a semi-predictable pattern within and between practices. Such events are termed demi-regularities (or demi-regs). These events indicate that a particular causal mechanism with enduring tendencies has been enacted (Lawson, 1997).

4.4.5 Criticism of Critical Realism

Critical Realism has been criticised as it has a tendency to describe the world in objective characteristics whereas a closer look may reveal a more ambiguous view of the world (Alvesson and Sköldberg, 2017). Indeed, qualitative research is often characterised by the attempt to delve beneath objective definitions of the world. One of the first stages in taking a Critical Realist approach is description of the phenomenon. However, this description itself may be highly value laden based on the perception and experience of the researcher (Mingers, 2014). This may in turn influence the causal mechanisms considered and test the validity of retroduction. Retroduction has the potential to generate a proliferation of potential causal mechanisms not all of which are testable, and it is questionable if these can be tested if mechanisms and events are unobservable (Mingers, 2014). A further criticism is the apparently mutually exclusive tenets of Critical Realism that reality both exists independent of people and

dependent on people (as part of the structures). This may be explained through the notion of emergence where reality emerges from the interactions between people but is separate from the actions of individuals (Mingers, 2014).

4.5 Critical Realism and this thesis

This chapter has described the need to define ontological and epistemological positions at the start of a research project as these influence the choice of methodology and the application of theoretical perspectives.

A Critical Realist approach was adopted because it supported the aims of the thesis: to study what pharmacists are doing (observed events) and from this use retroduction to generate hypothetical mechanisms that explain how social and contextual structures influence outcomes (how and why they work this way). These can be compared within and between practices (to identify demi-regularities).

This approach moves beyond simply considering success to be due to the observed event (for example, pharmacists work is successful because they complete a specified number of tasks) or the socially constructed ideas of why pharmacist work is successful (for example, the pharmacists are part of the team). Instead it allows inference from the observed data of how the interaction of many factors generate mechanisms that support success. Critical Realism thinking means we can never be sure of reality, but the more data collected the closer we get. This means that although the hypothesised mechanisms for success may appear correct, they may not apply in different contexts (for example, other practices or a change in type of tasks assigned to pharmacists).

Chapter 5 Case Study methodology

5.1 Introduction

This chapter describes the methodology that was used to explore pharmacists' work in general practice. It describes why Case Study was chosen, potential problems with Case Study research and why, although other epistemological approaches can be used with Case Study research, why a Critical Realism Case Study approach was used in this thesis.

The chapter will comprise of:

- Choice of Case Study – what is Case Study research, why you would use it and the potential problems with this approach.
- How different epistemological approaches can influence Case Study research – positivist approach versus a constructivist approach.
- Critical Realism Case Study Research – why Case Study is a good choice of methodology to support a Critical Realist approach to research.
- How to apply a Critical Realist Case Study approach.

5.2 Choice of Case Study

Case Study methodology has been used in many fields such as sociology (Feagin, Otrum, Sjoberg, 1991), education research (Yazan, 2015), Information Systems research (Tsang, 2014), business and marketing research (Dul and Kak, 2008), psychology (Bromley, 1986) and health service research (Baxter and Jack, 2008). It is used frequently in healthcare to explore, describe and explain specific phenomena. In this thesis, it was deemed suitable for both the topic being studied and the research questions being asked.

Case Study is often used where it is not possible to separate the phenomenon of interest from the surrounding context and when the researcher has little control over the phenomenon as would be the case with experimental design (Yin, 2014). It is not possible to control how

pharmacists work in GP practices. Practices have different systems for performing prescribing tasks including work processes, workload and ways of interacting with other staff, patients and other sectors of healthcare. Case Study allows the exploration of how these factors influence system performance.

Case Study research can be used to understand complex social phenomena and systems (Yin, 2006). One task performed by pharmacists, medication reconciliation, has been described as complex, as it involves many interactions between patients, GPs, pharmacists, administrative staff, technology, other artefacts and different sectors of the health service and as such the boundaries are hard to define. Changes in one component may unexpectedly affect other parts of the system (Bayoumi *et al.*, 2009; Nazar *et al.*, 2015; Pevnick, Shane, Schnipper, 2016). In many published evaluations of pharmacist led medication reconciliation after discharge, ways of working often had to be adapted to fit these local contextual factors (Nazar *et al.*, 2015). Other tasks undertaken by pharmacists are likely to involve similar interactions and components.

Case Study research can be descriptive and explore phenomena, for example to describe the impact of pharmacists working in GP (research question 2) but is often used to propose mechanisms for 'how' and 'why' outcomes emerge (research question 3, 4 and 5). (Yin, 2014)

Alternative research methodologies could have been used to study pharmacists' work, including quantitative and qualitative methods; however, Case Study methodology is most suited to support a Critical Realist philosophical approach.

5.3 Critique of Case Study research

The conceptual design of any research, including quantitative research, is researcher dependent but the technical design of quantitative, experimental studies is often considered more controlled and more 'objective' than qualitative research (Tellis, 1997; Verschuren, 2003).

Qualitative research has several disadvantages that the different methodologies all share. The reliability and validity of data collection and analysis can be questioned due to the subjective nature of these activities (Baker, S., 2012). The questions asked at interview, what data are recorded and how this is analysed is dependent in part on the researcher. Participant observation is considered more researcher dependent than semi-structured interview which in turn is considered more researcher dependent than survey (Tellis, 1997). To minimise the risk of these problems introducing bias into research, applying a theoretical research framework is recommended.

Case Study research has been criticised due to a lack of consensus on the design and implementation of Case Study methodology between researchers (Yazan, 2015). Case Study research has a degree of flexibility which can be useful in that several data sources and analytical approaches can be used (Stake, 1995; Yin, 2014). This flexibility can also be a source of criticism as Case Study methodology may not be considered as rigorous as some approaches such as Grounded Theory (Hyett, Kenny, Dickson-Swift, 2014). Indeed Yin stated that Case Study research is often considered inferior to other qualitative methods (Yin, 2014) This is often due to the absence of a recognised theoretical framework to guide Case Study research (Hyett, Kenny, Dickson-Swift, 2014). In a review of published qualitative Case Study research, key methodological components were often missing: specified study aims and questions, description of paradigm and theoretical perspectives that have influenced study design, detail of the theoretical framework used to plan and conduct the research, why particular cases were chosen (how its study will help answer the research questions) and descriptions of context and binding of the cases and triangulation of data. Many of the studies purporting to be Case Studies were actually ‘case reports’ (Hyett, Kenny, Dickson-Swift, 2014). It has been suggested that the term Case Study is often used inappropriately to add credibility to approaches used by some researchers (Merriam, 2009). Often these are case reports which do not include the methodological details required of a Case

Study. The adoption, description and justification of a particular theoretical and methodological framework is vital.

5.4 Epistemological approaches to Case Study research

Many theoretical and methodological frameworks for Case Study research have been described (Eisenhardt, 1989; Stake, 1995; Merriam, 2009; Yin, 2014). All are similar in how a case is defined and that an iterative, parallel research strategy is adopted. They differ in the epistemological stance of the author- Yin and Eisenhardt hold a more positivist position with Stake and Merriam being more constructivist (Yazan, 2015).

5.4.1 Positivist approach to Case Study research

Several leading authors demonstrate a positivistic approach in their description of Case Study research. One of the most influential Case Study researchers is Robert Yin (Yin, 2014). Yin describes a detailed framework for Case Study research by defining how to do it, what to do and when to do it.

Yin describes developing propositions that combine to form a theory that is to be tested by the Case Study. These are formed from a review of the literature and researcher knowledge of the research matter (Yin, 2014). Research questions should be translated into propositions so that the researcher speculates, on the basis of the literature and any other earlier evidence as to what they expect the findings of the research to be. The data collection and analysis can then be structured in order to support or refute the research propositions (Rowley, 2002).

Similar to Yin, Eisenhardt describes the use of constructs (Eisenhardt and Graebner, 2007). These are similar to the propositions described by Yin and are informed by prior knowledge and literature. They are used to define data collection and analysis but may not be part of the developed theory.

Yin describes methods for data collection and analysis that test propositions. Methods include the testing of rival theories, pattern matching and cross case data synthesis (Yin, 2014). Importantly, Yin states that any

data can be used in Case Study and that the inclusion of quantitative data aids triangulation of data. Yin argues against there being an irreconcilable philosophical disparity between qualitative and quantitative data and states:

> "R*egardless of whether one favours qualitative or quantitative research, there is a strong and essential common ground between the two."* (Yin, 2014)

Yin provides a framework for Case Study research that facilitates an objective approach to data collection and analysis. Yin adopts a deductive approach through testing propositions and theory but he is clear that new theory or themes can emerge. Similarly, Eisenhardt describes using the data collected and analysed based on pre-defined constructs to build theory (Eisenhardt, 1989).

Crotty suggests that three notions are fundamental in positivistic orientation in research: objectivity, validity and generalisability (Crotty, 1998). Yin describes four aspects of Case Study research that are essential for quality and demonstrate his positivistic stance: construct validity, internal validity, external validity and reliability.

- **Construct validity** involves ensuring the correct methods are adopted to explore the concepts being studied with the aim of increasing objectivity. This is achieved by linking data collection to the research questions and propositions.
- **Internal validity** is concerned with establishing a causal relationship whereby certain conditions are shown to lead to other conditions, as distinguished from spurious relationships. This is an essential component in explanatory or causal studies, rather than for purely descriptive studies.
- For generalisation of findings it is important to ensure **external validity.** Yin states that results of Case Studies are generalisable to

theoretical propositions and not to populations as in standard sampling theory.

- The ability of Case Study to produce repeatable results if the same data collection methods are adopted defines **reliability.** For this, thorough documentation of procedures and rigorous recording keeping is required.

Yin believes that the positivist approach provides a firmer foundation for understanding and managing issues such as validity and reliability, and for structuring data collection and analysis.

5.4.2 Constructivist approach to Case Study research

Although Yin and others suggest that Case Study methodology can be used as a theory *testing* process, others believe it should be used as a theory *building* method. They believe that Case Study methodology is based on a constructivist paradigm (Stake, 1995; Merriam, 2009). For constructivists, truth is relative and dependent on the observer's perspective and is built on the premise of a social construction of reality (Searle, 1995). A constructivist paradigm "recognizes the importance of the subjective human creation of meaning but doesn't reject outright some notion of objectivity. Pluralism, not relativism, is stressed with focus on the circular dynamic tension of subject and object" (Crabtree and Miller, 1999). The stories of participants and their views of reality are sought and explored and close working between researcher and participant is encouraged to develop an understanding of the phenomenon.

Stake believes a constructivist epistemology should orient Case Study research since:

> "*Most contemporary qualitative researchers hold that knowledge is constructed rather than discovered*".

He also states that:

> "*There are multiple perspectives or views of the case that need to be represented, but there is no way to establish, beyond contention, the best view*" (Stake, 1995)

Stake does not provide a precise definition of how to conduct Case Study research as it needs to be adaptable for different purposes and in different disciplines (Stake, 1995). Although Stake agrees that an iterative parallel approach to data collection and analysis should be employed, he does not specify how to collect data and when analysis should begin but states this should be based on "impression and intuition". Stake sees research as an interaction between researcher and participant, which is compatible with the constructivist epistemology.

Merriam also agrees that the epistemology that should orient qualitative Case Study is constructivism since she maintains that:

> "*The key philosophical assumption upon which all types of qualitative research are based is the view that reality is constructed by individuals interacting with their social worlds*". (Merriam, 1998)

In the same vein, she describes an ontological view commensurate with a constructive epistemology by stating:

> "*That reality is not an objective entity; rather, there are multiple interpretations of reality*". (Merriam, 1998)

Merriam provides a clear framework on how to collect data to provides a more structured implementation of a constructivist approach. Merriam and Stake both feel that validity and reliability are difficult to achieve in qualitative inquiry since they form part of positivistic tradition. Certainly, the conclusions of a Case Study research need to include enough detail so that the reader can see the logic in the conclusions drawn.

5.4.4 Critical Realism Case Study Research

Although positivist and interpretivist paradigms are more prevalent in Case Study research, Critical Realism has been proposed as a viable philosophical paradigm (Wynn and Williams, 2012). Critical Realist Case Study research has been promoted as a way to understand interactions between components within complex socio-technical systems and explore and explain causal links between empirically observed events and the mechanisms and structures that generated these events (Wynn and Williams, 2012).

Critical Realism has been described as a paradigm that is particularly well suited as a companion to Case Study research as it justifies the study of any situation, regardless of the number of research units involved, but only if the process involves thoughtful in-depth research with the objective of understanding 'why things are as they are' (Wynn and Williams, 2012). Critical Realism focuses on establishing causality within specific structural and contextual settings. This has important implications for the research questions chosen, the cases selected and the generalisability of findings. It is ideally suited to answering 'how' and 'why' questions, that attempt to identify underlying causative mechanisms. In this thesis, how does safety in the system for pharmacists performing medication tasks in a GP setting emerge and how can the evolution of safe systems be optimised?

Critical Realism uses retroduction to infer causality and looks for demi-regs to support proposed causal mechanisms. This may be considered similar to Yin's description of the use of pattern matching and rival explanations. Demi-regs are observed patterns which can support or refute proposed explanations through retroduction (Lawson, 1997).

Yin stated that findings in Case Study research could be generalised to the level of the theory and not to the universe. A Critical Realism approach accepts that the knowledge of those involved in research is subjective but that real structures and processes exist and directs the search for the causal relationship between actions and components and outcomes. Rather than

defining causal relationships through repeated observation and statistical methods (positivist approach) or by explaining the social and cultural meaning of events (constructivist approach), Critical Realism Case Study aims to generate explanations of the causality of events specific to that context. As Critical Realism takes an open system perspective, the exact contextual factors giving rise to any given outcome cannot be specified with certainty. Rather, tendencies for certain outcomes can be postulated based on common structures and contextual factors being present. Theories developed through Critical Realism therefore aim to explain how contextual factors influenced a particular outcome (so are generalisable to the theory generated) rather than predict outcomes based on all possible contextual settings (generalisable to the whole universe).

5.4.5 Application of Critical Realism to this Case Study

Bhaskar describes five stages that are required in any form of Critical Realism research (Bhaskar, 1978):

1. *Resolution* of the event or phenomena into its component parts and their interactions with other parts.

2. *Redescription* of the phenomena to describe how it relates to the concepts or issues of a particular theory.

3. *Retroduction* is the postulation of hypothetical mechanisms that, if they existed, would generate the observed phenomenon.

4. *Elimination* of alternative explanations and attempts to demonstrate the existence of the mechanism by experimental activity or by the prediction of other phenomena or events.

5. *Identification* of the correct generative mechanism from those hypothesised, and from that the development of an explanatory mid-range theory.

These stages have been adapted to generate principles for conducting and evaluating Critical Realist Case Study research (Wynn and Williams, 2012). [Box 5.1]

Box 5.1. Methodological Principles of Critical Realism Case Study research (Wynn and Williams, 2012)
Stages of Critical Realist Case Study
Explication of Events Identify and abstract the events being studied, usually from experiences, as a foundation for understanding what really happened in the underlying phenomena.
Explication of Structure and Context Identify components of social and physical structure, contextual environment, along with relationships among them. (Critically re-described from actor's viewpoint into theoretical perspective.)
Retroduction Identify and elaborate on powers/ tendencies of structure that may have interacted to generate explicated events.
Empirical Corroboration Ensure that proposed mechanisms have causal power and that they have better explanatory power than alternatives.
Triangulation & Multi-methods Employ multiple approaches to support causal analysis based on a variety of data types and sources, analytical methods, investigators, and theories.

These stages influenced the approach to data collection and analysis within this thesis and will be described in depth in the Methods chapter.

5.5 Discussion

A Case Study research methodology was chosen for this thesis as this is the best method to explore 'how' and 'why' questions - 'how' pharmacist work and 'why' they work in that way. . Using a Critical Realist Case Study approach supports the aims of this thesis – to explore 'how' and 'why' contextual factors and mechanisms influence pharmacists' work and from this, to make recommendations to enhance their impact.

Robust Case Study research is supported by the application of a research framework that will be described in the methods chapter (Chapter 7) and by having a theoretical perspective for data collection and analysis. The theoretical perspective adopted in the thesis is described in the next chapter.

Chapter 6 Systems theories and their application to the thesis

6.1 Introduction

The previous chapters have described the philosophical and methodological approaches applied in this thesis, both of which advocate a 'systems approach'. Case Study research involves adopting a holistic approach to study the phenomenon of interest, including the interactions between components. Similarly, Critical Realism approaches explore how outcomes emerge from these interactions. These concepts are key components of 'systems theory'.

The extensive literature on systems approaches can broadly be divided into two separate but linked fields (Cabrera, Colosi, Lobdell, 2008). The first is 'knowledge about systems' which consists of the theories that describe behaviour within systems. The second is the methods and conceptual frameworks that allow the practical application of theories to understand and influence work within systems.

Both of these areas will be covered in this chapter. It will be set out as follows:

- Discuss the types of systems found in healthcare
- Explain the evolution of 'systems thinking' theories
    - From reductionism though General Systems Theory to Complex Socio-technical Systems Theory
- Explore the application of Complex Systems Theory in healthcare
    - Normal Accident Theory
    - High Reliability Organisations
    - Resilience Engineering – as this is the theoretical perspective used in the Case Studies it will be explored in depth.
- Describe the different 'systems thinking' methods used within the thesis.
    - Functional Resonance Analysis Method
    - Systems Thinking for Everyday Work framework

6.2 Systems found in healthcare

A system is “an interconnected set of elements that is coherently organised in a way that achieves something” (Meadows and Wright, 2008). Therefore, a system has a purpose and a set of components that interact to achieve that purpose. [Figure 6.1]

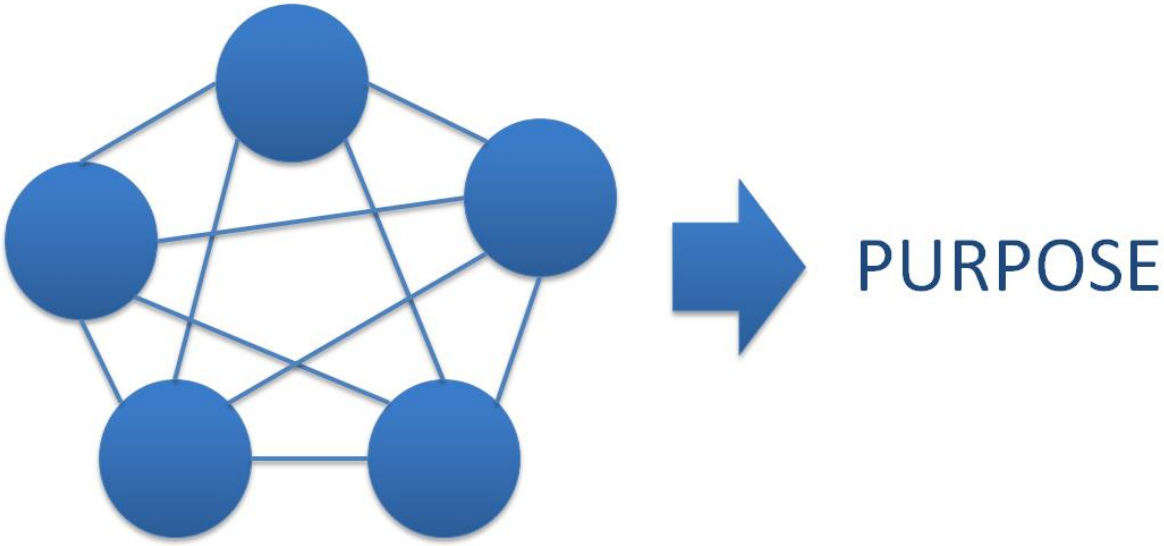

Figure 6.1- Simple representation of a system consisting of components that interact to achieve a purpose.

Although somewhat arbitrary, systems are often categorised as simple, complicated or complex (Glouberman and Zimmerman, 2002). Discussing systems within these terms is useful when considering the types of approaches that are used to understand and improve healthcare systems.

6.2.1 Simple systems

A simple system (for example, a recipe for making a meal) is one that is predictable and the interacting elements (ingredients, cooking equipment, cooking implements and the cook) are simple to understand. Systems are often nested within other systems, therefore, to follow your recipe there needs to be a system to buy ingredients and for that to be successful the

shops require a system to obtain and supply ingredients and so on. Systems interact with other systems: the system to follow your recipe may interact with a system to do laundry as you may delay completing one of the recipe instructions to hang up washing. Nevertheless, these types of systems are generally easy to understand in that interactions between components and resultant outcomes are predictable. It is easy to predict what would happen if one system component, such as the oven, was malfunctioning.

6.2.2 Complicated systems

In complicated systems there are lots of interacting components. Despite this, it is possible to break the system down into its individual components and determine how each works and the effect of that component on the overall performance of the system. Although the intricate workings of complicated systems, such as a jet engine, are likely to be too complicated for most of us to understand, engineers can dismantle this type of system to inspect and analyse the operation of each component. Simple and complicated systems are both predictable and can be understood by considering each component in isolation (so called, reduction). When things go wrong, the faulty element can usually be identified and replaced, allowing the system to return to normal functioning.

6.2.3 Complex systems

The terms ‘complicated’ and ‘complex’ are often used interchangeably; however, there are significant differences when applied to the understanding of systems. Complex systems do not develop or behave in the same way as a complicated system. Rather than being designed, they tend to grow or evolve. In such systems, interactions are not always predictable because they are numerous and can be influenced by feedback from other components and unpredicted changes in conditions. Complex systems are non-linear; small changes in interactions can cause large changes in outcomes. Therefore, these systems can be difficult to break down for analysis and prediction of performance (Hollnagel, Wears, Braithwaite, 2015).

6.2.4 Healthcare systems

Systems in healthcare including General Practice, are described as complex systems (Martin and Sturmberg, 2005; The Health Foundation, 2010; Mid Staffordshire NHS Foundation Trust Public Inquiry, 2013). The Health Foundation (2010) state that the characteristics of complex care systems include:

- a large number of dynamically interacting elements
- any element in the system is affected by, and affects, other elements or systems
- small changes can lead to large effects, due to the non-linear interactions
- it is challenging to define system boundaries
- energy is required to maintain the system organisation
- historical events influence and shape present system function.

General Practice systems contain numerous components whose interactions change rapidly and affect other components in the system (such as, patients, clinicians, administrative staff and the equipment they use). For example, different patient presentations can influence how clinicians respond and the attitude of a clinician may influence how a patient behaves. Small changes to system conditions can cause large changes to outcomes. For example, a small delay in referring or seeing a patient can alter outcome dramatically. Boundaries are difficult to define – the patient journey involves crossing transitions for care from home, GP, nursing homes and secondary care. Systems can be influenced by external factors - an influenza outbreak will increase presentations to GP meaning demand is greater than capacity. This may mean some people with illness are not seen and so their outcomes change. Previous experience alters how people respond; for example, previously seeing a patient with a rare condition may result in clinicians testing for this condition repeatedly. The system has guidelines and evidence-based processes, but unlike the example above of a complicated system, the jet engine, complexity means there is never a fully

specified 'manual' for system design that can be followed or used to identify the causes of problems.

6.3 Development and application of systems theories in healthcare

When studying and improving healthcare systems it is often recommended to take a 'systems approach' as this may improve the ability to understand current work processes, predict system behaviour and design modifications to improve related functioning (Leveson *et al.*, 2009; Mid Staffordshire NHS Foundation Trust Public Inquiry, 2013; Arnold and Wade, 2015). Different approaches have been used that derive from different theoretical backgrounds.

6.3.1 Scientific Management Theory

Many organisational approaches to improving healthcare performance have been modelled on methods originating in industry. Their origins lie in Scientific Management Theory which was developed by Fredrick Winslow Taylor at the end of the 19th century (Taylor, F. W., 1911). Taylor was a mechanical engineer (and previously a machinist in a steel factory) and developed a method where, rather than skilled workers controlling the process of production, management assumed control. Systems were reduced into component parts and the tasks involved. These tasks were analysed and defined, and people were matched to these tasks and trained how to perform that task in order to improve efficiency. This led to the evolution of manufacturing into large scale factories using production line manufacturing.

Scientific Management Theory adopts a 'complicated system' or reductionist approach as it implies that a system can be understood by breaking it down into its component parts and overall function can be improved by improving the functioning of each component.

Many current methods to understand and improve performance in healthcare, including cyclical audit methods such as Plan, Do, Study, Act (PDSA) cycles, are based on this philosophy (Taylor, M. J. *et al.*, 2014).

Tasks are defined, performance measured, changes implemented and performance re-measured to demonstrate improvement of that particular task. Priorities for improvement strategies often come from management or national strategy in a top-down manner similar to Scientific Management Theory. Humans become a component of the system that can be improved. Training and protocols are implemented to reduce variation of performance and improve overall efficiency and quality.

There have been successful applications of this approach. For example, in the reduction of infections related to central line insertions (Pronovost *et al.*, 2006). However, the systems within which this improvement intervention was implemented were more understandable and controllable (tractable) than many found in healthcare (Braithwaite, 2018).

Results in healthcare improvement projects are often not as expected due to system complexity. For example, in a study to evaluate the impact of a comprehensive pharmacist review of patients' medication after hospital discharge, the linear perspective suggested that this specific intervention would improve the safety and quality of medication regimens and so reduce healthcare utilisation (Holland *et al.*, 2005). Unexpectedly the opposite result was observed. The authors suggested that this emergent outcome may have been due to the increased number of interactions with different healthcare professionals increasing the complexity of care resulting in increased anxiety, confusion and dependence on healthcare workers.

Analysis of events with adverse outcomes is also based on a reductionist view of performance in systems (NHS England, 2015). In the UK, like many parts of the world, Root Cause Analysis (RCA) is the recommended method for such analysis. At its best, this should take a 'systems approach' to identify latent system conditions that interacted and contributed to the event and recommend evidence-based change to reduce the risk of recurrence. However, the results of such analyses are commonly based on linear 'cause and effect' assumptions and thinking (Trbovich and Shojania, 2017; Card, 2017; Kellogg *et al.*, 2017; Peerally *et al.*, 2017). Investigation

approaches have a tendency to focus on single system elements such as people and/or items of equipment whose performance is considered bimodal: either correct or incorrect. There is less focus on understanding the interacting relationships and dependencies between people and other elements of the system from which safety, performance and other outcomes in complex systems emerge (Peerally *et al.*, 2017). By focussing on components in isolation, proposed improvement interventions risk unintended consequences in other parts of the systems and/or improvement which is limited to the targeted component rather than the overall system.

Different approaches are needed to understand the complexity, dynamism and uncertainty associated with much of healthcare practice (Leveson *et al.*, 2009; McNab *et al.*, 2016; Hollnagel, 2016b). Studying other systems approaches such as General Systems Theory and Complex Systems Theory has allowed the development of methods to explore the characteristics of components within a system and how outcomes emerge from their interactions (Plsek and Greenhalgh, 2001; World Health Organisation, 2009; Peters, 2014).

6.3.2 General Systems Theory

Reductionist approaches were perfectly adequate to understand and improve performance during the industrial revolution. Systems at these times were mainly technical and existed in relatively controllable environments such as factories. As science began to study natural systems, such as living cells and ecological systems, alternative theoretical approaches were needed.

In the 1940s, Ludwig Von Bertalanffy developed General Systems Theory (GST) (von Bertalanffy, 1969). This theory proposed that, contrary to existing scientific methods, systems could not be understood by breaking them down into components parts and studying each part in isolation. Instead GST focused on the structure of systems and understanding the

interactions between components and between the systems and the external environment.

Von Bertalanffy realised that systems were not isolated or 'closed', but instead were 'open' with an inflow and an outflow of compounds that maintained equilibrium. They interacted with their environment both influencing, and being influenced by, the environment. For example, heat can influence living cells and cells can influence the surrounding environment. Von Bertalanffy described systems as being dynamic which means that the system changes how it works in order to keep achieving its purpose when conditions and interactions change. In closed systems, the 2nd law of thermodynamics describes a progressive reduction in order (entropy), however this did not happen in open, natural systems where order seemed to increase, for example, cells could replicate, resulting in increased order and indeed emergence of new properties.

GST proposed that the properties of a system emerge from the interaction of the components. In essence, systems were more than the sum of their parts. This can be taken to mean different things. For example, considering the mathematical meaning of the word 'sum', the output of systems may be considered greater than would be expected by adding up the output of each component. This supports a non-linear view of systems that they cannot be understood by closely examining each individual component. Less literally, this phrase can mean that properties of the system (for example safety and performance) cannot be measured or understood by exploring each component but only by considering the system as a whole.

6.3.3 Complex Systems Theory

By describing GST and the behaviour of open systems, Von Bertalanffy laid the foundations for the development of Complex Systems Theory. Complex Systems Theory was developed in the 1970s and 80s through cross discipline scientific study including biology, chemistry, mathematics and economics (Santa Fe Institute, 2021). The aim was to understand systems which

traditional methods of study had not been able to fully explain. It has been used to describe behaviour of systems such as the brain, immune system, ecology and weather.

GST describes open systems in a steady state with equal input and output, focussing mainly on the physical structure of systems and understanding and predicting interactions. Complex Systems Theory attempts to explain systems situated far from equilibrium, indeed they are often described as existing at the edge of chaos. In such systems it is often not possible to predict future system outputs.

Numerous characteristics of complex systems have been described, some key features are described in Box 6.1 (The Health Foundation, 2010; Kernick, 2018; Greenhalgh and Papoutsi, 2018; Braithwaite *et al.*, 2018). [Box 6.1]

Box 6.1 Characteristics of complex systems

Characteristic of complex system	**Explanation**	**Example in health care**
Open	No clear boundary with external environment	Successful treatment of a patient depends on the healthcare intervention, patient genetics, nutrition, environmental influences and behaviours.
Connectivity	Inter-relationships, interaction and inter-connectivity between system and environment	Treating a patient involves interactions between patients, carers and multiple healthcare practitioners in different settings.
Co-evolution	Adapt to environmental changes – some define complex evolving systems as those that also learn and evolve and attempt to influence their environment.	Services to continue to provide care during the COVID-19 pandemic rapidly adapted based on the new conditions – e.g. the use of telephone and video consulting in General Practice. This in turn influenced how patients accessed healthcare – contacting the surgery later in the day as there was no need to make early contact to ensure they got an appointment.
Sensitive to initial conditions	The same input can result in different outputs due to imperceptible differences	The result for two patients presenting with the same condition could be vastly different due to some small unnoticed difference. This could

	in the initial system – a non-linear response.	include a genetic difference, or a difference in the clinician's fatigue level or previous experience referring to a particular speciality or consultant.
Far from equilibrium	Systems are not at a steady state. This is where there is most variety and creativity	When demand for appointments is much greater than capacity to see patients – new ways of working are adopted to increase efficiency
Emergence	Outcomes are the result of multiple interactions and cannot be described by simple linear thinking. Examples include consciousness emerging from the connections in the brain and the patterns seen when birds flock. The 2nd law of thermodynamics states that systems tend toward disorder, but the opposite is seen in complex systems	Emergent properties of healthcare include safety, efficiency, effectiveness, wellbeing of patients and staff. These emerge from the interactions between components of the systems.
Distributed control	There is no one, controlling component, instead components feedback to influence each other thus 'distributing' control.	The control of systems across healthcare interfaces is distributed between patients, GPs and secondary care teams. If GPs increase referrals (or patients request more referrals), waiting times increase and patients may decline referral or spontaneously get better. If extra clinics are put on in secondary care and waiting lists reduce, there may be increased demand from GPs and patients.
Self-organising	As systems evolve and components adapt to changing conditions, patterns emerge, such as patterns visible in flocking sparrows which arise from simple rules.	Often systems in General Practice, such as communication of lab test results, are not designed but adapt and evolve as personnel, technology, capacity and demand and the evidence base, change.

In essence, the constantly changing environment and interactions results in complex systems persistently evolving and adapting from which patterns of collective behaviour (outcomes) emerge. Outcomes, such as safety, efficiency, effectiveness and wellbeing are described as emergent properties of complex systems. Unlike simple, linear systems (such as

production lines), it is not possible to predict the future performance of complex systems by studying the performance of individual components. A complex system approach studies the properties of the system to understand and influence emerging patterns of behaviour. Where GST described systems as 'more than the sum of their parts', complex systems are different from the sum of their parts.

Socio-technical Systems Theory

As well as being complex, healthcare systems are described as Socio-technical systems (Effken, 2002; Carayon *et al.*, 2011). Such systems consist of interactions between people, tasks, technology, environments (physical, and social), organisational structures and external factors (Carayon *et al.*, 2006). At the core of Socio-technical Systems Theory is the idea that the design and performance of any organisational system can only be understood and improved if the interactions between the 'social' and 'technical' aspects of work are brought together and treated as interdependent.

Socio-technical systems theory was developed through studying human work. One of the earliest was that of miners in 1940s and 1950s which compared two methods of mining (Trist and Bamforth, 1951). In the traditional methods, miners worked alone performing single tasks whereas in the new method, teams of miners worked together and became multi-skilled. Miners working alone often inherited dangerous conditions from previous shifts and had no way of influencing other's behaviour whereas miners working in teams could influence the behaviours of those they worked with making the job safer. As well as increasing safety, improved efficiency and productivity were also seen. From studies like these, the importance of optimising both the technical side of work (the actual mining) and the social side of work (how you influence others to ensure safety) became the main focus of Socio-technical Systems Theory. This was further developed by Carayon who produced one of the most influential models to

describe Socio-technical systems within health care, the Systems Engineering Initiative for Patient Safety (SEIPS). [Figure 6.2]

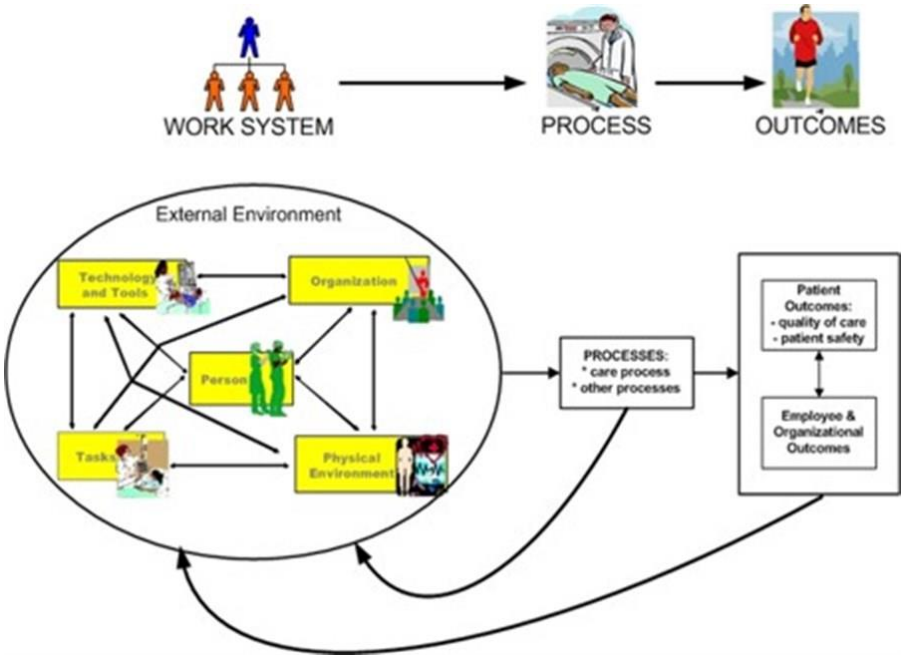

Figure 6.2 – Systems Engineering Initiative for Patient Safety (SEIPS) reproduced from Work system design for patient safety: the SEIPS model Carayon P *et al*. 2006 (Carayon *et al.*, 2006)

The SEIPS model conceptualises the interaction between different aspects of the work system (people, tools and technology, tasks, organisational and the internal environment). From these interactions, processes lead to healthcare outcomes. Although the name suggests its focus is on patient safety, it can be used to explore and understand systems in order to consider any emergent property of the system including effectiveness, efficiency or staff wellbeing.

6.3.4 Application of Complex Systems Theory

The utility of applying Complex Systems Theory within the socio-technical systems found in healthcare has been questioned due the difficulty of practical application and lack of empirical evidence of successful application (Brainard and Hunter, 2016). Adopting a complex systems approach may be used to justify a lack of intervention or design of change

as it assumes some type of natural evolution will occur (The Health Foundation, 2010). Complex systems are often intractable and the outcomes of the many possible paths cannot be predicted. The only way to predict the future is to wait and observe. Small, possibly unrecognised, changes can lead to large changes in outcome meaning that the results from one study are not transferrable.

Over the last three decades, three of the most influential approaches for considering safety and performance within complex systems have been Normal Accident Theory, High Reliability Organisations and Resilience Engineering (Haavik *et al.*, 2019). Normal Accident Theory proposes that unwanted outcomes in complex sociotechnical systems are inevitable (Perrow, 1984) and yet, so called High Reliability Organisations (HRO) (The Health Foundation, 2011), seem to be able to function successfully despite the complexity of their systems. Resilience Engineering considers how systems can be engineered to support continual adaptation to challenges and conditions to ensure optimal functioning.

Normal Accident theory

Normal Accident Theory (NAT) was developed in the 1980s by Perrow (Perrow, 1984). He proposed that it is not possible to maintain control and therefore safety in complex systems. Many unwanted events are unpreventable as the conditions that caused them are unanticipated and therefore cannot be designed out of systems. Such systems are therefore inherently susceptible to accidents, hence 'normal'.

He described two main problems with complex systems: their interactive complexity and the tight coupling of components. Interactive complexity refers to the number and nature of relationships and interdependencies in complex systems.

'Coupling' refers to the levels of dependency between components within a system. Tight coupling means that components are very interdependent and loose coupling means the opposite. In tightly coupled systems a change in

one part of the system can affect other parts and influence the output of the system or its ability to cope with a change in conditions.

In systems with high levels of interactive complexity and tight coupling, signals that appear normal can result in unexpected outcomes such as accidents. 'Negative synergy' describes a non-linear process where the interactions of 'errors' in equipment, design and operator actions result in far more serious outcomes than each would on its own (and would be predicted by linear processes). Although engineers design systems as if they are linear, as interactions increase in number, processes quickly become non-linear. This complexity leads to new and unexpected properties of the system.

The classic example described by Perrow to demonstrate NAT was the disaster at the Three Mile Island nuclear power plant where numerous seemingly inconsequential events led to the nuclear disaster. Perrow argued that it was the complexity of the system that led to the accident and that modern systems are prone to such disasters even if they were designed and managed well. NAT argues that no matter how well the system is designed, conditions and interactions that are unexpected can lead to unwanted outcomes. It proposes that reducing interactive complexity and tight coupling of components is one way to reduce the risks of disaster whereas adding more safety checks may paradoxically increase complexity and the risk of failure.

High Reliability Organisations

Contrary to the view of NAT, certain organisations whose systems have high levels of interactive complexity and tight coupling of components manage to have very good safety records. A group of researchers led by Todd La Porte researched these organisations to understand how they remained 'safe' (Roberts, 1990; The Health Foundation, 2011). This led to the concept of High Reliability Organisations (HROs). This is defined as those organizations that have a high safety record over a prolonged period of time despite

operating in a hazardous environment. The research group studied aircraft carriers, air traffic control and nuclear power operations. Where NAT describes the risks of such systems, HRO offers a potential response to reduce risks of unwanted outcomes.

The work to define and describe HROs advanced the causes of using ethnographic and sociological methodologies to understand complex systems (Bourrier, 2011). Initially accidents and near misses were studied but it became clear to La Porte's team that this was not how frontline teams viewed safety. Instead it was viewed as the presence of certain attributes rather than the absence of accidents. Therefore, they began to study normal operations to understand how operational safety is created and maintained. HROs were found to design systems to anticipate known problems, stop them propagating if they occurred and recover quickly to resume normal operations. They worked closely with frontline staff to understand the nature of work and create operating procedures and contingency plans that reflected frontline work. The aim was to avoid anticipated risks causing unwanted outcomes. Standardising work reduced the need for cognitive processing of information and decision making by frontline staff with the aim to reduce 'errors'

Certain key characteristics were identified that were present in HROs (Roberts, 1990; Lekka, 2011; The Health Foundation, 2011). [Box 6.2]

Box 6.2 – Characteristics of High Reliability Organisations	
Characteristic of an HRO	**Description**
Sensitivity to operations	Anticipation of failure through constant discussion with frontline staff
Preoccupation with failure	Attentive to minor issues, near misses and incidents that may indicate the system's health.
Reluctance to simplify	Rather than simplifying explanations of events where something may have or did go wrong, HROs embrace the system complexity. Events are analysed to understand the system issues involved rather than blaming inappropriately.
Deference to expertise	Input from frontline subject matter experts is essential in deciding how to deal with problems.
Commitment to resilience	Anticipate problems and improvise if there are unexpected conditions
Just culture	Encourage open reporting systems without fear of punishment. Follow up investigations and corrective actions, encourage a sense of personal accountability within all staff.
Learning orientation	Continuous training, open communication of investigations and outcomes, use organisational knowledge base from investigations to update procedures
Mindful leadership	Proactive analysis to identify system problems, bottom-up involvement in analysis and communication of incident, their investigation and outcomes, investment in safety management. Consideration of balancing production and safety
Strategy of redundancy	Not relying on one person to do a task but ensuring people are able to step in when needed and perform tasks.
Operator autonomy	Simultaneously centralise and decentralise decision making – so that subject matter experts can make decisions but the whole organisation can learn from these.

HRO approaches have attracted a lot of attention in healthcare as it is thought that there may be lessons to learn from how other industries cope with complexity (Aboumatar *et al.*, 2017). However, some feel that there

are several problems preventing healthcare from functioning as an HRO (Sutcliffe, Paine, Pronovost, 2017).

