

A theoretical exploration of hospital clinical pharmacists' perceptions, experiences and behavioural determinants in relation to provision of optimal and suboptimal pharmaceutical care.

MCLEAN, A.P.

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A theoretical exploration of hospital clinical pharmacists' perceptions, experiences and behavioural determinants in relation to provision of optimal and suboptimal pharmaceutical care

Amanda Penelope McLean

A theoretical exploration of hospital clinical
pharmacists' perceptions, experiences and
behavioural determinants in relation to provision
of optimal and suboptimal pharmaceutical care

Amanda Penelope McLean

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ABSTRACT

Background and context: Pharmaceutical care describes a range of patient-focussed activities delivered by pharmacists. The activities aim to optimise medicines use for patients, and reduce harm from adverse events with medicines.

This study was conducted in an NHS Scotland organisation, where the clinical pharmacy service has an established quality management system. It was evident that some gaps existed in the quality assurance parameters for clinical pharmacy services and pharmaceutical care, with there being no clearly defined route to report adverse events or near misses that arose from within the service. In quality management terms this meant it was difficult to determine whether optimal pharmaceutical care was being delivered, or to establish how accurate clinical pharmacists were in their pharmaceutical care activities; additionally, this meant it was difficult to evidence areas for quality improvement.

Aim: This study aimed to explore the perceptions, experiences and behavioural determinants of the hospital clinical pharmacists in relation to optimal and suboptimal pharmaceutical care within an NHS organisation in Scotland using a theoretical framework.

The research used the concept of suboptimal pharmaceutical care to describe the gap between pharmaceutical care as intended, and pharmaceutical care as delivered.

Design and methods: This research used qualitative study design and a phenomenological approach and was conducted in two phases, the first phase influencing the design of the second phase.

In Phase 1, focus group methodology was used to determine perceptions of hospital clinical pharmacists to optimal and suboptimal pharmaceutical care. Study participant (n=20) were hospital clinical pharmacists recruited from hospitals across the NHS Scotland health board. A topic guide focussed the discussions on the activities related to medicines reconciliation and Kardex/medicines review. Data generated from focus groups was in the form of written statements and audio recorded narrative to describe participants' perceptions of barriers and enablers to providing optimal pharmaceutical care.

The Theoretical Domains Framework (TDF), an integrative theoretical framework that describes behavioural determinants, was used to analyse the findings.

Phase 2 used in depth interviews to explore participants' (n=10) experiences of optimal and suboptimal pharmaceutical care. A semi-structured interview schedule was developed using TDF to facilitate identification of behavioural determinants to the provision of optimal and suboptimal pharmaceutical care.

Results: Within Phase 1, participants perceived that there were barriers to the delivery of optimal pharmaceutical care, citing time factors, lack of policy and procedure, conflicting priorities (including uncertainty over efficiency versus thoroughness), poor underpinning knowledge of medicines by doctors, and inadequate skills in completing and documenting activities as contributory factors. In Phase 2, key determinants were elicited and included knowledge (of trainees), time, policy, procedure or guidance on suboptimal pharmaceutical care, and personal and professional barriers and enablers, including professional embarrassment and hierarchy.

Conclusions: The study has allowed an exploration of an underacknowledged topic in clinical pharmacy practice, and identified behaviours, including role uncertainty and embarrassment, that may contribute to lack of reporting on suboptimal pharmaceutical care. Recommendations have been made using behavioural change technique interventions, and include educational interventions, skills training, modelling, enablement, persuasion, incentivisation, coercion, restriction and environmental restructuring. Implementation of these interventions, and evaluation of their effectiveness, will enable the organisation to have more robust quality assurance parameters within the clinical pharmacy service, and ensure continued conformance with the quality management system. Across the wider clinical pharmacy community, lessons may be learned about perceptions and experiences relating to suboptimal pharmaceutical care, and consideration made to capturing the learning opportunities that can arise when considering suboptimal pharmaceutical care in practice.

Key words: hospital clinical pharmacists; pharmaceutical care; suboptimal pharmaceutical care; Theoretical Domains Framework; behaviour change techniques; quality management.

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RESEARCH OUTPUTS

NHS Scotland Organisation R&D videoconferences, Edinburgh, May 2017 and April 2018; September 2019. Oral presentations on research background, recruitment, initial findings.

Health Sciences Research and Pharmacy Practice (HSRPP) Symposium, Newcastle. April 2018. Oral presentation: *How do hospital clinical pharmacists perceive and experience optimal and suboptimal pharmaceutical care?*

Robert Gordon University Life Sciences research conference, Aberdeen. May 2018. Poster presentation: *Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*. Appendix I Poster 1

NHS Scotland Event, Glasgow. June 2018. Poster presentation: *Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*. Appendix I Poster 1

UK Association of Hospital Chief Pharmacists seminar, Edinburgh. June 2018 (invited speaker). Oral presentation: *How do hospital clinical pharmacists perceive and experience optimal and suboptimal pharmaceutical care?*

European Society of Clinical Pharmacy (ESCP) conference, Belfast. October 2018. Poster presentation: *Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*. Appendix II Poster 2

Clinical Pharmacy Congress, London. June 2019. Poster presentation: *Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*. Appendix II Poster 2

NHS Scotland Organisation Nursing, Midwifery, and Allied Health Professions Doctoral Researchers Group, Edinburgh. September 2019. Oral presentation: *Methodology and research philosophy: How to translate a research idea (curiosity) into a research question*

RPS/University of Strathclyde Research and Development event, Glasgow. September 2019. Poster presentation. *Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*. Appendix III Poster 3

UKCPA Autumn symposium, London. November 2019. Poster presentation. *Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*. Abstract available at: <https://ukclinicalpharmacy.org/wp-content/uploads/2019/11/PM-UKCPA-Conference-2019-abstract-booklet-FINAL2.pdf> (Award for best submitted abstract) Appendix III Poster 3

ABBREVIATIONS and GLOSSARY

ACCP	American College of Clinical Pharmacy
BCT	Behaviour change technique
BSi	British Standards Institute
CAQDAS	computer assisted qualitative data analysis software
CD	Controlled drug
COM-B	Capability, opportunity, motivation – behaviour – a model for behaviour change
COS	Core outcome standards
CPD	Continuing professional development
DATIX	Electronic risk management system
ECS	Emergency care summary
EPMA	Electronic prescribing and medicines administration
ERDS	Education research and development services
ESCP	European Society of Clinical Pharmacy
ETTO	Efficiency thoroughness trade-off
FMEA	Failure modes and effects analysis
FY1	Foundation year 1 doctor in postgraduate training programme
GP	General Practitioner
GPhC	The General Pharmaceutical Council - the regulatory body for pharmacists and pharmacy technicians in the UK.
HIS	Healthcare Improvement Scotland
IDL	Immediate discharge letter
ISO	International organisation for standardisation
IT	Information technology
IV	Intravenous
KARDEX	Prescription and administration record used in hospitals
KPI	Key performance indicator
MDS	Monitored dose system
MI	Medicines Information
MMT	Medicines management team
MPharm	Masters in Pharmacy degree
MRC	Medical Research Council
MSc	Master of Science degree
NES	NHS Education Scotland
NG	Naso-gastric
NHS	National Health Service
NHSSO	NHS Scotland Organisation (research setting)
NPSA	National Patient Safety Agency (for England and Wales)
NPT	Normalisation Process Technique
PARiHS	Promoting Action on Research Implementation in Health Services
PCNE	Pharmaceutical Care Network Europe
PICO	Population, intervention, comparison, intervention

PIP	Pharmacist independent prescriber
QRGS	Quality Risk and Governance Services
RESEARCHER	The professional doctorate student
R&D	Research and development
RGU	Robert Gordon University
RPS	Royal Pharmaceutical Society (since 2010)
RPSGB	Royal Pharmaceutical Society of Great Britain (until 2010)
SACT	Systemic anti-cancer therapy
SCAN	South East Scotland Cancer Network
SEA	Significant Event Analysis
SOPC	Suboptimal pharmaceutical care
SPIDER	Sample, phenomenon of interest, design, evaluation, research type
TDF	Theoretical Domains Framework
TRAK or TRAKcare	TRAKcare electronic patient management system
WHO	World Health Organisation
UK	United Kingdom
UKCPA	United Kingdom Clinical Pharmacy Association
USA	United States of America

FOREWORD:

For the past 25 years, I have worked as a specialist pharmacist within pharmacy quality risk and governance services in an NHS Scotland Organisation. The role of our team is to provide support services and specialist advice across pharmacy services in primary and secondary care. My own specialist support and advisory roles include medicines governance, the safe use of medicines, managing adverse events and some aspects of quality management.

In my quality management advisory role, I have worked with clinical pharmacy services across my organisations' hospital pharmacies to establish processes that comply with the quality management system (ISO 9001) that we are accredited to. I have also worked with the organisations' pharmacy teams to establish processes for reporting adverse events. This work has included developing structures and processes for reporting on adverse events with medicines, as well as developing processes for reporting and learning from adverse events. The reporting, review, measuring and monitoring, and learning from adverse events provides a key function within the quality management system.

There were, however, some anomalies in the adverse event reporting process for clinical pharmacy. Although, as a group, clinical pharmacists were actively reporting on medication adverse events, for example prescribing errors, there was no clear route for them to report on issues or errors arising from within the clinical pharmacy service. In other words, it was difficult to establish how accurate clinical pharmacists were in their clinical pharmacy and pharmaceutical care roles, and this left a gap in the quality management system arrangements for clinical pharmacy. I had noted that there was a paucity of research in the quality management of clinical pharmacy services, and had reviewed published as well as grey literature to find measuring and monitoring methods that had been used elsewhere. I had found little that was of practical help.