- HROs studied are relatively closed systems such as nuclear plants which are not comparable to a hospital never mind healthcare in general. It has been argued that where it may be possible to apply at the level of a department or ward, it is not applicable at the level of a national 'healthcare system' or even a hospital.
- HROs require a culture of trust and respect between management and all levels of frontline staff which may not be present in much of healthcare. The HROs studied were simpler in hierarchical terms, lacking the multiple parallel hierarchies of different disciplines involved in care, and the clash between clinical and non-clinical management and leadership.
- To develop these characteristics in healthcare requires organisational redesign and where this has been successfully applied, large financial investment was required that is not available across health and care.
- The introduction of multiple standard procedures can increase the complexity of the system and can decrease people's flexibility to respond to unanticipated events. Indeed, blindly following rules may sometimes be the more dangerous option. This may be particularly problematic given healthcare complexity and variability.

Part of the HRO characteristic 'mindfulness to operations' is to encourage awareness of potential problems so that the response is timely and appropriate. The problem is how to support and develop the ability of staff to identify and respond to problems.

6.3.5 Resilience Engineering

Background

Resilience Engineering (RE) has many features in common with the HRO approach and has been promoted as another way to improve outcomes in complex systems. Both approaches promote understanding everyday work,

ensuring frontline teams have input into decision making and embracing a just culture. Indeed, commitment to resilience is a key feature of an HRO, but there are differences between the development of these approaches and their definition of resilience (Harvey, Waterson, Dainty, 2019).

HRO was developed as a response to NAT to demonstrate how safety can be controlled despite system complexity (Bourrier, 2011). This consists of ensuring systems are robust to known threats and are able to 'bounce back' from unexpected events. HRO has been described as too simplistic as it does not appreciate the uncertainty involved in complex systems (Leveson *et al.*, 2009). RE developed from a desire to enhance organisational responses when faced with uncertainty such as challenging conditions (lack of information, resources) and competing objectives (Harvey, Waterson, Dainty, 2019). Rather than just being able to 'bounce back', RE aims to design systems that can anticipate and respond flexibly to avoid threats and make the most of opportunities. In this way safety and performance of the organisation will increase. This approach may be more suited when system conditions and interactions are less predictable as may be the case in healthcare.

Definition

In RE, a system is considered resilient if:

> "*It can adjust its functioning prior to, during, or following events (changes, disturbances, and opportunities), and thereby sustain required operations under both expected and unexpected conditions.*" (Hollnagel, 2016)

This is a broader definition of resilience than in HRO as it includes the ability of the system to continually identify changing conditions and adjust functioning in order to optimise performance (Hollnagel and Fujita, 2013). Resilience is considered an emergent property of a system. It emerges from the interactions between components and so cannot be understood by considering components of a system in isolation but only by considering the

system as a whole (Hollnagel, 2011). Therefore, it is not something that can be measured and a system does not 'have resilience'. Rather, resilient behaviours or expressions can be observed and from these it can be inferred that a system has the potential for resilience.

RE is concerned with how we increase (or engineer) a system's potential for resilience. This involves characterising, recognising and supporting resilient performance. To do this, Hollnagel describes four cornerstones of resilience that should be considered (Pariès, 2013).

1. The ability to **respond** to expected and unexpected conditions by adjusting normal working practices to ensure outcomes are still acceptable.
   Knowing what to do.
2. The ability to **monitor** system conditions to identify changes in system conditions such as potential threats to successful working. This includes monitoring for potential changes from within the system (such as identifying reduced resources or missing information) and externally (for example the increase in demand for medical consultations due to an influenza epidemic).
   Knowing what to look for.
3. The ability to **anticipate** the presence and impact of threats and opportunities. This includes the ability to anticipate the outcome of any action taken.
   Knowing what to expect.
4. The ability to **learn** from past decisions and performance of the system. This includes successes and failures.
   Knowing what has happened.

The abilities are linked in that to respond appropriately you must be able to monitor to identify changes and anticipate what these changes mean. To know what to monitor you must be able to anticipate what will happen and have learned from previous events. Responses are also based on what has been learned from previous experience. The ability of a system to respond,

monitor, anticipate and learn defines its potential for resilience and to improve this potential we need to consider how we strengthen these abilities.

Others have suggested slightly different frameworks. For example, Berg and Aase describe the categories of anticipation, sense making, trade-offs and adaptations (Berg and Aase, 2018). Hollnagel would argue, however, that trade-offs are so ubiquitous that they cannot define resilient strategies. To monitor and respond appropriately is, in essence, adaptation and sense-making can easily be seen as the ability to learn from events and so 'make sense' of the current situation.

Safety-I and Safety-II

The term Safety-II has been used as a way to popularise and describe RE approaches in an accessible way (with traditional safety approaches being termed Safety-I) (Hollnagel, Wears, Braithwaite, 2015). There are three major differences between a Safety-II (RE) approach and other safety and performance approaches.

First of all, RE and Safety-II focus on everyday work and how it usually goes right rather than focussing on when it goes wrong. Traditional approaches to understanding safety performance of systems are to examine how safety is destroyed or degraded. Rarely do they explore how safety is created and maintained. Therefore, they study the absence of safety rather than studying safety. RE questions the validity of focusing on relatively infrequent, unwanted events as it does not always reveal how wanted outcomes usually occur and may limit our learning on how to improve care. Indeed, in systems that have very low rates of events with unwanted outcomes (such as HROs) safety can become 'invisible' (Weick, 1987). Instead, RE aims to study events both with wanted and unwanted outcomes i.e everyday work.

Secondly, RE and Safety-II aims to explore and attempts to reconcile the difference between *Work-as-Imagined* and *Work-as-Done*. *Work-as-Imagined*

is how those who do not do the job think it is performed and how it may be documented in guidance, protocols and procedures. *Work-as-Done* is the way people who do the job actually have to work in order to get the job done.

Often workers need to make adjustments in how they work by identifying and reacting appropriately to changing conditions. Staff may face unanticipated problems such as large numbers of patients, limited information being available, lack or malfunction of equipment and unexpected time pressure. Guidelines and protocols are often available, but work systems are rarely fully specified to deal with all possible conditions. A 'standard' way of completing tasks may have evolved as systems, technology and personnel change but not documented in written procedures.

Lastly, RE and Safety-II adopt a complex socio-technical systems approach. In complex systems conditions change constantly and all possible changes will not have been predicted. When faced with such conditions staff must adapt their usual approaches. These adjustments result in performance variability.

Adjustments include trade-offs and workarounds. Trade-offs are when people need to make a decision and have to consider different and competing priorities. One well known type of trade-off is the efficiency thoroughness trade-off. Examples would include signing prescriptions that are not on the patient's normal 'repeat' list without reviewing the patient or dealing with problems through telephone consultation when it may have been best practice to see and examine the patient (Hollnagel, 2009). Other trade-offs include short term versus long term goals (for example, treating pain but with risks of long-term medication side effects), financial versus efficacy trade-offs (for example, using a cheaper medication that is less effective).

Workarounds are used when people do not have all the information or equipment that they require. For example, prescribing a small quantity of medication until information on whether it should be continued is obtained.

A key tenet of RE is that both wanted and unwanted outcomes (success and failure) arise from the same sources; this is termed equivalence (Hollnagel, Wears, Braithwaite, 2015). System outcomes (safety, productivity and 'quality') emerge from the interaction of system components all of which exhibit performance variability found within everyday work. Most of the time system outcomes are effective and the adaptations that people need to make result in good outcomes. Occasionally the same approximate adjustments in performance that result in successful outcomes, do not have the desired effect and result in adverse outcomes.

RE recognises that the adaptive capacity of professionals is a key factor in continued successful work. The performance variability they demonstrate is essential to cope with varying conditions, however, this variability can also lead to unwanted outcomes. In complex systems, components can be closely coupled; therefore, performance variability of coupled components can combine. Small variations in one part of a system can combine with small variations in other parts of the system. These variations often cancel each other out but can also compound each other resulting in larger variation in outcomes which can cause both unexpectedly good and unexpectedly bad outcomes.

Difference between a Safety-I and a Safety-II analysis

Safety-I approaches were designed for use in linear, predictable systems. In healthcare settings orthodox Safety–I approaches typically attempt to quantify and analyse incidences of patient harm (or incidents that had the potential to lead to harm). Errors are normally seen as arising from technology malfunctions, organisational problems or so-called 'human error'. Humans are seen as another (potentially problematic) component of the system that can either function correctly (i.e. by following protocols

and guidelines) or incorrectly (by deviating from defined practice). It is presumed that if we ensure that all components of a system, including the humans, perform reliably as defined in protocols then nothing will go wrong.

A linear systems approach may describe these deviations from 'normal' practice as the cause of the event but a complex socio-technical systems approach recognises that these deviations are often 'normal practice' and are essential for successful functioning. System functions are not bimodal, separated into 'functioning' or 'malfunctioning'. Everyday performance is—and must be—flexible and variable. While some adverse outcomes can be attributed to failures and malfunctions, others are best understood as the result of coupled performance variability.

Resilience depends on local autonomy, creativity and willingness to act flexibly. In this way variation stops being something that we need to engineer out of systems, but something that organisations need to understand, support where beneficial and learn from. RE involves adopting a complex systems approach by considering what influences the work within the system, how ways of working have evolved and how outcomes emerge from the interactions of system components exhibiting performance variability. The aim is to understand and support appropriate adaptive behaviours. [Box 6.3]

Box – 6.3- Difference between a Safety-I and a Safety-II analysis	
Safety-I analysis	**Safety-II analysis**
Analyses one event with an unwanted outcome	Analyses events with wanted and unwanted outcomes – everyday work
Deep analysis of specific event	Prioritises breadth before depth – considers other events where there was a wanted outcome
Uses linear thinking to look for 'root causes'	Considers the adaptations that people need to make to cope with the conditions they face. Analyses how these combined and how outcomes emerged.
Tries to eliminate variability	Explores variability – where it is useful (and therefore supported) and where it is unhelpful (and should be damped).
Specifies work with increased regulation and protocols.	Recognises that performance variability is essential for success in varying conditions (Resilience)

Applying RE to healthcare: Resilient Health Care

The application of RE to healthcare has been termed Resilient HealthCare (RHC). RHC has been the subject of several books and concerns the ways in which healthcare systems can be designed to support people and teams to proactively create safety and improve performance in their everyday work. It has been suggested that RE is a particularly useful approach in systems that require a high level of human adaptation such as healthcare (Martinetti *et al.*, 2019).

The books have evolved as the field of RE has matured. The first book brought together those with an interest in this topic to describe and define resilient healthcare, arguing that it is a useful concept in the complex systems found in health care (Hollnagel, Braithwaite, Wears, 2013). It discussed that no industry has managed to successfully balance the need for safety, production and the ability to adapt to different conditions (Amalberti, 2013). For example, while air traffic management was very safe, it had lost its adaptability and while the fishing industry may be highly

productive and be able to adapt to changing conditions it is not as safe as other industries.

In this book, RE was very much a descriptive rather than an applied approach. Studies were included that described resilient behaviours in different setting, such as how people adapted their approaches to challenges. One of these studies, set in an intensive care unit, (Paries *et al.*, 2013) reported that resilient behaviours were more likely in certain staff groups. Doctors were the most likely to adapt behaviour and deviate from normal practice; however, this often required them to convince other professionals (for example nurses) to implement such advice.

The second book focussed on the work of frontline clinicians to describe everyday clinical work or *Work-as-Done* (Wears *et al.*, 2015). Again, this book contained descriptive studies. One example is the 'secret' second handover when paramedics handed-off patients to Emergency department staff (Sujan, Spurgeon, Cooke, 2015). A protocol was in place for handovers; however, the method was not thought fully effective and so as the paramedics left the Emergency department, a second handover with nursing staff occurred where other vital information (such as relevant psychosocial history not included in usual hand over protocols) was relayed. This was described as a resilient behaviour as actions that deviated from *Work-as-Imagined* were used for the benefit of the patient.

A study of inpatient diabetes care presented the Concepts for Applying Resilience Engineering (CARE) model (Ross, Alastair and Anderson, 2015). This model was used to describe resilient behaviours and why they were needed, focussing on how people adjust their actions based on a mismatch between demand and capacity. Rather than just describing resilient actions, this study began to look at how RE can be used to improve care.

The third book argued that there is a need to close the gap between *Work-as-Done* and W*ork-as-Imagined* and introduced some thoughts on how we can train people to understand and develop resilient behaviours (Hollnagel,

Wears, Braithwaite, 2016). The theme of the book was that it is not possible for frontline workers to follow all the guidance available to them and it is not possible for those removed from frontline work to understand all the pressures on staff. Rather than one or the other being correct, it sought to increase understanding of the problems that the gap between the two descriptions of work can cause and to provide examples and guidance on how to reconcile the two standpoints.

In one chapter, five Case Studies were compared to explore aligning *Work-as-Done* and *Work-as-Imagined* in different Emergency departments (Braithwaite *et al.*, 2016). It stated that "cross-fertilisation of viewpoints, ideas and understanding" was needed between people in different parts of the system to begin to understand system functioning from the perspectives of others in the system.

The book includes other suggestions for training people to be able to act in a resilient manner. Resilient behaviours are described as developing due to experience of dealing with problems regularly but infrequently enough for people to learn from these events (Cook and Ekstedt, 2016). Indeed learning from specific events is thought to increase the ability to not only respond to the same event but to similar events. In this way a repertoire of resilient behaviours is developed and refined. Ways to enhance such learning may be to include the use of serious gaming and simulation to allow people to explore the consequences of various actions (Ricciardi and De Paolis, 2014).

While being theoretically attractive, guidance and examples of how to enhance RHC has been lacking (Ellis *et al.*, 2019). The fourth volume entitled "Delivering Resilient Health Care" focussed on how to implement RHC (Hollnagel, Braithwaite, Wears, 2019). It used Cases Studies to give guidance on what data to collect and how to analyse it with a view to implementing change in frontline healthcare to improve the potential for resilience.

This book promoted the use of Case Study research methodology using different types of data to improve triangulation. The emphasis was often on qualitative data but quantitative data could also be used. One study used this approach to examine maternity care and used the four cornerstones of resilience as a framework for data analysis (Heggelund and Wiig, 2019). Another study presented so-called 'Resilient narratives' that were compound descriptions that were created to demonstrate resilient behaviours emerging under a particular theme (Anderson, J. *et al.*, 2019).

In addition to these books, Resilient Health Care has been the subject of several reports published in peer reviewed journals including a systematic review (Iflaifel *et al.*, 2020). This review included projects published in journals and book chapters and found that the main factors supporting the implementation of RHC were:

- Team working – communication, leadership, work structures
- Practical experience
- Exposure to diverse views and perspectives on the patient's situation
- Trade-offs
- Use of protocols to define variability
- System design to support resilient behaviours
- Workarounds

This review suggested that future study needs to consider resilient behaviours across system levels. Rather than focusing on frontline activities, the effects of behaviours elsewhere in the system including other parts of frontline care and at organisational levels needed to be studied.

Critique of RE

It has been suggested that relying too much on resilient behaviours can be detrimental to system functioning. (Wears and Vincent, 2013) Resilient behaviours may be used to achieve everyday success where a more considered and structured response would have been more beneficial. For

example, using workarounds to make up for a lack of information of equipment prevents system learning and improvement to provide these resources. This has three main problematic results.

Firstly, resilience is only needed because reliability is poor and workers are so used to coping without the correct information or resource and adapting to surprises that they become conditioned to ignoring warnings. They may continue to vary actions resulting in what has been termed ‘drift into failure’. In these situations, small changes in work processes are accepted as normal and acceptable, further small changes are then required to cope with changes in conditions. This continues until the work processes are very far from expected and may be more and more likely to lead to unwanted outcomes (Dekker, 2011).

Secondly, relying on resilient behaviours may also lead to frustration, cynicism and burnout as system problems are not fixed.

Lastly, local resilient actions may be globally maladaptive. This may mean that organisations inadvertently rely on resilient actions. Managers may not be alerted to system problems because people are using workarounds to ensure that the system continues to function. This may give management a distorted view on the ‘health’ of the system as everything seems to be working well. Additionally, this may deflect focus to frontline workers and teams if something does go wrong.

To implement Resilience Engineering, we cannot rely on local and immediate (so called ‘first order’) problem solving. This needs to be accompanied by ‘second order’ problem solving that looks to identify and rectify deeper system problems such as resource or information availability. Despite this, much of the published guidance on developing resilient behaviours in frontline workers focusses on training and experience (Ellis *et al.*, 2019). Berg et al 2018 identified that the RE literature often focuses on the micro system (e.g. frontline workers and their actions) rather than

considering how their actions are inextricably interlinked across the complex layers of systems found in healthcare (Berg and Aase, 2018).

Resilience Engineering in healthcare has been seen as antithetical to many established methods for process improvements. Existing Quality Improvement (QI) methods often seek to reduce variability in process with the aim to improve quality. Some have proposed that healthcare is already full of innovation and risk taking and that more standardisation would be beneficial (Amalberti, 2013). When designing and improving healthcare systems, the goal should be to comply with standard ways of working in some areas and only use resilient behaviours when needed (although this may be a considerable amount of the time). As QI is so firmly embedded in healthcare, attempts have been made to demonstrate how RE can support QI and a guide has been published to help QI practitioners use RE to take a complex systems approach to improving healthcare (Anderson, J. and Ross, 2020). This describes four stages where RHC approaches need to be considered: project set-up, capturing *Work-as-Done*, describing resilience in everyday work and choosing interventions and outcome measures.

It is also worth considering that improvement efforts may be affected by the resilient behaviours people employ. Changes may be resisted by people using workarounds to maintain current ways of working. On the other hand, effects of improvement interventions may be inflated. People may adapt how they are working resulting in increased effects that are due to adaptation rather than the implementation of the improvement intervention. This may reduce the success of interventions spread to different settings.

6.4 Methods to study complex systems

There are a number of methods that can be used to support the adoption of a 'systems approach' to studying and improving complex systems. Some of which will be used in this thesis. These will be summarised below to explain why and how they are used.

6.4.1 The Functional Resonance Analysis Method (FRAM)

The Functional Resonance Analysis Method (FRAM) is a method developed from RE that is one way to study and model complex socio-technical systems (Hollnagel, 2012). RE argues against the value of modelling system components and their interactions as this form of reductionism is unhelpful in complex systems. Instead, the FRAM models potential relationships between, and influences on, 'functions' which are defined as activities or sets of activities required to produce a certain outcome. This is achieved by identifying six specific aspects of each function: input, output, preconditions, resources, controls and time factors. [Box 6.4]

Box 6.4 – Functional Resonance Analysis Method - Aspects of the function 'Review prescribing task'

Aspect	Description	Example
Input (I)	What the function acts on or changes and starts the function	Patient next on task list
Output (O)	What emerges from the function - this can be an outcome or a state change	Prescribing task has been reviewed
Precondition (P)	Some condition that must be met before the function can start	The prescribing task has been sent to the pharmacist
Resources (R)	Anything (people, information, materials) needed to carry out the function or anything that is used up by the function	Information from hospital
Control (C)	Anything that controls or monitors the function	Protocol or guideline
Time (T)	Time constraint that may influence the function	Need to complete before going to next practice

A key principle of the FRAM is that everyday work is modelled. This must be achieved through observation and/ or discussion with those that do the work. As RE focuses on how people adapt how they work to cope with the condition faced, the FRAM explores the variability of function outcome. Again, this can be assessed in a number of ways such as quantitative analysis of function outcome, observation or reporting of differing outcomes.

Once this model is constructed it is then possible to consider how performance variability of coupled functions can affect system outcomes. In some instances, variability in one function will damp down variability in other functions, but occasionally they will cause larger than expected effects. This may result in unexpected wanted or unwanted outcomes. This has been termed ‘functional resonance’ which has been defined as, “the detectable signal that emerges from the unintended interaction of the everyday variability of multiple signals” (Hollnagel, 2012). It is based on the idea of stochastic resonance which occurs when a nonlinear input is superimposed on a period modulated signal that is normally weak to produce a detectable signal. In the FRAM, variability in several functions can combine to produce a result that can be detected either as a positive or negative outcome. [Figure 6.3]

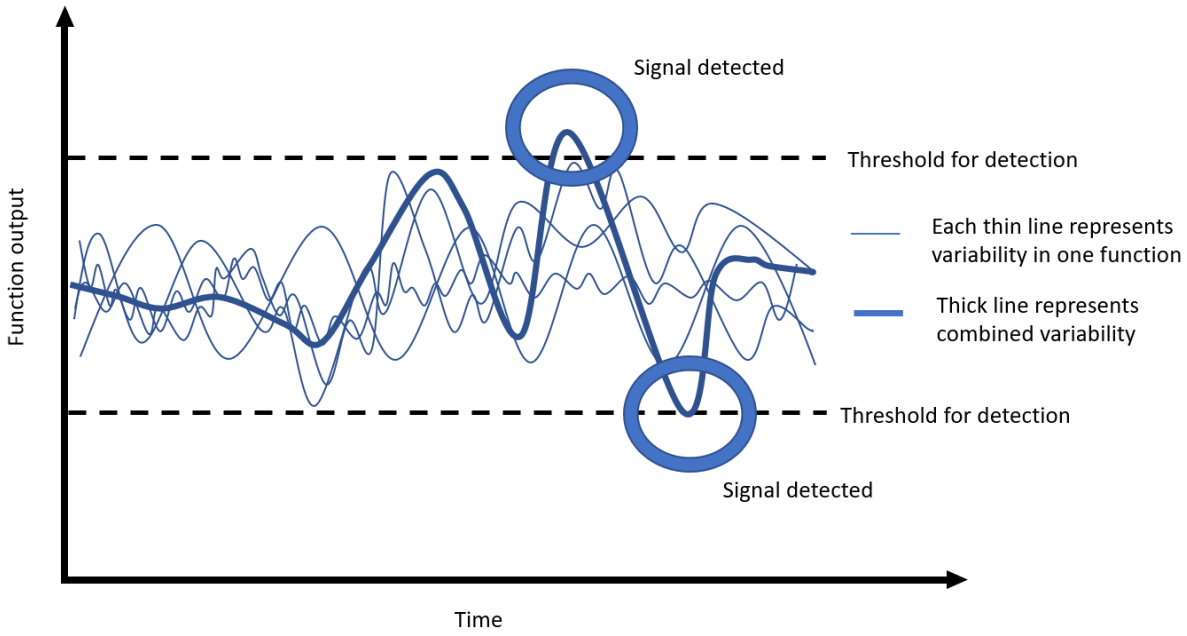

Figure 6.3 - Representation of how compound variability in function outputs can result in signals that can be detected – these can be positive or negative outcomes.

The crucial point of FRAM and RE is that everyday work is studied to model all possible linkages; actual interactions are only understood by considering particular events (or instantiations). There are a tremendous number of possible instantiations based on how the variability of function outputs interacts. Outcomes, both wanted and unwanted emerge from these interactions in variability (i.e. emerge from everyday work). The same functions can interact to cause different outcomes due to the combination of variability in interacting functions – equivalence.

The FRAM has been used in healthcare to prospectively study systems to plan implementation of guidelines (Clay-Williams, Hounsgaard, Hollnagel, 2015), to reconcile improvement suggestions with everyday work systems (McNab *et al.*, 2020) and to investigate episodes where something has gone wrong (Healthcare Safety Investigation Branch, 2019).

6.4.2 Systems Thinking for Everyday Work (STEW) framework

The Systems Thinking for Everyday Work (STEW) framework was specifically designed for use within primary healthcare. It was adapted from principles published for air traffic management (EUROCONTROL, 2014) by frontline primary care healthcare professionals and safety experts. (McNab *et al.*, 2020). It incorporates some of the approaches of General Systems theory, Complex Systems Theory and Resilience Engineering. The framework does not provide a method or a way to model systems, but instead consists of six interlinked principles that can direct enquiry such as team discussions or data collection and analysis.

The STEW framework is used to explore everyday work: how people work, what factors influences everyday work, how people adapt based on the system conditions they experience and how ways of working lead to outcomes. .

Each principle is described below and the application of the STEW framework to direct data collection and analysis is explained in depth in chapter 7.

The *Foundation concept e*xplains that the system as a whole should be studied rather than individual components to identify and explore the overall purpose of the system. This is a key principle of any systems approach as is the need to *Seek Multiple Perspectives.* People, at all organisational levels and regardless of responsibilities and status, are the local experts in the work they do. It is necessary to explore with them how they achieve success.

To understand system functioning, it is essential to explore how *conditions of work* influence the way people undertake work at any given time. Again, this is common to all systems approaches. Conditions of work include:

- **Demand** – includes patients' need for information, appointments and treatment and the staff need to complete work in a certain time.

- **Capacity** – the care system's ability to meet demand.
- **Resources** – everything that is required to perform a work function.
- **Constraints** – guidelines, protocols and limits on capacity that restrict decisions and actions either positively or negatively.

The *interactions and flow of work* influence how work is done and the outcome of work. Interactions between people, tasks, equipment, environments (e.g. physical, social, organisational) and external influences (e.g. national policy, regulatory obligations) are complex and dynamic and affect flow of work and care system performance and human wellbeing (e.g. patients and staff). This is a key component of Complex Systems Theory.

Resilience Engineering describes how people must continuously adapt how they work to achieve a successful outcome based on their own goals and the system conditions they face. From the interaction of this variability, both wanted and unwanted outcomes emerge. This *performance variability* should be explored to understand how it can be developed and performed safely.

Through consideration of these principles the aim is to *understand why decisions made sense at the time.* People do what makes sense to them based on the system conditions and interactions and their personal goals experienced at the time.

6.4.3 Other methods that adopt a complex systems approach

Many other methods to explore performance in complex socio-technical systems have been used in healthcare. For example, AcciMaps is a method used in accident analysis that graphically represents the interaction between different contributing factors. Rather than focussing on blame, it looks at the flow of events that occurred and the interaction between factors at different levels, for example from government policy to local equipment provision (Waterson *et al.*, 2017).

System-Theoretic Accident Model and Processes (STAMP) is another accident causation model and is closely related to the Systems-Theoretic Process Analysis (STPA) which is a hazard analysis method. Both adopt a complex system approach (Leveson *et al.*, 2003). In these models it is accepted that human adaptation is constant but also that pressures on systems (such as the pressure to be cost effective or high levels of demand) results in adaptation pushing work further from the envelope of safe practice. This can lead to a 'drift into failure'. These models view safety as a control problem. This means that work processes will evolve over time, but system design needs to ensure that these changes are controlled so that safety is maintained as performance evolves over time to meet the challenges faced.

6.5 Systems Thinking, Critical Realism and Case Study

The use of Critical Realism, Case Study methodology and a Systems Thinking theoretical perspective provide a congruent approach within this thesis.

Critical Realism requires an exploration of empirical data from which the researcher works backwards to explore the mechanisms that link context and structure with outcomes – in this way getting closer to understanding reality.

Case Study provides the perfect methodology to explore 'how' (what mechanisms are at play) and 'why' things happen (what influences those mechanisms) and therefore supports a Critical Realism approach.

To fully explore 'how' and 'why' things happen, and therefore how mechanisms lead from contextual factors to outcomes, a Systems Thinking approach is crucial to identifying and the factors that influence the interactions between components in a system.

6.5.1 Complex Socio-technical Systems and Critical Realism

If a Critical Realism standpoint is adopted, a Systems Thinking approach to research is essential to explore the mechanisms by which relationships between system components (structures and context) lead to outcomes.

Critical Realism and System Thinking have been described as 'developing around the same set of concepts and yet not realizing it' (Mingers, 2014). There are similarities in how causality is considered. Bhaskar recognises the distinction between closed and open systems where the former allows constant conjunctions of events to define causality whereas in the later a different way of understanding causality is needed (Bhaskar, 1978).

In Critical Realism, the aim is to study real events and from these identify causal mechanisms for what is observed and the physical and social

structures that can enact these mechanisms. Bhaskar describes ‘synchronic emergent powers’ where mechanisms combine to show the link between observed events and physical and social structures.

In Complex Systems Theory, system properties and behaviours emerge at a system level due to the structure of relationships between components rather than being ‘caused’ by one component or action (Checkland, 1981). The emergent properties of a system are properties possessed only by the entity as a whole, not by any of its components or the simple aggregation of the components.

In Critical Realism, the aim is to study real events and from these identify causal mechanisms for what is observed. Mechanisms have causal powers defined by the physical and social structure of the system and tendencies to produce certain events. The FRAM models real events (functions), the factors that influence these activities and how this can lead to both wanted and unwanted outcomes. Functions, or combinations of functions, may be considered mechanisms that result in outcomes and are influenced by contextual factors.

Functional resonance may offer a useful explanation for the causal tendencies of mechanisms. The output variability from different functions can combine to cause a variety of events that we can observe – both wanted and unwanted outcomes – but may tend to produce certain outcomes.

One of the key tenets of Safety-II is equivalence – that the same processes within a system are responsible for both positive and negative outcomes. To understand reality, you must explore these mechanisms through observation of the empirical reality. This must include both good and bad outcomes in order to gain as much knowledge of experiences and events to develop theory of mechanisms and structure.

6.5.2 Complex Socio-technical Systems and Case Study

Case Study research explores 'how' and 'why' things happen. This requires a systems perspective to fully understand the influences on decisions and actions.

Case Study research supports a Complex Socio-technical Systems approach by advocating the study of a phenomenon of interest by exploring interacting components and how outcomes emerge from these.

Pharmacist work in general practice is an example of a complex socio-technical system. There are many interactions between many people (pharmacists, patients, administrative staff, GPs, community pharmacy, secondary care professionals and pharmacy leaders) and technical components (electronic health records, hospital records, prescribing systems and guidance). Success is not dependent on one task being performed correctly, rather the interactions of many processes (for example medication review or reconciliation, communication to patient and other healthcare providers, compliance with medication regimes, other disease processes) will determine the outcomes that emerge.

These systems are open to outside influences which can affect work – a patient's daughter being on holiday may reduce the effectiveness of information transfer between patient, hospital and the pharmacist. Conditions – such as demand and capacity can change rapidly and unpredictably. It is likely systems have evolved to cope with these challenges. Exploration of these systems through a Case Study approach will aim to identify ways to increase the positive impact of pharmacists working in GP.

6.6 Justification of Systems Thinking theories and methods in this thesis

Applying a systems perspective within this research project was essential to support a Critical Realist Case Study methodology. Within Systems Thinking, Resilience Engineering appears a useful theoretical perspective to guide

data collection and analysis. This is because the aim is to understand how pharmacists work, why they work in that way and how does this achieve success. It is crucial that a system perspective is used to understand what influences their work, how their actions influence other parts of the systems and how ways of work emerge that help achieve positive outcomes.

Chapter 7 Methods

7.1 Introduction

Now that the philosophical and methodological approaches have been explained, this chapter will describe the methods that will be used to answer the research questions.

7.2 Case Study Theoretical Framework

For robust Case Study research, a theoretical framework should be used to design the project (Yin, 2014) Yin offers the most comprehensive framework and states that the following needs to be described: unit of analysis (the 'case'), selection of cases, use of propositions/constructs, data collection, logic linking data collected to propositions/constructs (within case analysis), and criteria for data interpretation (cross case data analysis). As discussed previously, Yin adopts a positivist approach to Case Study research by developing and testing propositions and theory. Others have used constructs to direct data collection and analysis within constructivist approaches to build theory. This study uses a Critical Realist approach and Yin's framework has been adapted for this study protocol.

7.3 Unit of analysis

Cases have been defined as "a phenomenon of some sort occurring in a bounded context" (Miles and Huberman, 1994). For Stake, the case is "a specific, a complex, functioning thing" more specifically "an integrated system" which "has a boundary and working parts" and purposive (Stake, 1995). The case may be bound by time and place (Cresswell, 2003) or by time and activity (Stake, 1995). An essential feature of Case Study research is that a holistic approach is adopted to study the case as a whole rather than examining one small part or component.

The unit of analysis for this study was the pharmacist performing prescribing tasks within a General Practice setting. The components of the system under study consisted of all staff in the practice and anything they used to

complete their work such as computer hardware and software, hospital letters and electronic case notes. The boundary was not limited to the practice - external interactions were studied including with community pharmacies, nursing homes and secondary care.

7.4 Selection of cases

Case Study research can involve a single case or it can look for similarities and differences between multiple cases. Although studying single cases can be informative, multiple Case Study is thought to increase the analytical power (Campbell, 1975) and increase generalisability of results (Ragin, 1992). A comparative multiple Case Study approach was adopted in order to create a rich theoretical framework of the impact of pharmacist implementation and how this was achieved.

When multiple cases are studied, purposive theoretical sampling is conventionally used to select the final set of cases (Eisenhardt, 1989). Cases were chosen that demonstrated interesting or unusual features whose exploration helped answer the study questions (Merriam, 1998). Theoretical sampling means that the theory being developed by analysis of the data in the first case directs the choice of subsequent cases. Thus, in Case Study design, theoretical sampling of cases is based on replication logic rather than sampling logic (Yin, 2014). As with the design of repeated experiments the aim is to determine if initial findings are replicated in other contexts. Cases are selected to determine if they confirm the findings of the first case (linear replication) or test predictions of contrasting results for specified reasons (theoretical replication). Other qualitative research methods, such as Grounded Theory or ethnography, use an *a priori* sampling logic to ensure representation from across the population of interest (Cresswell, 2003). Case Study design analyses one specific case and subsequently identifies other cases to test theoretical or linear replication. There is no ideal number of cases for multiple Case Study, but it has been recommended that between four and ten cases is usually adequate (Eisenhardt, 1989). One of the problems with Case Study research is that a further case could always

be analysed to test the developing theories in different contexts. Unlike other forms of qualitative research, the aim is not to achieve data saturation on a particular topic of interest. This may be possible within a single case if there were a large number of participants but it is unlikely to be possible at the level of multiple cases as new cases could always be selected with differing contexts that make data saturation difficult, if not impossible, to achieve.

The aim of the Case Studies was to understand the mechanisms and contextual factors that helped to create safety and maximise success. This is consistent with the Theoretical Perspective of Resilience Engineering that was applied within the Case Studies. Practices were chosen where the introduction of a pharmacist was considered successful by local health board leaders rather than selecting practices where their introduction had been problematic. Local Lead Clinical Pharmacists were approach and, following discussion of the aims of the project, were asked to suggest local practices where introduction of pharmacists was considered successful. The pharmacists working in these practices were then approached to discuss the project and determine if they wished to participate. GP partners were then contacted to determine if they wished to participate. Practices were chosen where it was thought there was most to be learned and also for pragmatic reasons such as access to pharmacists and other staff members. Subsequent cases were based on findings from previously studied cases to test the importance of emerging mechanisms in other settings.

The first case was selected from a pilot site testing new ways of working that were to be implemented in the 2018 Scottish GP contract (Scottish Government, 2015). The pilot started in April 2016 when extra funding was made available to employ pharmacists, nursing staff, physiotherapists, mental health practitioners and health care assistants to work in GP practices. The local Lead Clinical Pharmacist suggested four practices. Two of the practices shared the same pharmacists but in very different settings and were selected to explore the impact of these changes in context.

The first Case Study explored the impact of pharmacists in a practice with physical capacity to provide pharmacists with their own rooms. It was situated in a relatively affluent area and the practice list size was stable.

The same pharmacists worked at the second practice studied which was also part of the same Scottish Government funded initiative to test new ways of working as Practice one. Practice two was situated a few miles away in an area of high deprivation with limited room availability. The list size was rapidly increasing due to patients moving from a neighbouring practice. The second Case Study was chosen to explore the effects of these contextual factors while the pharmacists remained the same.

Case three aimed to study pharmacist work in a different health board to determine the effect on impact and mechanisms for successful work. Although health board B was not part of the Scottish Government funded pilot of new ways of working, it was believed by many national pharmacy leads to be ahead of the majority of regional health boards in the recruitment and implementation of pharmacists in GP practices. Practice three was one of two practices recommended by health board B pharmacy leads as practices where their introduction had been successful. Due to agreement for access to pharmacists and GPs in practice three it was selected as a Case.

Case four was also in health board B but was not suggested by local pharmacy leads. Instead, it had been highlighted by pharmacists and GPs working in health board B as they employed their pharmacist directly. Including this case aimed to explore the influence of a different method of pharmacist employment..

Characteristics of the four practices are shown in Table 7.2 [Table 7.2]

Table 7.2: Characteristics of practice in each Case Study

Characteristic	Practice 1, Health board area 1	Practice 2, Health board area 1	Practice 3, Health board area 2	Practice 4, Health board area 2
Practice List Size*	2932	5049	7975	12591
Percentage of patients living in data zones defined as 15% most deprived	0.5%	47.3%	18.8%	28.3%
Rurality	Semi-rural	Urban	Urban	Urban
Training Practice	Yes	Yes	Yes	Yes
Number of doctors including trainees	4	5	8	10
Time pharmacist in post	Pharmacist 1 – 15 months Pharmacist 2 – 10 years (doing new role 2 years)	Pharmacist 1 – 15 months Pharmacist 2 – 10 years (doing new role 2 years)	18 months Worked for health board in different role 6 years	Pharmacist 1- 6 years. Pharmacist 2 - 6 months
Pharmacist employment type and number of days per week	Health board employed 3.5 days	Health board employed 3.5 days	Health board employed, half time 2.5 days	Pharmacist 1 - 3 days. Pharmacist 2 - 2.5 days
Pharmacists work tasks per day	All medication reconciliation and up to 50 special requests	All medication reconciliation, chose specials from GP lists	Medication reconciliation	All medication reconciliation and all special requests (could be up to 80)
Number of chronic diseases per patient in case reviews, median (IQ range)	4 (3-6)	5 (4-6.26)	4 (3.75 – 5.25)	4 (3.75-5)
Number of medications per patient in case reviews, median (IQ range)	7.5 (5-10)	8 (7-11)	8.5 (5-10.25)	8 (5.75-11)

*List size from ISD data accessed 1.4.18 available at https://www.isdscotland.org/Health-Topics/General-Practice/Workforce-and-Practice-Populations/

7.5 Case Study constructs

The STEW framework was used to guide data collection and analysis (McNab *et al.*, 2020).

The STEW framework was used within this thesis to direct data collection and analysis and is described in detail in Table 7.1. [Table 7.1]

The *Foundation Principle* directs the study of the system as a whole and that the boundary for the case needs to be agreed. Although the focus of the thesis is on the systems within the practice, the interactions with systems elsewhere (for example, secondary fare of community pharmacy) was considered.

Multiple perspectives are needed to understand everyday work and so pharmacists, GPs, administrative staff were observed and interviewed.

Data was collected and analysed to explore the impact of *Work Conditions* on ways of working and outcomes. This included:

- **Demand** – includes number of tasks requiring completion, patients' need for information, appointments and treatment and the need to complete work in a certain time.
- **Capacity** – the ability to meet demand.
- **Resources** – everything that is required to perform a work function – such as information and access to Information Technology systems.
- **Constraints** – guidelines, protocols and limits on capacity that restrict decisions and actions either positively or negatively.

Interactions between professionals and with patients and the *Flow* or work were studied.

Performance Variability was explored to understand how pharmacists, GPs and administrative staff varied the way they worked and the impact on

outcomes. The reasons why people adapted how they work were explored to *Understand Why Decisions Made Sense at the Time*.

The STEW framework therefore directed the data that needed to be collected and also the analysis of the data to understand everyday work.

7.6 Data collection

Fieldwork was conducted during normal working (office) hours in clinical rooms, reception areas, administrative offices and break rooms. Data was collected sequentially from each practice to explore the constructs using non-participant observation (Marshall and Rossman, 1989), document analysis (Bowen, 2009) and semi-structured interview (Jamshed, 2014) to create a 'thick description' of each case (Yazan, 2015).

7.6.1 Non-participant observation

Non-participant observation has been described as, "The systematic description of events, behaviours, and artefacts in the social setting chosen for study" (Marshall and Rossman, 1989). It allows the researcher to describe the situation that exists when the phenomenon being studied takes place. This includes describing "behaviours, intentions, situations, and events as understood by one's informants" (deMunck and Sobo, 1998). In addition, it allows the opportunity to observe responses to unpredicted situations. It consists of observation but also conversation and informal interviews. For successful non-participant observation, the researcher needs to establish rapport and integrate into the social structure being observed and yet remain objective enough to accurately record what is taking place. Often non-participant observation requires the investment of a considerable amount of time.

Observation allows study of non-verbal expressions of feeling, interactions between people, how contextual factors influence the work being performed. It also allows an exploration of the difference between what people tell you they do and what they actually do.

This data collection method can be criticised as results may reflect more the researcher's interest in a particular process or the contextual factors that influence it. Thus, it is important to set out the frame of observation in advance and take rigorous notes. A guide for undertaking non-participant observation of pharmacists was developed and used to record detailed field notes. [Box 7.2] This was based on the work of Merriam and Saldana and was directed by the constructs (Merriam, 1988; Merriam, 1998; Saldana, 2013).

Box 7.2 - Non-participant observation guide

- Record questions and interactions with participants throughout
- Describe the physical environment
- Describe the participants
- What are people doing? Record activities – frequency, duration, interactions with other activities, informal/unplanned activities. Measure time to complete tasks.
- How, exactly, do they do this? What starts the activity, what needs to be present in order to undertake the activity, what influences how they do the activity and its outcome (time, competing goals, guidance, availability of resources)?
- What specific means and/or strategies do they use? When and why do they use these strategies? (Understand why decisions make sense)
- Do they vary how they complete activities and if so how and why? (Consider performance variability)
- Symbolic meaning of activities: what are they trying to accomplish? (Understand why decisions make sense at the time)
- How do members talk about, characterise, and understand what is going on?
- What assumptions are they making?
- What do I see going on here?

Detailed, handwritten, contemporaneous field notes were taken during non-participant observation. These were reviewed after each observational session and reflective memos written to record informal thoughts, questions about what was observed and what was learned. These memos linked observational data with theoretical perspectives to inform future observations and interview questions. Notes were later transcribed for coding.

7.6.2 Document analysis

Document analysis is a form of qualitative research in which data are extracted and interpreted from documents to aid understanding of a topic. (Bowen, 2009) Stages involved in document analysis include: creating the list of texts to be explored; accessing these texts; acknowledging and addressing bias; considering strategies for ensuring credibility; and developing a data collection and interpretation plan (O'Leary, 2014).

To explore the content of documents, two main methods are recommended. The first is to undertake thematic analysis to initially code and then theme content using the constant comparison method (Glaser and Strauss, 1967). The second method is ask questions of the document (O'Leary, 2014). This second method fitted with the overall approach to the Case Study and did not rule out the possibility of identifying emergent themes from the text.

Potential bias in the production of documents was considered by examining the role of the author and purpose of the document. Latent content, including the tone and style of writing and how this may relate to an unwritten agenda of the author, was considered.

In this project, document analysis was used to extract data from national, regional and practice level guidance for pharmacists. It was also used to extract data from case note entries made by pharmacists after prescribing task completion.

Guidance document analysis

Guidance documents were identified through discussion with key informants (practice pharmacist participants, health board pharmacy clinical leads and NHS Education for Scotland pharmacy team) and through a search of references of identified documents. Publications that were included ranged from national strategic reports providing guidance on the development of pharmacists' role, documents providing guidance utilising pharmacists in General Practice and local operating procedures. [Appendix 4]

A data extraction template was developed through consideration of the Case Study constructs to analyse guidance documents. Data were recorded relating to pharmacists' role, expected impact, influences on how they undertake tasks, definitions of success, how this can be maximised and emerging themes. After testing on one document, findings were discussed with the research team to ensure the template enabled extraction of the desired data.

Analysis of electronic health records

The electronic health record of 20 patients age 75 or over, on four or more medications, discharged from acute medicine wards were reviewed in each Case Study. Patients were chosen at random following a population search of the practice's electronic health record database. These patient characteristics were chosen as it was predicted that these patients were the most likely to be prescribed multiple medications and have numerous medication changes during hospital stay thus requiring more cognitively demanding pharmacist work. It was expected that this would produce more learning on how pharmacists worked and what influenced this work. A data collection template was developed based on the Case Study constructs and tested in the author's own GP practice. Results were discussed by the author and supervisor to ensure collected data matched the constructs.

Data collected included demographic patient information (number of medications and chronic medical conditions), the actions performed by the

pharmacist (number of medication changes, interactions with patients and healthcare professionals) and outcome details (patient re-presentation to primary care, readmission, and patient safety incidents such as medication related harm). Pharmacists' comments on what influenced decision making and their objectives were recorded.

Review of a selection of data entries for other pharmacist tasks such as completion of 'special requests' showed that less was written than for medication reconciliation and there was little useful information. Therefore, document analysis of electronic health records focussed only on medication reconciliation.

7.6.3 Semi-structured interview

Document analysis and observed data informed the content of the interviews with members of staff to obtain multiple perspectives on processes and to triangulate data.

Interviewing is one of the most common data collection methods in qualitative research (Jamshed, 2014). A semi-structured guide is often used to keep the interview on the desired topic. Although the use of qualitative interviews is efficient, it has been questioned whether it is the best way to gather data. What people say is influenced by professional identity as well as by what actually happens in the workplace; work-as-disclosed may be different from work-as-done (Shorrock, 2016). This may be due to "claims of jurisdiction" which may influence pharmacists' and doctors' perceptions (Abbott, 1988). For example, pharmacists have in-depth medication knowledge and so may feel that medication reconciliation is 'their territory' and that they can do it better than others. This may influence how they describe their work, for example, they may not discuss times when they were uncertain of the best course of action. Interviews have been described as an 'artificial procedure' or 'forced situation' which may not be the best way to observe social phenomena. As such, interviews were not used as the

only evidence source. They followed other data collection methods to explore observations and the findings of document analysis.

Pharmacists, practice managers, administrative staff and GPs with the most interaction with pharmacists were approached to be interviewed. Interview structure was directed by the Case Study constructs and consisted of a description of, and experience in, current roles, history of the development of their role, involvement in pharmacists' activities, opinions of the impact of pharmacists, ideas of why this impact has been achieved and how positive impact can be increased. Examples and patterns of observed or documented pharmacist actions were used to probe and explore these areas. For example, if a pattern emerged related to frequency of contact with patients or secondary care this could be explored at interview.

Interviews were conducted by the primary researcher, recorded and transcribed verbatim. Interviewees were asked to review transcripts to agree content and ensure consent to use data.

7.6.4 Anonymisation of data

Observation and interview data were anonymised by assigning a code to each participant and practice. In review of case notes, demographic data did not include any that would allow identification of patients.

7.6.5 Case Study Database

A Case Study database was created to store collected data and results of analysis of that data. Data was anonymised and stored on a password protected, encrypted laptop. The database included:

- Demographic information relating to the practice and the pharmacists
- Observational data and memos transcribed by the author
- Local and national guidance documents
- Completed document analysis templates of local and national guidance documents

- Completed data extraction templates from electronic case note review
- Interview transcripts that had been agreed by participants

7.7.7 Data collected

The following data were collected from the four practices. [Table 7.3]

Table 7.3: Data collected at each practice in the Case Studies

Type of data	**Practice 1**	**Practice 2**	**Practice 3**	**Practice 4**
Number of medications reconciliations case note reviews	20	20	20	20
Number of medication reconciliations observed	18	10	27	21
Number of 'special requests' observed	12	29	2	39
Total observation time (hours)	12	10	14.5	15
Interviews (number, total number of interviewees, total time)	6, 6,6 hours	5, 5, 3 hours	4, 7, 3 hours	5, 6, 3hours 20 mins
Roles of interviewees	2 pharmacists 2 GPs 1 admin staff member 1 practice manager	2 pharmacists 2 GPs 1 practice manager	1 pharmacist 4 GPs (joint interview) 1 admin staff member 1 practice manager	2 pharmacists 2 GPs (joint interview) 1 admin staff member 1 practice manager
GP = General Practitioner; admin = administrative staff member				

7.7 Data analysis

Rather than adopting a linear approach to data collection and analysis, where data collection is followed by analysis and interpretation of data, an iterative, parallel approach was adopted as recommended within Case Study research. (Yin, 2014) Several methods were used to analyse qualitative data, quantitative data and to synthesise data.

7.7.1 Qualitative data analysis methods used

Qualitative data included observation and interview transcription text, reflective memos and document analysis data. Following coding, two systematic and iterative approaches to analysing the qualitative data within the Case Study database were applied: thematic analysis and framework analysis.

Coding

The first step in analysis of the qualitative data was to read and re-read the data in order to gain a deep familiarisation of the data. Following this, the process of data coding began. A code is:

> *"A word or short phrase that symbolically assigns a summative, salient, essence-capturing, and/or evocative attribute for a portion of language-based or visual data."* (Saldana, 2013)

As such, a code can summarize, condense and reduce data and should reflect and capture the essence of a part of the data. Coding is a cyclical process that is an essential part of qualitative data analysis (Miles and Huberman, 1994).

Codes were assigned to the activities or tasks that people did (such as daily routines, occupational tasks, unanticipated or irregular activities), their encounters with others, their roles, their social types (confident, shy) and the organisation of their work. The meaning of these events was also coded

(for example a decision made to ensure safety, or concerns about misuse of medication) (Saldana, 2013).

Data were coded within QDA Miner [Provalis Research, Montreal, Canada, Version 1.4.6.0, 2002]. Coding was reviewed and discussed at monthly meetings between the author and supervisors.

Thematic analysis

Thematic analysis is a way to generate themes from the collected data. (Castleberry and Nolen, 2018) Themes are 'interpretive concepts or propositions that describe or explain aspects of the data' (Heath *et al.*, 2012). Thematic analysis is a method that can be used in many methodologies including Case Study research (Nowell *et al.*, 2017).

Coding is the first step in thematic analysis. Codes lead from the data to the idea that explains the data through identifying patterns within the data. Patterns allow the organisation of codes into categories which then leads to identification of themes.

Themes summarise coded data and whereas a code is explicit, a theme is an interpretation of data. Themes are identified by exploring the similarities, differences, frequency of occurrence and how codes are related to each other such as appearing together or in sequence.

Framework analysis

Framework Analysis is a type of thematic analysis (Gale *et al.*, 2013). It involves using a matrix system where the rows are data sources (such as an interview transcript) and the columns are preselected themes. Data are assigned to cells within the matrix allowing comparison between data sources (observed, document and interview data) to identify and explain similarities and differences. If used inductively, a first round of 'open' coding can be compared between researchers to develop an analytical framework consisting of codes that may or may not be linked into

categories. Alternatively, the framework can be generated by using predefined codes.

Framework analysis was used where data related to existing categories for the analysis of the impact of pharmacist work.

7.7.2 Analysis of quantitative data

Simple descriptive statistics (frequency counts, medians, inter-quartile ranges) were used to analyse quantitative data. This included observed time to complete medication reconciliation, number of days since discharge until medication reconciliation was completed, interactions with other professionals and outcomes. Results were included in the Case Study Database.

7.7.3 Stages of Critical Realist Case Study data analysis

Principles for conducting Critical Realist (CR) Case Study research, based on Bhaskar's original stages for conducting CR research, informed the approach to data analysis in this project (Wynn and Williams, 2012). These stages are summarised in Figure 7.1 and the data analysis methods used at each stage are listed in Box 7.3 and described in depth below. [Figure 7.1, Box 7.3]

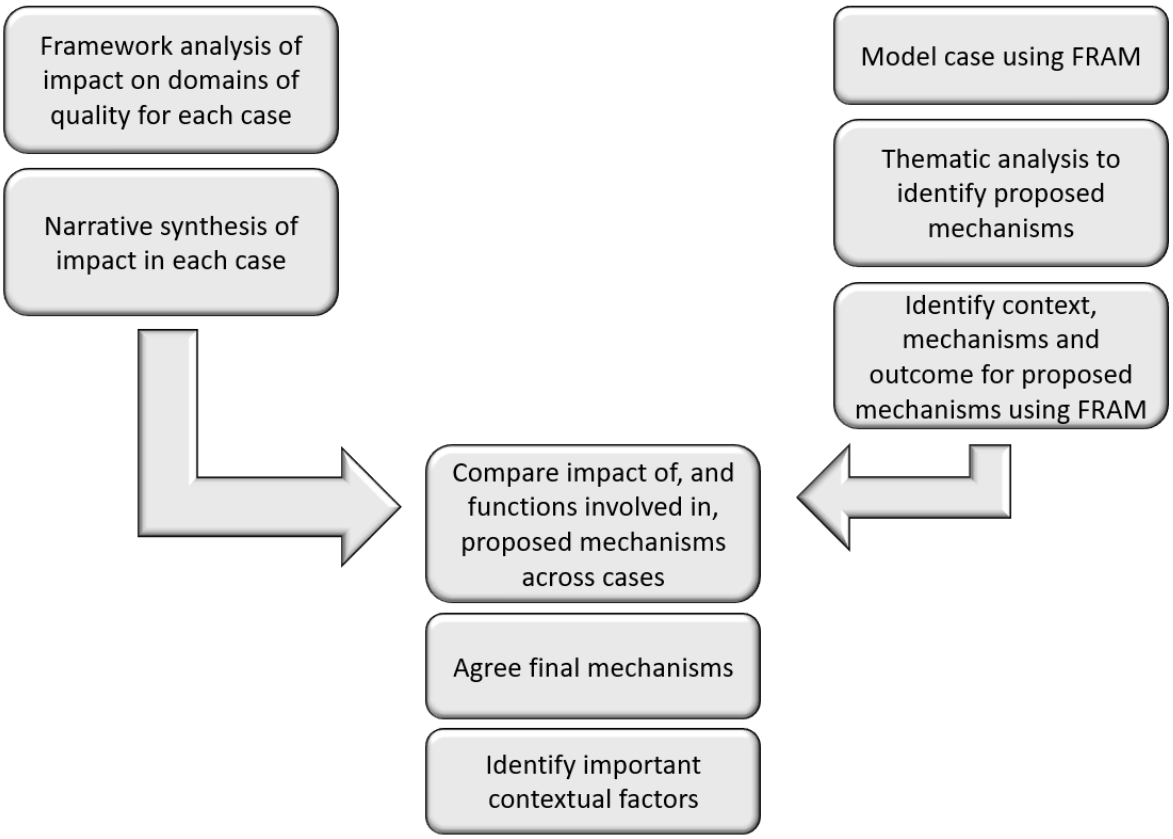

Figure 7.1 – Steps involved in data analysis.

Box 7.3 – Different stages of data analysis for Case Studies		
Data analysis stage	**Sub-section of each stage of data analysis**	**Details of data analysis at each stage**
Stage 1 - Explication of the case. Use the empirical evidence to describe in depth.	Stage 1a - Description of case.	Narrative description of reported and observed characteristics of people and physical environment.
	Stage 1b - Explication of the event - tasks involved	Narrative description of tasks observed and reported.
	Stage 1c - Explication of structure and context – model the system using the FRAM	Identified functions of the FRAM and aspects of each functions that link to other functions through analysis of coded observational and interview data. Identified variability of function output - reported at interview, observed or identified through document analysis.
	Stage 1d - Impact of pharmacists on quality, workload and wellbeing (RQ2)	Framework analysis of coded data using IHI domains of quality.
Stage 2 - Retroduction - generate hypothetical mechanisms	Stage 2a - Identify hypothetical mechanisms that may have influenced the impact of pharmacists in general practice (RQ3)	Thematic analysis of coded data to identify hypothetical mechanisms.

that may have led to the observed impact.	Stage 2b –Explore contextual factors and outcomes for proposed mechanisms. (RQ4, 5)	Compare FRAM model to proposed mechanisms to identify functions needed for proposed mechanisms and how contextual factors, mechanisms and outcomes were linked.
Stage 3 - Empirical Corroboration - compare data across cases to support or refute hypothetical mechanisms.	Stage 3a - Comparison of the impact of proposed mechanisms in each Case Study. (RQ3)	Narrative synthesis of Framework analysis results of impact for each case to identify if evidence of positive impact in each case.
	Stage 3b – Cross case comparison of proposed mechanisms. m(RQ4)	Cross case comparison of impact of proposed mechanisms and FRAM model functions involved to either agree, reject or merge as a final mechanism.
	Stage 3c - Identify contextual factors that supported agreed final mechanisms from the FRAM model. (RQ5)	Interrogation of FRAM model to identify important contextual factors for final mechanisms.
RQ = Research Question FRAM = Functional Resonance Analysis Method IHI = Institute of Healthcare Improvement		

Stage 1 -Explication of the case

Explication of the case involved a description of the case and the impact of pharmacists working in the practice. *Four stages are involved:*

Stage 1a - Description of case - the physical environment, staff (pharmacists, clinical and non-clinical staff) and patients
Stage 1b - Explication of the event - describe tasks involved
Stage 1c - Explication of structure and context – model the system using the FRAM
Stage 1d- Impact of pharmacists on quality, workload and wellbeing

Stage 1a - Description of case

Data was collected through observation, document analysis and interview to describe the case. This included the practice size, setting and patient demographic details, physical details of the practice, the experience and time commitment of the people involved, the location and interaction of different professionals and the tasks people performed.

Stage 1b - Explication of the event

The specific tasks performed by the pharmacists in each practice are described as are the tools used (such as paper documents, computers, protocols) and interactions with others (such as administrative staff, patients, carers, GPs and other colleagues such as those in secondary care and community pharmacy).

Stage 1c - Explication of structure and context

To explicate structural and contextual factors influencing the case, the system was modelled and explored using the Functional Resonance Analysis Method (FRAM). FRAM is described in chapter six (Hollnagel, 2012).

First, observation and interview data were analysed to identify any mention of actions (or functions) completed by pharmacists and other practice team members. These included functions related to:

- Processing and completion of the prescribing task
- Subsequent actions
- Actions that influenced this work.

The FRAM can model systems at different levels of granularity. For example, a function such as ‘obtain more information’ could be broken down to a number of other steps such as ‘open electronic record’, ‘select patient’, ‘open patient electronic health record’, ‘read past history’ and ‘read medication history’. Even these tasks can be broken down further. In this study, this level of granularity was not required because the aim was to understand what influenced the included functions.

Next, the data was analysed to identify aspects of that function and how these linked to other functions. System functions and aspects were uploaded to the FRAM Model Visualiser (FMV) software. [Zerprize, New Zealand, Version 0.4.1, 2016]

Evidence of variability in the timing and precision of task completion that could affect function output and the quality of work or the workload undertaken by the pharmacists was identified through observation of task completion, review of electronic case notes and was reported during interview. For example, determining if a task could be performed too late resulting in potential for poorer outcomes or imprecisely with potential for patient harm from medication. Completed FRAM models were reviewed with participants to ensure accuracy.

The FRAM model constructed in practice one was tested in subsequent practices to determine if all functions were activated and new functions were added if needed. In this way the FRAM model was developed and enhanced through analysis of cases to include all the functions required in different practices. Not all functions were enacted in each practice or in each episode of prescribing tasks completion. These are termed instantiations of the FRAM model. Function variability in each practice was determined.

Stage 1d - Impact of pharmacists working in GP practices (Research Question 2)

For each practice, Framework Analysis was used to analyse the impact of having a pharmacist in practice. The Institute for Healthcare Improvement (IHI) six domains of quality were used as the framework for considering care quality (Institute of Medicine (US) Committee on Quality of Health Care in America., 2001). These are safety, effectiveness, efficiency, timeliness, patient-centredness and equitable. [Box 7.4]

Box 7.4 – Institute for Healthcare Improvement quality domains and examples.

Institute for Healthcare Improvement quality domain	**Description**
Safety	Avoid harm to patients
Effectiveness	That care is delivered in line with best evidence (scientific knowledge)
Efficiency	Avoid waste
Timeliness	Reduce waiting for patient and health care professional
Patient-centredness	Patients' perspective guides clinical decisions
Equitable	Quality of care does not vary based on characteristics such as gender, ethnicity, socio-economic status, location

Additional categories were required. National drivers for pharmacist implementation into GP include the desire to reduce GP workload. The impact on quantity and cognitive difficulty of work was included as an

additional category. A final category was included – wellbeing. It is noted that this is not included in the IHI domains of quality, however it is included as one of the dual goals in the scientific discipline of Human Factors. Human Factors aims to improve performance of systems (equating to the IHI domains) as well as the wellbeing of all those involved in the system (patients as well as staff). It was thought essential that wellbeing is considered alongside the other domains and so was added as a ninth category.

Following coding of observational, document analysis and interview data, codes related to each of the above categories were identified and entered into a framework where each data source was a row and each of the categories was a column. For each case this data was compared between data sources to develop an understanding of the impact of pharmacists in each IHI category.

Stage 2 - Retroduction

Retroduction involves working backwards from empirical observations to generate hypothetical mechanisms that, if they existed, would explain observed phenomena. Mechanisms are described as “nothing other than the ways of acting of things” (Bhaskar, 1978).

Retroduction is the key stage to move from understanding of the system described from the observed data to generate ideas of how and why things happen the way they do. Mechanisms link context and outcomes and for each proposed mechanism the effect on outcomes and the contextual factors that influenced the mechanisms were identified. In all, a two-stage process was adopted.

Stage 2a - The first stage was to use thematic analysis of observation and interview data to identify hypothetical mechanisms that may have influenced the impact of pharmacists in general practice (Research Question 3).

Stage 2b - Next, the FRAM model was studied to explore what activities (functions) were needed for the proposed mechanisms and how contextual factors, mechanisms and outcomes are linked (Research Question 4, 5).

Stage 2a - What mechanisms influence the impact of pharmacists working in General Practice on quality of care, workload and wellbeing? (Research Question 3)

For each case, thematic analysis was used to analyse coded data to identify themes of how successful pharmacist working in GP practices was achieved.

Codes related to the mechanisms by which pharmacist working impacts on the different aspects of quality were reviewed and discussed at monthly coding meetings between the author and supervisors. The relationship between codes was explored by considering associated data resulting in merging and adapting codes. For example, the code 'Supportive learning environment' was merged with the code 'Formal and informal training' and eventually became 'Pharmacists' professional development in GP'. This was performed in a cyclical manner until themes explaining the data emerged. These themes were treated as hypothetical mechanisms as to why pharmacists' introduction had been successful.

Stage 2b - Reconciliation of proposed mechanisms with the FRAM model to identify how mechanisms influence the impact of pharmacists working in General Practice and how contextual factors, mechanisms and outcomes linked? (Research Question 4, 5)

Next, the data for each theme was reviewed and reconciled with the FRAM model to identify which functions of the FRAM model were included in the mechanism. This defined the functions needed for this mechanism to produce its outcome.

For example, the proposed mechanism ‘Team integration’ consisted of the interacting FRAM functions ‘Assign more work to pharmacists’, ‘Build trust in pharmacist’ and ‘Agree work between GP, pharmacist and health board’.

To identify contextual factors that influenced mechanisms, the FRAM model was reviewed to identify interacting functions. For example, ‘Team integration’, was influenced by the interacting function ‘Colocate pharmacists’ which was an important contextual requirement. ‘Team integration’ resulted in pharmacists completing more tasks through the output of function ‘Assign work to pharmacists’. In this way detailed descriptions of possible mechanisms, their influencing contextual factors and their outcomes were generated.

Stage 3 - Empirical Corroboration (Research Questions 3, 4 and 5)

The final stage of data analysis was empirical corroboration during which evidence across the four cases was compared. This consisted of three stages.

Stage 3a - Comparison of the impact of proposed mechanisms in each Case Study to identify if evidence of positive impact on the overall system performance and wellbeing was present in all cases. (Research Question 3)

Stage 3b - Compare the FRAM functions involved in each proposed mechanism to either agree as a final mechanism, reject or merge mechanisms. (Research Question 4)

Stage 3c - Following this, important contextual factors that supported agreed final mechanisms were identified. (Research Question 5)

Stage 3a - Cross case data analysis (Research Question 3)

Evidence supporting or refuting the importance of each proposed mechanism was identified across the four cases. Supporting evidence included demi-regularities. Conflicting evidence included mechanisms that

appeared important in one case and not in another. If mechanisms were not supported in all practices, they were either rejected as important to successful pharmacists work in GP, were adapted or merged with mechanisms that were always present or they were studied to determine if there were only relevant in specific contexts.

Stage 3b - Comparison of FRAM functions (Research Question 4)

If proposed mechanisms were present and had positive impact in each practice, they were accepted as final mechanisms. If not, the FRAM functions of proposed mechanisms and the impact described in each practice were compared to determine if there was overlap between mechanisms identified in different practices. If this was present, consideration was given to merging mechanisms. This was only accepted if the merging of mechanisms was deemed to increase understanding of how mechanisms positively impact system performance, workload and wellbeing. For example, 'Pharmacist training', 'Pharmacist mentoring' and 'Experience of pharmacists' all overlapped and were merged to form 'Pharmacist professional development in General Practice'.

If a mechanism was rejected due to not being present across all cases, the FRAM functions were analysed to determine if this mechanism may be important within another mechanism and if specific contextual factors influenced its importance. For example, 'Compliance with Protocols' was deemed important for pharmacists with less experience, early in their development before they were able to balance efficiency and thoroughness. mechanisms were reviewed to determine if they influenced other mechanisms

Stage 3c – Identification of important Contextual Factors (Research Questions 5)

The FRAM model was studied to identify the contextual factors that influenced the agreed final mechanisms.

7.8 Ethical considerations

Ethical approval was initially sought from the local NHS Ethics Committee, who deemed that the project did not require ethical review. [Appendix 1] This is because it only included data obtained as part of usual care, there was no patient identifiable material involved, interviews were with healthcare professionals whose participation was voluntary and that all data would be anonymised.

The University of Glasgow MVLS Ethics Committee was then approached to review the project. They reported no objection on ethical grounds. [Project number 200160135, Appendix 1]

Participation as Cases was voluntary and agreement of the pharmacists and GP partners was required. Participation in interviews was also voluntary and interviewees were provided with the participation information leaflet and completed an approved consent form prior to the interview.

Careful consideration of handling data and anonymity was given. Interviews were recorded and then transcribed by core members of the NES GP team. Recordings were deleted after checking transcripts. All electronic data was stored on an encrypted laptop computer. Practices and participants were not referred to by name and instead assigned a number that was used for all data in the secure Case database.

7.9 Reflexivity

Reflexivity is the process of reflecting on the influence of bidirectional relationships between the researcher and the research and the effect this has on how data are collected, analysed and the conclusion drawn. Reflexivity includes the impact of the role, beliefs and experience of the researcher on the participants (and vice versa). This may result in changes in behaviour and interview responses (Alvesson and Sköldberg, 2017).

Reflexivity is an attitude of attending systematically to the context of knowledge construction, especially to the effect of the researcher, at every step of the research process.

> "*A researcher's background and position will affect what they choose to investigate, the angle of investigation, the methods judged most adequate for this purpose, the findings considered most appropriate, and the framing and communication of conclusions.*" (Malterud, 2001)

The perspective or position of the researcher shapes all research - quantitative, qualitative, even laboratory science. Reflexivity needs to be considered to enhance the credibility of the research especially in qualitative research where researcher bias may be more influential in how data are collected, analysed and reported.

In data collection, it has been described that pharmacists may alter their actions or explanation of actions based on the position of the author (General Practitioner with national role in patient safety and quality improvement). Equally, the position of the author may influence what data was collected, what questions were asked and what notes were taken. This may be due to the researcher's existing views of the roles of pharmacists.

Similarly, the interest of the researcher in Resilience Engineering may result in increased priority being given to explaining the adaptations made by participants.

Several suggestions can encourage reflexivity within research. These include using multiple researchers; however, this is not feasible within this thesis. Keeping a research diary has been suggested and was used in this research. This recorded when and how data was collected and memos that interpreted collected data. Stating influences on researcher and participants was achieved through clear description of the theoretical framework and reflection on why participants performed and explained actions. This helps readers to determine if this influenced results.

7.9 Conclusions

This chapter has described the methods used in the remainder of this thesis. The way in which the chosen methodology, philosophical approach and theoretical perspective has influenced the methods has been described. The

thesis will now describe the application of these methods to four Case Studies of pharmacists working in General Practice. One chapter will be devoted to each Case Study, followed by a chapter than compares results across cases.

Chapter 8 Results - Case one

8.1 Introduction

This chapter presents the result from the first Case Study including a description of the setting, the pharmacists and the tasks they did. The way pharmacists work is described and modelled using the FRAM and the impact of pharmacists is described by presenting observational, interview and case note review data. Proposed mechanisms that increase the positive impact of pharmacists' work are then presented.

8.2 Description of case

Details of practice one are included in table 7.2. [Table 7.2] Practice one was a small practice situated within a village. The practice trained doctors as part of GP specialty training which meant that two of the doctors underwent regular training on giving educational feedback and helping trainees to identify and address learning needs. It also meant that the practice underwent regular accreditation visits to ensure that systems were in place to support GP specialty training.

The practice building was a converted residential property. On the ground floor were reception, the waiting room and consulting rooms. Upstairs were the practice manager's office and a large administrative room where staff received incoming telephone calls from patients, community pharmacies, secondary care and others.

The practice pharmacists worked alone in a small room upstairs. They had a computer, printer and telephone. The pharmacists stayed in their room when completing prescribing tasks but took breaks with administrative and clinical staff in the break room.

Two pharmacists worked within this practice for a total of three and a half days. Both were employed by the health board for 35 hours per week.

Pharmacist one divided her time between four practices and spent one day per week in practice one. Pharmacist one had eight years of experience working as a primary care pharmacist. In this role she had been responsible for developing and implementing initiatives such as cost savings switches (to less expensive medications) and patient safety projects (for example, ensuring the judicial use of antibiotics). Before this she had worked in secondary care and had completed a diploma in clinical pharmacy, a diploma in asthma management and was an independent prescriber.

Pharmacist two spent two and a half days per week in practice one and a similar amount of time in another practice. On three days of the week she travelled to the second practice at lunchtime. The second pharmacist had eight years of experience working in a community pharmacy and was working towards her independent prescribing qualification.

Eighteen months previously the primary care pharmacy department had started planning implementation of the new ways of working. New roles included tasks previously undertaken by GPs such as medication reconciliation, special requests and monitoring of high-risk drugs. Pharmacist one was involved in this developmental work and its implementation. Pharmacist two started this role 15 months previously and had been mentored by pharmacist one to undertake these tasks within practice one.

8.3 Data Analysis

8.3.1 Explication of event

In practice one, two main tasks were performed by the pharmacists: medication reconciliation after hospital discharge and completion of special requests. Pharmacists completed up to nine medication reconciliations and a mean of thirty special requests per day. Their agreement with the practice was that they could be assigned up to 50 special requests. Additional tasks included reviewing requests and blood test results for patients on Disease Modifying Anti Rheumatoid Drugs (DMARDS). Patients

could also request to speak to the pharmacist directly if they had a medication related query – these were not added to the electronic appointment booking system. There were rarely 50 special request tasks to complete but the number of additional tasks, such as responding to telephone queries, varied considerably and were not counted as part of the 50 agreed tasks. Uncompleted tasks were returned to administrative staff. On days when pharmacist two worked in a different practice in the afternoon this handover was at lunchtime.

At the start of each day the pharmacist reviewed their list of tasks and completed medication reconciliation then special requests.

Medication reconciliation tasks were assigned to pharmacists by administrative staff after they received a discharge document either in paper or electronic form. If received electronically, the paper document was printed and put into the pharmacists' 'in tray'. The pharmacist read the immediate discharge letter and gathered more information if needed from the patient's electronic health record, by contacting secondary care and/ or speaking to the patient, carers or community pharmacy. Secondary care was contacted if it was not clear if changes on discharge documents were intentional; often medications were missing and it was not clear if this was intentionally missing (the medication had been stopped in hospital) or if it had been omitted in error. Sometimes the request was discussed with a GP if they were unsure of the best course of action. Changes to the prescribing regime were made and the electronic record of the patient was updated.

Special requests were received by administrative staff from patients, either in person, at reception or by telephone. These requests were sent as an electronic task to the pharmacist who reviewed the case notes and made a decision on whether to issue the prescription or not. The electronic health record was reviewed to determine if they should issue the medication. If they did not have enough information to complete the request, such as the reason for ordering a particular medication, they would complete a small form that requested administrative staff to contact the patient and to arrange a discussion of the request with the pharmacist. If there was no

evidence of recent review of certain medication types (such as pain killers or antidepressants) the pharmacist used the same form to instruct administrative staff to contact the patient to arrange a review with a GP.

When DMARD prescription requests were reviewed, the pharmacist reviewed recent blood results and the notes of recent clinical encounters.

Once prescribing decisions had been made, prescriptions (if needed) were printed and the pharmacist phoned the patient or carer to ensure they were aware of changes. Sometimes they would contact the community pharmacy that dispensed the patient medications to ensure that changes were implemented. Follow up may be arranged, for example if blood test monitoring was required or if titration of dosage was needed. This was done by writing to the patient, contacting them by telephone or passing the task onto a member of the administrative team.

A protocol was used for medication reconciliation and for management of DMARD requests. There was no written protocol for special request processing although preferred ways of working had been discussed during training.

8.3.2 Explication of structure and context

A FRAM model that describes the work done by the pharmacists and what influences this work is shown in figure 8.1. Twenty-three functions were identified and are described within table 8.1. [Figure 8.1, Table 8.1]

8.3.3 Variability

Eight functions exhibited variability of output that could affect the quality of work performed or the amount of work completed. Work assigned to pharmacists was not always appropriate. Obtaining extra information could delay prescribing decisions and thus the issuing of prescriptions. Discussing prescribing queries with GPs could also be delayed as there was no formal agreement on how or when this should have taken place. The thoroughness of pharmacists and their anticipation of risk could result in extra checks (speaking to colleagues) that could delay decisions. The pharmacists saw their role mainly as increasing quality of the tasks assigned which could

delay processing of tasks. There was sufficient pharmacist capacity to complete the agreed tasks.

8.3.4 Impact of pharmacists working in GP practice one

Safe

Pharmacists identified and rectified potential prescribing safety problems. [Table 8.2] They regularly had to investigate and resolve unexplained discrepancies on discharge documents by contacting secondary care to reduce the risk of medication related harm.

GPs and administrative staff felt that pharmacists were more thorough than previous systems when GPs performed these tasks. It was thought this would improve patient safety by reducing the risk of avoidable harm from taking or omitting medications.

Effective

Pharmacists implemented effective evidence-based care including ensuring titration of medication to doses recommended by guidelines, arranging annual reviews and drug monitoring for patients prescribed blood pressure medication or anti-coagulant medication. [Table 8.3]

Compliance with regional and evidence-based guidance was thought to be greater when pharmacists performed prescribing tasks. Practice protocols were followed closely. In addition, GPs reported that they were more likely to follow protocols than when they previously performed these tasks as they were exposed repeatedly to pharmacists recording and discussing their actions.

Timely

Medication reconciliation was completed in a median of one day (interquartile (IQ) range 1-3 days) more quickly than the practice protocol which stated that this should be achieved within two working days. [Table 8.4]

Having a pharmacist increased capacity for prescribing task completion. This meant that prescribing tasks were completed within a shorter time frame than when GPs did this task.

Patient-centred

The protocol stated that all changes that were to be maintained should be discussed with the patient or carer within five working days and this was usually achieved. At other times, community pharmacists were contacted to ensure medication regime changes were implemented rather than explaining changes to patients, especially if a dose monitoring device was used to supply weekly medication packs to patients. [Table 8.5]

Rather than discussing and agreeing shared management plans with patients, discussions often aimed to ensure understanding of changes and follow-up. They were considered especially useful to explain complex regimes (such as reduction of oral steroid dosages).

Equitable

No evidence of care that was non-equitable was observed or reported although pharmacists were mainly available for telephone discussion which may be less suitable for some, such as deaf patients. However, they stated that they would alter their approach as needed and see patients in the practice. Practice one was in an affluent area and was described as having a lot of ‘worried well’ patients who appreciated having easy access to a pharmacist to discuss medication concerns. [Table 8.6]

Efficient

Pharmacists were observed encouraging the efficient use of medications by liaising with community pharmacy to reduce waste. Case note review showed that pharmacists stopped medication that was no longer being taken by patients but remained on the patient’s medication list meaning it could be ordered in error. [Table 8.7]

Pharmacists regularly contacted secondary care to clarify changes on discharge documents and GPs thought that the thoroughness of their approach may not be efficient.

Pharmacists felt that one of the main aims of their role was to be thorough and if they were unable to do this, were concerned about how this would appear.

Impact on workload

Quantity of work

Pharmacist completion of medication reconciliation and special requests was felt to decrease the quantity of work for GPs. Pharmacists generally tried not to send problems to GPs. Of the 50 prescribing tasks observed and reviewed three were reassigned to the GP (6%) [Table 8.7 and 8.8]

Administrative staff noticed an increase in requests to contact patients on behalf of the pharmacists and there was some concern that the introduction of pharmacists had increased the quantity of workload elsewhere. For example, there was a protocol for managing blood test results taken to monitor Disease Modifying Anti-Rheumatoid Drugs (DMARDs). It stated that a hospital-based specialist nurse should be contacted for advice if blood results were over a specified level. If this was the case, pharmacists telephoned the Rheumatology nurse specialist. Usually they had to leave a message and sometimes repeated telephone calls were required. This was to obtain guidance on whether medication should be withheld or doses altered. Demand in this service had increased following pharmacist introduction; however, it was noted that this was due to pharmacists observing an agreed protocol.

Pharmacists were thought to increase demand for patient reviews. For example, declining a prescription request for an antidepressant medication and arranging a review for a patient despite a recent GP review. This was

because the GP's decision to continue a prescription for a medication was not clearly recorded in the notes.

Cognitive workload

In practice one, administrative staff reported a reduction in the cognitive workload during the tasks they were asked to do. For example, they did not need to discuss medication queries with patients or secondary care professionals as these were passed to pharmacists. [Table 8.9]

One GP felt that although the quantity of work may have reduced, there had been an increase in the cognitive workload of certain tasks. It was felt that the pharmacist dealt with all the requests that were not clinically demanding but when there were difficult decisions to be made these would come back to the GP.

Well-being

Pharmacists enjoyed working as part of the practice team. They found it rewarding to think about the patient as a whole rather than just their medication. They enjoyed resolving problems and patient continuity, discussing medication with a patient on several occasions over a period of time. [Table 8.10]

Pharmacists employed by the health board felt that their role was not clearly defined. They felt tension between health board cost reduction work, the day-to-day practice work and the future development of patient facing roles.

Administration staff felt that the reduced cognitive workload reduced stress related to work tasks. They no longer had to deal with medication queries from patients, secondary care and community pharmacists for which they did not feel qualified and found it easier to access a pharmacist than a doctor.

GPs felt that the introduction of a pharmacist had improved their well-being as the reduction in workload meant they would get home earlier and did not need to finish paperwork at the weekend.

8.3.5 Retroduction

Four themes that described mechanisms to support successful pharmacist working in the GP practice were generated. These were:

- Team integration
- Compliance with protocols
- Pharmacist thoroughness
- Pharmacist training

Team integration

Team integration was described as essential to ensure successful pharmacist working within GP. It meant that pharmacists and other practice staff could approach each other to discuss and resolve problems. It was considered essential to understand each other's roles and to ensure that appropriate work was assigned. It also built the relationships that allowed development of the role as competence increased.

> *"The pharmacy team are a very nice bunch, mixed in well. I think our team have helped include them and I think that the engagement process has certainly been beneficial that way because I think everyone gets on better as they have taken on more roles."* (P1, PM1)

When reconciling this theme with the FRAM, the mechanism for team integration consisted of agreeing role priorities between the practice and the pharmacist, learning roles and building trust in each other's capabilities. This influenced the work that was sent to pharmacists. [Table 8.11] There is a cyclical component to team integration as successfully completing assigned tasks aided understanding of their role and value to the team and resulted in an increased number of tasks being assigned.

For this mechanism to be enacted, the pharmacists had to be colocated, an induction process was required and the health board, as the pharmacist's employer, had to have agreed work priorities with the practice. Involvement in training supported learning of each other's roles. To build trust, pharmacists had to demonstrate competence and impact. Competence was

demonstrated through successful completion of tasks and involvement in training. To demonstrate impact, pharmacist required sufficient pharmacist capacity to complete assigned tasks. [Figure 8.2]

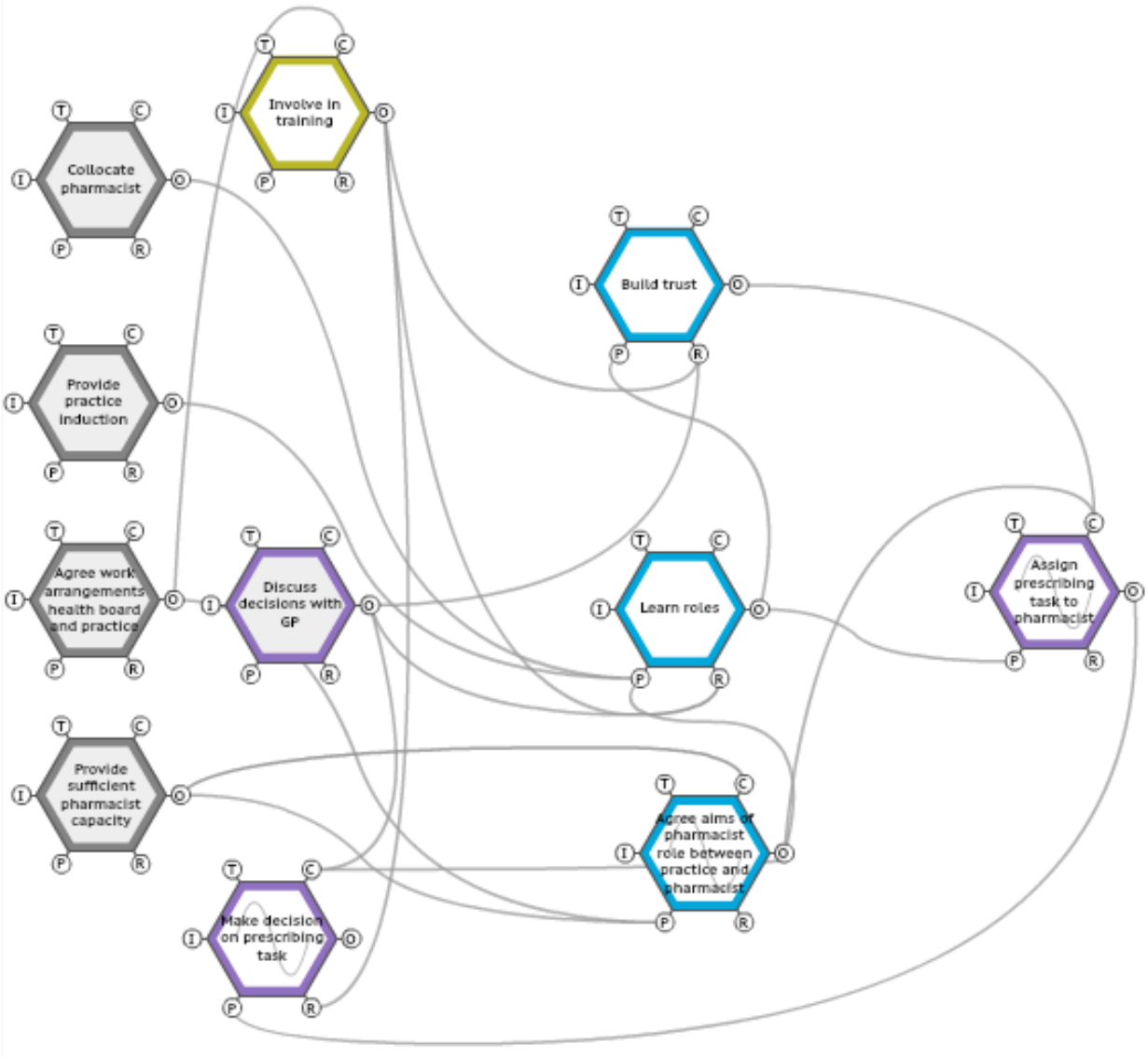

Figure 8.2 - Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Team Integration'

Pharmacist thoroughness

Pharmacist thoroughness was very important to the success of their implementation. The word 'thorough' was used frequently by all staff types to describe pharmacists identifying and rectifying potential prescribing problems to increase aspects of quality, namely safety, effectiveness, efficiency. Pharmacists identified and rectified potential prescribing

problems to reduce the risk of patient harm from prescribed or omitted medications, to ensure that effective monitoring took place and to reduce waste. This included rectifying discrepancies between hospital discharge and GP health record prescription regimes, evaluating medication interactions, ensuring medication reviews and monitoring had taken place and addressing concordance issues (not taking medication as prescribed), suboptimal dosing and formulary compliance.