At the same time, clinical pharmacy services were changing and adapting to pressures on services. I had conversations with clinical pharmacists who were trying to improve the quality, efficiency and effectiveness of the services, and those who were struggling with workload and capacity to provide the services they wanted to the patients who needed them. Anecdotally clinical pharmacists

were able to describe occasions when something had not gone as planned, where they had not provided the pharmaceutical care they had intended, or had used or given incorrect information, for example.

The opportunity to carry out research in this area arose from a chance conversation at a qualitative methods workshop at a conference. From that, I understood that research could help me understand how to develop a quality assurance process for clinical pharmacy, or at least understand why it was proving difficult to establish and implement a process. A professional practice doctorate would allow me to develop my professional practice, contribute to professional knowledge and build research skills. Building research capability had been a gap in my professional practice, and an area I wished to develop.

At the start of the research journey, I naively thought I would be able to identify areas where pharmacists had not delivered optimal pharmaceutical care, and use that data to develop a taxonomy to describe suboptimal pharmaceutical care, and therefore a reporting process. There were some potential barriers to this approach. Firstly, asking someone to disclose where things have not gone well, or where there has been an error or incident can be emotive and challenging. Secondly, there was no a priori definition of what optimal pharmaceutical care is, as a standard against which the service could be measured. The term suboptimal pharmaceutical care was devised, therefore, as a means of addressing both of these: suboptimal describes the point of interest, between optimal care and error or harm, and avoids the associated emotive language of error or incident. The lack of a definition of optimal or suboptimal pharmaceutical care influenced the design of the research.

The research aimed to help me understand what barriers, if any, there were to reporting suboptimal pharmaceutical care. I wanted to know what experiences clinical pharmacists had of what they perceived to be suboptimal when delivering pharmaceutical care. Furthermore, I wanted to understand whether the delivery of suboptimal pharmaceutical care was having emotional impact on the pharmacists who are my work colleagues, perhaps causing moral distress. I knew that burnout and moral distress amongst healthcare professionals was an emerging challenge to healthcare delivery, and was of interest to me in conducting this research.

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CHAPTER 1 BACKGROUND AND INTRODUCTION

1.1 Introduction to Chapter 1

This chapter will give background, setting and context to the research. The setting for the research was a National Health Service (NHS) Organisation in Scotland, and the focus will therefore be on pharmacy practice within Scotland and, where relevant, the United Kingdom (UK). The chapter will outline descriptions of clinical pharmacy and pharmaceutical care, and introduce the concept of suboptimal pharmaceutical care. This introductory chapter will cover how clinical pharmacists practice, the structures they work in, how they are trained and how they, and the pharmacy profession, are guided and supported. The chapter will then proceed to describe quality management systems, and specifically how quality management principles have been applied in this NHS Scotland organisation, and within the clinical pharmacy service. The chapter will conclude with discussion on medicines safety and the role of the clinical pharmacist, and how involvement in adverse events within medicines can lead to moral distress and burnout amongst healthcare professionals.

1.2 Clinical pharmacy and pharmaceutical care

The focus of this thesis is clinical pharmacy and pharmaceutical care and these terms are introduced and described here:

1.2.1 Clinical pharmacy

Clinical pharmacy is both a scientific discipline and a branch of pharmacy practice, which aims to *'optimise the therapeutic use of medicines by patients and professionals in order to maximise the likelihood that an optimal balance of clinical, humanistic and economic outcomes is achieved'* (European Society of Clinical Pharmacy 2005). Clinical pharmacy services arose from a societal need to improve the use of medicines, initially in the hospital setting, and thereafter across all healthcare settings (Hudson, McAnaw and Johnson 2007), and clinical pharmacists are described as practitioners who provide medicines management and the relating care for patients. For the purposes of this thesis, with the

research being conducted in the hospital setting, the definitions and applications will be focussed on hospital clinical pharmacy.

Clinical pharmacy practice is an established discipline across the world. The American College of Clinical Pharmacy (ACCP) defines clinical pharmacy as *'embodying the application by pharmacists of the scientific principles of pharmacology, toxicology, pharmacokinetics and therapeutics to the care of patients'* or in an abridged form as *'the area of pharmacy concerned with the science and practice of rational medicine use'* (American College of Clinical Pharmacists, 2008). The European Society of Clinical Pharmacy (ESCP) defines clinical pharmacy as *'a health specialty that describes the activities and services of a clinical pharmacist in developing and promoting the rational and appropriate use of medicines'* (European Society of Clinical Pharmacy 2005). Clinical pharmacy has been defined in the UK by the United Kingdom Clinical Pharmacy Association (UKCPA) as *'encompassing the knowledge, skills and attitudes required by pharmacists to contribute to patient care'* (United Kingdom Clinical Pharmacy Association 2005).

Clinical pharmacy practice can therefore be said to be a practice where skilled pharmacists promote the rational and effective use of medicines with the aim of improving health and wellbeing, and preventing disease, and through these actions improve the quality of life of patients.

In the UK, clinical pharmacy developed initially in secondary care (the term used to describe NHS hospitals that provide urgent and planned care) in the 1980's, as a means of putting the pharmacist nearer to the patient and to the healthcare team that are caring for the patient. The term clinical pharmacy was first formally acknowledged in the UK in the 1986 Nuffield Report (Nuffield Foundation 1986), which welcomed the changes in practice that clinical pharmacists could bring to hospital pharmacy services. Clinical pharmacy practice marked a move away from the product supply and prescription check functions of the pharmacist to one where the pharmacist was an integral part of the healthcare team. A rapid development of clinical pharmacy services followed and by the early 1990's the majority of NHS hospitals in the UK provided clinical pharmacy services. The range of clinical pharmacy services varied significantly when surveyed in the 1990's (Calvert 1999), and continues to do so, with little

agreement as to which components of a clinical pharmacy service are the most important (Rotta et al 2015; Onatade et al 2018), and effective (Gallagher et al 2014), making measurement and comparison of clinical pharmacy services difficult. Activities undertaken by clinical pharmacists to achieve the rational and effective use of medicines, include in broad terms (Onatade, Miller and Sanghera 2016; Rotta et al 2015):

- Medicines review, where the purpose is to review medicines prescription and administration charts, (referred to as a Kardex in this thesis) for accuracy, and to identify any prescribing or administration errors.
- Modifying drug doses or drug choices, in accordance with standards of practice, and with the individual patient's characteristics central to decision making.
- Review of the appropriateness of medicines at all stages of the patient journey with the purpose of ensuring medicine safety at transitions of care; this process is described as medicines reconciliation.
- Patient medicine counselling, putting the patient first, and providing information to the patient to enable effective use of medicines.
- Prescribing/deprescribing where the purpose is to ensure that medicine use is safe and effective and appropriate for each individual patient
- Authorising discharge, where the purpose is the safe transition of care which is patient focussed.

This list is not exhaustive: The components of a clinical pharmacy service will depend on the specialty, and on the availability of a competent clinical pharmacist to provide the service. This research programme will describe a number of key activities and functions within clinical pharmacy practice, and these are described here.

1.2.1.1 Medicines review

The review of medicines and administration charts for accuracy to identify prescribing or administration errors and discrepancies is an established and recognised component of a clinical pharmacists' role, and pharmacists have been described as a 'safety net' by doctors, (Dean et al 2002; Dornan et al 2009). Dean et al (2002) conducted a multi-centred qualitative study with 41 doctors in

secondary care and identified that new doctors in particular relied on pharmacists to notice and explain their mistakes. This was reinforced by the findings of the EQUIP study (Dornan et al 2009). The study demonstrated that doctors relied on pharmacists and nurses to identify and correct errors. In the systematic review section of the EQUIP study, the prescribing error detection rate was shown to be highest when data was collected by pharmacists. A similar finding on error detection was made by Phansalker et al (2007), who concluded that pharmacists were the most thorough compared with other healthcare professionals when conducting a review of prescribed medicines, but pointed out that some errors may remain undetected.

The aforementioned studies highlight the skill that pharmacists have in detecting prescribing mistakes and errors, however Donyai et al (2008) identified that there was a risk that overworked and stressed pharmacists could miss errors or incorrectly identify errors. This was supported by the findings of a small local study in the UK by Tully and Buchan (2009) who examined prescription errors during hospital inpatient care, and the factors that influenced their identification by pharmacists. They reported that workload predicted error identification rate and reported that 40% fewer prescribing errors were identified on the busiest days. They also reported that senior pharmacists were more likely to identify errors than junior pharmacists, suggesting an area for ongoing education.

As a service provided by clinical pharmacists, medicines review is frequently described as a key activity (Onatade, Miller and Sanghera 2016), and is described as a task that increases the safety and effectiveness of medicines use (Dean et al 2002). There is, however, a paucity of recent research into medicines review as a process.

1.2.1.2 Medicines reconciliation

Medicines reconciliation is a complex activity, with responsibility shared across the multidisciplinary team, and with implications for the safety of the patient (Scottish Government 2013; National Institute for Health and Care Excellence 2015; Royal Pharmaceutical Society 2013). The purpose of medicines reconciliation, within the hospital setting, is to obtain the most accurate list possible of all the medicines a patient is taking, at all stages of the patient

journey – that is, at admission, transfer and discharge. Medicines reconciliation should result in an accurate list of medicines, including both prescribed and non-prescribed (over the counter, herbal or illicit) medicines. The documented list should include name, dose, frequency and route, with any discrepancies or differences noted, along with reasons for any changes. The role of the clinical pharmacist may be to conduct medicines reconciliation, or to verify that it has taken place, and identify any resultant pharmaceutical care issues, depending on organisational policies.