> *Meds rec -10 - Ramipril and bisoprolol kept on reauthorisation of one. To monitor blood pressure and bloods. Phoned community pharmacy to get medication in synch and to check not double ordered and so reduces waste. (Observation P1)*

This was demonstrated by their ability to identify prescribing problems, seek extra information and discuss potential prescribing problems with GPs.

This mechanism was supported by pharmacists' knowledge and involvement in training. Sufficient pharmacist capacity was required to complete the work. [Figure 8.3, Table 8.11]

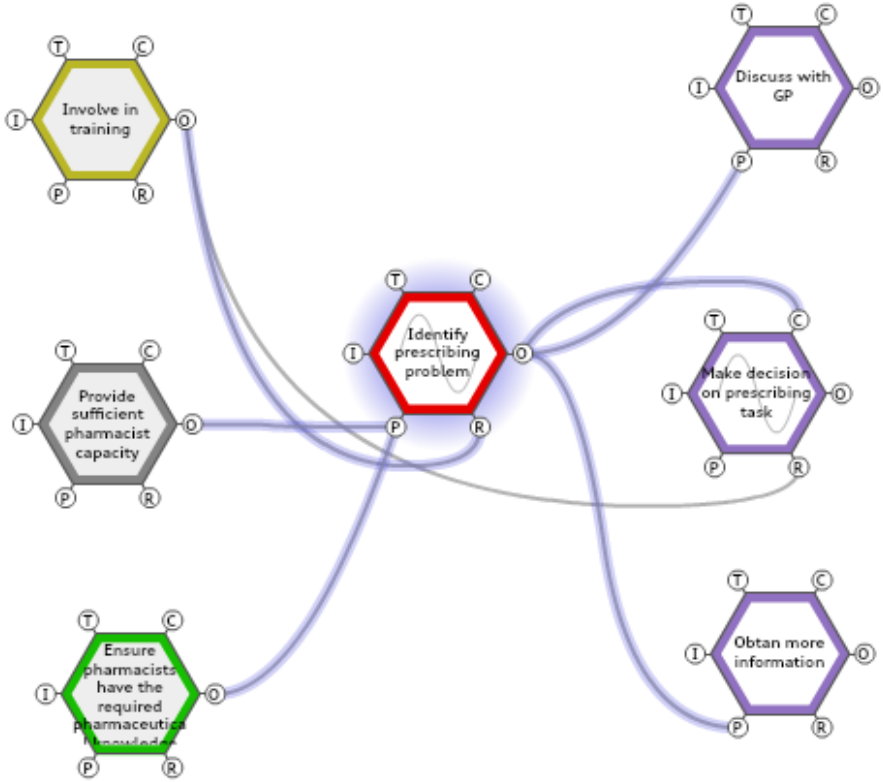

Figure 8.3 - Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Pharmacist thoroughness'

Compliance with protocols

Compliance with protocols was considered important. If pharmacists had the required knowledge to undertake prescribing tasks and had a protocol to follow, successful prescribing decisions would be made.

Pharmacists were observed to follow protocols rigidly and felt this was important for success.

> *"I would say the pharmacy department within primary care is still kind of protocol driven and process driven." (P1 Ph2)*

This influenced the prescribing decisions made and subsequent actions.

'Follow protocols' was a function in the FRAM model and influenced pharmacists obtaining more information, for example from secondary care. It also influenced the prescribing decisions made and subsequent actions. [Figure 8.4, Table 8.11]

These mechanisms required pharmacist knowledge, sufficient pharmacist capacity and the modification of pre-existing work processes to include pharmacists.

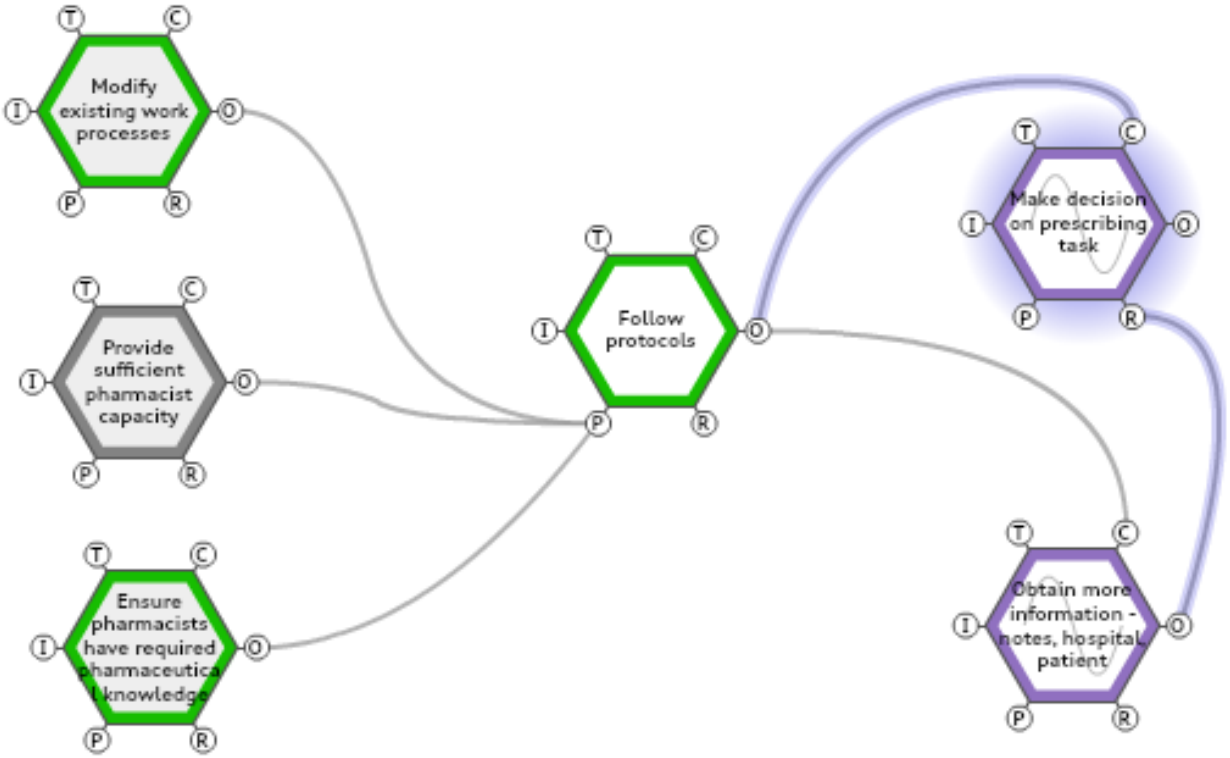

Figure 8.4 - Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Compliance with protocols'

Pharmacist training

Involving pharmacists in both formal and informal training within the practice was considered essential for successful working. When pharmacists first started in the practice, formal training on how to complete prescribing tasks was required. This needed to involve all relevant staff groups. Involving GPs ensured pharmacists knew how the practice managed specific medications; for example, keeping certain medications as special requests rather than repeats. Nursing staff involvement explained how DMARD and other reviews were completed. Administrative staff involvement explained their role in assigning tasks to pharmacists and completing any actions the pharmacist requested such as arranging medication reviews. Informal

learning (such as coffee break discussions) was important; not only to reinforce formal learning, but to discuss cases where the best course of action was uncertain. An environment that supported pharmacists to develop skills and confidence to deal with uncertain situations was essential.

> *"I think it is very important that they are allowed to have the space to make errors, I think that's how they learn and I think that is also how they become part of your team when stuff like that happens."* (P1, GP2)

Involving pharmacists in training was a function in the FRAM and influenced prescribing decisions made. It resulted in trust being built, increased learning of roles and improved ability to identify potential prescribing problems.

For this mechanism to be enacted, pharmacist colocation was required. Agreement that the practice had a role in pharmacist professional development and the capacity to deliver this training was also required. [Figure 8.5, Table 8.11]

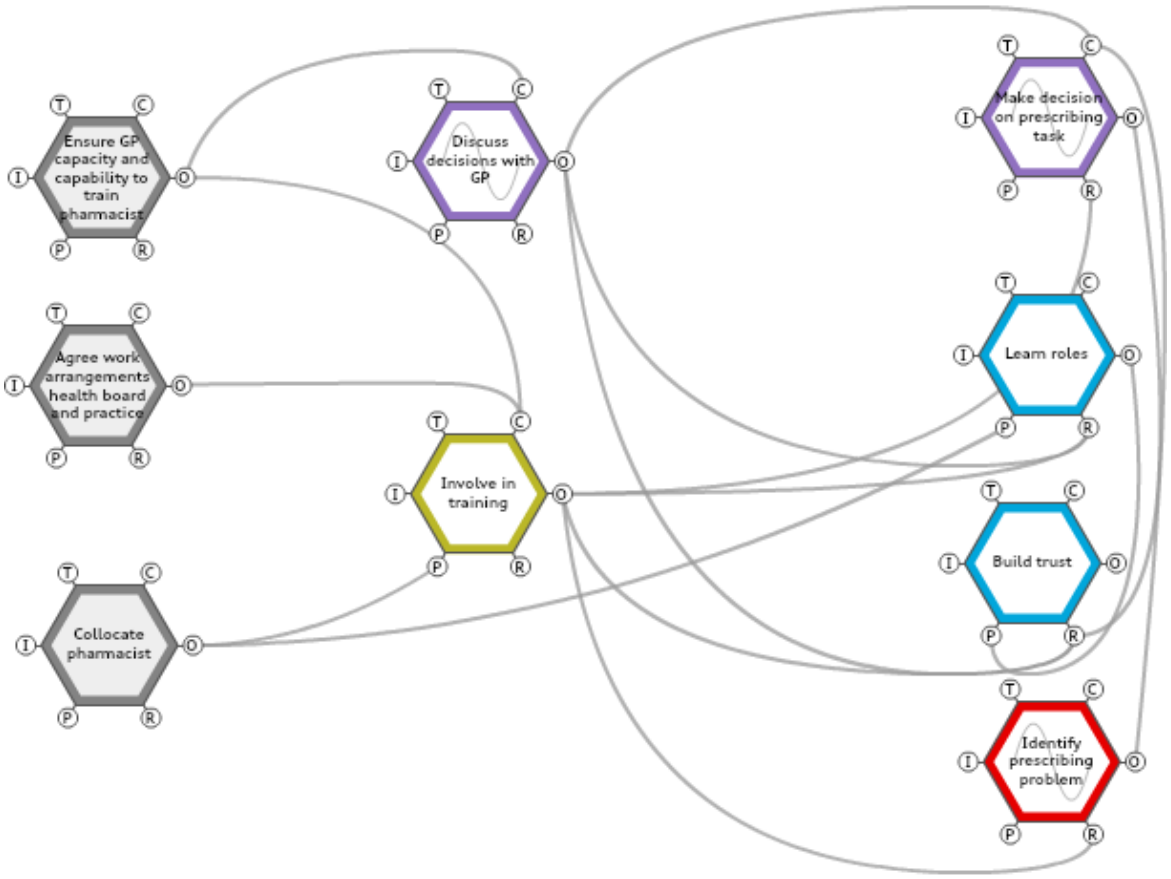

Figure 8.5 - Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Pharmacist training'

8.4 Summary of Case one

Impact

- Very thorough in terms of increasing safety and implementing guideline-based care.
- Followed protocols strictly.
- Discussed changes with patients to ensure changes understood.
- Reduced medication waste
- Could increase work in other areas (such as secondary care) due to following protocols strictly.
- Reduced number of prescribing tasks sent to GPs

- Some concern that this may increase the complexity of prescribing tasks sent to GPs.
- Increase number of tasks for administrative staff
- Reduces the cognitive difficulty of administrative staff tasks.
- Pharmacists enjoyed the work
- Increased wellbeing of staff and GPs.

Proposed mechanisms

- Team integration
- Compliance with protocols
- Pharmacist thoroughness
- Pharmacist training

Chapter 9 Results – Case two

9.1 Introduction

This chapter will present the results from Case Study two and will follow the same structure as the previous chapter.

9.2 Description of case

Practice two had more patients than practice one and was situated in an urban setting. [Table 7.2] It was classed as a 'Deep End' practice – defined as 'general practices serving the 100 most deprived populations in Scotland'. (Watt, 2011) Although practices one and two had differing patient demographics, they had similar levels of polypharmacy and multi-morbidity [Table 7.2].

The practice building was purpose built in 1988. It was constructed on one floor with a waiting area and reception area at the entrance and a corridor with five consulting rooms and a small kitchen/ break room. Room capacity was limited meaning that the pharmacists could be moved about during the day. There was usually not a consulting room for pharmacists, and they were often positioned in reception or in the break room.

As in practice one, pharmacist one spent one day per week in the practice while pharmacist two spent two and a half days per week in the practice. She spent one full day at the practice and three afternoons.

9.3 Data analysis

9.3.1 Explication of event

In this practice the pharmacists focussed on medication reconciliation. They reviewed DMARD prescription requests and did a small number of special requests.

Tasks were assigned to pharmacists by administrative staff creating a virtual appointment for the patient within the electronic appointment book. Pharmacists worked through this column of patients. The number of tasks varied from none to twenty. The protocol and the processes for completing medication reconciliation and reviewing DMARD requests were similar to practice one.

Special requests were not assigned to pharmacists. The GPs felt this is something that the pharmacists could perform but would require a lot of training in order to complete this task in the way the GPs wanted. They felt there was more impact from pharmacists concentrating on medication reconciliation. It was agreed with GPs that once medication reconciliation tasks received that day were completed, pharmacists would review special requests that were assigned to GPs. Although there was no written protocol, the pharmacists had discussed which special requests the GPs thought were appropriate for them to complete. These were special requests considered 'straightforward' by GPs which meant that there was no uncertainty about whether they should be continued (for example, blood pressure medication), medication that was unlikely to cause harm (emollient creams) and medication that was available over the counter (for example, mild laxatives). Pharmacists would read and select appropriate tasks, review the record and issue the prescription if appropriate.

9.3.2 Explication of structure and context

Updating the FRAM model with practice two data meant including an additional function 'Select prescribing task'. Functions, their interactions

and variability are described in table 8.1 and the FRAM model in Figure 8.1.[Table 8.1, Figure 8.1]

9.3.3 Variability

Nine functions exhibited variability of output that could affect quality of work performed or the amount of work completed. Work assigned to pharmacists was not always appropriate. As in practice one, pharmacist thoroughness (such as obtaining extra information) could delay the completion of tasks. Adding extra checks could also result in extra workload being generated. The selection of special requests was done in an *ad hoc* way and there was insufficient capacity for pharmacists to complete many special requests.

9.3.4 Impact of pharmacists working in GP practice two

Safe

Similar to practice one, pharmacists identified and rectified potential prescribing safety problems and GPs and administrative staff confirmed that they thought pharmacists reduced the risk of patient harm due to prescribed medication. [Table 8.2]

Effective

Pharmacists followed guidance closely for prescribed medication and practice staff noted the benefits of having the staff to improve the effectiveness of care. [Table 8.3]

Timely

Median time to complete medication reconciliation was two days and pharmacists provided quicker answers to medication queries from patients, community pharmacies and secondary care. [Table 8.4]

Patient-centred

Similar to practice one, although treatment options were not discussed and agreed with patients, pharmacists discussed changes with patients to ensure understanding and altered their approach based on patient characteristics. [Table 8.5]

Equitable

The population served by practice two was from an area of considerably higher deprivation levels than practice one. Pharmacists altered their approach to ensure both patient groups received the same quality of care. They found it more difficult to contact patients from practice two by telephone and used letters and the administrative staff to ensure contact was made to discuss medication changes. [Table 8.6]

Efficient

Pharmacists were observed reducing medication waste when performing medication reconciliation for a new nursing home patient. [Table 8.7]

Although GPs felt the medication reconciliation process was more efficient in terms of time, they felt that pharmacist's desire to ensure checks were made on medication could decrease efficiency. Rather than trust practice recall systems to ensure patients and their medication were reviewed regularly (for example annual Blood Pressure reviews), pharmacists would often allow a limited supply of medication (for example allowing one month of blood pressure tablets on repeat prescription) so that a prescription review by a GP or pharmacist would be initiated when the medication was reordered. This allowed the pharmacist to ensure patient compliance and that monitoring tasks were completed when due. Although this increased safety it reduced efficiency.

Impact on workload

Quantity of work

As in practice one, pharmacists reduced work quantity for GPs. GPs thought that they saved about half an hour's work per day which had allowed the GPs to increase appointment length to 15 minutes. [Table 8.8] Of the 59 prescribing tasks observed and reviewed eight were reassigned to the GP (14%) [Table 8.7 and 8.8]

Their impact had not been as great as had been hoped. When they started in the practice, it was decided that they should focus on medication reconciliation. The hope was that once they were competent to do this task, they would start to complete special requests. They did not have capacity to complete the special requests and only did these tasks if they had completed medication reconciliation.

As in practice one, increased workload in other parts of the system had been noted. Pharmacists followed agreed protocols which increased

secondary care workload. For example, GPs were more likely to monitor blood results themselves rather than contact secondary care for advice.

Unlike in practice one, administrative staff thought that pharmacists reduced their workload especially when dealing with medication queries from patients, secondary care or community pharmacies:

Inappropriate tasks were sometimes sent to pharmacists as they were seen as a very accessible resource. Administrative staff were keen not to send work to GPs as they felt they had high volumes of work.

Cognitive workload

Like practice one, administrative staff thought that having a pharmacist reduced the cognitive demands of their work as they could pass medication queries to the pharmacist. [Table 8.9]

Well-being

The reduction in quantity of work reduced feelings of stress among the GPs. Pharmacists enjoyed being part of the team. This was enhanced by sitting in reception as they felt it helped them understand how the whole practice ran. [Table 8.10]

9.3.5 Retroduction

The four hypothetical mechanisms discussed in practice one were also considered important in practice two. In addition, a fifth mechanism was identified.

- Team integration
- Pharmacist thoroughness
- Compliance with protocols
- Pharmacist training
- Attempts to deal with any task to try to reduce GP workload

Team integration

As in practice one, team integration was essential to successful pharmacist working. When pharmacists were part of the team, it meant that the pharmacists, administrative and clinical staff felt able to approach each other to discuss clinical and administrative problems. It resulted in an understanding of each other's role and ensured appropriate work was assigned to pharmacists. Importantly it helped to establish relationships that were essential for developing the role of the pharmacist.

> *"They've fitted in well and they came to our Christmas night out last year and em so the personality wise is really really important and we're a practice that wants change you know and we want we were embracing this idea of having other people working with us and workload being shared out."* (P2, PM)

As in practice one, team integration consisted of agreeing roles, work priorities and building trust in each other. The FRAM functions are shown in figure 8.2 and Table 8.11. [Figure 8.2, Table 8.11] These include colocation of pharmacists which was seen as important in this practice where pharmacists were often situated in reception. This was useful for the pharmacists to understand the working of the practice and the pressure on the GPs. The pharmacists were seen as very accessible and so reception staff regularly discussed queries from patients and other healthcare sectors.

Pharmacist thoroughness

Practice two data supported the mechanism that thoroughness of the pharmacist increased quality (specifically safety, effectiveness and reduced waste).

> *"Part of my role is to be thorough and investigate all changes."* (P2 Ph2)

This mechanism consisted of identifying potential prescribing problems (such as risk to patients from prescribed or omitted medications) and influenced the prescribing decisions and subsequent actions such as updating the electronic record and contacting patients or community pharmacies. It required sufficient pharmacy capacity and knowledge. Figure 3 shows the FRAM functions involved in the context, mechanism and outcome. [Figure 8.3, Table 8.11]

Compliance with protocols

As in Practice one, compliance with protocols was seen as important for successful task completion. Complying with protocols was considered part of a pharmacist's identity. They described themselves as 'black or white' meaning that they found it easy to make decisions where there was a clear right or wrong choice. This was supported by a protocol which meant decisions either followed the protocol (right decision) or did not (wrong decision).

> *"Pharmacists - in general we are quite anal, and you know like things something's right or wrong... I would say the pharmacy department within primary care is still kind of protocol driven."* (P2, Ph2)

This mechanism influenced the prescribing decisions made and required pharmacist knowledge, sufficient pharmacist capacity and the modification of pre-existing work processes to include pharmacists. The functions involved in this mechanism, its outcome and influencing contextual functions are shown in figure 8.4 and in Table 8.11. [Figure 8.4, Table 8.11]

Pharmacist training

Pharmacists accepted that they had to learn how to apply their knowledge when they started in primary care.

> *"I think we need to see how the knowledge you know see how it actually works in practice."* (P2, Ph2)

Initially they were instructed how to perform medication reconciliation by GPs. Later, this was achieved through informal feedback and discussion about cases. This was observed in relation to discussion of changes on a discharge document where sertraline was not included but it was not clear if it was intentionally stopped. The GP discussed their approach to this problem, which was to assume it was unintentional and discuss with the patient. This approach was then adopted by the pharmacists for future similar cases.

As pharmacists did not regularly complete special requests, there had been little training on this task and accepted ways of working had evolved. Pharmacists chose tasks that they perceived to be uncomplicated and avoided tasks where they were concerned that their decisions may be different from GPs. This included tasks to prescribe additional supplies of antidepressants and analgesics. Pharmacists were aware that GPs may have recently consulted with the patient on a different matter and were willing to prescribe these medications without review whereas the pharmacist would have arranged a review. Due to this, pharmacists completed fewer special requests than in practice one.

Formal educational situations, including practice meetings, were also important. At these a supportive learning environment was needed. If there was an unwanted outcome following a decision made by a pharmacist, the GPs and administrative staff stated that this would be used to learn.

> *"I mean they are part of the team we would you know they would be at our practice they come to our practice SEA (Significant Event*

Analysis) meetings ... and hopefully we would just kind of work our way through it." (P2, GP1)

Involvement in training could increase trust and understanding of each other's roles. It influenced prescribing decisions and their ability to identify potential prescribing problems.

It required that the practice had agreed this role in the pharmacists' development with the health board, that GPs had capacity and capability to perform this role and that pharmacists were colocated. The functions involved in the context, mechanism and outcome are shown in figure 8.5. [Figure 8.5, Table 8.11]

Attempts to deal with any task to try to reduce GP workload

Whereas in practice one, pharmacists had a defined role and focussed on increased quality, in practice two, pharmacists adapted how they worked to attempt to reduce GP workload. This was achieved through a flexible approach that resulted in them accepting and trying to process inappropriate requests from administrative staff.

- *Asked about optician letter – inappropriate but happy to review. Seen as easy access – even when consulting they are interrupted to give messages.* (P2 observation)
- *Community nurse called re wheezy patient using a lot of inhalers – passed to Ph1 as medication mentioned – obviously needed a house visit (as requested by community nurse). Ph1 feels whenever medication mentioned work sent to her as easy access but willing to review in case able to prevent task going to GP.* (P2 observation)

Although in principle, reception staff understood the tasks the pharmacists would complete, they prioritised reducing GP workload over precise direction of work in the hope that the pharmacist would be able to deal with a problem. Pharmacists accepted this role because in reception they could observe the amount of work assigned to GPs and heard administrative

staff speaking to patients. They would often intervene and speak to patients if they thought it was possible that they could help. They accepted all tasks that they were assigned and reviewed these to determine if they could complete the tasks or if GP input was required. Pharmacists were happy to do this as they felt that part of their role was to reduce GP workload.

This mechanism involved agreeing roles with the pharmacist, assigning and selecting prescribing tasks. It influenced the decisions pharmacists made and the mentoring and training they received. [Figure 9.1, Table 8.11]

To be enacted it was essential that pharmacists were integrated into teams. In addition, a further outcome of this mechanism was that it promoted team integration as the team felt pharmacists were not constrained in their role and were willing to help the work of the team. The precondition that roles were agreed with the health board was essential.

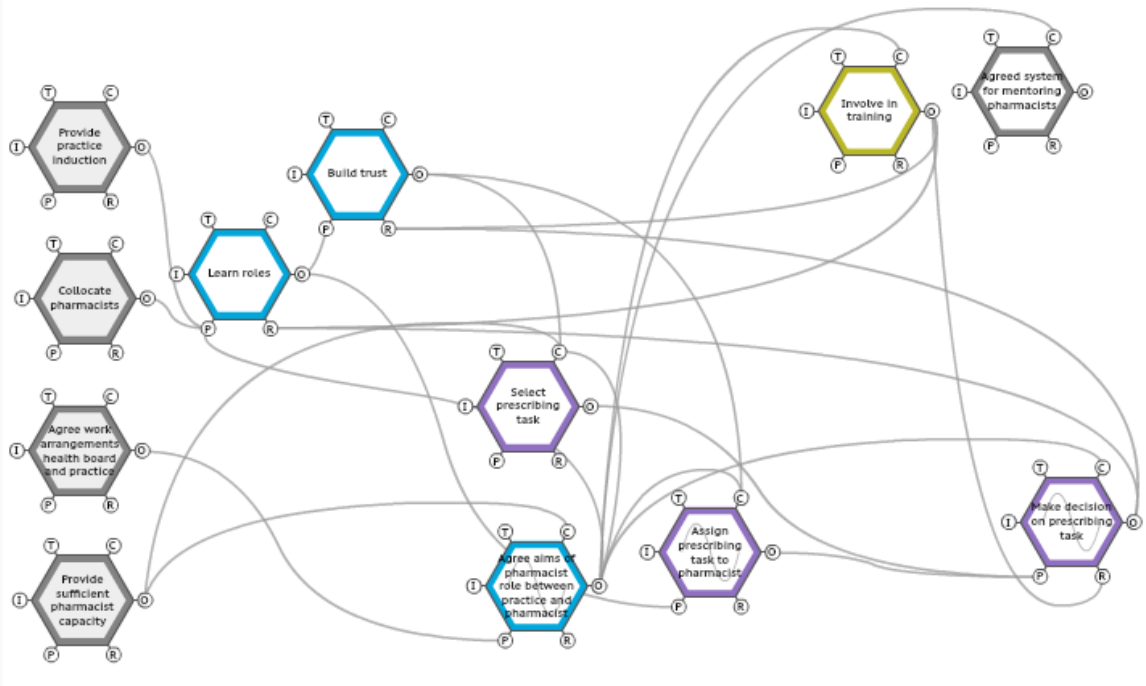

Figure 9.1 – Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Attempts to deal with any task to try to reduce GP workload'

9.4 Summary of Case Two

Comparison to previous practices

Despite Practice One and Two being very different in terms of deprivation levels of practice areas, availability of workspace for pharmacists and stability of list size, the findings were broadly similar. In both practices pharmacists and GPs shared the same goals of prioritising prescribing safety.

The main additional learning point was that situating pharmacists beside administrative staff increased their understanding of demand on the system. In Practice One, pharmacists worked in their own room and were unaware of varying demand. When aware of this demand, pharmacists adopted a flexible approach to increase system capacity.

Impact

- Very safe, increased the implementation of best prescribing practice.
- Followed protocols very closely.
- Changes discussed with patients to ensure understanding.
- Reduced waste but could increase work in other areas and in the practice as did not trust practice systems.
- Reduced work and improved wellbeing for GPs and admin staff.

Proposed mechanisms

- Team integration
- Pharmacist thoroughness
- Compliance with protocols
- Pharmacist training
- Attempts to deal with any task to try to reduce GP workload

Chapter 10 Results – Case three

10.1 Introduction

This chapter will present the results from Case Study three and will follow the same structure as the previous results chapters.

10.2 Description of case

Practice three was a medium sized practice. The building was in a town centre located over four floors. On the ground floor were reception, administration rooms and a consulting room. The rest of the consulting rooms were on the first floor with the second-floor housing meeting rooms and further administration space. In the basement was a kitchen and coffee room.

The pharmacist was usually located in a ground floor consulting room although could be positioned within administration rooms behind reception or on the second floor. The pharmacist remained in his room to complete tasks but had coffee breaks with the GPs and some administrative staff.

Before starting in the practice, the pharmacist had worked for the health board for five years in a different role. Prior to this he worked for a pharmaceutical company which involved working with GP practices to improve chronic disease management.

10.3 Data analysis

10.3.1 Explication of event

In practice three the main task performed by the pharmacist was medication reconciliation. Up to twenty electronic tasks were assigned to the pharmacist each day. This work took up all the time assigned to the pharmacist. The pharmacist had helped to produce a medication reconciliation protocol with local pharmacy leaders that was used throughout the health board area. This gave general instructions about how to complete the process of medication reconciliation. It gave suggestions of how extra information could be accessed if needed (for example by discussing with secondary care or patients). It stated that 'significant' changes should be discussed with patients within five working days. In previous practices, the protocol had stated that all changes should be discussed with patients.

At the start of the day the pharmacist reviewed the assigned tasks consisting of new tasks, tasks not completed the previous day and 'pending' tasks for which he was awaiting new information (for example blood test results). There were more medication reconciliation tasks at the start of the week than at the end of the week and he felt his goal was to complete them all by the end of the working week.

He had access to hospital prescribing information from the hospital's electronic prescribing system (Hospital Electronic Prescribing and Medicines Administration (HEPMA)). He often reviewed this to determine why medication had been started or if it was meant to have been stopped. For example, if he saw that it had been administered for three days during the admission and then stopped, it was likely that its omission from the immediate discharge letter was intentional. If he felt a GP would want to know about a discharge or if he wanted the GPs advice, he would send them an electronic task.

After completing the task, he sometimes contacted the patient or the community pharmacy. He made this judgement based on what he felt was necessary to ensure the patient took the correct medication regime. If he thought the patient was likely to have understood and remembered changes made in the hospital, he would not telephone them.

10.3.2 Explication of structure and context

The twenty-three functions activated in practice one were active in practice three. Functions, their interactions and variability are described in table 8.1 and the FRAM model in Figure 8.1. [Table 8.1 Figure 8.1]

The function 'Agree system for mentoring pharmacists' was included in this practice as specific time was set aside for this activity.

10.3.3 Variability

The pharmacist was only assigned medication reconciliation and so there was less variability in the appropriateness of tasks assigned. The pharmacist had access to the hospital electronic prescribing system which meant that they could access additional information more quickly and there was less delay for patients. The function 'Follow protocols' was enacted differently in this practice. In practice one and two, the protocol specified each action whereas in this practice it gave a rough guide of what pharmacists should do allowing a variation of actions. There were more formal agreements in place for discussion of problems and for pharmacist mentoring. As in practice one and two, there was not always sufficient pharmacist capacity to complete all assigned tasks. This sometimes meant they were delayed or handed back to GPs.

10.3.4 Impact of pharmacists working in GP practice three

Safe

As in previous practices, the pharmacists were considered to increase safety of medication reconciliation. [Table 8.2]

Effective

In practice three, the pharmacist regularly made decisions himself to improve the effectiveness of treatment. For example, while reviewing discharge medication, he noted that a patient was alternatively ordering laxative and medication to stop diarrhoea. He spoke to the patient's carer to get more information and develop a long-term solution. [Table 8.3]

The pharmacist consulted guidance to determine treatment. This included following guidance on calculating creatinine clearance rates for patients on Direct Oral Anticoagulants (DOACs). Pharmacists had changed practice systems to improve the monitoring of these drugs.

The pharmacist realised that it was not possible to always follow guidance. He commented when performing medication reconciliation that he often did not change to recommended medication as he either felt this would confuse the patient or that he did not have time due to the number of tasks assigned to him.

Timely

In practice three it took slightly longer from discharge to complete medication reconciliation compared to practices one and two; the median time was 3 days (inter-quartile range 2-5 days). [Table 8.4]

Patient-centred

The pharmacist was observed discussing different treatment options with the patient and exploring their preferences. This was also demonstrated in review of case notes where discussions of the pros and cons of different options were recorded. [Table 8.5]

Equitable

The pharmacist adopted different approaches to ensure that the care of patients was equitable. For example, when he needed to discuss medication with a patient who had reduced hearing and struggled to use the telephone, he checked permissions and contacted a relative to arrange a face to face discussion. [Table 8.6]

Efficient

The pharmacist reduced waste by ensuring medications were needed and by checking if further blood tests were needed by reviewing hospital results. [Table 8.7]

Although administrative staff felt that the pharmacists sped up processing of discharge letters, the pharmacist did not, and thought that their thorough approach may delay the process.

The observed median time (and inter-quartile range) to complete the process of medication reconciliation was 8mins (4.3mins – 15mins). This is longer than in practices one and two.

Impact on workload

Quantity of work

As in other practices the pharmacist reduced GP work and this had allowed them to increase appointment time to twelve and a half minutes. Administrative staff also noticed a reduction in workload. [Table 8.8] Of the 49 prescribing tasks observed and reviewed four were reassigned to the GP (8%) [Table 8.7 and 8.8]

In practice three the pharmacist made decisions to reduce work that may come to the GPs in the future by anticipating and addressing future medication queries from patients and carers. He also ensured follow up test results came back to him thus reducing GP workload.

Cognitive workload

Administrative staff passed very few queries from patients or secondary care to pharmacists and felt that the cognitive difficulty of their work had remained the same. The GPs did not think that there was an increase in the cognitive difficulty of the tasks they had to do. [Table 8.9]

Wellbeing

Like other practices, the reduction in the quantity of work reduced feelings of stress. Pharmacist wellbeing was also supported by ensuring pharmacists were not doing monotonous, uninteresting tasks. [Table 8.10]

10.3.5 Retroduction

The following mechanisms were proposed:

- Team integration
- Pharmacist thoroughness
- Mentoring
- Anticipates risk and prevents increased work
- Balances thoroughness and efficiency

Team integration

As in other practices, this was essential for successful pharmacist working.

> *"We always make sure they are part of the team, encourage them to come to coffee with us eh so they have an informal relationship with us too."* (P3, GP1)

Initial induction was similar to other practices and included spending time with different team members, learning how GPs completed prescribing tasks and adapting these. They also attended practice meetings and practice social functions. The pharmacist was curious about how practice systems worked and spent time exploring these.

> *"Finding out how the practice itself works I think that's one of the problems is every practice is so different that even you know if you are quite experienced in one practice to be able to go into another practice and being able to do the same thing I think actually still takes quite a bedding in time."* (P3, Ph1)

The team integration mechanism consisted of functions similar to other practices. [Fig 8.2, Table 8.11] It resulted in increased work being assigned to pharmacists.

> *"They gradually start taking on the extra work em and actually for the most part because the processes are practice specific it's the practices that are showing them how to do things."* (P3, Ph1)

Pharmacist thoroughness

As in other practices, the pharmacists were considered very thorough especially at identifying prescribing safety issues.

> *"I think they are maybe a bit more aware [of potential prescribing safety issues] because it's their everyday job ...they would pick up on things like even GP or anybody else would maybe even miss." (P3, Admin 1)*

The pharmacist described himself as a 'pessimist' and considers all potential problems that could affect prescribing safety or workload. For example, liaising with the community pharmacy to make sure the patient took the correct medication.

> *"There's one particular patient that I know if he's been discharged from hospital [and there are medication changes] I need to make sure the pharmacy pick up his old blister packs and that's the only way that that will not go wrong."* (P3, Ph1)

Thoroughness required sufficient pharmacist knowledge and capacity and influenced prescribing decisions. [Figure 8.3, Table 8.11]

Mentoring

In practice three, GPs and pharmacists learning from each other was considered important. GPs regularly contacted the pharmacist to ask about prescribing tasks, for example to ask the relevance of a warning that appeared on the electronic prescribing system. The GPs and pharmacist regularly discussed difficult prescribing decisions informally at breaks. The GPs clearly trusted the advice the pharmacist gave.

Initially, the pharmacist received training to complete medication reconciliation but further development consisted of more than training. After this basic level of training had been provided, GPs saw their role as facilitating pharmacist development through mentoring so that pharmacists could make decisions independently.

> *"I think with the new contract one of the main things is everything needs to be working at the top of their licence. These are professionals who are very well trained and are very capable of looking after what we are asking them to look after and I think you need to appreciate that and give them to opportunity to do that."* (P3, GP2)

The practice approached mentoring like they did with the training of GP specialty trainees. This involved incrementally increasing the complexity of tasks they assigned the pharmacist while checking the quality of their work. When they felt the pharmacist was competent, they would trust them to complete these tasks but encourage them to discuss unusual situations.

Time was assigned for pharmacist and GP discussion. This included a weekly 20-minute slot for discussion of prescribing problems and a monthly developmental tutorial for the pharmacist. During these interactions the GPs asked the pharmacist to consider the benefits and risks of different options. This helped to develop understanding of the potential outcomes of their actions across the system.

Mentoring consisted of involvement in training, discussion with GPs and assigning tasks to pharmacists. [Figure 10.1, Table 8.11] It influenced the decisions made, the identification of prescribing problems and subsequent actions. It also improved team integration as pharmacists had an increased understanding of different roles and helped to build trust. It required the practice to agree this role in pharmacist development and to have the capacity and capability to mentor the pharmacist.

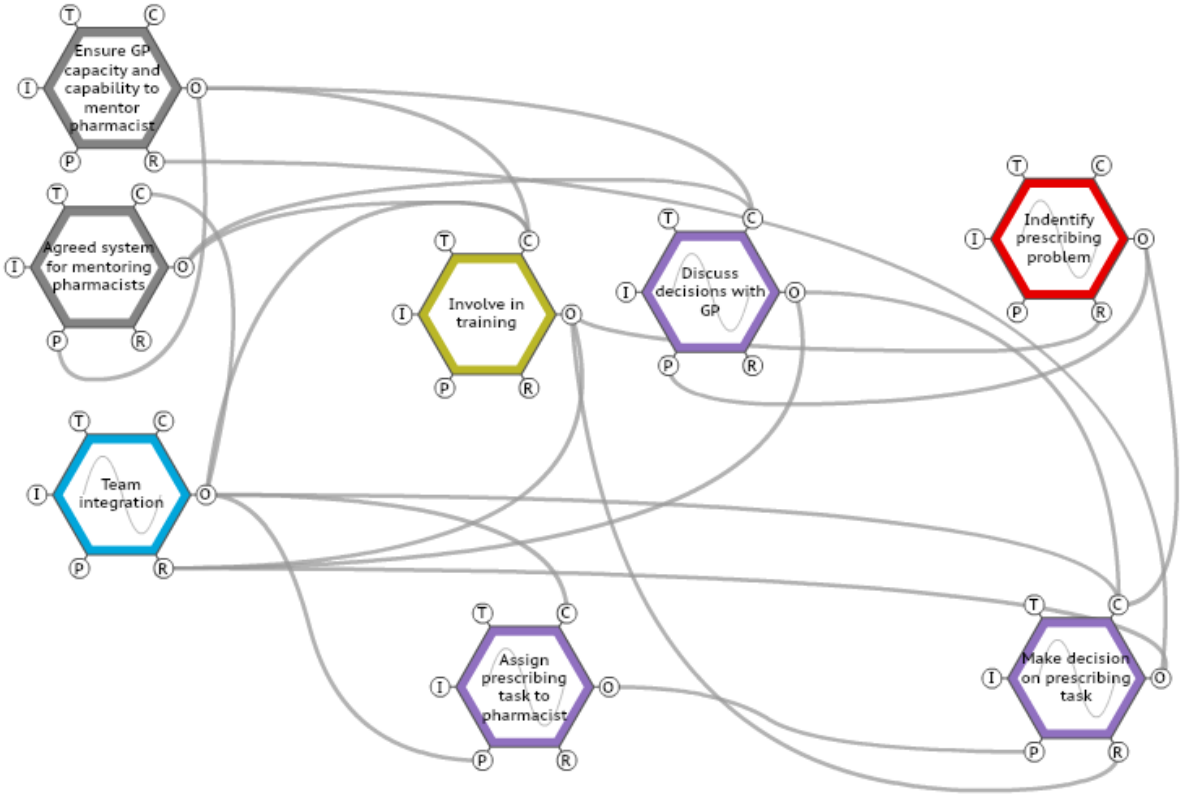

Figure 10.1 – Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Mentoring' with Team integration contracted

Anticipates risk and prevents increased practice work

In practice two, the pharmacists adopted a flexible approach to attempt to reduce the number of tasks directed to GPs. In practice three, the pharmacist proactively identified situations that may result in future work for the practice and prevent this work. He developed a system for ensuring work generated by his decisions, such as blood results or asking the administrative team to arrange clinical review, came back to him and not to a GP.

He anticipated problems that could cause extra GP work in the future. One example was ensuring a nursing home had a supply of all medication as he knew that they often called late on Friday looking for urgent prescriptions.

Another example was when dealing with the discharge letter for an elderly patient with mental health problems. She used a medication compliance aid

and changes were due. He spoke about the changes to the daughter who told him that the Community Psychiatric Nurse (CPN) was due to visit the next day and medication may be changed. He therefore contacted the community pharmacy to inform them of the situation so that they did not contact the surgery requesting updated medication. He then added a telephone appointment for himself the next day (after the CPN had visited) so that he could discuss suggested changes with the daughter and arrange a new medication compliance aid. He recorded this clearly in the notes as he was concerned the daughter, community pharmacy or CPN may telephone to discuss changes and he wanted to make sure they spoke to him to prevent work being passed to the on-call GP. This demonstrated that he had considered the situation from different perspectives and anticipated how work could be created for GPs or administrative staff. Delaying changing the blister pack may have reduced work for the practice and the community pharmacy and reduced confusion for the patient and her daughter.

He also identified patients who may not accept medication changes made during hospital admissions. He either directly discussed proposed changes with these patients or did not make the changes on the GP electronic prescribing system. By doing this he aimed to prevent the patient making future appointments with the GP to discuss the changes. Although the pharmacist was happy to discuss decisions with GPs, he felt that his role was to find answers to prevent GPs needing to deal with these issues.

> *"I don't want to burden anybody else with all of this stuff, so you spend a lot of time trying to find ways and find the answer."* (P3, Ph1)

This mechanism consisted of 'Identification of prescribing problem' and 'Make decisions on prescribing task'. [Figure 10.2, Table 8.11] In practices one and two, prescribing problems identified consisted of identifying problems related to safety and quality and to reduce waste. In practice three this function also identified problems that may cause extra work for the GPs or administrative staff.

It influenced the prescribing decisions made and could improve team integration as the value of the pharmacist was more evident. It required agreement on the role of the pharmacist and sufficient capacity. To be effective it required the pharmacist to understand the effect of decisions on the system as a whole which was achieved through mentoring.

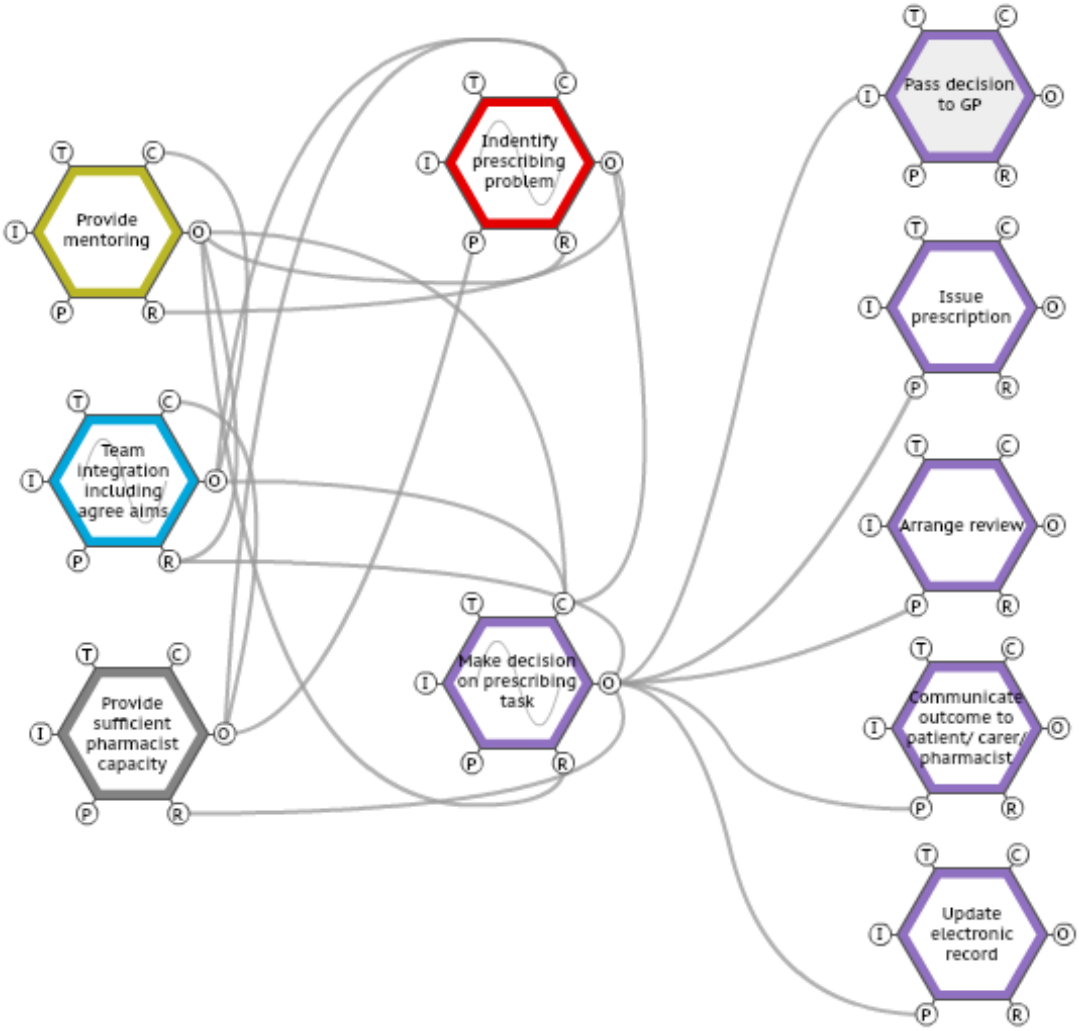

Figure 10.2 – Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Anticipates risk and prevents increased practice work' with Team integration and Mentoring contracted

Balance thoroughness and efficiency

The pharmacist varied his approach to suit the situation he faced. Decisions were based on the perceived risk to the patient and the workload that this would take or could create. If he perceived that a decision was low risk – for example a dose change to a medication unlikely to cause harm for a patient without cognitive impairment, he would be unlikely to contact the patient to discuss the change. He often contacted community pharmacies rather than the patient to ensure medication changes were implemented. A discharge letter included quinine as a new medication. He stated that this would not usually be recommended due to potential adverse effects and usually he would contact the patient to stop it. However, on review of the patient's record he noted chronic leg pain for which the patient was prescribed opiates. He decided to leave her on quinine as if he stopped this, he predicted that the patient would request an increased opiate dose. The thorough action would have been to discuss this with the patient and stop the medication, but the efficient action was to leave the quinine on the prescription.

This mechanism consisted of 'Make decision on prescribing task' and 'Identify prescribing problem' and influenced subsequent actions. [Figure 10.3, Table 8.11]

Successful balancing of competing goals required the pharmacist to understand the effects of their decisions on all parts of the system - the patient and carers, the effect on their own work, the administrative staff, GPs, community pharmacy and secondary care. This was achieved through team integration and mentoring. It was important that there was a shared understanding of the pharmacist's role. Trust in each other was essential. The practice had to trust the pharmacist to make acceptable decisions and the pharmacist had to trust the practice would be supportive if he varied his approach and the result was not as planned.

This adaptation was supported by a minimally specified protocol. The protocol used was described as 'purposefully vague'. By this he meant he had several options of what he could do to suit the conditions he faced.

"Not a written down thing but just thoroughly understand and confident that [the pharmacist] was doing it in a thorough way but it wasn't a protocol driven thing GP." (P3, GP1)

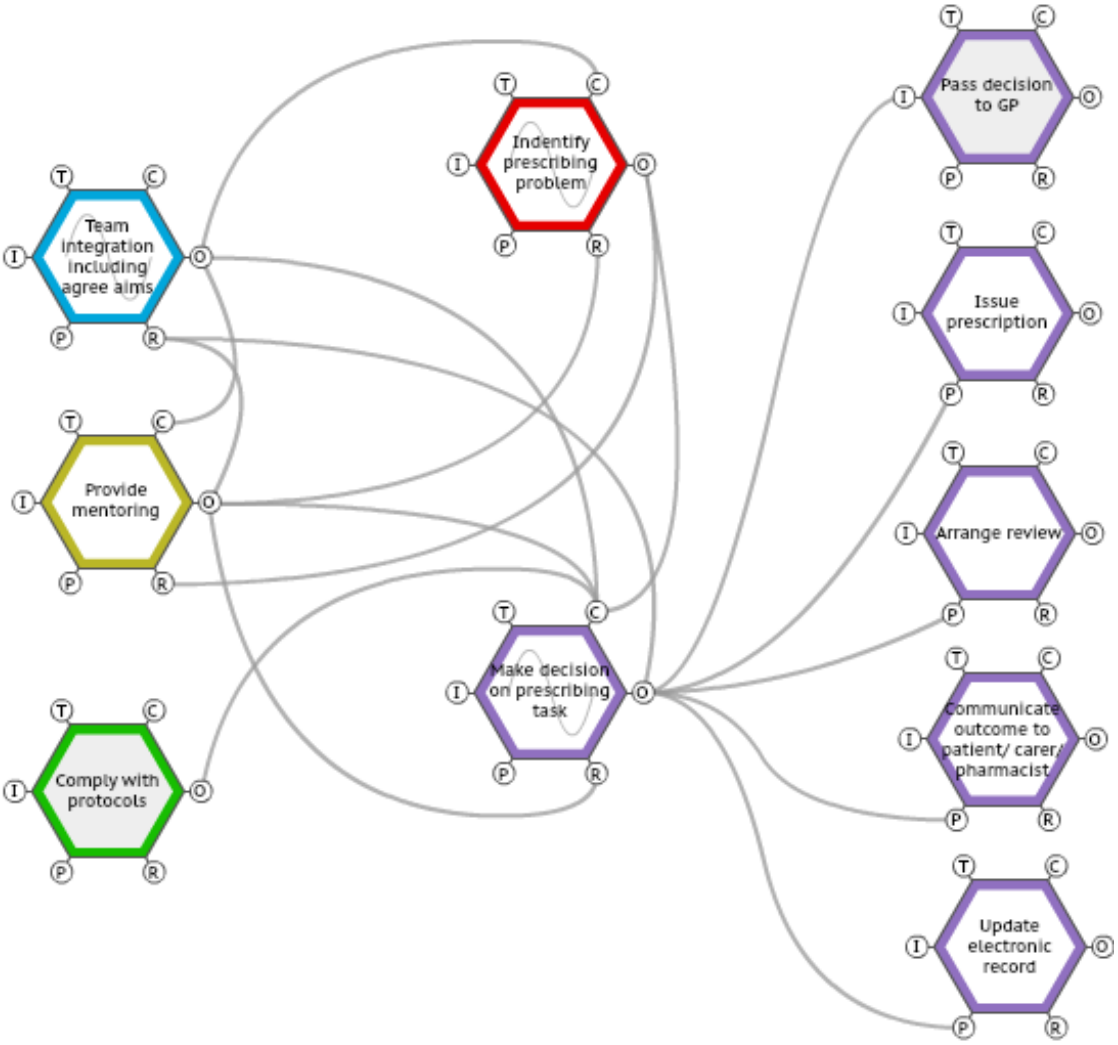

Figure 10.3 - Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Balance thoroughness and efficiency' with Team integration, Mentoring and Comply with protocols contracted

10.4 Summary of Case three

Comparison with previous cases

In Practice Three, the pharmacist was again very thorough but as well as focussing on prescribing risks for the patient, he identified and reduced risks of extra work for the practice.

It took longer from discharge until medication Reconciliation was completed. This was because the pharmacist was aware of the next steps in the process and completed it in time to prevent harm, patient inconvenience and extra practice work rather than to fit the shorter time frame of previous Practices. The protocol used allowed this flexibility.

Completing each medication reconciliation took, on average, longer than in Practice One or Two. This was due to attempts by the pharmacist to prevent future work, for example by contacting pharmacies, arranging further reviews and reviewing results on hospital systems.

Impact

- Pharmacist very safe and implemented evidence-based medication changes but took longer to complete tasks.
- Patient centred discussions on proposed changes.
- Anticipated and prevented work.
- No effect on administrative staff workload, reduced GP workload.

Proposed mechanisms

- Team integration
- Pharmacist thoroughness
- Mentoring
- Anticipates risk and prevent increased work
- Balance thoroughness and efficiency

Chapter 11 Results – Case four

11.1 Introduction

This chapter will present the results from Case Study four and will follow the same structure as the previous results chapters.

11.2 Description of Case

Practice four was the largest practice studied and was situated in a medium sized town (population approximately 21000). Two pharmacists worked in the practice. Pharmacist one (Ph1) was employed by the practice for 24 hours per week. He did not have set hours but agreed when he would work with the practice manager. The rest of his working week was made up of locum community (commercial) pharmacy shifts. He had been in post for 10 years and had been qualified as an independent prescriber for a similar time. He had completed a diploma in asthma management. He started working for the practice for four hours per week and his time commitment increased as his role developed. Initially he performed prescribing audits to improve the quality of prescribing. He then started to perform medication reconciliation following hospital discharge. Next he started to run the Disease Modifying Anti Rheumatoid Drug (DMARD) monitoring system. Finally, he began processing special requests.

During the study period a second pharmacist (Pharmacist two (Ph2)) began work in the practice. He was employed by the health board for 17.5 hours per week and had set hours. The rest of his working week was in a different GP practice. His work consisted of medication reconciliation post discharge and cost savings medication switches that were directed by the health board. He was learning how to do special requests from pharmacist one.

The practice was situated in the centre of the town. The consulting rooms were all on the ground floor along with a large reception, administration and practice manager rooms. Upstairs were formal and informal meetings rooms and a kitchen.

Both pharmacists usually worked in one of the consulting rooms and rarely mixed with administrative staff or GPs.

11.3 Data analysis

11.3.1 Explication of event

In practice four, pharmacists were electronically assigned prescribing tasks by the administrative team. Between 60 and 80 special requests were sent per day and up to 30 medication reconciliations following discharge. Additional tasks included processing requests for Disease Modifying Anti Rheumatoid Drugs (DMARDS) and dealing with patient medication queries. Pharmacist one ran a hypertension clinic in the practice where he saw patients for an annual review of hypertension to provide lifestyle and medication advice.

Pharmacist one's job was solely focussed on completing prescribing tasks from the list and he described choosing different tasks dependent on his perception of urgency and to vary his workload. For example, he usually started with special requests as he felt they needed to be completed within 24 hours in order to fulfil the practice's commitment to process requests within 48 hours. Pharmacist one dealt with most requests he was sent. For some requests, such as for palliative patients, he thought the patient's own GP would want to see the request and so would reassign it to them.

After an hour of processing special requests, he would switch to a different task. He felt this stopped him getting bored, which he felt could lead to mistakes. Medication reconciliation was usually performed next. The practice tried to complete medication reconciliation within seven days of discharge.

After performing medication reconciliation for an hour, he would usually change back to another task. He often scanned the task list looking for urgent requests. He also looked for what he described as interesting tasks. These tended to be from GPs regarding medication interactions or availability issues. He enjoyed researching these problems and replying to the GPs as he felt this was a break from the monotony of processing assigned prescribing tasks.

If needed, the pharmacist arranged review through administrative staff. He rarely telephoned patients or the community pharmacy. Reviews were arranged for blood tests (for medication monitoring purposes) and medication reviews (such as for antidepressants or analgesics).

A review of all prescribed medication was often undertaken while making a decision about an assigned prescribing task. The pharmacist would check that medication was being ordered at the correct frequency and that all monitoring was being performed.

Pharmacist two spent half his time in practice four working on the same electronic task list as pharmacist one. The rest of the time he completed work as directed by the health board. This involved searches and switches to cheaper medication and reviews of specific prescribing areas such as pain medication prescribing. When he started in the practice, he had received training from pharmacist one and worked in a similar manner.

Although pharmacist one, the GPs and the practice manager thought they probably did have protocols for prescribing work, they were not used. As a health board employee, pharmacist two was aware of the protocol used in the health board area but rarely referred to it as he knew how to perform the task.

11.3.2 Explication of Structure and Context

In practice four, the functions 'select an appropriate special request' and 'agree system for mentoring' were not enacted.[Figure 8.1] The function 'agree work arrangement – health board and practice' was not enacted as the practice employed the pharmacist and so could more easily specify work roles. The function 'select prescribing task' was included. Pharmacist one would switch between his various tasks during the day. This was performed in order to prioritise urgent tasks and to reduce boredom that could occur if doing the same task repeatedly.

11.3.3 Variability

Similar to other practices, assigning of tasks to pharmacists may be inappropriate. In practice four, the pharmacists dealt with a much larger number and type of prescribing tasks, yet some things were supposed to be sent to GPs but were still initially sent to the pharmacist – for example titration of epilepsy medication. There was no written list of pharmacist tasks and staff were therefore unsure of what should go straight to GPs. Prescribing decisions could be delayed if demand outstripped capacity and at these times prescribing tasks would be sent to GPs. Capacity was usually sufficient but there was no replacement when pharmacists were on annual leave. Pharmacists varied the tasks they performed for several reasons: to ensure he did not get bored performing one task repeatedly that could lead to errors due to distraction; when a task appeared urgent; if a task looked interesting and to optimise flow of work. He realised he needed to keep up to date with all aspects of his work – medication reconciliation, special requests and other prescribing tasks. These all required different subsequent actions in other parts of the system (administrative staff would ensure patients received special requests and community pharmacies may have to make up medication compliance aids for patients). If he focussed on one type of task the flow of work for others would be reduced which may result in delays for patients or other staff being unable to complete their tasks. Due to these factors he would switch regularly between tasks during the day.

11.3.4 Impact of pharmacists working in GP practice four

Safe

Pharmacist one described a pragmatic approach to safety. He tried to prevent safety issues by arranging suitable reviews and contacting community pharmacies. In some cases, additional actions may have been beneficial to reduce the risk of harm to the patient, for example additional blood test monitoring after medication changes and ensuring the patient was aware of temporarily withheld medication. [Table 8.2]

Effective

Pharmacist one implemented effective, evidence-based treatments including monitoring of medication. In one discharge document, a comment is made asking if the patient should be on a specific evidence-based medication. There was no record of this being actioned. [Table 8.3]

Timely

In practice four the median time until medication reconciliation was completed was 5.5 days (IQ range 3-9 days). This was longer than in other practices. Practice staff reported that the pharmacists responded very quickly to queries. [Table 8.4]

Patient-centred

Pharmacist one rarely contacted patients to discuss medication changes. He described contacting patients only where he felt this was crucial to ensure changes were implemented. Pharmacist one demonstrated other ways of ensuring changes were implemented, for example sending a detailed instruction to the community pharmacy to describe the reduction plan for a patient's medication. [Table 8.5]

Pharmacist one ran a hypertension clinic in the practice. At this clinic he implemented evidence-based practice to optimise treatment and described

a pragmatic approach where he varied his approach depending on the patients he was seeing.

Pharmacist one made decisions based on his perception of what would be in the best interests of the patient. For example, in two of the observed medication reconciliations this involved not implementing recommended changes (Observed medication reconciliation 12 and 19) as it could cause confusion, but these decisions were not discussed with the patient.

Equitable

Pharmacist one described how he may alter approaches to ensure care delivery was equitable for patients who could not understand him either due to impaired hearing, confusion or language barriers. [Table 8.6]

Efficient

Pharmacist one had the shortest median time for completion of observed medication reconciliation of 4.5mins (Inter-quartile range 3mins – 11.8mins). [Table 8.7]

Pharmacist one often made decisions to increase efficiency such as rejecting medication requests if the patient had adequate supplies.

Again, a pragmatic approach was adopted, if something was ordered slightly early and there were no patient safety concerns he would issue it in order to reduce work coming back to the practice. He would revert to a stricter approach if he had concern regarding the medication due to safety or abuse potential.

Impact on workload

Quantity of work

The GPs thought that the amount of work that the pharmacists completed was hugely beneficial. [Table 8.8] Of the 80 prescribing tasks observed and reviewed five were reassigned to the GP (6%) [Table 8.7 and 8.8]

Compared to other practices he completed many more prescribing tasks each day, often numbering over one hundred (including 60-80 special requests and up to 30 medication reconciliations).

The administrative staff felt that pharmacist one arranged more reviews and follow up than were necessary which resulted in increased work for them.

The pharmacist made decisions to reduce work elsewhere, for example making a decision on discrepancies on the discharge document, synchronising recall for monitoring of medication and long-term conditions.

Cognitive workload

The GPs felt that pharmacist one supported them with difficult prescribing decisions. For example, answering queries from GPs about medication interactions and developing a plan and starting work to prevent problems due to shortage of clomipramine. [Table 8.9]

Wellbeing

Pharmacist one enjoyed his role in practice as he felt he was maximising the impact of his knowledge. GPs also noted a benefit to well-being as they felt less stress due to reduced workload. [Table 8.10]

11.3.5 Retroduction

The following mechanisms were proposed for practice four:

- Team integration
- Pharmacists work in similar way to GPs
- Anticipates risks and prevents increased work
- Balance thoroughness and efficiency
- Experience of pharmacist
- Take responsibility for prescribing tasks

Team Integration

Pharmacist one had been working at the practice for ten years and was considered part of the team. This had been achieved slowly over several years as he spent more time with the other team members and his role developed.

> *"It's just evolved he just came in and he was only supposed to be was just popping in every so often then he was just became part of the team just one of us."* (P4, Admin 1)

As in other practices, integration into the team involved the agreement on and understanding of each other's roles and the generation of trust which was essential to allow assignment of tasks to pharmacists. [Figure 8.2, Table 8.11]

> *"Yes, you wouldn't be trusting necessarily their opinion …if it was a service with different people doing it and you did not who it was."* (P4, GP2)

For trust to develop, colocation and therefore familiarity were essential:

> *"You trust the people you know. You know you trust the district nurse you know not the district nurse you do not know and the district nurse you see regularly and comes to the Christmas night out."* (P4, GP2)

Involvement in staff training and supporting staff that did prescribing projects also helped team integration.

> *"He's developed because he works with us, he works within the team so he comes to all the staff training and everything - he is part of the development and comes to meetings."* (P4, PM1)

The GPs saw the pharmacist as part of the clinical team and valued his opinion as they would a GP colleague.

> *"[The pharmacist] is more of an equal – he's already got the experience."* (P4, GP1)

This was achieved through experience of beneficial application of his knowledge.

> *"Suppose there is a few situations where there has been someone on a medication or there is a couple of medicines long term where there has been an obvious interaction that's never been picked up. And I maybe in that situation suggest to them that this is not suitable and that we should change to an alternative. I would like to think when flagging these things up they would think that's quite good - this guy has spotted this and he is pointing us in the right direction here. Probably going to them with a few things like that hopefully have instilled a wee bit of confidence they know I know what I am doing."* (P4, Ph1)

Pharmacist works in similar way to GPs

In practice four, the pharmacist was described as making decisions like a GP.

> *"He works a bit like I would work - would probably deal with a certain level of uncertainty which is perhaps more than other pharmacist that you have dealt with."* (P4 GP2)

This meant that he had similar goals to the GPs: to complete as many prescribing tasks as possible while remaining safe.

> *"He has probably gauged what we accept - every practice will have a different threshold for what they will and will not do. How many times they will review before issuing Co-codamol without reviewing someone. I think he has probably developed that awareness as well."* (P4, GP1)

This mechanism consisted of the functions 'Select prescribing task' and 'Make decision on prescribing task'. [Figure 11.1, Table 8.11]

One of the reasons that the pharmacist worked in this way was that the GP practice employed pharmacist one. Due to this they were able to decide what prescribing tasks he should perform.

> *"We can determine what pharmacist one does to a certain extent - obviously as he's progressed with his prescribing and everything it's great so he can do more and more."* (P4, PM1)

Pharmacist one was happy with this management of his work.

> *"The GP employer should be able to ask you to do what they want as long as it is within your sphere of professionalism."* (P4, Ph1)

This resulted in the expansion of the role of pharmacist one, meaning more tasks were assigned to the pharmacist.

> *"You sort of came in here and you did what you wanted you to do - rather than you coming in with an instruction from somewhere else. All that I was doing in the beginning was the complex discharge letters and any sort of annual project cost saving ... that was about 4 hours per week and I think it just stemmed from there."* (P4, Ph1)

> *"I think some of the younger GPs were quite proactive seeing what I was able to do and then it just kind of went on from there. I think the next thing I started to do a bit more of is the repeats reviewed then after that we went on to the acute prescribing and dealing with the letters."* (P4, Ph1)

This mechanism required the practice to have complete control over the pharmacist's work. In addition, informal mentoring has helped to develop these ways of working. This consisted of an initial period of training followed by informal discussions about prescribing problems. More recently pharmacist one has helped informally mentor the second pharmacist employed by the health board (Ph 2). Pharmacist 2 splits his time between practice work and health board priority work meaning the practice did not have full control over what type of work he did, however, he was developing similar ways of working and his employers have noted the benefit to his development.

> *"Speaking to his (Ph2's) management they recognise that him being here with a pharmacist who has already been here has developed him... He just fits that system we are running, the way we work, and hasn't tried to change it, or he just does the same as Ph1 effectively just does the same."* (P4 GP1)

The mechanisms influence the outcome of prescribing decisions. This is demonstrated in Figure 11.1. [Figure 11.1]

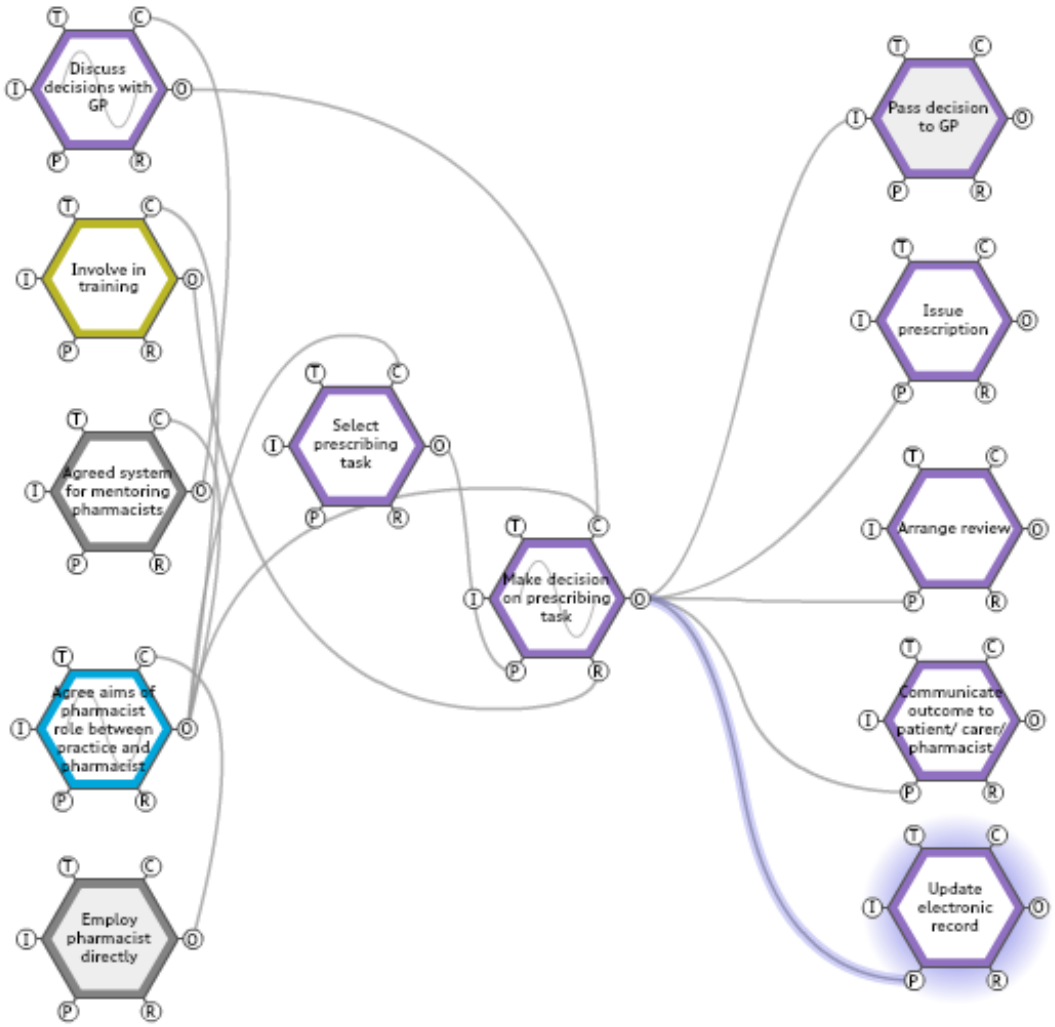

Figure 11.1 – Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Pharmacist work in similar manner to GPs'

<u>Anticipates risk and prevent increased work</u>

Similar to practice three, the ability of the pharmacist to anticipate problems and prevent these problems resulting in future additional practice work was seen as important. This involved identifying when a decision he made may cause a problem later in the week and mitigate the risk of this causing extra work for GPs or administrative staff by writing instructions in the notes. For example, a patient had requested analgesics early, he knew the patient and that he would complain that he needed his medication later

in the week. He calculated how many tablets he had and when they would run out and wrote clearly in the notes what the administrative staff should say to the patient if he called. This would prevent the patient being passed to a GP. The administrative staff found this useful:

> *"We all know that come in at five o'clock on a Friday and demand their prescriptions he always knows and writes in the notes this is not now due until, you know that sort of thing he does anticipate that. He is so helpful."* (P4, Admin1)

This mechanism consisted of 'Identification of prescribing problem' and 'make decisions on prescribing task'. It influenced the prescribing decisions made and could improve team integration. It required agreement on the role of the pharmacist and sufficient capacity. To be effective it required the pharmacist to understand the effect of decisions on the system as a whole which was achieved through mentoring. [Figure 10.2, Table 8.11]

Balance thoroughness and efficiency

When performing prescribing tasks such as special requests and medication reconciliation, pharmacist one was sometimes very thorough in terms of identifying risk to patients and implementing best practice:

> *Recalculated creatinine clearance for patients on Direct Oral Anti-Coagulant medication (DOACs) to ensure correct medication dose.* (Case Note review 4)

At other times the decisions he made may not be considered the most thorough:

> *No recheck of BP or bloods arranged despite increase in ACE inhibitor during admission.* (Case Note review 7)

> *Discharge document asked why patient not on an ACE/ A2 – would be recommended due to their medical history. No record of this being addressed.* (Case Note Review 12)

He identified but did not implement changes to increase cost-effectiveness (change from gaviscon to peptac) stating:

> *"I don't have time to mess about with stuff like also the patient will moan -not worth the bother."* (P4, Ph1)

If medications were missing from an immediate discharge letter, he would make a decision rather than contacting secondary care to confirm if this was intentional.

Patients were rarely contacted to discuss the medication reconciliation changes as it was not seen as high risk.

> *"Really it should always be done [phone patients after medication reconciliation] but realistically it doesn't happen - again that is just due to workload."* (P4, Ph1)

The pharmacist was not taught to work this way; it had developed slowly during his years in post. The mechanism was supported by team integration, mentoring and not using highly specified protocols. This way of working required an understanding of the system and the aims of his role. It requires him to take responsibility for his actions and to feel that he was empowered to make these decisions.

> *"I think part of it is that he is working independently he's not got management above him other than us. We are not sort of that way inclined and I think what you find with the other services and seeing how the other side have structures and management and there's kind of expectations and regular feedback, appraisal, and all that kind of thing – which we probably do a lot less of. I don't know if people feel a bit restricted by that in many senses... They lose their*

> *autonomy a little bit, but I think having them in practice they can develop that bit more because they'll gauge with each practice what is acceptable and what they are able to do."* (P4, GP1)

The mechanism is shown in the extraction for the FRAM model Figure 10.2. [Figure 10.2, Table 8.11]

Experience of pharmacist

It was common for those working in practice four to say that the system of pharmacist working was successful due to pharmacist one's experience. He had been at the practice for 10 years and his role had slowly evolved and expanded over that time. Experience can be defined as 'the knowledge and skill that you have gained through doing something for a period of time'. (The Oxford English Dictionary: online, 2021) The knowledge and skill the pharmacist had gained was to be able to quickly and safely make prescribing decisions.

Experience resulted in the pharmacist knowing some of the patients and common problems that would arise. He would often have dealt with these before the GP was aware of the problem.

> *"He has been here longer now and he knows the patients and he knows the ones that are, so you will say to him 'you know so and so' and he will say 'I have sorted that'. He is working the way we would work."* (P4, GP2)

Development through experience requires team integration, time in post and a mentoring approach from the GPs. [Figure 11.2, Table 8.11] This promotes reflection and learning from decisions and identification of prescribing problems. It influences subsequent actions and though enhancing integration into the team, influences the work assigned to pharmacists as the role developed.

"We were at various points where we had been rather short of bodies and he has come through and said I can do this and I can do that and this will this help, can I increase my hours and we said yes as it was worth every penny." (P4, GP1)

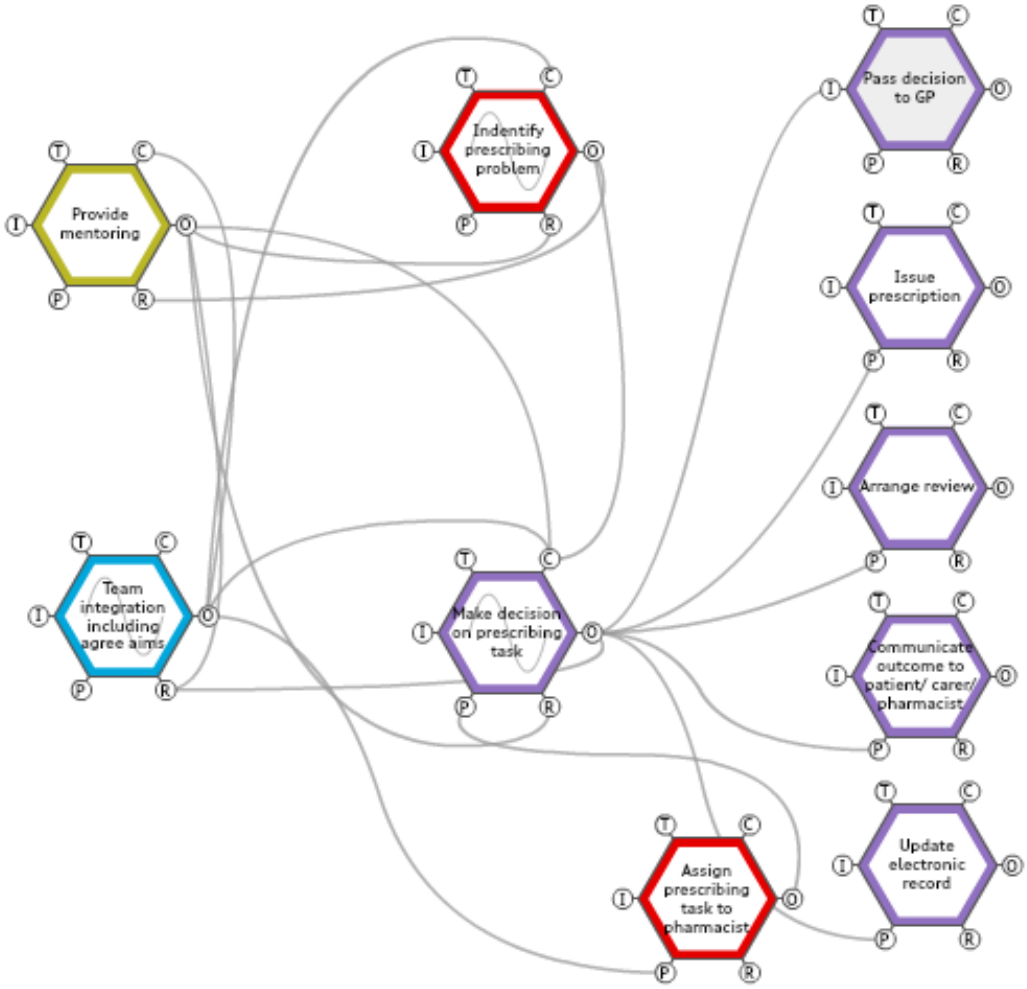

Figure 11.2 – Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Experience of pharmacist' with Team integration and Mentoring contracted

Take responsibility for prescribing tasks

For a successful system, pharmacists had to take responsibility for the prescribing tasks that they were assigned. This meant dealing with difficult decisions instead of passing them to GPs.

> *"He is also prepared to take that level, this is what we are happy with. He signed those prescriptions by himself...he is taking responsibility for that prescription."* (P4, GP2)

> *"He knows himself what is acceptable and his level of professional.. I can't think what the word is... confidence he is working towards the top of his capacity really."* (P4, GP1)

It was suggested that pharmacists who entered GP work from community as opposed to hospital pharmacy may be more used to working more independently at a higher level.

> *"Don't know if there is a difference with someone like Ph1 who comes from community pharmacy therefore who has a lot more autonomy as a community pharmacist, where he is giving minor ailments advice who had done all his prescribing list versus someone who has come from a hospital which is a lot more prescriptive."* (P4, GP1)

It was also supported by learning from the GPs. Consulting with patients where he had to make decisions was important.

> *"I think just working more with GPs makes me see if from their side of the desk if you like, and also being a prescriber as well makes you far more confident especially in the community about resolving a situation without having to contact a GP so I think just my whole development over the years finding more time in the surgery working closely with GPs and I think also doing clinics as well and seeing patients and applying more rather than sticking rigidly to a guideline you have to look at the patient and apply some common sense to their sort of situation."* (P4, Ph1)

This level of working was supported by team integration and mentoring of the pharmacist. [Figure 11.3, Table 8.11] The pharmacist would be less likely to pass the decision to the GP.

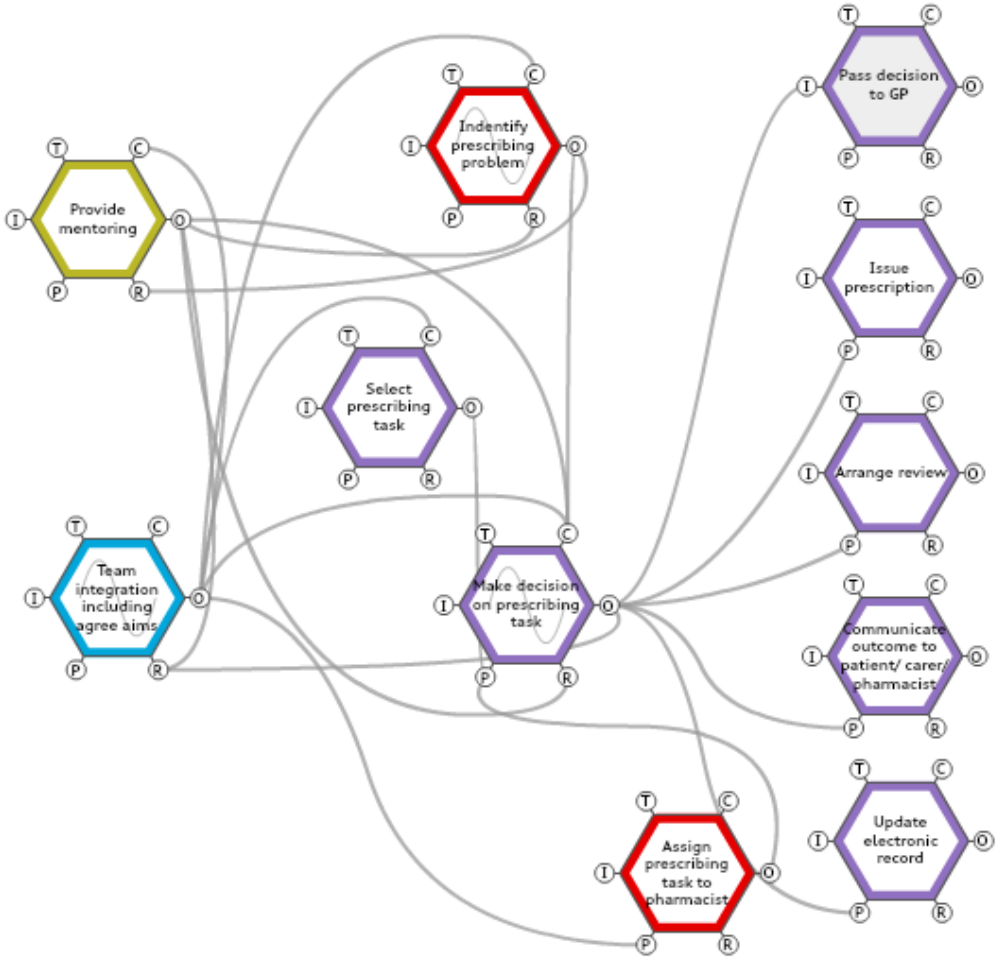

Figure 11.3 – Extract of Functional Resonance Analysis Method model demonstrating context mechanism and outcome for mechanism 'Take responsibility for prescribing tasks' with Team integration and Mentoring contracted.

11.4 Summary of Case four

Comparison with other practices

Case four had a unique model of pharmacist employment. As he was employed by the practice the goals of the role were clear. He was considered to work like a GP and prioritised efficiency over thoroughness meaning that he completed many more tasks than other pharmacists. In

some instances, this was at the cost of thoroughness, but he demonstrated the ability to identify potential safety concerns and revert to a more thorough approach.

Impact

- Pharmacists thought to be thorough (safe and effective) but would often make less thorough decisions.
- Highest number of prescribing tasks completed by pharmacist.
- Shortest time to complete tasks.
- Rarely contacted patients to discuss changes.
- Anticipated and prevented work for administrative staff and GPs.
- Increased workload for administrative staff
- Large reduction in work and increased wellbeing for GPs

Proposed mechanisms

- Team integration
- Pharmacists work in similar way to GPs
- Anticipates risk and prevents increased practice work
- Balance thoroughness and efficiency
- Experience of pharmacist
- Take responsibility for prescribing tasks

Chapter 12 Cross-case Analysis

12.1 Introduction

This chapter will analyse the results from each practice reported in the previous chapters to:

- Compare the impact of pharmacist working in the four cases to describe the impact on:
  - Quality of care
  - Workload and wellbeing
- Compare proposed mechanism between cases to:
  - Generate final mechanisms persistent across all cases
  - Describe how these influence the impact of pharmacists working in General Practice
  - Identify the contextual factors that support the identified mechanisms

12.2 Comparison of the impact of pharmacists in the four cases

The impact in each practice is summarised in Table 12.1 and described below. The reasons for the differences will be explored when proposed mechanisms are compared.