Systematic reviews of medicines reconciliation have shown mixed results: a systematic review in 2016, examining 17 studies found that pharmacist-led medicines reconciliation improved post hospitalisation healthcare utilisation (Mekonnen, McLachlan and Brien 2016). However, this was not the findings of a systematic review in 2018. Cheema et al restricted the review to 18 randomised controlled trials with medicines reconciliation, and found that whilst there was a reduction in medicine discrepancies, this did not lead to a significant reduction in adverse drug events, nor to a decreased level of healthcare utilisation (Cheema et al 2018). Variability in the quality of the included studies prompted the authors of this systematic review to advise caution in the interpretation of the findings, and a call for improved outcome measures to be established (Cheema et al 2018).

1.2.1.3 Pharmacist independent prescribing

Pharmacists have been able to prescribe in the UK since 2006, and this has facilitated some changes to practice for clinical pharmacy teams. Pharmacist independent prescribers (PIPs) prescribe autonomously, whilst working within their area of competency, across different clinical conditions. It is important that pharmacist independent prescribers learn from errors and near misses, and to do this, that they record and report prescribing errors and near misses (Royal Pharmaceutical Society 2016). The In-practice Guidance for Pharmacists (General Pharmaceutical Council 2019) states that pharmacists must reflect on feedback or concerns that come from others, and act to prevent the same thing recurring.

There are a number of studies that have examined the accuracy of pharmacist's prescribing by looking at error rate (Baqir et al 2015) and at appropriateness of prescribing (Latter et al 2012). Baqir et al (2015) explored the nature, extent and prevalence of pharmacist prescribing errors by using data from pharmacists in a NE England Trust. As the number of errors were low, it was not possible to categorise them by their nature, but prevalence of error was reported at 0.3% for pharmacists. There have been other UK studies that have attempted to compare pharmacist prescribing error rates with those of doctors. Taylor and Davies (2019), found that 6% of pharmacist independent prescribers' discharge prescriptions had errors (N= 395), compared with 46% of those from doctors (N=706). A similar UK study conducted found that pharmacist independent prescribers had an accuracy of 99.8% (0.2% error rate; N=532) and doctors 89.5% (10.5% error rate; N=2416) for discharge prescriptions (Phillips et al 2019). The variation is perhaps due to the different data collection methods. The reported studies did not describe how prescribing errors for pharmacists are normally collected and collated.

1.2.1.4 Prioritising the delivery of clinical pharmacy services

With increasing pressures on services, clinical pharmacy services have looked at mechanisms for targeting resource to where it is most needed. One of the ways of doing this has been to prioritise the clinical pharmacy services, or target pharmaceutical care, using prioritisation tools; these tools are called by a variety of names, as described in a systematic review (Alshakrah, Steinke and Lewis 2019). The systematic review of prioritisation tools identified 17 different tools from the literature. Terms for the tools included priority coding, pharmacy risk screening tool (Cottrell, Caldwell and Jardine 2013) and pharmaceutical assessment screening tool (Hickson et al 2017). There were some common features of the prioritisation tools: the majority aimed to identify patients most at risk from adverse drug reactions, adverse events or medication errors. None of the included studies showed a measurable impact on prescription errors or adverse drug events. However, key themes identified from the studies were the positive impact of risk assessment tools on both patient care and provision of pharmacy services. The review also highlighted the limitations of risk prioritisation tools. The systematic review concluded that because of the

heterogeneity of the different tools being used, it was not possible to measure objectively the impact of tools on patient outcomes and on workforce efficiency, and concluded that further research is needed in this area (Alshakrah, Steinke and Lewis 2019).

Other studies of risk prioritisation tools have examined the accuracy of priority coding of patients by pharmacists. Hickson et al (2017) noted when attempting to validate a tool that they had developed, that accuracy in coding was limited, with just under half of patients not being scored according to the tool (Hickson et al 2017). A qualitative study exploring decision making in priority coding processes (Saxby et al 2017), found that clinical judgement often overrode the scoring tool. This is supported by an unpublished mixed methods study in the NHS Scotland organisation clinical pharmacy service (NHS Scotland Organisation Pharmacy 2019). The study compared the priority coding decisions of pharmacists with those of the research team, with the research team following the priority coding tool precisely as written. The study concluded that there were variations between individuals in the way the tool was used. In addition, the local study also found that clinical judgement often overrode the scoring tool, and that the priority coding tool was used more for work planning than prioritising patients, and this reflected the findings of both Hickson et al and of Saxby et al (Hickson et al 2017; Saxby et al 2017).

1.2.1.5 Establishing quality assurance in clinical pharmacy

Quality assurance is defined as *'the maintenance of a desired level of quality in a service or product, especially by means of attention to every stage of the process of delivery or production'* (Oxford Dictionary 2020). Establishing the 'desired level of quality' can be difficult when there is a lack of a uniform or consistent description of clinical pharmacy, and this has been previously described, (Calvert 1999, Cotter, Barber and McKee 1994). Calvert (1999) identified that the lack of a uniform description or definition of a clinical pharmacy service, and a paucity of research into service effectiveness, had resulted in clinical pharmacy services that had developed based on opinion rather than evidence. Onatade et al (2018), more recently, described the lack of agreed priorities, measures or defined outcomes for hospital clinical pharmacy as

a barrier to services being delivered effectively and consistently (Onatade et al 2018).

The lack of a standard description or definition of clinical pharmacy services, or of standards for clinical pharmacy services (Agnew and Friel 2014) makes quality assurance programmes difficult to implement. Instead, because of the difficult nature of measuring the direct impact of a clinical pharmacy service on patient outcomes, the tendency has been to collect activity data – the number and uptake of interventions made, or the number of patients visited, for example. Activity measures of the frequency of ward visits have been described for England (Onatade, Miller and Sanghera 2016; McLeod et al 2014). However, a measure of activity or ward visits does not assess the quality of the service provided on those visits.

Other research has investigated the theoretical application of quality risk management to clinical pharmacy processes in an Austrian hospital, using failure modes and effects analysis (FMEA) (Wunder et al 2013). The theoretical description in this study identified a range of clinical pharmacy processes and their associated potential failure points. For example, it was identified that there could be a patient hazard due to a missing intervention that a pharmacist either overlooked or did not know. The study gave suggestions for prevention, such as gaining knowledge, and standardising work practices but did not provide any mechanisms for detecting failures. Although described as quality risk management, the outlined description was theory based, and limited to a select few clinical pharmacy processes.

In summary, extant literature shows that there is a gap in knowledge in demonstrating quality assurance within clinical pharmacy services, and that the focus of measurement is often on activity rather than outcomes. Clinical pharmacy practice can take place across different healthcare settings, however in this study the focus was on hospital clinical pharmacy and as such the focus of this introductory chapter will predominantly be in that setting.

1.2.2 Pharmaceutical care

Clinical pharmacy *activities* can be described under the philosophical umbrella of pharmaceutical care. Pharmaceutical care was described in the USA by Heplar

and Strand (1990) as: *'the responsible provision of drug therapy for the purpose of achieving definite outcomes which improve the patient's quality of life'* and this definition has been widely accepted worldwide as a description for the philosophy by which clinical pharmacists' practice. The Pharmaceutical Care Network Europe (PCNE) consensus definition offers the following definition: *'Pharmaceutical care is the pharmacist's contribution to the care of individuals in order to optimize medicine use and improve health outcomes'* (Allemann et al 2014).

An adaptation of the original Hepler and Strand definition was coined by the Scottish Government in the document *Prescription for Excellence* (Scottish Government 2013a) to include emphasis on partnership working, and to incorporate reference to minimising adverse events with medicines; the revised definition of pharmaceutical care being: *'a model of pharmacy practice which requires pharmacists to work in partnership with patients and other health and social care professionals to obtain optimal outcomes with medicines and eliminate adverse events where possible'*.

The above definitions describe having the patient as the focus of the care, working collaboratively both with patients and other healthcare professionals, maximising the benefits of medicines, optimising outcomes, and reducing adverse events. However, similarly to discussions on the assessment and evaluation of clinical pharmacy previously described, there is little agreement about which components of pharmaceutical care are the most important- i.e. make the most difference to the patient (Onatade et al 2018). Definitions for pharmaceutical care refer to outcomes – 'definite outcomes' (Hepler and Strand 1990), 'health outcomes' (PCNE), 'optimal outcomes with medicines' (Scottish Government 2013a) - and there is therefore a latent expectation that the outcomes are measurable. However, there is little consensus on what outcome measures to use in pharmaceutical care, and this creates a barrier to comparing practice and to developing interventions. A systematic review by Beuscart et al (2017), exploring the outcome reporting of medicines review as a pharmaceutical care intervention in older patients, for example, found it difficult to compare effectiveness of interventions because of the lack of a core set of outcome measures. That is not to say interventions were not effective, but that

measuring the effectiveness had not been guided, and studies therefore could not be compared. The lack of core outcome measures continues to be problematic when looking for evidence for pharmaceutical care interventions, and whilst core outcome sets (COS) are a valuable addition when assessing interventions, even the developers of COS highlight that they will only state WHAT should be measured and not HOW (Millar et al 2017).

Without outcomes driving it, or a set of established procedures, pharmaceutical care will vary depending on who is delivering it, as well as being by its nature individual to the patient in receipt of it, and a definition of optimal pharmaceutical care remains elusive.