Practice	Safety	Effectiveness	Timely	Patient centred	Equitable	Efficient	Workload	Wellbeing
1	+++	+++	+++	+	+	++	+	++
2	+++	+++	+++	+	+	++	+	++
3	+++	++	++	+	+	+	++	++
4	++	+	+	+	+	+++	+++	++

Table 12.1 Summary of the findings of impact of pharmacists in each practice. The number of '+' signs assigned to each area are a subjective

grading of relative impact. '+++' impact of significant positive impact; '++' evidence of moderate positive impact; '+' evidence of less positive impact

12.2.1 Safe

In all practices, pharmacists were thought to increase safety. [Table 8.2] In practices one, two and three this was the case for nearly all prescribing tasks. In practice four, the pharmacist would occasionally not make decisions, such as arranging reviews that may be considered as the 'safe thing to do'.

12.2.2 Effective

In practice one and two the pharmacists always aimed to improve the effectiveness of prescribing by implementing and maximising evidence-based treatments. In practice three, this was not always the case especially if this may increase future work for the practice. In practice four, the pharmacist often did not make changes to prescribing to conform with what would be considered best, evidence-based care. [Table 8.3]

12.2.3 Timely

In practices one and two, tasks were processed soon after they were assigned to pharmacists. This complied with the target within their protocol. In practice three the time was slightly longer, and it was longer still in practice four. [Table 8.4]

12.2.4 Patient centred

There was little evidence of patient centred consulting. In practices one and two, patients were frequently contacted to ensure they understood changes. This happened less often in practice three and very rarely in practice four. In practice three the pharmacists demonstrated a patient centred approach where the patient's ideas and concerns about medication changes were explored. [Table 8.5]

12.2.5 Equitable

In all practices, pharmacists described adopting different approaches to ensure equitable care. [Table 8.6]

12.2.6 Efficient

In practice three, medication reconciliation took longer than other practices, and in practice four it was the shortest. [Table 8.7] The pharmacist in practice four was least likely to arrange further appointments. In all practices, pharmacists reduced medication waste. In practices one and two there was evidence of increasing workload in other parts of the health service. In practice two, pharmacists could increase work within the practice due to arranging additional reviews as they did not trust practice recall systems. In practices three and four the pharmacists anticipated additional work and made decisions to prevent it.

12.2.7 Workload

Quantity of work

In practice four, the pharmacist completed the greatest number of prescribing tasks. [Table 8.8] In practices three and four, the pharmacists were less likely to create work elsewhere (for example contacting secondary care). They also anticipated future work for the practice and tried to prevent it. In practice two, the pharmacists attempted to deal with tasks that should have been sent to GPs in order to reduce their workload. It was suggestion that pharmacists increased the amount of administrative staff work in practices one and four.

Cognitive difficulty of work

Administrative staff thought that pharmacists reduced the cognitive difficulty of their work in practices one and two. [Table 8.9] In practice one, a GP felt that pharmacists completed many of the straightforward tasks leaving the more complex decisions to the GPs.

12.2.9 Wellbeing

In all practices, the introduction of pharmacists was thought to improve the wellbeing of GPs and administrative staff. [Table 8.10] Pharmacists enjoyed the work, but it was noted that there were different expectations from the practice and the health board. This was not an issue in practice four who employed their own pharmacist. Varying tasks was important to pharmacist wellbeing.

12.3 Comparison of proposed mechanism between cases

The proposed mechanisms in each practice are as follows:

Table 12.2 – Proposed mechanisms in each Case Study

Practice	Proposed mechanisms
Practice one	Team integration Pharmacist training Compliance with protocols Pharmacist thoroughness
Practice two	Team integration Pharmacist training Compliance with protocols Pharmacist thoroughness Attempt to deal with any task to try to reduce GP workload
Practice three	Team integration Pharmacist thoroughness Mentoring Anticipates risk and prevent increased work Balances thoroughness and efficiency
Practice four	Team integration Pharmacists work in similar way to GPs Anticipates risks and prevents increased work Balance thoroughness and efficiency Experience of pharmacist Take responsibility for prescribing tasks

Evidence of the importance of the mechanisms in each practice is listed in Table 12.3. [Table 12.3] The observed impact (in bold) of proposed mechanisms in each practice is detailed below. The agreement, merging or

rejection of proposed mechanisms is described to identify agreed final mechanisms. [Table 8.11 and Figure 8.1]

Next, contextual factors that support the agreed final mechanisms were identified – through examination of functions that influence the mechanisms in the FRAM model. [Table 8.11, Figure 8.1]

12.3.1 Final mechanism 1 - Team integration

Team integration is an agreed final mechanism as in all practices this was necessary for successful pharmacist working. [Table 12.3] Through agreeing and learning roles and building trust, team integration **increased the quantity of work** completed by pharmacists. Integration increased understanding of practice processes from the perspectives of different team members and allowed pharmacists to consider the effect of their actions elsewhere in the system. There was a cyclical component to the mechanism as the more they integrated into the team, the more work they were assigned as this showed their value to the team, built trust and aided integration.

Contextual factors that support mechanism

Colocation of pharmacists with GPs and induction into the team were critical to successful team integration. Both promoted learning about each other's roles and the processes within the practice, successful team integration also ensured that the perspectives of those in different parts of the system were understood. For example, the pharmacist understood how decisions they made could increase work for clinical or administrative staff. Similarly, GPs could appreciate how their actions could influence pharmacists' work. For example, if they did not write a lot of information in the notes about a new medication, pharmacists may arrange an earlier review of a medication than was intended.

Team integration also required that the pharmacist's tasks were agreed. In practice four, where the pharmacist was directly employed by the practice,

tasks were agreed easily, in other practices negotiation with the employer was required.

12.3.2 Final mechanism 2 - Pharmacists' professional development in General Practice

The FRAM functions for the mechanisms, 'pharmacist training', 'mentoring' and 'experience' overlap and were combined to generate the mechanism 'Pharmacists' professional development in General Practice'. [Figures 8.5, 10.1, 11.2] All improved decision making to increase the **safety** and **effectiveness** of care and 'mentoring' and 'experience' increased the **quantity of work.**

Pharmacist training

Training concerned the ability of the pharmacist to complete the assigned task. The FRAM functions described training and discussion with GPs and impacted on decision making and team integration. In practices one and two, it was presumed that if pharmacists had sufficient pharmaceutical knowledge, had a protocol to follow and were trained to do this within the context of the practice then they would be successful (deliver **safe, effective** care). In practice three and four, it became clear that more than training was needed, such as mentoring and experience.

Pharmacist mentoring

Mentoring developed the ability to apply pharmaceutical knowledge to the GP context and deal with more complex problems where there was a degree of uncertainty as to the best course of action. The FRAM functions involved training, discussion with GPs and assigning appropriate tasks. In practice three, although training to complete tasks was initially needed, to increase impact, regular mentoring was scheduled and deemed important. In practice four, mentoring was informal but as in practice three, developed understanding of practice processes from the perspectives of all involved (administrative staff, clinical staff, patients, other community and

secondary care teams) and an appreciation of likely outcomes of decisions made. This impacted decision making and team integration.

There was evidence of mentoring in all practices, for example in practice one reflecting on 'errors' with the help of the GPs and exposure to more complex patients was identified as important to their development.

One of the pharmacists in practice one and two had a role in training other pharmacists starting in General Practice. She described training pharmacists to complete tasks rather than adopting a mentoring role.

> *Pharmacist 1 trains new pharmacists – says uses protocol to train rather than showing what she does – not really mentoring model.* (Memo after observation Practice 2)

Team integration was both necessary for, and improved by, mentoring. Effective mentoring increased the **safety, effectiveness** and **quantity of work** undertaken by pharmacists. It could also increase **patient centredness** of decision making through exploring the decision options available to the pharmacist and the possibility to explore these with patients.

<u>Experience of pharmacist</u>

Experience consisted of the outcome of training and mentoring over time, coupled with reflection and learning by the pharmacist. The FRAM model for 'Experience of pharmacist' included those for training and mentoring.

There was evidence in all practices that experience was important. Experience included previously dealing with a problem (making them more confident to deal with a similar problem) and knowledge of specific patients and situations. This proposed mechanism enhanced pharmacists' ability to identify and anticipate future prescribing problems thus improving the **safety, effectiveness** and **quantity of work** completed.

'Experience' consisted of more than just time in the role, it required the pharmacist to reflect and learn from their decisions and actions. This was supported by training and mentoring. Initially pharmacists completed training, during which they learned to complete different tasks by observing a pharmacist or GP. As pharmacists progressed, formal and informal mentoring aided their ability to reflect, learn and develop. When the pharmacist asked questions of the GPs, the responses aimed to help the pharmacist make decisions in future similar situations.

Contextual factors that support mechanism

Agreement by the practice and GPs to support the pharmacist's development was needed as was capacity to provide this support.

A key aspect of pharmacists' development was that they moved beyond focussing on the task they were completing to thinking more widely about the effect of their decisions in other parts of the system – for example on administrative staff, GPs, community pharmacy, secondary care both immediately and in the future.

In practices where the pharmacist was employed by the health board, development consisted of informal learning in the practice supported by formal learning with peers in other practices and annual evaluation and support of development through appraisal. This was not done in practice four.

12.3.3 Final mechanism 3 -Takes responsibility for assigned prescribing tasks

The two mechanisms 'Attempt to deal with any task to try to reduce GP workload' and 'Take responsibility for prescribing tasks' were combined to create the third agreed mechanism. The FRAM functions for 'Attempt to deal with any task to try to reduce GP workload' form the first part of the FRAM model for 'Take responsibility for prescribing tasks' as the first concerns acceptance or selection of the task and the second describes the

action performed once the task is assigned or selected. The impact is on **quantity of work** completed, and team integration is enhanced.

Although advice may have been sought from others, if the pharmacist still maintained responsibility it demonstrated their value to the rest of the team which enhanced team integration. It also increased their experience dealing with more complex decisions and reflection on these decisions enhanced their development.

Attempt to deal with any task to try to reduce GP workload

In practice two, pharmacists attempted to deal with tasks that should have been assigned to a GP – often described as 'being flexible'. This was to try to reduce GP workload. In all practices, the pharmacists were perceived as happy to help with any queries related to medication.

In practice one, the number of tasks assigned to pharmacists was agreed. Despite this the pharmacist completed tasks that were not 'counted' – for example patients who telephoned for medication queries. The number was therefore arbitrary, and the pharmacist completed as many tasks as possible within the hours of work.

In practice four, the priority of the pharmacist was to reduce GP workload. He would suggest ways he could achieve this when GP capacity was reduced. This flexible approach increased impact on **quantity of work**.

By trying to complete different types of task, the pharmacist learned more about the different aspects of work in the practice (thus increasing experience and decision-making ability) and demonstrated their impact on the **quantity of work** completed. This reinforced team integration.

Take responsibility for prescribing tasks

This proposed mechanism builds on the mechanism 'Attempt to deal with any tasks to try to reduce GP workload'. To maximise impact pharmacists had to take responsibility for the tasks they were assigned. This was

observed in all practices and was fundamental to having impact on **workload**.

Pharmacists work in similar way to GPs

Although this mechanism may seem similar, it was rejected as a final mechanism. In practice four, the pharmacist was treated as an equal to the GPs and considered to work in same manner as the GPs.

This proposed mechanism captured the desire to maximise impact on **quantity of work** completed. It does not demonstrate the impact on **safety** or **effectiveness** of pharmacists and was not described in other practices.

Contextual factors that support mechanism

In order to take responsibility for tasks, roles and tasks had to be agreed, pharmacists had to have adequate knowledge and skills and they had to accept their role within the practice. This mechanism required clear agreement on tasks and the purpose of their role between the pharmacist, practice and employer. As before this was more easily agreed when the pharmacist was directly employed by the practice.

12.3.4 Final mechanism 4 - Balances thoroughness and efficiency

The fourth final mechanism is balancing of thoroughness and efficiency. Although this mechanism was generated from evidence in practices three and four, it was present in all practices and included the FRAM functions for 'Pharmacist thoroughness' which was closely linked to 'Compliance with protocols'.

Balancing efficiency and thoroughness lead to increased **efficiency** and increased **quantity of work completed** at the cost of reduced **safety**, **effectiveness** and **patient centredness.**

Pharmacist thoroughness

In all practices, the thoroughness of the pharmacists was highlighted as increasing **safety and effectiveness**; however, problems with this approach were also noted. Pharmacists often wanted to make sure that monitoring was completed. Practices had recall systems to ensure patients and their medications were reviewed regularly (for example annual Blood Pressure reviews). Rather than trusting these systems, pharmacists would often allow a limited supply of medication (for example allowing one month of blood pressure tablets on repeat prescription) so that a prescription review by a GP or pharmacist would be initiated when the medication was reordered. This allowed the pharmacist to ensure patient compliance and that monitoring tasks were completed when due. Although this increased safety it reduced efficiency.

> *They'll still put it [a new anti-hypertensive medication] on for 12 reauthorisations just in case they don't come to that appointment [annual review appointment]... they want belt and braces* (P2, GP1)

Therefore, thoroughness could reduce the **quantity of work** undertaken by pharmacists and so had to be balanced with efficiency.

Compliance with protocols

Compliance with protocols was one way in which pharmacists were 'thorough'. It was seen as important in practice one and two where the protocol specified each step in the process.

> *In the eMIS medicines section click once on the medicine which correlates with medicine on IDL which will turn section blue as this allows missed medicines on IDL to be identified easily. (*Protocol P1 and P2)

The DMARD protocol was also very specific, stating when contact should be made with the Rheumatology nurse specialists. The pharmacist followed

protocols closely even when they knew the answer that they would receive. This approach resulted in generation of work elsewhere.

Unlike practices one and two, in practice three, it was thought compliance with over rigid protocols may restrict the amount of work a pharmacist could complete. Similarly, in practice four, protocols were considered restrictive and so were not used. However, the pharmacist complained that the administrative staff often sent inappropriate requests and some form of protocol may have been beneficial.

Therefore, protocols may be useful to aid the **safety** and **effectiveness** of work but if they are overly specified may restrict the work of the pharmacist leading to less impact on **quantity of work** completed and increased work elsewhere. Compliance with protocols is therefore rejected as a mechanism for maximising success.

Contextual factors that support mechanism

To trade-off effectively between competing demands, required understanding of the system from different perspectives. This was achieved through team integration and pharmacist development. It was supported by agreed aims of the pharmacist's role and a flexible approach to pharmacist decision making – allowing them to alter their decision based on the situation they faced. This was inhibited by over specified protocols which limited pharmacists' options and could reduce efficiency. Protocols were useful when they supported learning of tasks but were rarely used afterwards.

Different thresholds for trading-off between efficiency and thoroughness were present in each practice which reflected the agreed roles and values of the pharmacists and GPs in that practice.

In practices one and two, the pharmacists favoured thoroughness. This was because they saw their role as identifying and rectifying every problem. The

GPs accepted this as long as the pharmacists had time to complete assigned tasks.

The pharmacist in practice three was aware of the need to show impact in terms of both the quantity of work completed but also the need to increase safety and effectiveness and so would often be less thorough in order to be more efficient but only when he felt the risk of being efficient (or the benefit of a thorough action) was low.

In practice four the pharmacist prioritised efficiency more than thoroughness. This was clear in the observed actions and the case notes that were reviewed. This was because he was employed by the pharmacist and the shared goal and values were to reduce GP workload while remaining safe but without having to investigate and rectify all potential problems.

The pharmacist in practice four changed from prioritising efficiency to prioritising thoroughness when he considered certain tasks and medications to be high risk. These medications included anti-coagulant medication and analgesics; if ordered early they would not be issued. He weighed up the potential risks and benefit to the patient and to the practice which gave him a variety of ways to respond in such situations. When he felt there was a high likelihood of harm for the patient he would revert to the thorough action.

Other indicators that made him revert to a more thorough way of working (leading indicators) included the use of compliance aids. Previous experience dealing with similar requests was important. Similar leading indicators were employed by pharmacists in other practices which resulted in them reverting to being thorough.

12.3.5 Final mechanism 5 - Anticipates risks and prevents increased work

In practices two and three, pharmacists anticipated and rectified prescribing problems as part of the thoroughness of their actions. These

related to **safety** and **effectiveness** of medications prescribed. In addition to anticipating risks to safety and effectiveness, in practices three and four, pharmacists anticipated the risk of increased future work for the practice. Decisions were made to reduce the risk of extra work. To have maximum impact on **workload**, anticipation is crucial.

Contextual factors that support mechanism

Anticipation of risks and of future work was necessary to balance thoroughness and efficiency and maximise impact. It required team integration and development to appreciate potential problems in different parts of the system. It required taking responsibility in order to act to reduce the risk and future work.

12.4 Interaction between mechanisms

The agreed final mechanisms describe successful ways of working, and important processes, the practice need to enact. The interaction of the mechanisms and important contextual factors are shown in Figure 12.1. [Figure 12.1] Although each mechanism was present in each practice, there was variability in how each mechanism was enacted. With variability seen in all mechanisms, the interactions of the mechanisms resulted in positive outcomes in all practices. For example, in practice one and two, there was more thoroughness than efficiency, but there was adequate capacity to allow pharmacists to take responsibility for prescribing decisions. This contrasts with practice four, where, due to high demand and limited capacity, efficiency was favoured over thoroughness in order to ensure the pharmacist was able to take responsibility for tasks.

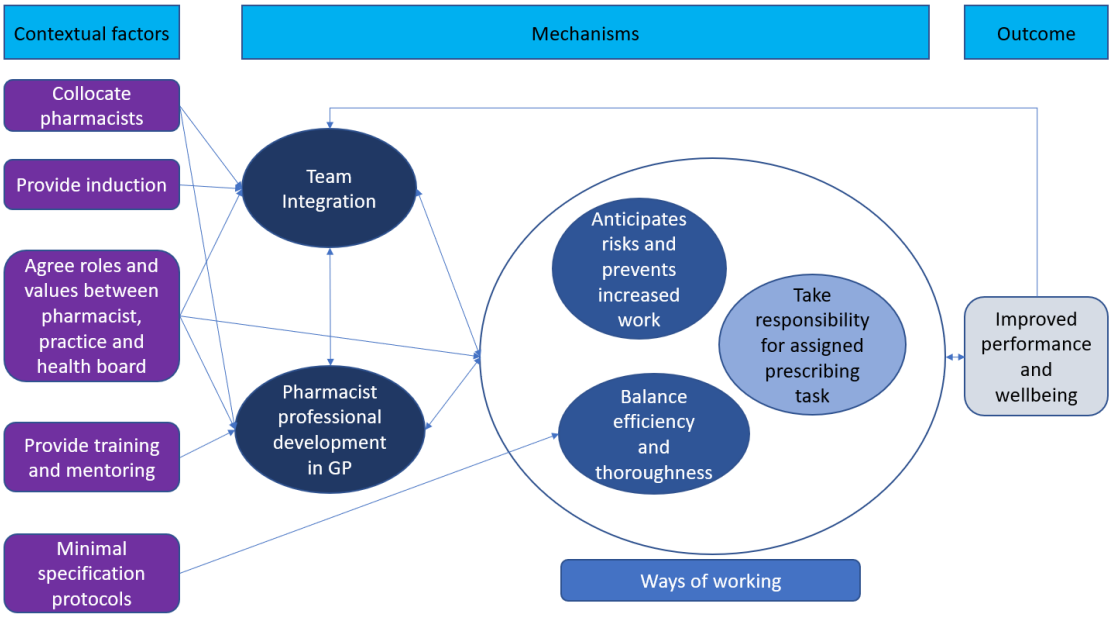

Figure 12.1 - Model describing the interaction between different generative mechanisms and the important contextual factors.

12.5 Conclusions

This chapter has compared the impact of pharmacists across the four practices. It then considered the proposed mechanisms from each case and compared supporting and refuting evidence. From this, agreed, final mechanisms have been identified and the contextual factors that support these mechanisms.

Chapter 13 Discussion

The discussion chapter will be structured as follows. First, the results will be summarised to answer each research question. Findings will be compared to the relevant published literature in turn. Next the strengths and weaknesses of the thesis will be discussed. Recommendations for policy, practice, education, regulation and research will be presented in Chapter 14.

13.1 Summary of findings

13.1.1 Research Question 1

When pharmacists complete medication reconciliation in the community after hospital discharge:

a. What approaches have been used?

b. What is the effect on discrepancy identification and resolution, the clinical relevance of resolved discrepancies and healthcare utilisation in terms of readmission rates, emergency department attendance and primary care workload?

The systematic review in chapter 3 identified studies describing many different approaches to medication reconciliation. These varied by setting in which it was undertaken (for example, community pharmacy, patient's home, GP practice), timing of medication reconciliation after discharge and the degree of collaboration with GPs. It showed that pharmacists completed the task effectively and identified more discrepancies than GPs completing medication reconciliation. The clinical relevance of these discrepancies was unclear and there was no clear beneficial impact on health care utilisation, such as readmission or GP workload. There was little description of factors that influenced success or otherwise.

The lack of impact on healthcare utilisation contradicted the results of a systematic review analysing the impact of medication reconciliation undertaken in hospital during care transitions. This may have been because

the hospital-based studies included interventions that comprised of more than medication reconciliation.

From this it was clear that pharmacists can successfully complete tasks previously performed by other professionals; however, increasing the positive impact of pharmacists working in GP requires more than just successfully completing a specified task. Subsequent studies in the thesis studied the impact of pharmacists in GP settings and the factors that influenced their positive impact.

13.1.2 Research Question 2

What is the impact of pharmacists working in general practices on:

a. Quality of care?
b. Workload and wellbeing?

Quality of Care

Safety

In all four Case Studies, pharmacists increased the safety of prescribed medication by, for example, identifying possible interactions and ensuring monitoring was undertaken. This finding was also reported in the systematic review where pharmacists potentially increase the safety of prescribed medication through identification and resolution of unintended discrepancies following discharge from hospital.

Avery reported that 5% of prescriptions produced in general practice potentially have an 'error' (Avery *et al.*, 2012). Involvement of pharmacists may be one way to reduce this 'error' rate (Nkansah *et al.*, 2010; Avery *et al.*, 2012). For example, in specific treatment areas, such as chronic pain prescribing, pharmacists have been able to make recommendations about safe prescribing (McDermott *et al.*, 2006) and pharmacists have been shown to reduce high risk prescribing (Guthrie *et al.*, 2011). These studies evaluated pharmacists performing specific tasks (such as medication reconciliation or chronic pain prescribing) rather than evaluating the impact of pharmacists in their new integrated roles in General Practice. Initial

studies of pharmacists undertaking roles in GP demonstrate that GP staff believed that pharmacists improved safety of prescribed medication (Mann *et al.*, 2018; Maskrey *et al.*, 2018).

Effectiveness

The pharmacists in this thesis made prescribing decisions based on best evidence and increased concordance with evidence-based guidance and thus could increase the effectiveness of treatment.

The impact of pharmacists working with GP teams has previously been shown to objectively improve effectiveness of long-term condition management, such as diabetes, blood pressure, lipid management, cardiovascular risk, chronic pain and to improve measures of patient reported control of asthma and COPD (Choe *et al.*, 2005; Karikari and Khachi, 2013; Bruhn *et al.*, 2013; Tan *et al.*, 2014). In these studies, pharmacists introduced new services that usually included face-to-face review of patients and often a multi-disciplinary team. The vast majority of the work of the pharmacists in this thesis was making one-off decisions on an assigned prescribing task. Although they may increase the effectiveness of care, evidence of the impact on measurable outcomes (such as diabetes or blood pressure control) of these roles is still lacking.

Timeliness

Pharmacists completed prescribing tasks more quickly after the task was assigned to them compared to when GPs were assigned these tasks. Similar results have been seen in other studies (Freeman *et al.*, 2012).

Person-centredness

Pharmacists adapted their approach to suit different patient characteristics, such as reduced hearing, confusion and concerns about abuse of medication. Patient centred consulting, where pharmacists explored the patient's ideas, concerns, expectations, health beliefs and discussed treatment options, was rarely seen.

Pharmacists have previously been shown to consult in a patient centred manner while working in GP practices (Chen and Britten, 2000; Nkansah *et al.*, 2010). Although patient centred approaches are included as part of the IHI quality domains, pharmacists reported not having sufficient capacity to adopt this approach with all patients and maintain safe, effective and efficient care.

Equitable

Ensuring health care provision is equitable across Scotland is one of the goals of the 2018 GP contract (Scottish Government, 2017). Pharmacists have been shown to improve access and care for individuals with disabilities, (Wakeham *et al.*, 2017) but there was little evidence to show how this was achieved proactively in this thesis. There is a paucity of studies published with pharmacists working in GP roles that have studied the impact on equity of care. The Govan Social and Healthcare Integration Pathway (SHIP) Project used a Multi-Disciplinary Team approach to improve healthcare access and outcomes for those living in a very deprived area of Glasgow (Din *et al.*, 2020). As part of this project pharmacists conducted medication reviews which were received positively by patients and resulted in deprescribing and medication counselling. The pharmacist's impact on improving equity of care has not been demonstrated in this thesis and perhaps could have been explored in this thesis in more depth by including Case Studies where pharmacists were introduced with the aim of improving equity such as in the SHIP project.

Efficiency

Pharmacists made cost effective decisions but did not do this consistently due to the volume of work they had to complete. Pharmacists have an established role in many primary care settings to improve cost effectiveness (Bush *et al.*, 2018). They have been shown to make efficiency savings (Karikari and Khachi, 2013) and reduce the number of medications prescribed, for example in chronic pain (Nkansah *et al.*, 2010; Neilson *et al.*, 2015). Again, these studies have not looked at pharmacists doing work

previously performed by GPs, instead they often acted to advise on the most cost effective treatment or performed a new service to review prescribing in a specific disease area. Evaluation of pharmacists based in English GP practices, reported benefits in deprescribing of medication which may improve efficiency in terms of cost and time for prescribing and monitoring (Mann *et al.*, 2018).

Decisions to increase safety and effectiveness decreased efficiency in practice systems by, for example, arranging reviews that were not necessary. This is not something reported in other studies.

Workload and wellbeing

Workload

The systematic review failed to show a significant reduction in GP workload. In the Case Studies, although pharmacists reduced aspects of GP workload, work in related systems was increased and extra work was generated for the practice due to efforts to maximise safety and effectiveness.

Reduced workload has been reported in other studies of pharmacists working in General Practice. In a retrospective study of pharmacist activity in an English Clinical Commissioning Group (CCG), GP based pharmacists' activity was reviewed across 49 practices (Bush *et al.*, 2018). It was estimated that over a 4-month period, four full time equivalent pharmacists saved 628 GP appointments and an additional 647 hours of GP work. Therefore, one pharmacist would save 7.2 appointments and an additional 7.4 hours of GP time (for example for administrative work) per week.

A study in Scotland reported that providing 225 hours of pharmacists' time saved 78.4 hours of GP time (Maskrey *et al.*, 2018). Therefore, one pharmacist (with a 35 hours per week contract) would save 12 hours of GP time per week.

In case studies in England, pharmacists were thought to free roughly 7-10.5 hours of GP time per week (Bush *et al.*, 2018).

Although providing useful quantitative data, often these studies looked only at the effect on reduction on GP demand through completion of specified tasks rather than considering impact on other parts of the system. In this thesis, the effect on the workload of administrative staff was variable, in one case study, it was thought to have increased their work. Decisions to increase safety and effectiveness also increased practice workload by, for example, arranging patient reviews that were not considered necessary by GPs. In addition, the introduction of pharmacists increased work in other parts of health care system (such as rheumatology services). These aspects of the impact of pharmacists have not been evaluated and a systems approach to quantitively measure the impact of pharmacist is needed if the introduction of pharmacists is to be justified on the basis of a positive impact on workload.

Wellbeing

GPs reported improved wellbeing due to reduced demand. Administrative staff felt that the cognitive difficulty of their work reduced, therefore lessening work-related stress. Pharmacists enjoyed the work but found that they had to cope with different priorities such as the GP practice prioritising workload, their employer (the health board) prioritising cost efficiencies and their own professional drive to expand their role to patient facing roles.

In a study of pharmacists' perception of working in GP practices, 90% of pharmacists enjoyed their new roles in GP. Patient contact and providing holistic care helped to increase pharmacist job satisfaction (Butterworth *et al.*, 2017).

13.1.3 Research Question 3, 4 and 5

Research Question 3 - What mechanisms influence the impact of pharmacists working in General Practice on quality of care, workload and wellbeing?

Research Question 4 - How do identified mechanisms influence the impact of pharmacists working in General Practice on quality of care, workload and wellbeing?

Research Question 5 - What contextual factors influence the identified mechanisms that impact on quality of care, workload and wellbeing?

The Case Studies identified five mechanisms and influencing contextual factors that were important to increase the positive impact of pharmacists working in GP practices. These mechanisms describe actions of pharmacists, GP staff and organisations. To move beyond reliance on personal or individual organisation behaviours we need to consider how systems support such behaviours and therefore important contextual factors need to be defined. Individual actions to support successful and resilient systems have been described as 'kinetic energy', whereas 'potential energy' is created through system design to enhance these actions (Hollnagel, Wears, Braithwaite, 2016).

Team integration

Many studies have reported the importance of integration of pharmacists into GP teams (Pottie *et al.*, 2008; Bradley *et al.*, 2008; Butterworth *et al.*, 2017; Ryan *et al.*, 2018; Hazen *et al.*, 2019). Team integration improves the 'quality of relationship' between healthcare providers yet this is often disregarded when interdisciplinary work is designed (Hovey and Craig, 2011). The 'quality of relationship' means how people learn from, with and about each other to collaborate and maximise success.

A systematic review of non-dispensing pharmacists in primary care settings identified that for disease specific outcomes, such as management of a specific chronic disease, team integration was less important than for patient centred outcomes (Hazen *et al.*, 2019); however, when completing tasks previously performed by GPs, such as in this thesis, integration was essential (Bradley *et al.*, 2008).

Trust enhanced team integration and was promoted by pharmacists taking responsibility and completing tasks. Similar results have been reported in studies of pharmacist integration in GP practices in Australia (Tan *et al.*, 2014)

Bradley reported that pharmacists who came from community (commercial) pharmacy found it more difficult to integrate (Bradley *et al.*, 2018). This was not seen in the Case Studies as pharmacists with this type of experience were familiar with the fast pace and repetitiveness of GP prescribing tasks.

Contextual factors

The importance of clear role descriptions is necessary to ensure a professional awareness of different roles and how these integrate (Tan *et al.*, 2014; Ryan *et al.*, 2018). This awareness can be increased through producing educational material to describe roles and prioritising time for team building (Ryan *et al.*, 2018).

Colocation of pharmacists and GPs and an effective induction process have been shown to be necessary to begin the process of integration as direct contact helps to build relationships (Blondal, Sporrong, Almarsdottir, 2017; Ryan *et al.*, 2018; Bush *et al.*, 2018). Involvement in team education helped to build relationships by showing the value of the professional's role to the team (Blondal, Sporrong, Almarsdottir, 2017). It has been suggested that a minimum time working in a practice (two-days per week) is necessary to promote integration (Bush *et al.*, 2018) and that dedicated workspace was important (Bradley *et al.*, 2018).

In the Case Studies, colocation and inductions were deemed essential. Pharmacists often moved workspace and the benefit of sitting near administrative staff was noted as one way to understand different perspectives of prescribing tasks and to increase flexibility by attempting to complete tasks that may usually be sent to GPs.

Pharmacists' professional development in General Practice

Successful pharmacist working required the pharmacist to contextualise their knowledge to the GP environment. To ensure this happened, the practice and the GPs had to take an active role in supporting the development of the pharmacist (Farrell *et al.*, 2008; Pottie *et al.*, 2008; Ryan *et al.*, 2018).

Pharmacists have been accused of being risk adverse (Rosenthal, Austin, Tsuyuki, 2016) and 'black-or-white' meaning they see decisions about prescribing as having a right or wrong answer, often based on evidence, guidance or regulation (Farrell *et al.*, 2008; Pottie *et al.*, 2008). In GP, situations may not be covered by a guideline. As pharmacists developed, they understood this and were able to manage uncertainty better.

The 'black and white' approach has been described as the lower of three levels of pharmacists' development (Gibson, Vosper, Furniss, 2020). *Competence* is when decisions are mainly rule based. When pharmacists become *proficient,* they adopt a holistic, patient centred approach. At this stage they often revert to analytical, rule-based approaches when they deal with more complex decisions, such as where there is a degree of uncertainty as to the best course of action. Finally, pharmacists become *experts*. Once they have reached this stage, their understanding of situations becomes more intuitive than analytical, they balance guidance with individual patient wishes and needs and understand the possible effects of their actions within their own and related systems.

Contextual factors

Many pharmacists undertaking new roles in GP want more mentoring from GPs when they start (Bradley *et al.*, 2008). Mentoring has been shown to improve performance compared to conventional learning methods (Bloom, 1984) and is used in GP specialty training (Royal College of General Practitioners, 2020). Funding to support GP mentoring was not in place in any of the Case Study practices, but it has been suggested that this may aid

practice involvement in pharmacist development as variation in GP and practice support in pharmacist development has been reported (Mann *et al.*, 2018).

Competence frameworks that are specific for General Practice Pharmacists have been recommended to support pharmacists' development (Mann *et al.*, 2018). In 2016, NHS Education for Scotland published the General Practice Clinical Pharmacist Competency & Capability Framework (NHS Education for Scotland, 2016). This was based on the Royal Pharmaceutical Society's Advanced Pharmacy Framework which provides a framework for development across the profession (Royal Pharmaceutical Society, 2013).

The GP Clinical Pharmacist Competency & Capability framework describes competence and capabilities expected at four levels. The first is Foundation level – which would equate to the first 100 days of a qualified pharmacist working in a GP practice. This is followed by Advanced 1, Advanced 2 and finally Mastery level. Only at Mastery level is the pharmacist expected to practice fully autonomously. The framework describes "Supervised Learning Events" that can be used by supervisors and pharmacists to demonstrate the competencies and capabilities.

Although rarely mentioned by study participants, it appears a useful, practical tool for pharmacists to self-assess their current level of development and create a plan to enhance their development. It can also be a useful tool for GP practices and other employing organisations to assess the level at which potential recruits can work.

<u>Takes responsibility for assigned prescribing tasks</u>

This mechanism had two aspects: a flexible approach meaning the pharmacist accepted different types of task and that the pharmacist made a decision rather than passing the decision to someone else such as a GP or secondary care colleague

Pharmacist flexibility has been shown to be important to their successful integration into GP (Bradley *et al.*, 2008) and it has been argued that an approach based on the needs of the practice is required (Mann *et al.*, 2018). Being flexible in accepting assigned prescribing tasks increased understanding of different parts of the system and were considered a good use of pharmacists' skills and knowledge. In Scotland, pharmacists are being asked to work to 'the top of their licence' (Scottish Government, 2016b). This may be inhibited by limiting their tasks to a small number of agreed tasks.

While integration is essential for role development, completion of assigned tasks reinforces team integration by showing the value of the pharmacist within the team (Tan *et al.*, 2014). It has been suggested that pharmacists avoid making decisions due to lack of confidence, reluctance to take responsibility for decisions and fear of uncertainty (Rosenthal, Austin, Tsuyuki, 2010). Several reasons for this have been postulated. These include pharmacists feeling that their role is educating others about medications rather than making the decisions themselves and taking responsibility for patient care (Gregory, Whyte, Austin, 2016; Rosenthal, Austin, Tsuyuki, 2016). This has impact at all levels of pharmacist development. For example, students attracted to pharmacy may desire a role where they are not responsible directly for patient care and once qualified, the cultural expectations of the profession may reinforce this way of working (Noble *et al.*, 2014). The high number of tasks assigned to pharmacists are thought to restrict the time available to develop decision making skills. The ability to take responsibility for clinical decisions is essential to maximise the positive impact of pharmacists and should be developed at all stages of their careers.

Contextual factors

Mismatches between expected roles and actual roles have been reported and so it is essential that these are defined (Mann *et al.*, 2018). Pharmacists employed by health boards reported being pulled in three directions: the

need to complete work for the GP practice; the requirements of their employer to meet their goals (safety and cost); and the drive of their professional body to develop the roles of the pharmacist beyond completion of prescribing tasks to completion of patient facing roles. Being qualified as an independent prescriber was considered important in English Case Studies in order to take responsibility and maximise impact (Mann *et al.*, 2018).

Key performance indicators that fit the practice goals are considered important (Mann *et al.*, 2018). One danger of KPIs is that targets can reduce flexibility and limit pharmacists' exposure to situations that can help their devlopment (Mann *et al.*, 2018). Targets therefore need to match what the practice needs and the development of pharmacists.

Care needs to be taken that targets are appropriate and are based on system outcomes rather than process measures that reduce flexibility for practices and pharmacists. For example, a target to contact patients within two days of discharge to discuss medication changes may not improve safety, effectiveness or patient centredness and may mean that pharmacists cannot adopt a flexible approach based on the task they are undertaking.

The GP Clinical Pharmacist Competency & Capability Framework promotes an approach where pharmacists seek out and take responsibility for appropriate work tasks with the aim of reducing workload of other staff members (NHS Education for Scotland, 2016).

Balances thoroughness and efficiency

Once pharmacists had taken responsibility for decisions, they had to balance competing goals such as thoroughness and efficiency. This type of trade-off is called an Efficiency Thoroughness Trade-off (ETTO) which has been described across different industries and is considered a ubiquitous part of normal work (Tucker and Spear, 2006; Hollnagel, 2009). ETTOs describe how people balance the need to be efficient (get through many prescribing tasks) against being thorough (ensure maximum safety and effectiveness of treatment). Other trade-offs may include trading off against short term effectiveness of a drug (such as diazepam to help anxiety) and long-term

safety issues (such as addiction). Similarly, pharmacists may have to trade-off between patient preference for a drug (such as specific type of inhaler) versus cost savings (using formulary recommended inhaler). These trade-offs need to be made by pharmacists in order to take responsibility and complete tasks and to adopt a patient-centred approach.

Although in early Resilient Engineering studies, ETTOs were thought to be examples of resilient behaviours, Hollnagel has stated that they are too ubiquitous to define resilience (Hollnagel, 2009). Trade-offs are found in all areas of life, for example, it may be maximally thorough to check your car (including tyres condition and windscreen washer fluid levels) before each journey, but the efficient approach would be to get in your car and drive and check for issues less frequently. Similarly, when a GP signs repeat prescriptions, the thorough approach is to check the records of each patient. If this action was followed, then the GP would have little time for other actions (such as consulting) and so the efficient action of signing prescriptions without checking records is followed. This is a riskier behaviour but essential for the work to be done. ETTOs have previously been described in medication reviews in General Practice (Duncan *et al.*, 2019). Medication reviews were performed quickly in order to complete as many as possible and would usually not follow the thorough action of involving patients.

To understand the problem and the possible outcomes of decisions required an understanding of the wider system; pharmacists needed to understand the long- and short-term consequences of different actions for the patient, the administrative staff, community pharmacy, and secondary care. Pharmacist development should aim to enhance this type of ‘system understanding’.

Other terms have been used to describe ‘systems understanding’. For example, ‘expert’ pharmacists have been described as having a ‘situational understanding’ (Gibson, Vosper, Furniss, 2020). This means that they have moved beyond processing facts and completing tasks and are able to see

'the big picture' of how their decision could affect that patient (who may have multiple medications and illnesses) and other parts of the system (for example, creating extra work for secondary care).

Contextual factors

To trade-off successfully pharmacists need to have shared values, clear goals and to understand both the problem and the possible outcomes of decisions made.

Shared 'values' means that both pharmacists and practice team members have similar beliefs and attitudes. In practice one and two this was evident in the desire for pharmacists to increase safety; whereas in practice four the belief was that they should reduce workload. Despite this, in all practices there was an acceptance that both thoroughness and efficiency cannot be maximised but instead each needs to be optimised. This clearly has an influence on the goals that pharmacists have in these practices.

Clear goals are an important part of all mechanisms and have been previously described as important for pharmacists working in GP (Ryan *et al.*, 2018). While it is tempting to presume this means defined goals such as number and type of specific tasks a pharmacist needs to complete, this is counterproductive as it reduces the flexibility pharmacists have to learn from different tasks and adapt how they are working based on capacity and demand.

As well as flexibility in *what* tasks are performed, the findings of this thesis would suggest that flexibility in *how* tasks are performed is important and this needs to be supported by the practice and the employer. Work should be goal orientated rather than process orientated (Hollnagel, Woods, Leveson, 2017). This can be supported by protocols that have minimal specification to support local adaptation allowing pharmacists to choose the most sensible approach.

Governance arrangements that do not make this explicit, risk limiting pharmacists' ability to adapt successfully. A focus on a holistic, system-based approach has shown more favourable outcomes (such as reduced readmissions after pharmacist medication review) compared to approaches that are more task orientated (Luetsch, Rowett, Twigg, 2021).

National policy documents, such as Prescription for Excellence promote the expansion of pharmacist roles to increase safe, effective, patient centred care while simultaneously describing the intention to reduce GP workload (Scottish Government, 2013). The potential conflict of these goals is not mentioned. Similarly, the GP Clinical Pharmacist Competency & Capability Framework describes the need for pharmacists to increase both safety and efficiency but does at least note the need for altering the approach when there are competing goals (NHS Education for Scotland, 2016).