1.2.2.1 Suboptimal pharmaceutical care

When planning the research, it became apparent that there was a need to clarify and describe what was not 'optimal' in terms of pharmaceutical care, and this led to the establishment of the novel term suboptimal pharmaceutical care.

Suboptimal means '*not at the best possible level or standard*' (Merriam-Webster dictionary 2019). Suboptimal is a term familiar to those working in healthcare through the term 'suboptimal dosing' for example as a descriptor for failing to achieve therapeutic levels when it comes to medicines.

The term suboptimal has been applied in nursing, with the description of *suboptimal care*, which has been used when describing the suboptimal care of the acutely unwell patient. Quirke, Coombs and McEldowney (2011) carried out a systematic review and concept analysis on the topic, and found that although suboptimal care was commonly used as a phrase in nursing, there was no clearly defined concept. The authors concluded that suboptimal care was a patient safety issue and needed objective measures. Attributes of suboptimal care were described as delays, poor assessment and inadequate patient management, and antecedents to suboptimal care were identified as being patient complexity, workforce, and organisational and educational factors (Quirke, Coombs and McEldowney 2011). In nursing of the acutely unwell patient, the term suboptimal has been selected as a preferred term, being less judgemental than 'poor care', and is proactive, with an intended desire to improve rather than criticise (Price et al 2015).

A similar approach was taken when adopting terminology for this study, with suboptimal pharmaceutical care being deemed less judgemental than poor or substandard pharmaceutical care. There is an associated inference that suboptimal pharmaceutical care can be improved, and that understanding the attributes and factors that enable suboptimal pharmaceutical care to be delivered will facilitate service improvement.

In attempting to describe the point at which pharmaceutical care becomes suboptimal, a schematic was designed and used throughout the research. The schematic is positional and not directional, with optimal being the intentional action (Figure 1.1)



Figure 1.1 Schematic for suboptimal pharmaceutical care

It was not anticipated that there was harm to the patient through the delivery of suboptimal pharmaceutical care. The hypothesis was rather that optimal pharmaceutical care, with its philosophy of improving outcomes with medicines, was not being achieved 100% of the time. A literature search could not find any reference to suboptimal pharmaceutical care, and this therefore became a novel concept described in this research.

1.3 Hospital Clinical Pharmacy practice in Scotland and the UK

This section will outline hospital clinical pharmacy practice in the UK, with a contextual focus on Scotland, since the programme of research was carried out in Scotland. The section will describe how pharmacists are educated and trained, and the professional and practical educational and training support that exists once they are qualified. Further, this section will describe the regulatory and ethical frameworks hospital clinical pharmacists operate within in Scotland and the UK.

1.3.1 The training and professional development of hospital clinical pharmacists in the UK

Pharmacists start their training as an undergraduate, and progress through pre-registration and foundation years. They will then have the opportunity to undertake post-graduate level education and training. In addition, pharmacists must undergo continuing professional development (CPD) throughout their career, and this professional development forms an important component of the regulatory framework that pharmacists operate within. Understanding the training and the professional development that clinical pharmacists undertake, and the regulatory framework within which they operate is important when looking at the way attitudes, perceptions and behaviours form in relation to professional roles at work. The different stages of training will be briefly described, before describing professional development, and professional and ethical guidance.

1.3.1.1 Undergraduate training in the UK

Pharmacist training in the UK starts with the four year MPharm degree course. The course is intended to give students a grounding in theoretical knowledge, professional behaviours and the clinical skills needed to become a pharmacist (General Pharmaceutical Council 2011). All pharmacy undergraduate courses must be accredited by the General Pharmaceutical Council (GPhC), and to enable this the GPhC has outlined ten standards for the initial education and training of pharmacists. The ten standards are:

1. Patient and public safety
2. Monitoring, review and evaluation of initial education and training
3. Equality, diversity and fairness
4. Selection of students and trainees
5. Curriculum delivery and the student experience
6. Support and development for students and trainees
7. Support and development for academic staff and pre-registration tutors
8. Management of initial education and training
9. Resources and capacity
10. Outcomes

During the undergraduate course, trainees must gather evidence of compliance with each standard, and are expected to follow a curriculum that covers five broad areas of syllabus (General Pharmaceutical Council 2011):

1. How medicines work (including therapeutics and applied sciences)
2. How people work (including health conditions and social sciences)
3. How systems work (including management, regulation and governance)
4. Core and transferable skills (including research and appraisal skills)
5. Attitudes and values (including professionalism)

A pharmacy degree allows pharmacists to enter different branches of practice, including hospital pharmacy.

1.3.1.2 Pre-registration training in the UK

On successful completion of the four year course, the pharmacist trainee enters a 52 week pre-registration training period, where they are under the supervision of a tutor. The training will take place predominantly in one sector of pharmacy practice, with opportunities to experience other sectors. Pre-registration training may change in the future (Rudkin et al 2020), with reforms planned to better equip pharmacists for increasingly clinical roles across multiple sectors .

During the pre-registration period, the trainee is expected to develop and to demonstrate knowledge and competence against 76 performance standards that are assessed by the individual's tutor (General Pharmaceutical Council 2019a).

The performance standards operate within the three units of personal

effectiveness, interpersonal skills and medicines and health, and include standards that the trainee must demonstrate compliance with (Figure 1.2).

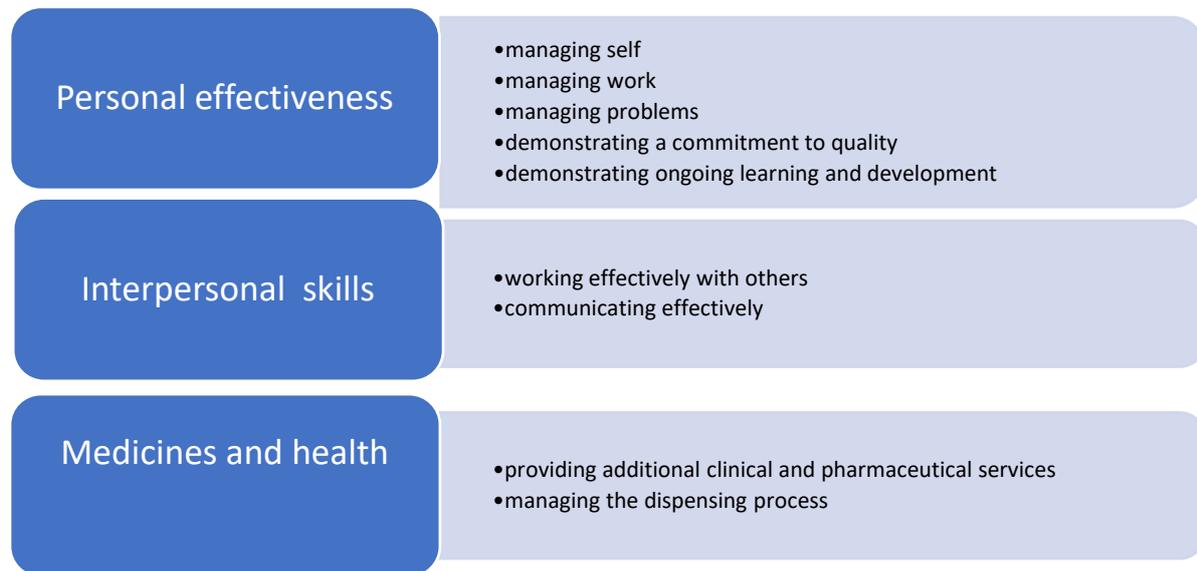


Figure 1.2. Performance standards for pre-registration training (adapted from General Pharmaceutical Council 2019a)

In addition, the trainee will be expected to demonstrate competence in nine professional attributes:

- 1 Person centred care
- 2 Communication and consultation skills
- 3 Problem solving, clinical analysis and decision making
- 4 Self directed learning and motivation
- 5 Multi-professional working and leadership
- 6 Quality management and organisation
- 7 Professional integrity and ethics
- 8 Resilience and adaptability
- 9 Pharmacy in practice

The trainee is required to keep a portfolio of evidence that will demonstrate their achievement of these nine professional attributes, as well as the performance standards, and the portfolio is examined as part of their overall assessment. The trainee will also start to keep a record of their ongoing CPD (continuous professional development) during their pre-registration year. The period of pre-registration training ends with a registration assessment. This period of training may take place within the hospital pharmacy setting, but that is not a

prerequisite to a future role in hospital pharmacy. By the time the trainee has become a pharmacist they will have gained therapeutic knowledge, as well as a grounding in quality, governance and professionalism.

1.3.1.3 Early years and foundation training for hospital pharmacists in Scotland

Newly registered pharmacists enter a period of foundation training, within the sector they are first employed. During this period, they will learn to apply the clinical knowledge they have gained during undergraduate and pre-registration training to the workplace, whilst under the supervision of more senior colleagues, and with support from a work-based tutor. In Scotland, foundation training is delivered through use of the NES Pharmacy competency-based training programme, which is accredited by the Royal Pharmaceutical Society (RPS). Foundation training generally takes two years to complete. The aim of the foundation training period is to allow pharmacists to develop a range of skills, build on their knowledge using a framework for learning, and gain experience that will equip them in their future roles (Royal Pharmaceutical Society 2018; NHS Education Scotland 2019). The foundation framework aims to develop the attributes of a pharmacist across nine areas:

1. Professional accountability
2. Evidence-informed decision making
3. Person-centred care
4. Communication and consultation skills
5. Collaborative working
6. Leadership and management
7. Education
8. Research and evaluation
9. Resilience and adaptability

During the foundation training period, pharmacists are expected to carry out an audit or quality improvement programme, and further develop their professional self.