Recent work to identify competencies required for pharmacists to work successfully in GP in Scotland, focussed on the possession of adequate knowledge and the ability to assess patients and information rather than the ability to balance different priorities (Mueller, T. *et al.*, 2021).

Anticipates risks and prevents increased work

In order to trade-off successfully the pharmacist must be able to anticipate the risks of the different decisions to the patient and to the organisation. The ability to anticipate the risk to safety is clearly key to improving the safety of prescribed medication. The Case Studies also showed the importance of anticipating the potential for actions to increase workload. This is supported by the identification of 'leading indicators' of potential problems both to safety and to workload. Leading indicators are soft signs that something may not be right (Rubio-Romero *et al.*, 2018). For example, in the ETTO example above describing GPs signing repeat prescriptions, while making this trade-off, GPs may scan prescriptions for medications of concern (such as opiates). When pharmacists conduct prescribing tasks, leading indicators included drugs with potential for abuse, high risk medication, obvious medication interactions, medication compliance aids

and previous experience dealing with the patient or their carer. When these were identified pharmacists changed their actions to become more thorough to reduce risk of patient harm and increased workload.

Anticipating threats to quality and workload and responding to reduce risk was found to be important in successful pharmacist working. Anticipating and responding are two of the cornerstones of resilience (Pariès, 2013). The remaining two cornerstones (monitoring and learning) were also crucial to successful work. The ability to monitor system functioning to identify threats and learn from previous events was evident in the Case Studies.

Contextual factors

Pharmacists demonstrated a repertoire of resilient behaviour. Development of these requires 'exposure to disruption' (Nyssen and Berastegui, 2017). This means taking responsibility for prescribing decisions in difficult situations, for example when there is missing information or uncertainty as to the best decision. Coping with these decisions and reflecting on decisions and outcomes helps to develop resilient behaviours. For this reason, taking responsibility for prescribing tasks supports the ability to anticipate and reduce the risk of problems.

The GP Clinical Pharmacist Competency & Capability framework recognises the need for pharmacists to anticipate potential medication problems such as interactions or addictions, but it does not include the need to recognise the effect of decisions on future healthcare utilisation (NHS Education for Scotland, 2016).

<u>Other important factors for success reported in literature</u>

A method to share good practice with peers has been suggested as helping pharmacists integrate successfully in GP (Mann *et al.*, 2018). This was not noted in this thesis, pehaps because health board employed pharmacists already worked in more than one practice and so already shared good practice without requiring a formal system. Similarly, a local GP lead or champion has been reported to be important (Mann *et al.*, 2018). In this

research, there was not always a GP who performed this role. This may be because the pharmacists in three practices were employed by the health board and so although all the GPs contributed to the pharmacists' development, there was no obvious assigned lead.

13.2 Strengths and Limitations

13.2.1 Philosophical approach

The Critical Realism approach was useful to explore *how* and *why* outcomes arose and the links to contextual factors. A critique of Critical Realism is provided in chapter four but particularly relevant to this thesis is that an infinite number of mechanisms could have been proposed. Context and mechanisms can be considered at different levels. For example, shared values and goals were considered an important contextual factor, but to consider how these can be achieved, they would need to be treated as an outcome and other mechanisms and contextual factors sought.

Given that a realist approach was adopted for the Case Studies, it could be argued that a realist review of the literature to understand the mechanisms that increase the success of pharmacists working in General Practice should have been conducted. This approach was considered but it became clear that very little contextual information was provided in the published studies to allow this approach.

13.2.2 Methodology

Similar to the philosophical approach, Case Study research is ideal for exploring *why* and *how* things happen, but it does not offer quantitative 'answers'. An experimental approach would be needed to achieve this. In Case Study research the theory produced is relevant to the cases and not always generalisable to all possible cases and therefore the wider utility of the findings of this thesis may be limited (Yin, 2014).

Theoretical perspective

Using Resilience Engineering as a theoretical perspective to direct data collection and analysis increased the robustness of the Case Study approach (Yin, 2014) but may have limited learning about the mechanisms at play as more importance may have been assigned to certain findings. Two of the cornerstones of resilience are the need to anticipate and respond to threats and opportunities (Pariès, 2013). This may have influenced the importance placed on these aspects of pharmacists' work. It may have been useful to compare different theoretical approaches to understanding the data. For example, Normalisation Process Theory is used to understand the factors required for successful intervention implementation (May *et al.*, 2009). This approach is especially useful in complex interventions and may have provided a theoretical approach and framework that would have produced different findings.

In addition, RE influenced the choice of cases which may have introduced selection bias and influenced findings. Included practices were all recommended as examples where pharmacist introduction had been successful as this was consistent with a RE theoretical approach. This may mean that the practices that were studied did not reflect reality in the majority of Scottish practices. It may be that additional or different findings may have been found in practices where their introduction was not deemed successful.

Methods

Choice of cases

The four cases chosen included different practice sizes, levels of deprivation and pharmacist employment models but further Case Studies could have been conducted that may have generated other findings. All four practices were training practices. Such practices are used to inducting and developing new team members. This may limit the findings of this thesis as in non-

training practices, additional factors important in pharmacist integration may have been identified.

The same pharmacists worked in practices one and two. This was chosen intentionally to examine different contexts rather than different pharmacists, but it may have resulted in similar results and less learning.

Little was learned about equity of access. Although one of the practices was a Deep End practice, perhaps purposively including practices where pharmacists were used to improve equity of access may have increased learning. For example, pharmacists are used within the Govan Social and Healthcare Integration Pathway (SHIP) Project and this may have been useful to study (Din *et al.*, 2020).

Data collection and analysis

A system-thinking approach directed data collection and analysis. This helped ensure that perspectives of, and the impact on, all staff in the practice were included; however, the opinions of patients were not directly sought. In all systems approaches, agreement of a boundary for analysis is needed but this boundary is not 'real' as components are influenced from outside the system of study and vice versa (McNab *et al.*, 2020). Not involving patients is a limitation of the thesis as the inclusion of patients would have helped to determine the impact of pharmacists' introduction. However, the aim was to determine the parts of the practice system that influenced impact and it was thought that this did not require direct patient input although conversations with patients were observed and the outcome of consultations were reviewed in case notes.

It is also important to consider if participants altered their behaviour or what they said based on their own perception of their role or due to the identity of the observer and interviewer. For example, pharmacists have been reported to identify as being very thorough and maybe felt that they should demonstrate these behaviours during the study. It may be that when not being observed they acted differently, however case note review

examined their actions prior to the commencement of observation and interview and similar levels of thoroughness were identified.

Observation and interviews were undertaken by a GP with a national role in safety. This may have influenced pharmacists to show how safe and capable they could be and to support the development of their new roles. Completion of this research by a pharmacist may have altered findings as a GP may have pre-existing opinions of pharmacists working in this setting. To counteract this, pharmacists were fully involved as participants and a robust research approach was employed. Collaboration on the development of recommendations and a multi-disciplinary approach to future research is required.

The thesis identified an important missing factor in the Institute of Health Improvement (IHI) domains of quality – wellbeing. This is also not included in the Scottish Government's three domains of quality: safety, effectiveness and patient centeredness. From a Human Factors perspective, interventions should have the dual aims of improving system performance indicators (such as safety and quality) as well as wellbeing of those in the system (patients and staff). When implementing change, it can be easy to overlook the need to ensure, enhance or at least maintain staff wellbeing and so including this aspect as a specific domain will be helpful when planning and evaluating future improvement projects.

The FRAM model provided a useful representation of the interactions between different actions and supported the Critical Realism approach. Combinations of functions described mechanisms that produced outcomes and were influenced by functions which indicated important contextual factors. Unfortunately, the FRAM cannot assign the level of importance of different functions. Although there is development to include quantification into the FRAM, it is unlikely to be possible when used in projects such as this as the variability of each function is based on unique conditions.

While the FRAM has distinct theoretical foundations in Resilience Engineering, currently there is no defined path from the FRAM model to recommendations for change. In this thesis, Critical Realism provided a way to examine the important contextual factors that can act as levers for change. Previously studies have used a Quality Improvement approach to identify areas within the FRAM for small tests of change (McNab *et al.*, 2018). A combination of both approaches has been reported before and is likely to be the optimal use of FRAM as it can identify important contextual factors to support change (national policy drivers) and more local process changes (Ross, Al *et al.*, 2018).

Evolved role of pharmacists

Since completion of the Case Study data collection, the role of pharmacists has evolved. In many practices, pharmacists started their new roles by performing medicines reconciliation, as was seen in Cases Two and Three. The plan of the 2018 GMS GP contract was that more pharmacotherapy tasks were transferred to pharmacists (described in Chapter 1 and Box 1.1) which has now happened in many practices with other staff, such as pharmacy technicians, joining teams. This may date the description of how pharmacists worked in this thesis; however, Practice Four had a more established pharmacist who had gradually increased the repertoire of task undertaken. Inclusion of this practice adds learning to how the role of pharmacists can evolve and become integrated into everyday General Practice.

Chapter 14 Recommendations and Conclusions

This chapter will provide detailed system wide recommendations based on the findings of this thesis. Recommendations are based on contextual factors that influenced mechanisms to increase the 'potential energy' to support behaviours within a successful resilient system. Recommendations relate to policy, education and research. Recommendations require to be developed in more detail with relevant stakeholders such as those responsible for employing and providing training for GP Clinical Pharmacists.

Key recommendations are listed in Box 14.1. [Box 1] A full list and description of recommendations follows.

Box 14.1 Key recommendations for introduction of pharmacists into General Medical Practice

1. Integrate pharmacists into GP teams to learn roles, understand different perspectives of system function and develop shared goals.
2. Mentor pharmacists to develop understanding of role and wider impact of decisions on quality and workload – this requires local and national support.
3. Allow flexibility of how pharmacists work to support practice need, learn about different tasks and adapt approaches when needed.
4. Policy makers and those involved in pharmacist employment and development need to recognise that it is not possible to be maximally safe and efficient.

14.1 Recommendation for GP practice policy

Recommendation 1 - Pharmacists should receive an induction from the GP practice to:

- learn the roles of those working in the practice
- ensure practice staff understand the role of the pharmacist
- understand the processes in the practice from perspectives of team members.

Recommendation 2 – Practices should locate pharmacists with administrative staff for at least part of their week.

Recommendation 3 - Protocols for pharmacists' work in GP practices should have minimal specification to support local adaptation.

Recommendation 4 - There should be an agreed formal or informal system to mentor pharmacists in the practice.

For these recommendations to be implemented, GPs should understand pharmacists' need for development and accept their role in pharmacist development.

Recommendation 5 - A flexible approach to assignment of tasks based on practice need should be promoted.

Being overly prescriptive in relation to the types of tasks assigned to pharmacists, by, for example, agreeing a daily quota or limited type of prescribing tasks assigned, may be counterproductive. Processing varying types of tasks supports development.

14.2 Recommendations for regional Health board policy

Recommendation 6 – Pharmacists' work should be located in the GP practice.

Recommendation 7 - Work roles and goals should be agreed between the health board, the practice and the pharmacist.

Agreed work roles and goals should support pharmacists to work independently (Recommendation 15) and adopt a flexible approach to completing tasks (Recommendation 5).

Recommendation 8 - Pharmacists need access to appropriate information including hospital electronic prescribing systems.

14.3 Recommendation for national policy

Recommendation 9 – National policy should recognise that it is not possible to be maximally safe and efficient.

It is easy to pronounce that the introduction of pharmacists into general practice will improve safety, increase effectiveness and reduce GP workload. While there may be evidence to support some effect in all these areas it is not possible to be maximally safe, effective and efficient. If the aim of introducing pharmacists into GP is to reduce work for GPs, then pharmacists need to trade-off and not be maximally safe. If the goal is to be maximally safe, then the number of pharmacists required will increase and more work in other parts of healthcare will be generated. This needs to be made explicit at a national level and considered in local governance systems.

The impact of pharmacist introduction will be disappointing for some unless there is a realisation that financial constraints will mean that sufficient capacity to maximise all these outcomes is not possible.

Recommendation 10 - GP mentoring of pharmacists should be supported

Time for mentoring pharmacists by GPs needs to be supported nationally. This could be achieved by utilising the increased capacity created when pharmacists work in GP practices and through financial incentivisation. Parallels can be drawn with the model for mentoring GP specialty trainees as they provide increased capacity for practices and practices receive a small financial incentive for providing mentorship and assurance. This is

likely to be relevant to many professions that are increasing their role providing primary care services, such as paramedics, physiotherapists and mental health practitioners.

14.4 Recommendations for pharmacist education and training

> Recommendation 11 – Responsibility for pharmacist development should be shared between practice, health board and pharmacist

Pharmacists should be trained to complete tasks by GPs or pharmacists either in the practice or in another setting - but this is only the first step in optimising impact.

> Recommendation 12 - Pharmacists should be encouraged to reflect on and learn from decisions through mentoring.

Pharmacists need to balance competing goals (such as safety and efficiency). Discussing, reflecting and learning from cases helps to develop a shared understanding of how to trade-off between competing goals.

> Recommendation 13 - The GP Clinical Pharmacist Competency & Capability framework could be enhanced to support the development of pharmacists' ability to cope with uncertainty and adopt a flexible approach to their new role.

Pharmacists' decision making has been described as 'black and white', a finding supported in this thesis. Undergraduate, preregistration and GP pharmacist training needs to consider how pharmacists can optimally deal with uncertainty or areas of 'grey'. Some efforts are already being made in this area with guidance about how pharmacist training can help them to deal with complexity (Gibson, Vosper, Furniss, 2020) and the NES GP Clinical Pharmacist Competency & Capability framework which provides a structure for pharmacists' development (NHS Education for Scotland, 2016). Although a useful developmental framework which includes capabilities related to

taking responsibility for decisions and managing uncertainty, it does not include two key capabilities for optimising impact:

1. Adapting to balance competing goals such as between being maximally safe, effective and efficient.
2. Anticipating and mitigating to reduce the potential for additional workload resulting from decisions.

14.5 Recommendations for future research

This thesis identified, but did not quantify, the effects of pharmacist implementation on other parts of the heath and care system. A quantitative study is needed that does more than look at GP time saved by pharmacist introduction, but also evaluates their impact on other parts of the system such as extra workload in primary and secondary care, admission rates and patient wellbeing. This will allow economic evaluation of their impact across the health and care system which can direct national policy either to support the increasing the number of GP Clinical Pharmacists or to consider other models, for example expanding GP or Advanced Nurse Practitioner numbers.

Similarly, the recommendations developed in this thesis for successful implementation of pharmacists in GP practices have not been assessed quantitatively. Future research should aim to test the impact of recommendations. One option is to develop scenarios where the benefits of different approaches could be compared. For example, the thorough approach may improve concordance with current evidence, but may increase workload for the practice, secondary care and others. The cost effectiveness and health benefits of different decisions could be compared in an attempt to demonstrate the optimal response.

Similar scenarios may be a useful approach to train pharmacists. The use of scenarios could increase understanding of their role and processes in GP by demonstrating the impact of different decisions on the patient, the practice

and other areas of healthcare. It could develop their capability to balance different goals and encourage reflection and related learning on events.

The best way to mentor pharmacists should also be evaluated. In this thesis and in a large study in England, a model akin to the mentoring of GP registrars is suggested, where support is gradually reduced as pharmacists develop competency (Mann *et al.*, 2018). This would require to be supported by Scottish Government and the territorial health boards that employ pharmacists.

The effective use of the Multi-Disciplinary Team (MDT) is often promoted as the way forward in primary care (Scottish Government, 2017). The role of the pharmacists as part of an MDT and the optimal system to provide benefit in collaborative working needs further research. This could explore the patient characteristics and scenarios where pharmacists' input is most beneficial, such as patients with complex medication regimes and those with long term conditions.

14.6 Conclusions

This thesis has systematically reviewed the published evidence of the impact of pharmacists in completing medication reconciliation in the community after hospital discharge. Pharmacists identified more discrepancies than when the task was completed by GPs, but there was no statistically significant impact on patient outcomes or healthcare use.

Four Case Studies adopted a system approach to explore the impact of pharmacists working in GP practices and to understand and model the systems employed. Pharmacists increased safety and effectiveness of prescribing and overall, reduced GP workload; however, the actions to be safe and effective could increase workload in secondary care and within the practice for GPs and administrative staff.

A Critical Realism approach to Case Study research combined with the use of the Functional Resonance Analysis method identified important mechanisms and contextual factors to increase the impact of pharmacists.

Five final mechanisms were generated: team integration, pharmacists' professional development, taking responsibility for assigned prescribing tasks, balancing thoroughness and efficiency and anticipating risk and preventing future work. From this, thirteen recommendations were generated to support the effective implementation of pharmacists into General Practice.

Although further research is required to provide evidence of the impact of these recommendations, these recommendations should be considered by all involved in the recruitment, supervision, training and management of pharmacists in general practice as well as those with governance, regulatory and national policy roles.

Tables

Table 2.1 – Summary of Systematic Reviews of pharmacist led medication reconciliation interventions

Year	Author	Purpose of systematic review	Setting	Number of studies	Measure	Findings
2009	Bayoumi et al	To examine the effectiveness of medication reconciliation interventions in primary care	Primary care	1 RCT 3 before and after studies	Number of unintentional discrepancies between GP record and discharge document post discharge	Few studies and poor quality. Conflicting findings and even where benefit of intervention shown unlikely to be clinically important due to high discrepancy rate post intervention. Rigorous RCT needed. Conflicting data unable to be pooled due to study heterogeneity. Effect on workload unknown – thought that process more complex than initially thought.
2011	Hesselink et al	Systematically review interventions tested in RCTs that aimed to improve transition from secondary to primary care.	Hospital and community-based interventions	36	Any outcome that assessed the quality or safety of the handover	Studies related to information sharing, coordination of care, communication. Most multicomponent interventions. Unlikely any one component responsible for improvements.
2012	Mueller et al	Summarize evidence for the various medication reconciliation interventions in hospitals and identify the most successful interventions	Hospital	26 controlled studies	Discrepancies Potential adverse drug events Adverse drug events Health care usage	15 out of 26 employed pharmacist led interventions – diverse roles, 6 IT based and 5 used other interventions. All reduced discrepancy rate but inconsistent findings on healthcare usage post discharge.

2013	Kwan et al	To assess the effectiveness of medication reconciliation interventions to reduce clinically significant discrepancies and readmission or emergency department visit within 30 days.	Hospital	18 5 RCT 1 quasi experimental 3 before and after 9 post intervention data only	Unintentional discrepancy rates	Most unintentional discrepancies were not clinically relevant. Medication reconciliation alone probably does not affect healthcare usage. Most studies had several interventions and pharmacists were important in most successful interventions (involved in 17 of the 20 studies included).
2014	Lehnbom et al	To assess the effectiveness of medication reconciliation and medication review interventions at identifying and rectifying discrepancies and problems. To assess impact of discrepancies.	Hospital Community Residential aged care facilities	83 4 related to community	Reduction in unintentional discrepancies between GP record and discharge document	Medication reconciliation can identify discrepancies but little evidence of the effect on clinical impact. Many are minor. Many studies were observational with no control group. Those that had a control group often usual care involved patients receiving at least some of the intervention. Overall felt has potential to identify and rectify discrepancies but effect on clinical outcome not clear.
2015	Nazar et al	The effect of community pharmacy interventions on all potential outcomes	Community	14 controlled trials	All reported outcomes were of interest.	Pharmacist involvement can reduce drug related problems. Impact on other outcomes such as patient adherence to medication was inconsistent Complex interventions and not clear which component responsible for success – suggests review of qualitative and uncontrolled literature may be valuable to understand why some interventions work.
2015	Michaelsen et al	Prevalence and type of medication error at discharge	Hospital	15	Discrepancies Errors	Average patient had between 1.2–5.3 discrepancies when leaving the hospital. Those on more medications had more discrepancies.

					'Types of error'	
2016	Mekonnen et al	Effectiveness of pharmacist led interventions at admission to and discharge from hospital	Intervention started by hospital-based pharmacist – some continued in community	17 RCT 8 Before and after 6 Non-randomised CT 3	Readmissions Adverse drug event related revisits Hospital readmissions ED visits Mortality Meta-analysis of 13 studies	Results very variable but overall reduction in healthcare usage. Pooled data reduction in readmission, ED visit, ADE related admission. No difference in mortality or combined readmission/ED visit.

Table 3.2 – Description of study and intervention characteristics including collaboration between pharmacist and GP of studies included in the Systematic Review.

Study	Country	Study design	Risk of bias	Authors extracting data and assessing bias	Characteristics and number of participants	Setting	Number of contacts	Timing of contacts	Length of follow-up observation	Collaboration with healthcare team
Nazareth *et* al 2001 (Nazareth *et al.*, 2001)	UK	RCT	Low	DM, PB	Patients discharged from elderly care wards. Intervention = 181 Control =181	Home visit by community pharmacist	1 or 2	7-14 days	3 and 6 months	Liaise with GPs
Holland *et al* 2005 (Holland *et al.*, 2005)	UK	RCT	Low	DM, JM	Age >80 on two or more medicines Intervention = 429 Control = 400	Home visit	2	14 and 60 days	6 months	Send report to GP
Ho *et al* 2014 (Ho *et al.*, 2014)	USA	RCT	Mod	DM, MR	Admitted to one of 4 Veteran Affairs hospital with acute coronary syndrome. Exclude if used non-Veteran Affairs pharmacy Intervention = 122 Control = 119	Primary care clinic	2	7-10 days – visit 30 days phone call	12 months	Send report to GP
Duggan *et al* 1998 (Duggan *et al.*, 1998)	UK	RCT	Mod	DM, GM	Age 16-79 recruited by ward pharmacist Intervention = 237 Control =264	Community pharmacy	None	None	N/A	Not clear
Hawes *et al* 2014	USA	RCT	Mod	DM, AR	Year 1: long term condition or more than 3 admissions or 8 or more medication. Year 2 – 8 or more medications	Primary care clinic	1	3 days	30 days	Seen prior to GP appt

(Hawes *et al.*, 2014)					Intervention = 24 Control = 37					
Lapointe-Shaw *et al* (Lapointe-Shaw *et al.*, 2020)2019	Canada	Cohort	Mod	DM	Intervention 67163 Matched controls 67163	Community pharmacy or patient's home	1	7-14 days	30 days	Option to report to GP
Shcherbakova *et al* 2016 (Shcherbakova and Tereso, 2016)	USA	Cohort	Mod	DM, JM	Patients enrolled in health plan 180 days before admission Intervention = 156 Control =89	Home visit	1	8 days	30 days	Contact GP to authorize changes
Kilcup *et al* 2013 (Kilcup *et al.*, 2013)	USA	Cohort	Mod	DM, AR	Patients considered high risk readmission Intervention = 243 Control = 251	Home visit	1	3-7 days	30 days	Send report to GP
Setter et al 2009 (Setter *et al.*, 2009)	USA	Cohort	Mod	DM, GM	Age >50 transitioning from acute to home care with long term condition Intervention = 110 Control = 110	Home visit	1	Not clear	60 days	Work with community nurses and send report to GP
Polinski *et al* 2016 (Polinski *et al.*, 2016)	USA	Cohort	Mod	DM, GW	Considered high or moderate risk of readmission Intervention = 131 Control = 131	By telephone or in-patient home	Mean number contacts 5 – details not fully reported	3 days	30 days	Contacted GP to arrange appts and report medication changes and health concerns
Tedesco *et al* 2016 (Tedesco *et al.*, 2016)	USA	Cohort	Mod	DM, GW	Age >65 Intervention = 34 Control = 43	Primary care clinic	1 or 2 Phone call and follow up face-to-	Phone call within 3 days, face-to-	30 days	Discussed with GP

							face review if needed	face 7-14 days		
Zeitouni *et al* 2014 (Zeitouni *et al.*, 2014)	USA	Cohort	High	DM, GM	Identified as high risk of readmission Intervention = 72 Control = 24	Primary care clinic	1	2 days	30 days	Arranged appt with GP
Boockvar *et al* 2006 (Boockvar *et al.*, 2006)	USA	Pre/post intervention	Mod	DM, GM	Nursing home residents Intervention = 87 Control = 81	Nursing home	1	1 day	60 days	Send report to GP report who responds to each request
Gray *et al* 2008 (Gray *et al.*, 2008)	UK	Pre/post intervention	High	DM, MR	Discharged from elderly care wards Intervention = 41 Control = 45	GP practice	None	None	N/A	Email, send note or discuss with GP if needed
Vuong *et al* 2017 (Vuong *et al.*, 2017)	Canada	QI project - Pre/post intervention	High	DM, MR	Nursing home residents Intervention = monthly sample of 10 patients	Nursing home	1	2 days before nursing home admission	90 days	Three-way telephone call – pharmacist, nurse and GP.

Table 3.3 –Identification, resolution and clinical relevance of discrepancies and reported healthcare utilization in studies included in the Systematic Review.

Study design	Study	Risk of bias	Discrepancy resolution	Clinical relevance of discrepancies	Healthcare utilization
RCT	Nazareth *et al* 2001 (Nazareth *et al.*, 2001)	Low	Not evaluated	Not evaluated	No statistically significant effect on readmission rate or GP attendance at 3 and 6 months. Hospital readmission at 3 months Intervention = 64/164 (39.0%) Control = 69/176 (39.2%) Hospital readmission between 3-6 months Intervention = 38/136 (27.9%) Control =43/151 (28.4%) Mean pharmacist time per visit: Journey time 17mins, visit time 38 mins, admin time 32 mins (total 1hour 27 mins)
	Holland *et al* 2005 (Holland *et al.*, 2005)	Low	Not evaluated	Not evaluated	Increased readmission rate at 6 months by 30% Total number admission over 6 months: Intervention = 234/429 (54.5%) Control = 178/426 (41.8%) Increased need for GP home visit by 43% Intervention 204 visits Control 125 visits Rate ratio 1.41 p=0.002
	Ho *et al* 2014 (Ho *et al.*, 2014)	Mod	Not evaluated	Not evaluated	No statistically significant reduction in readmission rate for re-vascularisation or for myocardial infarction at 12 months. Intervention = 22/122(18.0%) Control = 26/119 (21.8%) Mean pharmacist time 3 hours 51 minutes
	Duggan *et al* 1998 (Duggan *et al.*, 1998)	Mod	Remaining unintentional discrepancy rate (per drug prescribed):	Consensus panel judged to have possible adverse effects: Intervention = 51/1408 (3.6%) Control = 83/1328 (6.3%) Definite adverse effect:	Not evaluated

			Control 700/1328 (52.7%) Intervention 454/1408 (32.2%)	Intervention = 23/1408 (1.6%) Control 41/1328 (3.1%) Absolute risk reduction 5.3% NNT = 19	
	Hawes *et al* 2014 (Hawes *et al.*, 2014)	Mod	Increased discrepancy resolution rate per patient: Intervention 6/12 (50%) Control 2/21 (9.5%)	Type of discrepancy reported not clinical relevance	Reduced readmission rate at 30 days Intervention = 0/24 = 0% Control = 12/37 (40.5%) Reduced emergency department attendance at 30 days Intervention = 0/24 (0%) Control = 11/37 (29.7%)

Cohort	Lapointe-Shaw *et al* 2019 (Lapointe-Shaw *et al.*, 2020)	Mod	Not evaluated	Not evaluated	Readmission rate
					• Overall
					  ○ Intervention = 7387/67163 (11%)
					  ○ Control = 7642/6713 (11.4%)
					• Heart Failure
					  ○ Intervention = 628/4210 (14.9%)
					  ○ Control = 653/4210 (15.5%)
					• COPD
					  ○ Intervention = 400/3084 (13%)
					  ○ Control = 378/3084 (12.3%)
					• New high-risk medication
					  ○ Intervention =4656/41792 (11.1%)
					  ○ Control = 4960/41792 (11.9%)
					
					Emergency department attendance
					• Overall
					  ○ Intervention = 15135/67163 (22.5%)
					  ○ Control = 15287/6713 (22.8%)
					• Heart Failure
					  ○ Intervention = 1032/4210 (24.5)
					  ○ Control = 1082/4210 (25.7%)
					• COPD
					  ○ Intervention = 674/3084 (21.9%)
					  ○ Control = 644/3084 (20.9%)
					• New high-risk medication
					  ○ Intervention =9691/41792 (23.2%)

					○ Control = 10039/41792 (24.0%) Outpatient attendance • Overall ○ Intervention = median 2 (Interquartile range 1-3) ○ Control = median 2 (Interquartile range 1-3) • Heart Failure ○ Intervention = median 2 (Interquartile range 1-3) ○ Control = median 2 (Interquartile range 1-3) • COPD ○ Intervention = median 1 (Interquartile range 1-2) ○ Control = median 1 (Interquartile range 1-2) • New high-risk medication ○ Intervention = median 2 (Interquartile range 1-3) ○ Control = median 2 (Interquartile range 1-3)
	Shcherbakova *et al* 2016 (Shcherbakova and Tereso, 2016)	Mod	Pharmacist identified 301 medication related problems in 156 patients = mean 1.93 per patient No figures reported for control group.	Type of discrepancy reported not clinical relevance	No statistically significant effect on readmission rate at 30 days Intervention = 16/156 (10.3%) Control = 6/89 (6.7%) No statistically significant difference in emergency department attendance at 30 days Intervention 34/156 (21.8%) Control = 13/89 (14.6%)
	Kilcup *et al* 2013 (Kilcup *et al.*, 2013)	Mod	Pharmacist resolved discrepancies present in >80% of patients (exact figures not given)	Type of discrepancy reported not clinical relevance	Reduction of readmission at 7 days and 14 days but not statistically significant at 30 days 30-day readmission rate: Intervention = 28/243 (11.5%) Control = 34/251 (13.5%) (p=0.29)

			Data on control group not measured and reported		
	Setter *et al* 2009 (Setter *et al.*, 2009)	Mod	Increased resolution rate: Intervention 154/220 (70%) Control 139/231(60%)	Discrepancies classified as patient or system factors and not by clinical relevance	Reduced number of days admitted to hospital per patient in intervention group. Intervention = 0.4 ± 1.2 Control = 1.1 ± 4.2 Reduced planned physician visits: Intervention: 2.9 ± 1.5 Control: 3.5 ± 2.7 Reduced unplanned physician visit: Intervention: 0.2 ± 0.6 Control: 0.4 ± 1.0
	Polinski *et al* 2016 (Polinski *et al.*, 2016)	Mod	Discrepancy rate not reported	State 88 of 131 (67%) of medication reconciliation an omission of a pre-hospital medication or an identified gap based on clinical guidelines was identified. Drug-drug interactions present in 21 of 131 (16%) of cases – no comment on severity.	Reduced 30-day readmission rate Intervention group 16/131 (12.2%) Control group 29/131 (22.1%) Risk ratio (95% confidence interval) = 0.5 (0.29, 0.88)
	Tedesco *et al* 2016 (Tedesco *et al.*, 2016)	Mod	Not evaluated	Not evaluated	Readmission 30 days Intervention 5/34 (14.7%) Control 12/45 (26.7%) P=0.27
	Zeitouni *et al* 2014 (Zeitouni *et al.*, 2014)	High	Not reported	Not reported	Reduction in readmission at one month: Intervention 27% Control 45%
Pre/post intervention studies	Boockvar *et al* 2006 (Boockvar *et al.*, 2006)	Mod	Found 696 discrepancies following 259 discharges =2.69 per patient (not measured in pre-intervention phase)	Calculated a drug discrepancy risk index, where this was raised 2 reviewers reviewed notes to determine if possible discrepancy related adverse drug event: Post-intervention 1/43 (2.3%) Pre-intervention 10/69 (14.5%)	No figures reported but states no difference in readmission rate Physician responded to discrepancies: Awareness of discrepancy 429/598 (71.7%) Intention to review 41/598 (6.9%) Intention to adjust regime 49/598 (8.2%) Intention to increase monitoring 23/598 (3.8%)

	Gray *et al* 2008 (Gray *et al.*, 2008)	High	Increased resolution rate. Intervention 33 plans implemented out of 41 (80.5%) Control 23 plans implemented out of 45 (51%)	Examples of discrepancy listed but not quantified	Not evaluated
	Vuong *et al* 2017 (Vuong *et al.*, 2017)	High	No pre-intervention data presented. Mean discrepancy rate of 2 per medication reconciliation reported post intervention	No pre intervention data presented – mean number of clinical concerns per medication reconciliation post intervention = 6.	90-day readmission and ED attendance rate - no difference pre and post intervention - remained at median of 13% for each cohort Freed up three hours of nursing time and one-hour physician time. Consulted with pharmacist for two hours.

Table 7.1 – Relation of data collected in each case to each Case Study construct

Case Study Construct	**Description of application to data collection** **Observational data**	**Description of application to data collection** **Document analysis**	**Description of application to data collection** **Semi-structured interview**
Foundation concept Most problems and solutions belong to the care system. Attempt to explore and understand overall system safety and success, rather than focussing on isolated parts, events or outcomes.	Observed staff to identify their objectives during work to determine what they consider to be overall system success and if their actions are aimed at achieving this. The boundary for analysis is described above within description of the unit of analysis.	Reviewed guidance documents and electronic case notes to identify purpose of system and overall impact of pharmacists.	Explored perceptions of the overall purpose of the system and the impact of pharmacists through discussion with GPs, staff and pharmacists. Compared this to observed data and local and national guidance.
Seek Multiple Perspectives Appreciate that people, at all organisational levels and regardless of responsibilities and status, are the local experts in the work they do. Explore with them how they achieve success.	Representatives from all practice staff groups observed processing prescribing tasks and interacting with pharmacists	Protocols and clinical governance documents reviewed to determine: • definition of roles and responsibilities • staff contribution to their creation	Explored perceptions of different staff groups of how the system functions. Explored attitudes of different staff groups towards how to achieve success.
Consider Work Conditions	Observed influence of capacity, demand, resources and	Reviewed protocols to determine if provision made for	Explored perception of pharmacists and other staff of

Appreciate that the interacting combination of demand, capacity, resource availability and constraints influences the way people undertake work at any given time. Explore the influence of conditions of work on safety and success.	constraints on how pharmacists work.	ensuring resource availability, changes in demand and capacity.	how they dealt with varying and unexpected system conditions and the effect on overall system functioning.
Analyse Interactions and Work Flow Appreciate that interactions between people, tasks, equipment, environments (e.g. physical, social, organisational) and external influences (e.g. national policy, regulatory obligations) are complex and dynamic and affect care system performance and human wellbeing (e.g patients and staff). Explore influence of interactions and flow on safety and success.	Observation identified interactions of pharmacists with other staff, patient, carers and other healthcare sectors and effect these had on the flow of work and the outcomes.	Reviewed protocols to determine if there is a clear mechanism for interacting with other staff, patients and other healthcare sectors. Assessed how often these interactions took place and their effect.	Explored perceptions of effect of communication systems and interactions with other staff, technology, patients and carers on flow of information and work. Patterns of activity related to interactions and flow of work identified through observation and case note review were explored through interview to identify why these arose and their effect on system functioning.
Explore Performance Variability Appreciate that people continuously adapt and vary how they work to achieve a successful	Observed and explored different approaches used by pharmacists and other staff and the effects of these.	Case notes analysed to identify variability in how prescribing tasks completed.	Patterns of variability in how prescribing tasks completed identified through observation and document analyses explored in interview to

outcome based on their own goals and the system conditions they face. Explore how important performance variability is to success and how it can be developed and performed safely.			identify overall impact of these variable ways of working.
Understand Why Decisions Make Sense at the Time Explore why staff make decisions and how this influences success; people do what makes sense to them based on the system conditions experienced at the time.	Observed and questioned pharmacists performing prescribing tasks to understand why they choose specific actions.	Reviewed protocols to determine if options included for dealing with unanticipated conditions considered. Case notes reviewed to determine if reasons for actions recorded and, if so, to explore these reasons.	Explored why staff made decisions observed and seen in case note review. Explored how pharmacists varying performance was perceived by other staff when there is a successful outcome and when there is an unsuccessful outcome

Table 8.1 – FRAM functions and their interactions and variability in each Functional Resonance Analysis Method model.