1.3.1.4 Post-graduate training for hospital clinical pharmacists in Scotland

Once a hospital clinical pharmacist has completed foundation level training, they have the opportunity to progress their career through post-graduate training. An MSc in advanced clinical pharmacy is a formal training route that many hospital clinical pharmacists will opt to take to progress their career, and learning will include, for example, advanced therapeutics, quality improvement and research skills.

1.3.1.5 Pharmacist independent prescribing for hospital clinical pharmacists in Scotland

NHS Education Scotland supports pharmacists in training for independent prescribing, and in implementing those skills into practice. The training consists of University based training, supported by clinical skills training, and patient-centred consultation skills. Once pharmacist independent prescribers have been assessed as being competent they must register with the GPhC, as the regulatory body for pharmacists. The core competencies for pharmacist prescribers have been described (Royal Pharmaceutical Society 2016), and are incorporated into the knowledge and skills training, and include prescribing governance and consultation competencies. Standards have been established for pharmacist independent prescribers, and include taking responsibility for prescribing, prescribing within level of competency, using clinical judgement, and raising concerns (General Pharmaceutical Council 2019). Once a pharmacist independent prescriber has been assessed as competent, their on-going competence is assured through CPD and professional revalidation.

1.3.1.6 Continuing professional development (CPD) and professional revalidation of pharmacists in the UK

All pharmacists must keep a record of CPD as part of their registration as a pharmacist with the General Pharmaceutical Council (GPhC). In 2018, CPD recording became aligned with the newly introduced revalidation process in the revalidation framework (General Pharmaceutical Council 2018). For revalidation, pharmacists are required to submit four CPD records, a peer discussion record

and a reflective account statement. However, professionally, pharmacists are expected to undertake as much learning activity as necessary to support safe and effective practice, and the submission of records for revalidation would be expected to be part of a wider range of CPD activities.

Pharmacy professionals must follow the nine standards that have been issued by the GPhC, (Figure 1.3), and the process of revalidation aligns to these standards by asking that the reflective account refers back to the standards, with three different standards being proposed for each year. The nine standards are:

- 1 Person centred
- 2 Partnership working
- 3 Effective communication
- 4 Professional knowledge and skills
- 5 Effective leadership
- 6 Speaking up about concerns
- 7 Respect for personal privacy and confidentiality
- 8 Professional behaviour
- 9 Professional judgement



Figure 1.3. GPhC Standards for Pharmacy Professionals (use approved; picture source: GPhC)

In summary, pharmacist training in the UK is grounded in theory, skills and professional behaviours, which is maintained and built on through further

training, CPD and ongoing development, and is assessed at revalidation annually. Pharmacists are trained to understand their role in the medicine journey, and to reflect on their opportunities for learning.

1.3.2 Professional regulation and professional development for pharmacists in the UK

Pharmacists are regulated as a profession to assure standards of practice. All pharmacists in the UK are regulated by the independent regulator, the General Pharmaceutical Council (GPhC), as required by the Pharmacy Order (UK Government 2010). The GPhC are responsible for professional standards for all pharmacists, including fitness to practice, continuing professional development (CPD) and premises standards.

Individual pharmacists may take professional guidance and support from a range of organisations, as appropriate to their speciality and to their level of experience, and are held accountable for maintaining appropriate levels of professional practice. In addition, pharmacists have the option to register with their professional body, the Royal Pharmaceutical Society (RPS). The RPS aims to develop the professionalism of pharmacists through the provision of guidance, educational support, information about medicines and pharmacy practice.

1.3.3 Specialist professional guidance for hospital pharmacists in the UK

As hospital clinical pharmacists progress through their careers, they are likely to specialise in a clinical area. At this stage, they may opt to join one or more specialist interest groups pertinent to their specialty. Specialist interest groups all offer support and guidance relevant to their specialty, and can be a source of practical advice for a specialty, as well a network that can be accessed to share information. Specialist interest groups often have a range of educational materials, peer to peer networks and competency frameworks to facilitate professional development within a specialty. Some specialist interest groups offer study days and conferences, and will have different means of communicating out guidance and advice, and of enabling peer to peer discussions.

1.3.4 Ethical Guidance for Pharmacists in Scotland and the UK

Ethical and moral guidance for pharmacists may come from the GPhC, as the regulator, or the RPS, as the professional body, and additionally from Government, in the form of reports, standards, statements or ethical frameworks. The research study took place in Scotland, and policy context was considered in relation to Scotland, and to the UK. As part of devolution, health is devolved to the Scottish Government; primary legislation, however, relating to medicines, and to the pharmacy profession are not devolved. When considering the planned research study, the researcher reflected on the key professional drivers that were in place when the research was planned in 2014, updated in 2017 when the research was taking place and reviewed in 2019. The researcher identified those drivers that were influential in their own professional development, and that prompted interest in the research topic (Table 1.1).

Pharmacists in the UK have been developing services that enable the principles of ethical guidance to be implemented, in their professional conduct and behaviours (General Pharmaceutical Council 2017; Scottish Government 2013a; Lord Carter 2016), in openness, honesty and candour including the reporting of errors (General Pharmaceutical Council 2014; Royal Pharmaceutical Society 2014; Royal Pharmaceutical Society 2016a) and in sharing lessons learned (Royal Pharmaceutical Society 2014; Healthcare Improvement Scotland 2016; Royal Pharmaceutical Society 2016a; Royal Pharmaceutical Society 2019). However, whilst these guidance documents provide the ethical framework for pharmacists to work within, they do not describe, for example, *how* to report pharmacist prescribing errors, or *how* to share learning from errors, and that leaves a gap in practice and variation across the profession.

Table 1.1 therefore summarises the key statements made in the grey literature that are significant in relation to this research, relating to professionalism, duty of candour and reporting and learning from errors. Many of these statements apply across different sectors of pharmacy, but are selected here as being pertinent to hospital pharmacy, and to clinical pharmacy in particular. The statements and quotes are those that influenced the researcher, and that raised the question of how the principles of professionalism, duty of candour and learning from error were being applied to hospital clinical pharmacy practice.

Table 1.1 Key statements relating to professionalism, duty of candour, error reporting and learning from error			
Source	Year	Title of document	Exemplar quotes relating to professionalism, duty of candour, error reporting and learning from error
Department of Health	2008	Pharmacy in England –Building on strengths – delivering the future	<i>'with greater clinical responsibilities come greater expectations: of safety, of quality and of accountability'</i>
General Pharmaceutical Council	(Ongoing) 2017	Standards of conduct, ethics and performance,	Seven principles for behaviour <ol style="list-style-type: none"> 1. Make patients your first concern 2. Use your professional judgement in the interest of patients and the public 3. Show respect for others 4. Encourage patients and the public to participate in decisions about their care 5. Develop your professional knowledge and competence 6. Be honest and trustworthy 7. Take responsibility for your working practices
General Pharmaceutical Council (joint statement with other professional bodies)	2014	Openness and honesty - the professional duty of candour	<i>'Be open and honest with patients when something goes wrong with their treatment or care which has caused, or has the potential to cause, harm or distress'.</i> <i>'Be open and honest with colleagues and employers'</i> <i>'Raise concerns where appropriate'.</i>
Royal Pharmaceutical Society	2014	Medicines Ethics and Practice	Just Culture: <i>'pharmacists are encouraged to learn from mistakes or incidents, and to share lessons learnt throughout the profession. They are further urged to use this shared learning to reduce the likelihood of similar mistakes and incidents from happening again'.</i>
Scottish Government	2013a	Prescription for Excellence	Professionalism: <i>'a set of values behaviours and relationships'</i> <i>It includes such components as integrity, honesty, duty, accountability, commitment, responsibility and independent judgment'</i>

Source	Year	Title of document	Exemplar quotes relating to professionalism, duty of candour, error reporting and learning from error
Healthcare Improvement Scotland	2016	Governance and Assurance: Learning from Adverse Events	Learning and Improvement summary: <i>'consistently share learning and demonstrate improvements'</i>
Royal Pharmaceutical Society	2016a	Professional standards for the reporting, learning, sharing, taking action, and review of incidents	<i>'Reporting sharing and learning from incidents is a key professional role for all pharmacists to ensure the safety of patients'.</i>
Scottish Government	2017	Achieving excellence in Pharmaceutical Care	Transformation of pharmacy roles: <i>'increasing capacity and offering the best person-centred care in the best setting'.</i>
Lord Carter's Report for the Department of Health & Social care	2016	Operational productivity and performance in NHS Hospitals: unwarranted variations	Report identified <i>'unwarranted variation, and inefficiencies in hospitals'</i> , including pharmacy. Proposed an increase in access to pharmacy services, with 80% of pharmacy services being clinical, & with seven day working.
Royal Pharmaceutical Society	2019	In-practice guidance for pharmacist prescribers	<i>'Pharmacist prescribers must record, report, and learn from errors and near misses to manage the risk of making and repeating mistakes'.</i>

To summarise this section, pharmacists are guided throughout their careers by a framework of governance, underpinned by knowledge and skills gained through education and training. Principle values that pharmacists are expected to adhere to include integrity, honesty, openness and accountability. Pharmacists are required to make patients their first concern, and are encouraged to learn from mistakes, errors and near misses, and to share learning with other pharmacy colleagues to reduce the likelihood of similar events happening again.

1.4 The NHS Scotland organisation research setting

This section will firstly describe the NHS Scotland organisation where the research was conducted, and then the hospital pharmacy services. The section will go on to describe how the hospital clinical pharmacy services are organised and delivered within the organisation.

1.4.1 The NHS Scotland organisation

The organisation is a health board located in Scotland. The organisation has four acute hospital sites and one hospital delivering acute psychiatric services, and serves a population of around nearly 890,000, set to rise to 925,000 by 2025.

The organisation's Strategic Plan 2014-2024: *Our Health, Our Care, Our Future*, (NHS Scotland Organisation 2014) outlines the challenges facing the health service in the current decade. The document outlines a vision for services that will require changes in practices and in mind set. This strategic plan aligns with the Scottish Government vision set out in '2020 Vision for health a social care – a route map' – with its triad of quality ambitions of '*Quality of Care, Health of the Population, and Value and Financial Sustainability*' (Scottish Government 2013b).

1.4.2 NHS Scotland organisation pharmacy strategy

The pharmacy strategy 2018-2020 (NHS Scotland Organisation 2018) describes the intended direction for all pharmacy services in the NHS Scotland organisation. The strategic vision is for a pharmacy service that will '*work proactively with others in healthcare to deliver first class pharmaceutical services, with the patient at the centre of care*'. The primary aim from this vision is '*to work collaboratively with patients and providers to provide safe supplies of medicines, in the best setting for the patient*'. The strategy describes how this will be done, by having a workforce that is skilled, competent and compassionate, and by making the best use of resources available, particularly in terms of workforce. The pharmacy strategy is adopted by all pharmacy services, including clinical pharmacy, and the ethos and principles of the pharmacy strategy are incorporated into the planning and delivery of services.

1.4.3 Organisation and management of hospital pharmacy services in the organisation

Hospital pharmacy services are delivered across five main hospital sites, with some pharmacy services provided across smaller satellite locations. The five main sites are managed by a site lead pharmacist. The line management of clinical pharmacy services differs across each hospital site, with the site lead having overall responsibility for all staff and service on their site. In addition, there are two clinical pharmacy leads, for acute and for primary care. The organisational structure of the pharmacy service is described in Figure 1.4.

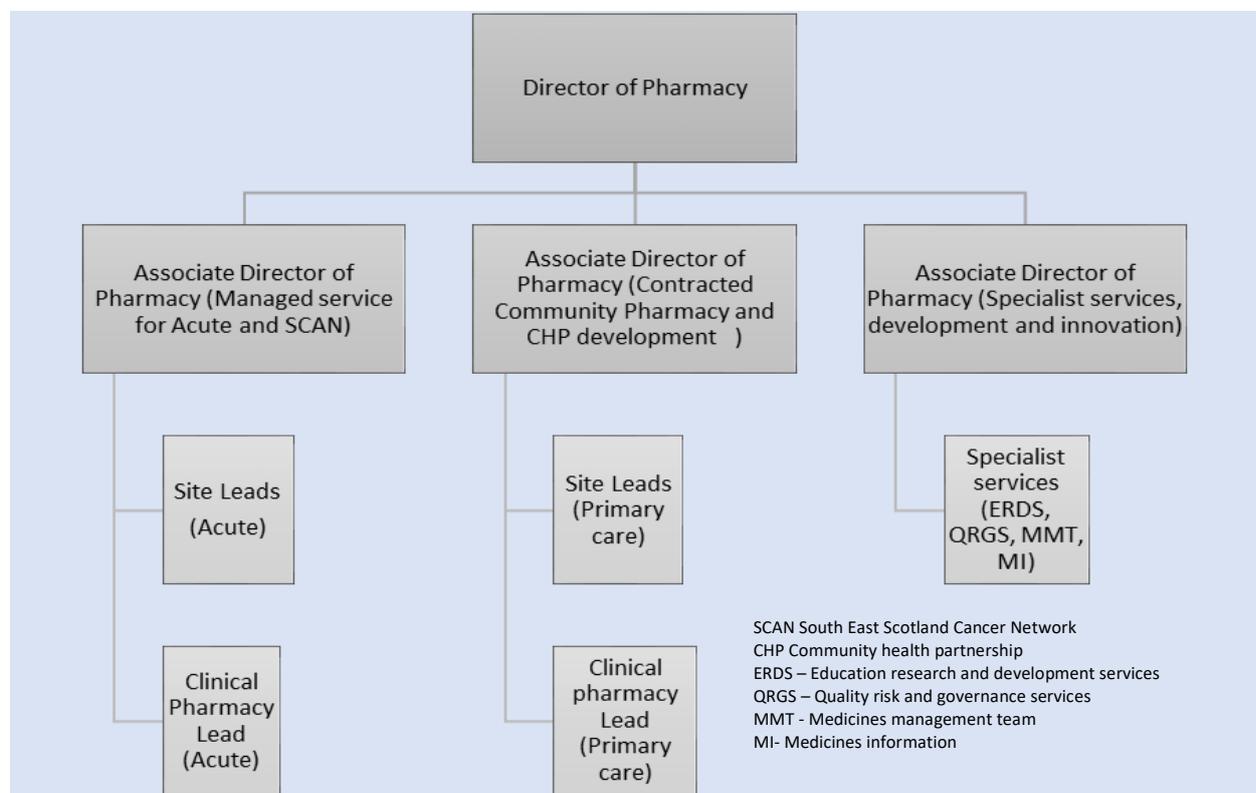


Figure 1.4 Organisational structure for organisations' hospital pharmacy services

Clinical pharmacy leads are responsible for the strategic direction of clinical pharmacy services and chair the clinical pharmacy operations group.

The clinical pharmacy operational group has representatives from all five hospital sites, and has as its remit the provision of operational guidance and direction to clinical pharmacy services, and to act as a conduit for communication and information to and from other sources. The groups'

workstreams include efficiency and effectiveness, performance, education and training, and quality improvement across the clinical pharmacy services.

In addition to the clinical pharmacy operational group, there are clinical pharmacist groups at each of the five sites for cascade of information. These differ across the sites in their meeting frequency, and in their structure and organisation. Clinical pharmacy is an integral part of the hospital pharmacy service in the organisation, and employs the major proportion of pharmacists within its service.

1.4.4 Roles and responsibilities of clinical pharmacists in the organisation.

The roles and responsibilities of clinical pharmacists are described in several ways including:

- a) in a job description,
- b) in a process map as part of the quality management system, and
- c) on the organisations' intranet pages for clinical pharmacy services.

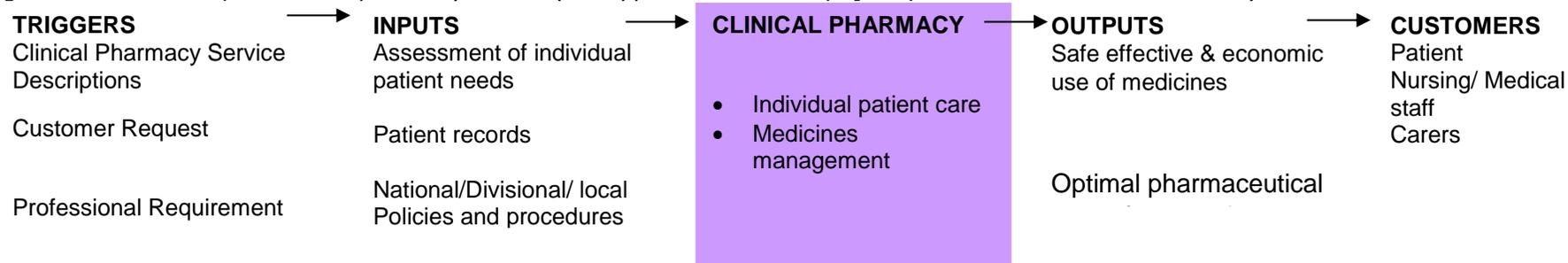
1.4.4.1 Job Description

Clinical pharmacists in the organisation have a job description describing their core roles and responsibilities. The job description for a clinical pharmacist describes areas of responsibility, and includes the tasks and activities to be undertaken by the post holder in order to meet those responsibilities. The tasks and activities are described under the core headings 'clinical', 'resource management' and 'education and research'. The job description is reviewed every two years as part of ongoing personal development processes.

1.4.4.2 Process Map for Clinical Pharmacy

The process map for clinical pharmacy (Figure 1.5) describes the relationship between key clinical pharmacy processes and their controls and measurements, and these will be expanded on later in this chapter. Process maps form an integral part of the quality management system for the organisations' pharmacy services, as will be described later in this chapter.

Figure 1.5 Process map for clinical pharmacy service (use approved: Pharmacy Quality Risk and Governance Services)



KEY ACTIVITIES	CONTROL	MEASURE (MONITORING)
Systematic approach to individual patient care, including where relevant non-medical prescribing	Pharmacist/pharmacy staff competency Prioritisation of patients via triage and/or referral tools; division procedures Defined screening criteria – <i>national/local screening criteria</i> Documentation of activity	Competency assessment Key performance indicators Peer review/appraisal/case-based discussion Nonconformity reporting
Discharge and transition planning (including medicine reconciliation)	Division policy and local procedures Documentation of activity	complaints/adverse events via DATIX adverse event reporting system Workload statistics (numbers only)
Optimisation of medication regimen (targeted patients) including non-medical prescribing	Pharmacist competency Documentation of medicines information/advice provided National/Division/Local policies and procedures	Competency assessment Peer review/case-based discussion Ad hoc audit Key Performance Indicators
Medicines Supply Procedures: safe, effective and economical Stock sheet review	Pharmacy Staff competency Division/Local policies and procedures/formulary Operating procedures, Medicine supply and usage data	Competency assessment Complaints & customer feedback Key performance indicator (joint with Stores)
Medicines Management: safe, effective and economical CD Check Implementation of national contracts Education and training of multidisciplinary team	Division/Local policies and procedures Documentation of activity/medicines information/financial reports & advice supplied Legal requirement Operating procedures/ checklist Skills and knowledge	Nonconformity reporting Workload statistics Nonconformity reporting Implementation of contract/nonconformity reporting Competency/feedback

1.4.4.3 Intranet description of clinical pharmacy service

The role and purpose of the clinical pharmacy service has been described by the organisation's clinical pharmacy operations group, and is made available to all clinical pharmacists via the organisation's intranet. The following core roles and responsibilities of clinical pharmacists are taken from the intranet pages.