Function	Functions influenced by its output	Functions that influence this function	Variability
Assign prescribing task to pharmacist	Make decision on prescribing task	Agree aims of pharmacist role between practice and pharmacist Learn roles Build trust	P1,2 Yes – imprecise – inappropriate work sent to pharmacist P3 No –stricter control on pharmacist work but restrictive P4 – Yes – no precise list of what should go to the pharmacist
Obtain more information - notes, hospital, patient	Make decision on prescribing task Anticipate risk	Follow protocols	P1, 2 -Yes – could be late and delay decisions P3 – No had access to electronic hospital notes and gave rapid answer P4 – No – rarely needed to do this, either made a quick decision or arranged review
Discuss decisions with GP	Make decision on prescribing task Learn roles Build trust Provide access to hospital systems Agree work arrangements health board and practice	Ensure GP capacity and capability to mentor pharmacist Anticipate of risk Agree system for mentoring pharmacists	P1 and P2 - Yes - not agreed resulted in variable precision (which tasks sent to GP) and timing (when GPs responded). P3 – No - more formal arrangement P4 – No – informal system that had evolved over years – all aware of each other's actions

Make decision on prescribing task	Arrange review Update electronic record Communicate outcome to patient/ carer/ pharmacist Issue prescription Build trust Pass decision to GP	Follow protocols Assign prescribing task to pharmacist Select appropriate special request task Agree aims of pharmacist role between practice and pharmacist Anticipate risk Involve in training Discuss decisions with GP Obtain more information - notes, hospital, patient Select prescribing task	P1, 2 - Yes – could be delayed due to waiting for more information P3 - could be delayed due to demand>capacity and capability P4 - could be delayed due to demand>capacity and capability
Arrange review		Make decision on prescribing task	No
Update electronic record		Make decision on prescribing task	No
Communicate outcome to patient/ carer/ pharmacist		Make decision on prescribing task	P1, 2, 3 – No P4 – rarely spoke to patients even when complex medication changes
Involve in training	Make decision on prescribing task Anticipate risk Learn roles Build trust Ensure GP capacity and capability to mentor pharmacist Select appropriate special request task	Agree system for mentoring pharmacists Agree work arrangements health board and practice	No
Follow protocols	Make decision on prescribing task Obtain more information - notes, hospital, patient	Provide sufficient pharmacist capacity Modify existing work processes Ensure pharmacists have required pharmaceutical knowledge	P1,2 - highly specified protocol P3 – minimally specified protocol P4 – no protocol

Anticipate risk	Obtain more information - notes, hospital, patient Discuss decisions with GP Make decision on prescribing task	Provide sufficient pharmacist capacity Involve in training	P1,2 - Yes – imprecise - could anticipate risk when risk seemed low resulting in need for further information and delay P3 – No P4 – No
Issue prescription		Make decision on prescribing task	P1,2 - Yes - could be delayed P3,4 – No
Agree aims of pharmacist role between practice and pharmacist	Assign prescribing task to pharmacist Make decision on prescribing task Learn roles Select prescribing task Select appropriate special request task	Agree work arrangements health board and practice Provide sufficient pharmacist capacity Employ pharmacist directly	P1,2 -Yes – imprecise different opinion of main role – safety versus quantity of workload P3 – No clearly defined but restricted role P4 – No – very clear role
Learn roles	Assign prescribing task to pharmacist	Discuss decisions with GP Involve in training Agree aims of pharmacist role between practice and pharmacist Build trust Provide practice induction Colocate pharmacist	No
Build trust	Assign prescribing task to pharmacist Select appropriate special request task	Discuss decisions with GP Make decision on prescribing task Involve in training Learn roles	No
Agree work arrangements health board and practice	Agree aims of pharmacist role between practice and pharmacist Involve in training Discuss decisions with GP		No

	Agree system for mentoring pharmacists		
Provide practice induction	Learn roles		No
Colocate pharmacist	Learn roles		No
Provide sufficient pharmacist capacity	Follow protocols Anticipate risk Agree aims of pharmacist role between practice and pharmacist Select appropriate special request task Select prescribing task		P1 - No P 2,3 - Yes – imprecise did not match demand and so less work assigned to pharmacists P4 – Yes – usually sufficient but not during annual leave
Modify existing work processes	Follow protocols		No
Ensure GP capacity and capability to mentor pharmacist	Discuss decisions with GP Involve in training Agree system for mentoring pharmacists	Agree work arrangements health board and practice	No – in all practices taken on as additional work as see the future benefit
Ensure pharmacists have required pharmaceutical knowledge	Follow protocols		No
Pass decision to GP		Make decision on prescribing task	No
Provide access to hospital systems	Obtain more information - notes, hospital, patient		No
Additional functions Practice 2			
Select appropriate special request task (only in practice 2)	Make decision on prescribing task	Build trust Agree aims of pharmacist role between practice and pharmacist Involve in training Provide sufficient pharmacist capacity	P2 - Yes – no defined list of which ones they would choose and dependent on capacity and capability
Additional functions Practice 3			
Agree system for mentoring pharmacists	Involve in training Discuss with GP	Agree work arrangements health board and practice Ensure GP capacity and capability to mentor pharmacist	No

Addition function Practice 4			
Select prescribing task	Make decision on prescribing task	Agree aims of pharmacist role between practice and pharmacist Provide sufficient pharmacist capacity	P4 - Yes – varied dependent on demand and capacity of that day to optimise quantity of work completed
Employ pharmacist directly	Agree aims of pharmacist role between practice and pharmacist		No

Table 8.2 – Evidence from each practice on impact of pharmacists on safety in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	CN review 12 – changed omeprazole to lansoprazole as patient started on clopidogrel (potential interaction)	CN review 5 – corrected apixaban dose on the discharge document. CN review 6 – contacted secondary care to determine if ramipril was meant to be stopped or missed from discharge document unintentionally	CN review 15 – arranged blood test after change of diuretics CN review 20- checked hospital computer system to determine if discharge medication was required and if it could therefore be stopped.	CN review 4 – noted that compliance aid used and medications issued previous day – phoned community pharmacy to ensure changes enacted. CN review 7 – no recheck of BP or bloods arranged despite increase in ACE inhibitor during admission Case note review 2 – instruction on discharge document for patient to miss methotrexate for one week – recorded but no evidence patient contracted.
Observational data	Meds rec 7 - Patient discharged on co-codamol, pharmacist checked her weight and, as it was recorded as less than 50kg, contacted the patient to reduce the dose of co-codamol SR 7- metformin checked old notes and why previously stopped and added as a one-off	Meds rec 2 - discharged on a changed dose of phenytoin. Blood levels were recommended after ten days. The pharmacist printed the IDL and kept it in a folder to check that the blood test was taken and dealt with appropriately. Meds rec 7 – discharge document missing	Meds rec 13 - hospital initiated medication contraindicated due to the patient's renal function. This was discussed with a GP and the medication changed. Meds rec 6 – telephones community pharmacy to prevent wrong medications being sent to patient.	Special request 19– on a tetracycline antibiotic for acne – arrange check of liver function blood tests. Special request 24 - inhaler – patient was due review as noted to have high usage of inhaler. Telephoned community pharmacy to tell the patient that the prescription was being

	prescription to ensure no adverse effects and that bloods get done	medication (alendronic acid) not clear if intentional. Pharmacist checks hospital electronic system and notes reduced renal function as cause – arranges recheck and review to discuss if should be restarted.		held at the practice – he could get it that day but would have to make an appointment for an asthma review. Meds rec 11 – patient with compliance aid and uses a specific pharmacy. Contacts the pharmacy to make sure all changes implemented.
Interview data	I think it is safer yeah definitely, definitely safer and they're able to identify more potential problems and follow up things ... maybe these things don't need to be followed up but they are actually doing it in essence to you know provide patient safety (P1, GP1) Sometimes the pharmacists are insanely thorough - you know this person is come out on sando-K for three days, yes we would have checked his UEs within a week, we wouldn't have	They do it [medication reconciliation] much much better. They do it more thoroughly they're more thorough they just, they spend much more time on it than we used to spend on it but I think that's sort of very good use of time in terms of patient safety (P2, GP1) I just think it's safer. It's just I'd much rather find problems like someone is still taking medication that they were meant to stop taking a year ago that kind of thing. (P2, GP1)	They are possibly more thorough and make sure everything is done and if there is any dubiety they clarify it with the hospital which we probably would have just sent it to the secretary and got it clarified which would take a few more days so I think in that sense they are better (P3, GP2) I think they are maybe a bit more aware [of potential prescribing safety issues] because it's their everyday job ...they would pick up on things like even GP or anybody	I think pharmacists work slightly different to the how a GP would work and maybe they will pick up on things that maybe we would not pick up on because of their knowledge. (P4, GP1) Sometimes just having an expert around, there was an issue with Epipens and beta blockers the pharmacist found out all the stuff about that. (P4, GP 2)

	gone back to check what there potassiums were like in the lead up to admission. We wouldn't have done all of that and you go, well actually they have been relatively hypokalaemic before maybe we should stop the bendroflumethiazide, so they are bringing a different level of thoroughness which I think for some cases has been really good. (P1 GP2)		else would maybe even miss. (P3, Admin 1)	

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.3 – Evidence from each practice on impact of pharmacists on effectiveness in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	CN review 1 – arranged review of Blood Pressure after medication changes during admission CN review 6 – arranged blood test monitoring in relation to digoxin and amiodarone as not clear in discharge document	CN 9 – discussed with patient to ensure on correct secondary prevention medications (post stroke)	CN review 18 – rechecked dose of apixaban. CN review 19 – arranged review of effect of newly started medication (carbocisteine) as per guidelines.	CN review 4 - Recalculated dosing of apixaban but height and weight out of date and so review arranged with practice nurse CN Review 12 - IDL asks why patient not on an ACE/ A2 – would be recommended due to their medical history. No record of this being addressed. CN review 17 – arranged bloods and titration of ACE
Observational data	Meds rec 14 – while reviewing record noted no recent blood pressure recorded – arranged appointment Meds rec 9 – notes candesartan – checks if annual review due and arranges bloods and blood pressure and checks on optimal dose.	Meds rec 10 - patient started on amiodarone had all recommended pre-check bloods and arranged follow-up as per protocol. Meds rec 5 – diabetic and blood pressure medication missing – not clear if intentional. Pharmacist notes admission for one day	Meds rec 11– noted alternatively ordering laxative and medication to stop diarrhoea. He spoke to the patient's carer to get more information and develop a long-term solution. Meds rec 7, 13, 19, 26 – arranges evidence-based blood test monitoring	Special request 5 – titration of ramipril. Checks blood pressure and bloods and arranges next review for titration. SR Mirabegron 7 – checks that blood pressure controlled and then issues.

		and that both would still be recommended based on medical history and blood results and so keeps on GP record.		
Interview data	There was a chap - I think must have IBD [Inflammatory Bowel Disease] –I spoke to gastro- only because his liver tests were just little bit abnormal I thought you know protocol actually is.. I would have probably just given him his drug but I thought, you know pharmacists are always phoning so I should - so I phoned them and they told me to stop it. So I would have done the wrong thing. (P1, GP1) DMARD (monitoring) is more robust... they have a much clearer protocol and policy for how things are issued. (P1 GP2)	They helped us put in a really strong protocol for recalls and even though the GPs and Practice Nurses were aware it was something they had to monitor they keep a tighter rein on that (P2, PM) They arrange the follow up for new drugs, they are just so much more thorough because that's all they have they haven't got everything else going on in their heads. (P2 GP1)	I've started doing the DOAC work here, so that has been quite eye opening. I think in terms of finding things that weren't being monitored that should be or the frequency was wrong, or the dose was wrong - so I think there is quite a few systems that we can put in place. (P3, Ph1)	He will probably do a bit more research into things when you ask for an acute he will probably research the patient a bit more I don't mean that GPs don't but he will go into things a bit more and maybe bring them back for more checks or blood pressure checks. (P4, Admin 1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.4 – Evidence from each practice on impact of pharmacists on timeliness of interventions in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	Median time from discharge until medication reconciliation complete = 1 day (IQ range 1-3 days)	Median time from discharge until medication reconciliation complete = 2 days (IQ range 1-3.25 days)	Median time from discharge until medication reconciliation complete = 3 days (IQ range 2-5 days)	Median time from discharge until medication reconciliation complete = 5.5 days (IQ range 3-9 days)
Observational data	No evidence	No evidence	No evidence	No evidence
Interview data	Lot of patients phone up (with a medication query) we could put them through to the pharmacist where before we would have put a message for the GP to then phone them back and discuss it which would take longer. (P1, PM1)	They get a response to any queries - the pharmacy or the patients get that quicker, before that it would go into a GP and it would take some time to come back out to them (P2, Admin 1) It helps the patient as well because it gets things done almost immediately from it (prescription request) coming from like the hospice for instance. (P2, Admin 1)	I don't know if we speed it up I suspect quite the reverse but I think things that didn't happen before might get done but I think the things that we do take longer partly because of that because we are looking at things that weren't getting looked at before . Yeah I'm not sure it might be yeah it might free up time for somebody else. (P3, Ph1)	The turnaround is quick em I mean if you send something say in the morning it would more of less be done by the afternoon or the next day. (P4, Admin 1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.5 – Evidence from each practice on impact of pharmacists on patient centeredness in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	Discussed 17 of 20 with patient or carer (85%). CN review 3 – discharge document had blood pressure meds recorded as twice daily, in GP record once a day. Contacted patient and reviewed previous blood pressure and agreed with patient to maintain current dosing	Discussed 15 of 20 with patient or carer (75%). Informed of changes no evidence that their concerns discussed	Discussed 19 of 20 with patient or carer (95%) CN review 1 – checked and discussed compliance with patient. Rerecorded discussions on reasons for and against taking new medication	No evidence that changes were discussed with patients. CN review 18 – staged reduction of prednisolone dose – discussion may have been useful.
Observational data	Number (%) of observed medication reconciliations that were discussed with patients = 11/18 (61) Meds rec 16 – phoned patient as discrepancy in dose of sertraline on discharge document and GP record – patient wanted to remain on previous dose and so continued.	Number (%) of observed medication reconciliations that were discussed with patients = 5/10 (50) Regularly calls to discuss changes with patient but not to discuss their concerns and wishes.	Number (%) of observed medication reconciliations that were discussed with patients = 11/27 (41) Meds rec 24 - observed discussing different treatment options (analgesics) with the patient and exploring their preferences.	Number (%) of observed medication reconciliations that were discussed with patients = 1/21 (5) Meds rec 12 - patient discharged on Isosorbide Mononitrate 90mg daily. Discharge letter recommended that the patient took one and a half 60mg tablets, whereas he had previously been on a 50mg and a 40mg tablet. Pharmacist one stated

				that changing to the new regime could increase confusion as he may take two 60mg capsules and so kept the medication regime as it was before discharge.
Interview data	I have exposed them to difficult patients - so they were disagreeing with one of our patients was wanting antihistamines above BNF guidance and I said we will hand that onto the pharmacists and they said she couldn't have it and she came in saying to me, I want it. They [the pharmacists] have an hour and half argument with her and came out saying I think we might need to give it to her. (P1, GP2)	I think sometimes you do uncover other issues so again I've seen someone else recently you know who was on naproxen but she's taking her husband omeprazole. We were going to stop her naproxen because she didn't order her PPI. (P2 Ph2)	The work (on consulting) that I've done before has all been face to face consultation skills stuff and there are particular things that are telephone specific which NHS 24 are quite uniquely placed to be able to give guidance. (P3 Ph1)	When I am in a blood pressure clinic for example and someone frail elderly person comes in and their blood pressure is 150 over 90 if you applied the letter of the law you would be striving to get that down whereas the likelihood is by bumping up their medication you are just going to cause them more problems and I think also working with GPs has taught me that at times there are no sort of urgency to try and treat things like that. That sometimes maybe just leaving things as they are and check again in a few weeks is also a good option. (P4, Ph1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.6 – Evidence from each practice on impact of pharmacists on delivery of care that is equitable in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	No evidence	No evidence	No evidence	No evidence
Observational data	Stated would offer alternatives for those unable to use telephone to discuss changes.	Meds rec 8 - unable to contact numerous patients by telephone – sent letters and asked the administrative staff to arrange discussion of medication changes.	Meds rec 6 - when needed to discuss changes in medication with a patient who had reduced hearing and struggled to use the telephone, checked permissions and contacted a relative to arrange a face to face discussion.	Meds rec 2 – patient known to be confused. Asks administrative staff to contact family member and arrange blood pressure and blood tests needed for medication change. Speaks to community pharmacy to ensure medication changes in place.
Interview data		We get a lot of elderly patients who come out and they are confused they went in with certain medications and come out and have maybe got another five medications or they are changing the way their medications work and I think actually just expecting them to understand - we put this onto repeat and this is what you have to take - we have got someone who can really make it clear and if they are a bit confused they are happy to meet up with them which is so much better especially for the elderly I think it has worked well. (P2, Admin 1)	I think we can standardise a lot of things. We need to be able to drop people in so as this becomes a (consistent) service. (P3 Ph1)	I have different ways of dealing with these (when a review is due). I might phone them or send a note or hold the prescription and let the (community) pharmacy know. It is different for each patient but it needs to be safe for every patient. (P4 Ph1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.7 – Evidence from each practice on impact of pharmacists on efficiency in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review (Total 20 per Case Study)	CS review 3 - enalapril 2x per day in discharge taking once per day. Blood pressure normal - checked with patient and decided to continue on once daily dosage without need to discuss with GP.	In eight case note reviews, further check that changes in discharge document were intended. Twice checked with GP where decision could have been made by pharmacist. CN review 10 – discussed with GP that amlodipine missing from discharge document CN 11 – discussed with GP if ferrous sulphate should continue CN 12 – discussed with secondary care to confirm changes	CN review 3 – change in bisoprolol dose – made decision themselves CN review 7 - Discharge document contained medication that should have been stopped – Pharmacist dealt with himself – did not check with secondary care. CN review 11 – discharge document suggests decrease analgesics – pharmacist spoke to patient and agreed to stop completely. CN review 13 – noted some medications not formulary choice but did not alter as did not want to confuse patient.	CN review 5 and 7 – identified medication missing from discharge document that was probably an error (unintentional discrepancy) made decision himself rather than pass decision to GP or contact secondary care.
Observational data	Median time to complete meds rec (Inter-quartile range (mins)) = 6.5 (4-10.8)	Median time to complete meds rec (Inter-quartile range (mins)) =7 (4-11) Meds rec 1 – discussed all medications with nursing	Median time to complete meds rec (Inter-quartile range (mins)) = 8 (4.3 – 15)	Median time to complete meds rec (Inter-quartile range (mins)) = 4.5 (3-11.8)

	Special request 1 - phoned community pharmacy to synchronise ordering and ensure not over ordering to reduce waste Special request 6 - fluoxetine been seen by GP two weeks before but not clear from notes if anti-depressant reviewed – arranges review	home to determine if still required Meds rec 9– new medication started – allowed one reorder – will then require review.	Meds rec 2 - phoned a nursing home to ensure they were not ordering medication too early Meds rec 19 - Angiotensin Converting Enzyme medication had been started, rather than automatically ordering blood test monitoring, the pharmacist reviewed the results of blood test taken in hospital.	Meds rec 9 – started apixiban – due to renal function review due in 3 months. Instead of adding this recall date – synchronises with existing date for annual long-term condition monitoring appointment. Meds rec 19 – discharge document changes antacid to formulary choice (more cost efficient) – pharmacist does not change as would take longer and may result in patient contacting practice. Less cost-efficient more time efficient. Special request 2 - analgesic – due review. Says has a variety of responses depending on perceived risk. Issues this prescription and adds note stating review due.
Interview data	Sifting through that number of the notes and going into portal and doing all of that for a yield of possible one or	It's a slightly negatively effect they are not very good at trusting our recall systems so one of the irritations it to keep	My hope my intention when I'm doing these things is that it will free up time further down the line so if you do if you	A lot of the time they'll maybe send something back saying no they should have plenty until and they will put an

	two errors or changes or things that we could do. (P1, GP2) I always feel that it looks terrible on the notes. you know for example if your issuing a PPI and you've looked and thought actually that could probably get stepped down, but I really don't have time today (P1 Ph1)	putting reauthorisations on. (P2, GP1)	deal with a discharge well today hopefully we can prevent that phone call from the nursing home in five days' time. (P3 Ph1)	actual date. So we reiterate that to the patient look you got a two month supply you know you are phoning like four weeks too early it's just you can't keep churning out all this medication when it's not necessarily needed. (P4, Admin 1) I didn't see any harm in just issuing it at the time I think delaying it was probably causing more work and probably inconvenience for the patient. (P4, Ph1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.8 – Evidence from each practice on impact of pharmacists on quantity of work completed in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	Arranged follow up = 8 Discussed with community pharmacy = 3 Discussed with GP = 0 Discussed with secondary care = 4 Number of contacts with practice or secondary care in subsequent 30 days • Related to admission = 25 • New problem = 12	Arranged follow up = 5 Discussed with community pharmacy = 5 Discussed with GP = 4 Discussed with secondary care = 11 Number of contacts with practice or secondary care in subsequent 30 days • Related to admission = 20 • New problem = 5	Arranged follow up = 5 Discussed with community pharmacy = 11 Discussed with GP = 0 Discussed with secondary care = 0 Number of contacts with practice or secondary care in subsequent 30 days • Related to admission = 24 • New problem = 9	Arranged follow up =2 Discussed with community pharmacy = 1 Discussed with GP = 0 Discussed with secondary care = 0 Number of contacts with practice or secondary care in subsequent 30 days • Related to admission = 2 • New problem = 6
Observational data	Number of prescribing tasks completed per hour of observation = 2.7 Of 30 tasks observed (18 meds rec and 12 special request) – 3 result in task to GP to make decision (10%) Special request methotrexate 10 - Message stated that recently restarted at rheumatology clinic but no letter yet. Pharmacist telephoned the patient	Number of prescribing tasks completed per hour of observation = 3.9 Of 39 tasks observed (10 meds rec and 29 special requests) – 5 result in task to GP to make decision (13%)	Number of prescribing tasks completed per hour of observation = 2.1 Of 29 tasks observed (27 meds rec and 2 special request) – 4 result in task to GP to make decision Meds rec 14 - When monitoring of blood tests required after discharge, used a 'pending folder' to ensure results came back to him and did not require extra work from GPs.	Number of prescribing tasks completed per hour of observation = 5 Of 60 tasks observed (21 meds rec and 29 special requests) – 5 result in task to GP to make decision Special request 28 – omeprazole issued by GP one month before from electronic health record notes not clear if to continue. He interprets the clinical scenario and

	(who stated she had been told to restart and blood monitoring frequency). Then telephoned the rheumatology nurse three times to confirm.		Med rec 17 - patient was discharged to a nursing home who regularly requested medication urgently on Friday afternoons. He anticipated this problem and contacted them to ensure they understood all medication changes and had sufficient medication. Meds rec 18 – strength of analgesic reduced. Recently had discussed this with pharmacist and expected her to call to increase strength again and so kept at previous level.	continues medication rather than speaking to GP. Meds rec 18 – discharge document states patient was hypotensive during admission and that losartan stopped however still on discharge document at lower dose. Pharmacist stops the medication rather than contacting the hospital to explain discrepancy.
Interview data	So they have to keep doing the IDLs I can't stand them and I love when they've done the bits and I just have to do my little bit of coding or whatever - check it over. (P1, GP 1) That's probably been the only negative actually I'm just thinking that we	Yes, so they deal with lots of queries from the chemist and things like that actually we probably don't notice that as much as that as that would have being stuff that was just handled - the eh manufacturing problems (P2, GP1)	It's been a god send for medicines reconciliation and workload pressures that we are all feeling. (P3, GP3) One issue is workload there's a workload reduction and therefore freeing up for time for us and that's particularly noticeable for us at the	The amount of work that P1 takes from us is...the way you notice it is when he is not here. You see the huge amount of work that he just gets on with and we are not really having to get on with. (P4, GP1) It's just the stuff he gets through. You read about

	have seen quite a big increase in the number messages that we get left to recall people in. (P1, Admin 1) So there's that so that is maybe extra work that has occurred because of them following guidelines but I don't think that we can blame their process for that. (P1, GP1)	At first we envisaged they would do virtually all the special requests but what it's actually proved is we need lots more pharmacy time in order to get through all that. (P2, GP1) I think the rheumatology nurses take far more phone calls than they used to but that's you know we're used to dealing with a level of risk you know and bloods being off a little bit we all sort of say right I'll keep a wee eye on that and not worry about that too much but that where are they go no its out with protocol you know. (P2, GP1)	moment when they go on annual leave. (P3, GP1) As I say it would be the pharmacist that would [phone hospitals] all of that so it does save us [admin] a lot of time (P3, Admin 1) You know certainly if you were in a practice like here relatively short of GPs you don't really want to pass that onto somebody else because you know they've already got things coming out their ears (P3, Ph1)	other places where they have pharmacist and it seems to create work, and they knock everything back and you are like - only every so often will he ask you something. (P4, GP2) Because he was just over cautious because he didn't know them so he was just thinking to be on the safe side I better get them in for bloods better get them in for which is fine em but it was the workload for us was just beginning to get too much. (P4, Admin 1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.9 – Evidence from each practice on impact of pharmacists on cognitive workload in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	No evidence	No evidence	No evidence	No evidence
Observational data	Observed additional tasks - taking telephone queries from patients (4), secondary care professionals (2) and community pharmacy (3). Deals with 7/9 (78%) other two tasks sent to GP	Observed additional tasks - taking telephone queries from patients (2), secondary care professionals (1) and community nurse team (1). Deals with 3/4 (75%) passed Community nurse query to GP as needed house visit.	Observed additional tasks - queries from GPs (2) and having to research the answer – stated enjoyed dealing with complex problems and felt this was part of his role.	Observed additional tasks -deals with query from a GP regarding potential medication interactions.
Interview data	I think with the pharmacist coming into the practice - its pushed all of the more difficult prescribing and all of the riskier prescribing onto myself and GP1 [another partner] so it's in some ways all of the straight forward protocol prescribing is done, it just means your workload with prescribing is different, it is more complicated. (P1, GP2) The receptionists love it because they don't really want to discuss medication queries with patients and then they	It takes a bit of pressure off of us cause it's like I am not saying we are not professional but like they are obviously at pharmacy standard where they understand what other people are talking about, so it is good in that sense. (P2, Admin 1)	I don't think that any increase in workload if a patient has then queried change in medication, I think the offload of work far, far, far outstrips that. (P3, GP1)	The one I ended up getting involved with was the clomipramine - he knew about it first I suspect form his [community work] he had already printed out the list and had been through everybody and written wee notes of what dose they were on who they were under. (GP 2 P4)

	sometimes get all fuddled up and so its cut and dried put them through to the pharmacist the pharmacist can just deal with it and usually have the answers. (P1, Admin 2)			

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Table 8.10 – Evidence from each practice on impact of pharmacists on wellbeing in the Case Studies

Data collection method	Practice 1	Practice 2	Practice 3	Practice 4
Case note review	No evidence	No evidence	No evidence	No evidence
Observational data	No evidence	Felt that sitting in reception area helped to integrate them as could learn more of administrative staff perspective. During observation – describes feeling caught between work GP want (to reduce workload), what the health board want (to reduce costs) and where pharmacy profession should be going (more patient contact)	When sending queries to GPs said he felt he should be able to process such queries.	Alternates between types of prescribing task to prevent boredom.
Interview data	I find it really interesting working in a GP practice like learning all the ropes of that and I think it's good having more access to patients information and notes and in community you are a bit blind getting a script that you don't know what's going on before it and I enjoy like my clinical knowledge is increasing feeling that you are kind of inputting to the practice and helping hopefully. (P1, Ph1)	We just bite the bullet and moved to 15-minute appointments (P2, GP1) I mean you still have our list each of you know 15 special requests but at that which you actually could fire through in sort of 30 – 40 minutes and when I think before we used to spend hours doing them so yeah no it has its reduced a bit of stress just because it's not as tedious either and it much you know its relieved a lot of the boredom but you know doing a list of special requests (P2,GP1)	I think that's what we need to do is make sure people have still got that variety that they kind of came here for in the first place eh and is still seeing patients which is what they kind of came here or in the first place so ... it's making sure they've got time to fit in the stuff they actually want to do as well as the stuff they need to do. (P3, Ph1)	I enjoy it, it certainly beats being on the front line of community and I think also it does become a bit tedious when you have 100 acute requests on a Monday and Tuesday but when that sort of eases up and you get an unusual question or when you are doing discharge letters it helps you to use your knowledge a bit more. (P4, Ph1)

Key: GP = General Practitioner, Ph = pharmacist, P = Practice

Table 8.11 – All proposed mechanisms, the functions representing context, mechanisms and outcome and the practice in which this mechanism was generated from the Case Studies

Mechanism	**Context (functions from FRAM)**	**Mechanism (functions from FRAM)**	**Outcome (functions from FRAM)**	**Practices in which this mechanism generated**
Team integration	Colocate pharmacists Provide induction process Agree work arrangements health board and practice Involve in training Make prescribing decisions Provide sufficient pharmacist capacity	Agree aims of pharmacist role between practice and pharmacist Learn roles Build trust	Assign prescribing task to pharmacist • Appropriate work • Increasing the types and amount and work • Understand system	P1, 2, 3, 4
Pharmacist training	Agree work arrangements health board and practice Colocate pharmacists Ensure GP capacity and capability to mentor pharmacist	Involve in training Discuss decisions with GP	Make prescribing decisions Team integration – building trust and learning roles Identify prescribing problem	P 1, 2
Mentoring	Team integration Ensure GP capacity and capability to mentor pharmacist Agreed system for mentoring pharmacists	Involve in training Discuss with GP Assign prescribing tasks to pharmacist	Make decision on prescribing task and subsequent action Team integration – building trust and learning roles Identify prescribing problem	P3
Experience of pharmacist	Provide mentoring • Involve in training • Discuss with GP	Make decision on prescribing task Identify prescribing problem	Subsequent action e.g. contacting patients or carers	P4

	• Assign prescribing tasks to pharmacist Team integration • Agree aims of pharmacist role between practice and pharmacist • Build trust • Learn roles		Assign prescribing task to pharmacist	
Attempt to deal with any task to try to reduce GP workload	Colocate pharmacists Provide sufficient pharmacist capacity Agree work arrangements health board and practice Provide practice induction Build trust Learn roles	Agree aims of pharmacist role between practice and pharmacist Assign prescribing task to pharmacist Select prescribing task	Make decision on prescribing task Involve in training Agree system for mentoring pharmacist	P2
Take responsibility for prescribing task	Provide mentoring • Involve in training • Discuss with GP • Assign prescribing tasks to pharmacist Team integration • Agree aims of pharmacist role between practice and pharmacist • Build trust • Learn roles	Make decision on prescribing task Identify prescribing problem Assign prescribing task to pharmacist Select prescribing task	Subsequent action e.g. contacting patients or carers	P4

Compliance with protocols	Ensure pharmacists have required pharmaceutical knowledge • Provide sufficient pharmacist capacity • Modify existing work processes	Follow protocols	Make prescribing decision (and subsequent actions) • Obtain more information - notes, hospital, patient	P 1, 2
Pharmacist thoroughness	Ensure pharmacists have required pharmaceutical knowledge Provide sufficient pharmacist capacity Involve in training	Identify prescribing problem	Make prescribing decisions (and subsequent actions) Discuss with GP Obtain more information	P 1, 2, 3
Balance thoroughness and efficiency	Provide mentoring • Involve in training • Discuss with GP • Assign prescribing tasks to pharmacist Team integration • Agree aims of pharmacist role between practice and pharmacist • Build trust • Learn roles Comply with protocols	Make decision on prescribing task Identify prescribing problem	Subsequent action e.g. contacting patients or carers	P3, 4

Anticipates and prevents increased practice work	Provide mentoring • Involve in training • Discuss with GP • Assign prescribing tasks to pharmacist Team integration • Agree aims of pharmacist role between practice and pharmacist • Build trust Learn roles Provide sufficient pharmacist capacity	Make decision on prescribing task Identify prescribing problem	Subsequent action e.g. contacting patients or carers	P3, 4
Pharmacist work in similar manner to GP	Involve in training Discuss with GP Agreed system for mentoring pharmacists Agree aims of pharmacist role between practice and pharmacist Employ pharmacist directly	Make decision on prescribing task Select prescribing task	Subsequent action e.g. contacting patients or carers	P4

Table 12.3 – Agreed final mechanisms and evidence for each mechanism from the Case Studies

Mechanism	Practice 1	Practice 2	Practice 3	Practice 4
Team integration	The pharmacy team are a very nice bunch, mixed in well. I think our team have helped include them and I think that the engagement process has certainly been beneficial that way because I think everyone gets on better as they have taken on more roles (P1, PM1) I think a problem was not really knowing exactly what a pharmacist could do, you know. (P1 Admin 1)	They've fitted in well and they came to our Christmas night out last year and em so the personality wise is really, really important and we're a practice that wants change you know and we want we were embracing this idea of having other people working with us and workload being shared out (P2, PM)	'I didn't know that he would deal with that, so it's good to know in more depth what they do' Admin 1 P3 We always make sure they are part of the team, encourage them to come to coffee with us eh so they have an informal relationship with us too. (P3, GP1) Finding out how the practice itself works I think that's one of the problems is every practice is so different that even you know if you are quite experienced in one practice to be able to go into another practice and being able to do the same thing I think actually still takes quite a bedding in time. (P3, Ph1)	I think to develop that trust and that relationship and that good working relationship I think it is better to have them here. GP1 P4 He's worked with us self-employed so he's been in the team so he's developed because he works with us he works within the team so he comes to all the staff training and everything he is part of the development and comes to meetings. (P4, PM1)
Pharmacists 'professional development in General Practice (encompasses	I think it is very important that they are allowed to have the space to make errors, I	I know their limitations if you like - it's a bit like cause we train here - you sort of	Discusses difficult decision (risks vs benefits of alendronic acid) with GP to help him think through pros	He has been here longer now and he knows the patients and he knows the ones that are, so you

training, mentoring, experience)	think that's how they learn, and I think that is also how they become part of your team (P1, GP 2) I have exposed them to difficult patients ...and I think that sort of learning has been really useful. P1 GP 2)	get to know very quickly what you think your registrars limitations are (P2 GP2) I think we need to see how the knowledge you know see how it actually works in practice (P2, Ph2)	and cons – says this will help him with similar situations in future. (Observation P3)	will say to him 'you know so and so' and he will say 'I have sorted that'. He is working the way we would work. (P4, GP2) I suppose from sort of asking the question of others for a few years and getting the answer back it has helped me to become more aware of what to do myself. (P4, Ph1)
Compliance with protocols	I would say the pharmacy department within primary care is still kind of protocol driven and process driven (P1 Ph2) It's not good when somebody follows a protocol so rigidly you have to develop another protocol to counterbalance that (P1 GP 2)	I think when the protocols are put in place it's a huge benefit to the pharmacists and GPs so that they know they are within the guidelines and will stick to it. GP1 P2 Pharmacists - in general we are quite anal, and you know like things something's right or wrong... I would say the pharmacy department within primary care is	[Over specified protocols] encourage a dependent nature which is not what we need and not what we want at all. We need these pharmacists to be working independently as professionals and making decisions which they can justify keep it simple. (GP2 P3) If I go on holiday ... we need to be able to drop somebody else in the practice and pick up the work that I've been doing that means that I need to be doing it the same way	None of us believe in slavishly sticking to them [protocols]. GP2 P4 If they put them in with that [protocols] - it becomes very restrictive then the GPs will not buy into that as that is not how GPs work. The work gets done – it just gets done. GP1 P4 I have had a few calls, inappropriate calls, being put through … querying the dose of something the doctor had issued

		still kind of protocol driven (P2, Ph2)	as somebody in another practice. (P3, Ph1) I think we can standardise a lot of things what we can't standardise is the minutia of how things are done in the practice (P3, Ph1)	just a few hours ago, I just have to pass it on I did not know the answer to the questions. I think it just depends who answers the phone. (P4, Ph1)
Balance thoroughness and efficiency (includes pharmacist thoroughness)	Sometimes the pharmacists are insanely thorough you know this person is come out on sando-K for three days, yes we would have checked his UEs within a week, we wouldn't have gone back to check what there potassium's were like in the lead up to admission. Sifting through that number of the notes and going into portal and doing all of that for a yield of possible one or two errors or changes or things that we could do. I'm not sure that's right. (P1, GP2) Sometimes if stuff's missing it's sort of	They'll still put it [a new anti-hypertensive medication] on for 12 reauthorisations just in case they don't come to that appointment [annual review appointment] ... they want belt and braces (P2, GP1) If they've have got the time to do it – fine, cause it's a good way of testing the problem is that we just have too much of a workload we couldn't operate like that I'm sure some GPs attempt to operate	Says add adcal – no mention why – looks in HEPMA and finds due to hypocalcaemia – not due to falls – so he changes it to adcal D3 without discussing. Observed meds rec P3 If somebody is in a situation where they are about to run out of anti-depressant there isn't a slot for them to discuss with a doctor the least risk - we will continue it. I will speak to them make sure there is nothing desperately urgent going on.	It should always be done [phone patients after meds rec] but realistically it doesn't happen again that is just due to workload. (P4, Ph1) I don't have time to mess about with stuff like that (change antacid to formulary recommendation) also the patient will moan not worth the bother. (P4, Ph1) Meds rec 11, Practice 4 - Ringing alarm bells for me- blister pack and [a specific local community pharmacy] – need to get it done and make sure

	making a clinical judgement about it, checking on clinical portal.. potentially phoning the ward and also speaking to the patient so sometimes the patients are aware of things that have stopped. P1 Ph1	like that but em I couldn't (P2, GP1)		they know what they are doing. He has probably gauged what we accept - every practice will have a different threshold for what they will and will not do. How many times they will review before issuing Co-codamol without reviewing someone. I think he has probably developed that awareness as well. (P4, GP1)
Takes responsibility for tasks to try to reduce GP workload	They're completely happy to deal with any query and we put notes on their desks (P1, admin 1)	Asked about optician letter – inappropriate but happy to review. Seen as easy access – even when consulting they are interrupted to give messages. (P2 observation) Community nurse called re wheezy patient using a lot of inhalers – passed to Ph1 as medication mentioned – obviously needed a house visit	If somebody is in a situation where they are about to run out of anti-depressant there isn't a slot for them to discuss with a doctor the least risk - we will continue it. I will speak to them make sure there is nothing desperately urgent going (P3, Ph1) I think with the new contact one of the main things is everything needs to be working at the top of their licence. These are	If I don't know something try to find out or gather as much information as I can and then if I was still not sure then I would probably pass that on and let someone else decide. (P4 ph1) At various points where we had been rather short of bodies and he has come through and said I can do this and I can do that and this will this help. P4 GP2

		(as requested by community nurse). Ph1 feels whenever medication mentioned work sent to her as easy access but willing to review in case able to prevent task going to GP. (P2 observation)	professionals who are very well trained and are very capable of looking after what we are asking them to look after and I think you need to appreciate that and give them to opportunity to do that. (P3, GP2)	
Anticipates and prevents increased practice work	Sifting through that number of the notes and going into portal and doing all of that for a yield of possible one or two errors or changes or things that we could do. (P1, GP2)	They do it more thoroughly they're more thorough they eh	I don't want to burden anybody else with all of this stuff so you spend a lot of time trying to find ways and find the answer. (P3, Ph1) There's one particular patient that I know if he's been discharged from hospital [and there are medication changes] I need to make sure the pharmacy pick up his old blister packs and that's the only way that that will not go wrong. (P3, Ph1)	We all know that come in at five o'clock on a Friday and demand their prescriptions he always knows and writes in the notes this is not now due until, you know that sort of thing he does anticipate that. He is so helpful. (P4, Admin1)

Key: CN = Case note review, Meds Rec = medication reconciliation event studied, GP = General Practitioner, Ph = pharmacist, P = Practice, Admin = administrative staff member

Figures

Figure 8.1 - Functional Resonance Analysis Method model for pharmacists work in all four practices

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Appendices

Appendix 1 - Letters from ethics committees

University of Glasgow

19/5/17

MVLS College Ethics Committee

Project Title: Pharmacist-led medicines reconciliation post hospital discharge: a multiple case study exploring system safety using a Safety-II approach

Project No: 200160135

Dear Prof Morrison

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. It is happy therefore to approve the project.

- Project end date: End October 2018
- The data should be held securely for a period of ten years after the completion of the research project, or for longer if specified by the research funder or sponsor, in accordance with the University's Code of Good Practice in Research: (http://www.gla.ac.uk/media/media_227599_en.pdf)
- The research should be carried out only on the sites, and/or with the groups defined in the application.
- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes
- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely,

Jesse Dawson
MD. BSc (Hons). FRCP. FESO
Clinical Reader / Honorary Consultant
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Date 10th April 2017
Our Ref WoS ASD 17004
Direct line 0141 232 1784
E-mail Judith.Godden@ggc.scot.nhs.uk

Dear Duncan

Full title of project: **Pharmacist-led medicines reconciliation post hospital discharge: a multiple case study exploring system safety using a Safety-II approach**

You have sought advice from the West of Scotland Research Ethics Service Office on the above project. This has been considered by the Scientific Officer and you are advised that based on the submitted documentation (email correspondence 22nd March 2017) it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition). This advice is based on the following.

- The project is a service evaluation using only data obtained as part of usual care and will not involve any patient identifiable data before publication or data sharing.
- The project involves interviews with professional healthcare staff on the subject of medicine reconciliation. Recruitment is invitational and the transcripts from face to face interviews will be irreversibly anonymised so that the respondent's identity is fully protected and it is not possible to identify the individual from any direct quotation used in the reporting of your project.

Note that this advice is issued on behalf of the West of Scotland Research Ethics Service and does not constitute a favourable opinion from a REC. It is intended to satisfy journal editors and conference organisers and others who may require evidence of consideration of the need for ethical review prior to publication or presentation of your results.

However, if you, your sponsor/funder or any NHS organisation feels that the project should be managed as research and/or that ethical review by a NHS REC is essential, please write setting out your reasons and we will be pleased to consider further.

Where NHS organisations have clarified that a project is not to be managed as research, the Research Governance Framework states that it should not be presented as research within the NHS. This letter has been copied to NHS Greater Glasgow & Clyde R&D Department for their information

Kind regards

Dr Judith Godden, WoSRES Scientific Officer/Manager

Appendix 2 – Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	In published paper
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	25-27
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	28
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	Not available
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	Page 29-30 and Table 3.1
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	28-29
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Appendix 3
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	29

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	30-31
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	30-31
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	31
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	31
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	32

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	31
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	Not done
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Fig 3.1 and 3.2
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	35, Table 3.2
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Table 3.2
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	Table 3.3 Figure 3.2
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	37-38

Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	37-38
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	40-41
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	42-33
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	44-46
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	No external funders

Appendix 3 – Medline search syntax with results from 1.9.17

Medline final search – 1.9.17

1. exp Pharmacists/ or pharmacis*.mp.	30516	
2. exp Pharmacy/ or pharmacy.mp.	55892	
3. exp Community Pharmacy Services/ or community pharm*.mp.	6731	
4. Pharmacists' Aides/ or pharmacy technician.mp.	723	
5. exp Community Pharmacy Services/	3942	
6. medication reconciliation.mp. or exp Medication Reconciliation/	1355	
7. medicines reconciliation.mp.	46	
8. medication therapy management.mp. or exp Medication Therapy Management/	1791	
9. exp Medication Errors/ or medication erro*.mp.	16543	
10. patient compliance.mp. or exp Patient Compliance/	76858	
11. medication discrepancy.mp.	59	
12. medication discrepancies.mp.	215	
13. medication adherence.mp. or exp Medication Adherence/	19068	
14. medication compliance.mp.	1420	
15. medication counselling.mp.	62	
16. medical history taking.mp. or exp Medical History Taking/	20931	
17. Medication review.mp	822	
18. (medication adj3 reconciliation).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier]	1378	
19. patient discharge.mp. or exp Patient Discharge/	26639	
20. discharge.mp.	167713	
21. transitio*.mp.	356801	
22. patient transfer.mp. or exp Patient Transfer/	7897	
23. continuity of care.mp. or exp "Continuity of Patient Care"/	224173	
24. patient readmission.mp. or exp Patient Readmission/	13342	
25. community.mp.	479541	
26. primary health care.mp. or exp Primary Health Care/	151489	
27. primary care.mp.	99621	

28. residential care.mp.	2836
29. ambulatory care.mp. or exp Ambulatory Care/	73643
30. exp Nursing Homes/ or nursing hom*.mp.	68198
31. home care services.mp. or exp Home Care Services/	46536
32. long term care.mp. or exp Long-Term Care/	46111
33. exp General Practice/ or exp General Practitioners/	78313
34. family practice.mp. or exp Family Practice/	68226
35. office practice.mp.	1087
36. family doctor.mp.	2593
37. home visit.mp. or exp House Calls/	4673
38. office visit.mp. or exp Office Visits/	7994
39. primary physician.mp.	804
40. primary clinician.mp.	56
41. general practitioner.mp.	17817
42. rehabilitation.mp. or exp Rehabilitation/	380205
43. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42	1120327
43. 1 or 2 or 3 or 4 or 5	71603
44. 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18	119140
45. 19 or 20 or 21 or 22 or 23 or 24	716622
46. 42 and 43 and 44 and 45	532

Appendix 4 - Documents included in guidance document analysis

Practice level guidance

Medication reconciliation protocols from Forth Valley, Greater Glasgow and Clyde, Ayrshire and Arran

Medication Reconciliation protocols for Case Studies 1,2 and 3.

National Policy Documents

Achieving Excellence in Pharmaceutical Care: a Strategy for Scotland. Pharmacy and Medicines Division, Scottish Government Aug 2017

Realistic Medicine. Chief Medical Officer's annual report 2014-15. Scottish Government 2015

Realising Realistic Medicine. Chief Medical Officer's annual report 2015-16. Scottish Government 2016

Improving Together: A national framework for quality and GP clusters in Scotland. Scottish Government Jan 2017

Pulling together: transforming urgent care for the people of Scotland. The Report of the Independent Review of Primary Care Out of Hours Services. Scottish Government Nov 2015

Prescription for Excellence: A Vision and Action Plan for the right pharmaceutical care through integrated partnership and innovation. Scottish Government Sept 2013

Evidence promoted to support pharmacists working in GP

GP Clusters Briefing Paper 5. Partnership Working with Pharmacists. Scottish School of Primary Care. Sept 2016

New Ways of Working in Inverclyde - HSCP Evaluation of Pharmacists and Technicians in General Practice 2017

Documents supporting development of pharmacist role from national organisations

Primary Care Fund Pharmacists in GP Practices – Supporting Information Pack. Scottish Government May 2016

General Practice Clinical Pharmacist competence and capability framework. NHS Education for Scotland. Sept 2016

Pharmacists and general practice: A practical and timely part of solving the primary care workload and workforce crisis NHS Alliance/ Royal Pharmaceutical Society Oct 2014

Developing clinical pharmacists in general practice. NHS Health Education England Centre for Pharmacy Postgraduate Education, University of Manchester April 2016

Scottish Patient Safety Programme - Primary Care. Medication reconciliation documentation, including website and audit bundle information, and highlight report. Health Improvement Scotland Jan 2016

Safer Use of Medicines – Medicines Reconciliation: Revised Definition, Goals and Measures and Recommended Practice Statements for the Scottish Patient Safety Programme. Scottish Government Sept 2013

A Guide for GPs considering employing a pharmacist Primary Care. Pharmacy Association 2016