- To provide information on medicines to the multidisciplinary team (MDT)
- To review medicines and advise on changes to medicine treatment when appropriate
- To check the accuracy and appropriateness of medicines prescribed in immediate discharge letters (IDL)
- To review medicines prescription and administration charts for accuracy and identify prescribing or administration errors
- To arrange for the supply of medicines that require preparation in the pharmacy aseptic unit
- To facilitate the supply of medicines for patients
- To provide advice on medicines policy/governance/safety
- To report adverse events with medicines including adverse drug reactions, medication errors, near misses
- To train and educate other MDT members on medicines especially when new medicines are being introduced

In addition to these core roles there are multiple roles that are shared with other members of the MDT. Some of these are administrative roles –for example, facilitating the completion of unlicensed medicines request forms, formulary and non-formulary medicines request forms and individual patient treatment request forms to ensure these medicines can be obtained for patients; supporting the writing of protocols and guidelines to guide practice with medicines. There are roles that fulfil legal or professional requirements - checks on controlled drugs, stock list review, antimicrobial stewardship. In addition, there are roles that support patient education, counselling, compliance, the transition to other care settings or discharge, and monitoring patients for side effects and toxicity and efficacy. Finally, there are multidisciplinary team support roles through participating in meetings, providing specialist feedback on formulary adherence

and medicines expenditure, and collaborating in quality improvement projects and audit.

In summary, the roles, responsibilities and functions described for the clinical pharmacy services within the organisation reflect those described for clinical pharmacy and pharmaceutical care earlier in this chapter. That is, to rationalise and improve the use of medicines, with the aim of improving health outcomes, and by working with patients and other healthcare practitioners, ultimately improve the quality of life of patients. There are clear descriptions of these roles and responsibilities available to clinical pharmacists. In addition, description of specific tasks and activities are described through operating procedures.

Having discussed in this section how clinical pharmacy operates in the organisation, the following section will discuss quality management, and quality management systems and how they are of relevance and importance to clinical pharmacy practice within the organisation.

1.5 Quality Management

This section will describe the general principles of a quality management system, and how quality management has become an integral part of the organisation's hospital pharmacy service and, of relevance to this thesis, to the clinical pharmacy service. In the context of this professional doctorate, understanding the principles of a quality management system is important, since the researcher's role in quality management was a trigger for the research.

1.5.1 General principles of quality management

Quality management is *'a style of management focussing on the principles of quality, especially in the development and implementation of working practices'* and that *'guides a business, organisation or department towards delivering the best product or service it can'* (Oxford Dictionary 2020a).

A quality management system is *'a collection of standards and practices established within an organisation to ensure consistent quality of products or services'* (Oxford Dictionary 2020b). The standardised system for quality management is described in the international standard, ISO 9001:2015.

ISO, or the International Organisation for Standardisation, is a non-government organisation made up of the standards organisations of its member countries. The aim of the ISO is to establish standards that aim to facilitate the creation of products and services that are safe, reliable and of good quality. The British Standards Institute (BSi) is one of the member bodies, and publishes standards in the UK. Organisations that adopt a quality management system will generally pursue certification to the standard, via an accredited body, such as BSi. Accreditation and certification give an organisation credentials, and demonstrates to their customers that they have systems in place that meet the requirements of the standard.

The seven fundamental principles of quality management, as per the International Organisation for Standardisation, are (International Organisation for Standardisation 2015):

- Customer focus – to meet and exceed customer requirements
- Leadership – to establish unity of purpose and direction
- Engagement of people – to create a competent and empowered workforce

- Process approach – to achieve consistent and predictable results
- Improvement – focussing on improvement for success
- Evidence based decision making – using data and information to make decisions
- Relationship management – managing relationships with all interesting parties including suppliers

Each principle of quality management must be demonstrated by an accredited organisation, as part of the ongoing assessment process.

1.5.1.1 The International standard for quality management systems (ISO 9001)

The international standard for quality management systems (ISO 9001) consists of a set of requirements that organisations must meet, demonstrating an ability to provide services that consistently meet customer and relevant statutory and regulatory requirements. Further, the standard describes how the organisation should aim to enhance customer satisfaction, through improvement, and through the assurance of conformity to customer and applicable statutory and regulatory requirements (British Standards Institute 2015). In the context of this research, the need to meet ISO 9001 standards within the clinical pharmacy service were important considerations, and will be discussed later in this chapter.

The international standard for quality management consists of a number of clauses that the organisation must demonstrate compliance with, the broad headings of which are (British Standards Institute 2015):

- Context of the organisation
- Leadership
- Planning
- Support and resources
- Operations
- Performance evaluation
- Improvement

Each clause contains a series of subclauses, and the remainder of this section will describe the seven subclauses that are most pertinent to this research and this thesis: customer focus; monitoring and measuring; competence;

determining and reviewing the requirements for services; control of service provision; monitoring, measuring, analysis and evaluation; nonconformity and corrective action. Table 1.2 describes the requirements of the organisation for each subclause, and thus outlines in principle the challenges that face the clinical pharmacy service:

Table 1.2 Requirements of organisation related to key ISO 9001 subclauses
(adapted from British Standards Institute 2015)

ISO 9001 Clause	Key Subclause	Requirements of organisation
Leadership	Customer focus	To demonstrate leadership and commitment by ensuring that requirements for delivering the service are determined, understood and consistently met, and that any risks or opportunities to enhance customer focus are determined and addressed.
Support and Resources	Monitoring and measurement	To verify that services conform to requirements using valid and reliable measures and monitors. To ensure, through measurement and monitoring, that services continue to be fit for purpose.
Support and Resources	Competence	To ensure personnel are competent on the basis of their education, on-going training and experience, and that they continue to be competent for the tasks they are required to do.
Operations	Determining requirements for service	To ensure that statutory and regulatory requirements, as well as those requirements deemed necessary by the organisation, are defined.
Operations	Reviewing requirements for service	To ensure requirements are continually reviewed to ensure services can continue to be provided consistently.
Operations	Control of service provision	To describe the characteristics of services provided, the anticipated results, the monitoring and measuring resources, the environment and infrastructure, the employment of competent persons, the validation of review processes, and the implementation of actions to prevent human error.
Performance evaluation	Monitoring, measurement, analysis and evaluation	To determine what needs to be measured and monitored, the methods to be used and the frequency of the measurement and monitoring.
Improvement	Nonconformity and corrective action	To describe the actions to be taken when a nonconformity arises in order to control and correct, and to deal with the consequence of the nonconformity.

1.5.1.2 Nonconformity and corrective action

The subclause nonconformity and corrective action will now be further detailed since it was pertinent to the research, as will be described later in this chapter.

The definition of nonconformity used in the quality management standard is *'any failure to meet a requirement, where that requirement is defined by the organisation. A requirement can be that of a customer, of a statutory or regulatory body, of ISO 9001 or of the organisation'* (British Standards Institute 2015). When a nonconformity arises, actions should be taken firstly to control and correct the nonconformity (correcting actions), and secondly to deal with the consequences of the nonconformity. In addressing the consequence of a nonconformity, there should be an evaluation of the need for action to eliminate root causes. This is achieved by reviewing and analysing the nonconformity, determining the causes of the nonconformity and determining if similar nonconformities exist or could potentially occur; this is corrective action. Finally, any corrective action taken to address the nonconformity should be assessed for effectiveness.

Organisations that have an accredited quality management system need to demonstrate that they comply with the required arrangements, and must continually review their processes for collecting information that provides evidence for compliance, which is then assessed at internal and external audit.

1.5.2 Quality management in the organisations' pharmacy departments

The NHS Scotland organisation's hospital pharmacy service has had accreditation to the ISO 9001 quality management system for over 25 years. The decision to pursue accreditation came from a desire to establish core standards of practice across pharmacy services, under a quality management system. The scope of registration of the quality management system includes clinical pharmacy services.

The maintenance of accreditation requires systematic evaluation by external audit of the quality management system for all pharmacy processes. The external audits are conducted by BSi auditors, and are complemented by internal quality audits carried out by the organisations' pharmacy quality risk and governance services. All pharmacy services that are within the scope of registration must comply with the ISO 9001 quality management standard (British Standards Institute 2015) in all aspects of service provision. As described, the requirements include the legal, regulatory, professional and

ethical frameworks that apply, and for clinical pharmacy services some of the legal, regulatory, professional and ethical frameworks that apply have been described earlier in this chapter.

When the current version of the ISO 9001 standard was issued in 2015, (British Standards Institute 2015), all accredited organisations were required to transition to the new standard to continue accreditation. There were significant changes in the 2015 iteration of the standard: there was more emphasis on risk-based thinking, customer focus, performance evaluation and aligning with the organisation's strategy; it also built on the previous standard's emphasis on continuous and systemic improvement of processes.

For clinical pharmacy, as well as for all other pharmacy services in the organisation, the specific arrangements in place to comply with the quality management standards are described in a process map (Figure 1.5). Any changes in process or activity must be reflected in the process map. The process map shows key clinical pharmacy activities, and the monitors or controls and the measures for these key activities are described. One of the challenges in establishing and updating the process map was the paucity of measures that can be applied to the clinical pharmacy process, from a quality management perspective. This has been described earlier in this chapter in relation to the paucity of quality assurance measures that are established in practice for clinical pharmacy, and for pharmaceutical care in the UK. The next section will describe and evaluate those elements of measuring, monitoring and control that have so far been introduced into the hospital clinical pharmacy services, and highlight the gaps that exist.

1.5.3 Quality management for organisations' hospital clinical pharmacy services

This section will describe the current quality management measures and controls for the hospital clinical pharmacy services within the organisation, and how service performance is assessed. The measures and controls are described in the clinical pharmacy process map (Figure 1.5). Controls include the competency of the workforce, prioritisation and screening, the documentation of activity; measures or monitors include key performance indicators (KPI's), peer review,

nonconformity reporting and DATIX reporting of adverse events, and these are described here:

1.5.3.1 Competency of workforce

The competency requirement of clinical pharmacists is described in job plans and job descriptions. Staff selection will include assessment of current competency, and once employed, staff will be trained in local work practices. Line management and personal development are recorded through the TURAS platform (the NHS Education for Scotland training and learning platform). Demonstration of ongoing control is assessed through audit, and through ongoing internal reporting processes. Descriptions of the training, on-going professional development and CPD requirements for pharmacists were described earlier in this chapter.

1.5.3.2 Prioritisation and screening

In the organisation, in common with other hospital pharmacy services across the UK, there has been a necessary move towards maximising the efficiency and effectiveness of the clinical pharmacy service over the past five to ten years in order to meet targets. One of the ways of doing this has been to help clinical pharmacists to prioritise their workload or target their pharmaceutical care to patients who will most benefit, using a form of triage or screening, and this has been described (1.2.1.4). Within the organisation, the process for prioritising patients uses the term priority coding.

The priority coding process used in the organisation starts when a patient is admitted. Pharmaceutical care issues are identified from a knowledge of their medicines on admission, then checked and recorded during medicines reconciliation processes. Further care issues may be identified for any new medicines that are added during patient stay. From information about patient, disease and medicines, pharmacists allocate a prioritisation code to patients that determines the frequency with which the patient will be reviewed during their stay (Table 1.3), with codes of *Phar 1* to *Phar 4* denoting frequency of review. Additionally, all patients are prioritised for review at the point of discharge, denoted by the code *Phar D*. The prioritisation coding can change during the

patient's stay if there is change to patient or to medicines, however that will only occur if the pharmacist becomes aware of the change.

Table 1.3 Agreed frequency of patient visits: priority coding

Code	Phar 1	Phar 2	Phar 3	Phar 4	Phar D
Visit frequency	Review within 24 hours Mon-Fri and daily	Review at 3 days	Review at 7 days	Review at 14 days	Review at discharge

Monitoring of the priority coding process is achieved through reportage as a key performance indicator (1.5.4.5). The key performance indicator for this process assesses the proportion of high priority patients seen, i.e. those coded as 'Phar 1', according to predetermined screening criteria, with the target being 100%.

1.5.3.3 Screening criteria

Screening criteria are incorporated into the priority coding tool that has been designed for prioritisation of patients within the organisation. Screening criteria have been established under broad headings of medicine factors, patient factors and disease factors (Appendix 1.1). The core set of screening criteria were established and approved by lead clinical pharmacists, with additional speciality-specific criteria developed locally by specialist clinical pharmacy teams. The screening criteria acts as a control of the clinical pharmacy activity of taking a systematic approach to individual patient care.

1.5.3.4 Documentation of activity

All information relating to the pharmaceutical care issues should be recorded onto the TRAKcare system, which is the electronic patient record system in use within the organisation. Documentation on TRAK provides a permanent record of the pharmaceutical care issues, from admission to discharge. TRAKcare can be accessed by pharmacy staff in secondary and primary care at any point in the patient's journey. Documentation recorded by clinical pharmacists includes the priority code, details of medicines reconciliation, ongoing pharmaceutical care issues and discharge planning information. In addition, the pharmacist will

document on the patient's Kardex/medicine chart to indicate that they have reviewed the medicines prescribed.

The controls described in 1.5.3.1 to 1.5.3.4 that are in place for clinical pharmacy activities give levels of assurance that are assessed by the following monitors:

1.5.3.5 Key performance indicators (KPIs)

All the organisations' pharmacy services define and report on their KPIs to the senior management team: this is how the service has decided to measure the performance and effectiveness of the quality management service. The two key performance indicators for the clinical pharmacy service are:

1. Proportion of Priority 1 code patients seen, according to referral criteria (target 100%)
2. Proportion of independent prescribers who have used their qualification in the last 28 days (target 100%)

KPI 1 is an indicator of the ability of clinical pharmacists to see patients that have been assessed as requiring a daily visit, and is therefore an activity indicator rather than a quality indicator. KPI 2 is an indicator of those pharmacist prescribers that are able to use their prescribing in their current role, and is therefore an organisational indicator rather than a quality indicator.

KPI data has been collected from clinical pharmacy services at all sites to comply with the performance measurement element of the quality management system (British Standards Institute 2015). For example, during 2018/2019 the proportion of Priority code 1 patients seen within target time ranged from 5% for one site for one month, to 80% for another site, for one month's worth of data.

1.5.3.6 Peer review

Within the organisation, clinical pharmacists take part in informal peer review. Peer review is a process often used in healthcare, with the aim of improving quality of care (Al-Lamki, 2009). Peer review, when conducted as intended, allows participants to reflect on their practice compared with that of others. It

requires a skill set, depends on the openness and transparency of participants, and relies on the presentation of a case that can be thoroughly examined.

The current process described as peer review varies across the organisations' hospital sites both in frequency and in content. The programme varies and occasionally includes case presentations, inviting discussion and feedback by attendees, but also may include educational sessions on, for example, updates and training, new drugs, current practice in a clinical area.

In summary, informal peer review has some elements of the intended purpose of allowing peer discussion of a case, but lacks the formality of process that could enable wider shared learning, and is not used consistently.

1.5.3.7 Nonconformity reporting

Within the quality management system (British Standards Institute, 2015) there is a requirement to report on deficiencies in service or product provision, and these are called nonconformities, described earlier in this chapter. The principle purpose of nonconformity reporting is to identify areas for quality improvement.

For the organisations' pharmacy services, nonconformity reporting has become well established across most of the technical services – dispensary, aseptic and distribution. Nonconformity reporting can work successfully where there is a defined process, with built in checks: the medicine is selected, it is checked and is either right or wrong. Nonconformity reports are used to reflect on what has happened, to share with the team and to address any areas that can be improved. Within the technical and medicine supply services in the pharmacy service, nonconformity reporting is the established process used when an error or failure occurs, and the error is identified before the 'product' leaves the department. This is sometimes referred to in other pharmacy disciplines (community pharmacy, for example) as a near miss. However, if the error or failure has left the department, or has been through multiple checks which should have detected the error or failure, then that event is classed as an adverse event across NHS Scotland, and this will be discussed further later in this section.

Within clinical pharmacy services it has been difficult to establish nonconformity reporting: the process for identifying pharmaceutical care issues is predominantly cognitive. There are however some clinical pharmacy tasks and activities that lend themselves to nonconformity reporting – regulatory roles like controlled drug checks and the review of stock lists for wards, that are timetabled, and a failure to carry out these tasks could constitute a nonconformity, and be reportable. That said, the lack of definition of what constitutes a nonconformity for pharmaceutical care activities undertaken by clinical pharmacists leaves a gap in meeting quality management system requirements, and was the focus of this research.

1.5.3.8 Adverse event reporting on DATIX

Adverse event reporting has been established within the quality management system for the organisations' pharmacy services as the process for reporting errors and incidents. Adverse event as a term to describe errors and incidents was adopted by Healthcare Improvement Scotland, and NHS Scotland has used this terminology since 2012. The Healthcare Improvement Scotland definition of an adverse event is: '*an event that could have caused, or did result in, harm to people or groups of people*' (Healthcare Improvement Scotland 2019). Across NHS Scotland all health boards have adverse event reporting systems, and all but one utilises the DATIX electronic risk management system. The DATIX system functions both for reporting of adverse events, and for their subsequent management, including investigation and feedback.

Across the organisations' pharmacy services, serious near misses, adverse events and informal complaints (for example when a 'customer' contacts the department to report an error) are reported using the DATIX risk management system. This has been defined locally in procedures to cover the requirements of the accredited quality management system.

A detailed search of the DATIX risk management system database was conducted by the researcher during planning of the research study. The search concluded that for the period 2015-2018 clinical pharmacists were rarely reporting incidents that arose from within the clinical pharmacy service, even though adverse event reporting is included in the process map (Figure 1.5) as a

monitor. In addition, the DATIX risk management system database was examined by the researcher to establish what pharmacist independent prescribing errors were being recorded on the DATIX system; no examples were found in the period 2015 to 2018, either self-reported or reported by another individual.

There was, however, substantial evidence that clinical pharmacists were using the reporting system to record adverse events with medicines, as part of a medicine safety role. Examination of the DATIX risk management system database provided evidence that pharmacists report approximately 17% of all medication adverse events in the organisation, across multiple reporting categories (Figure 1.6).

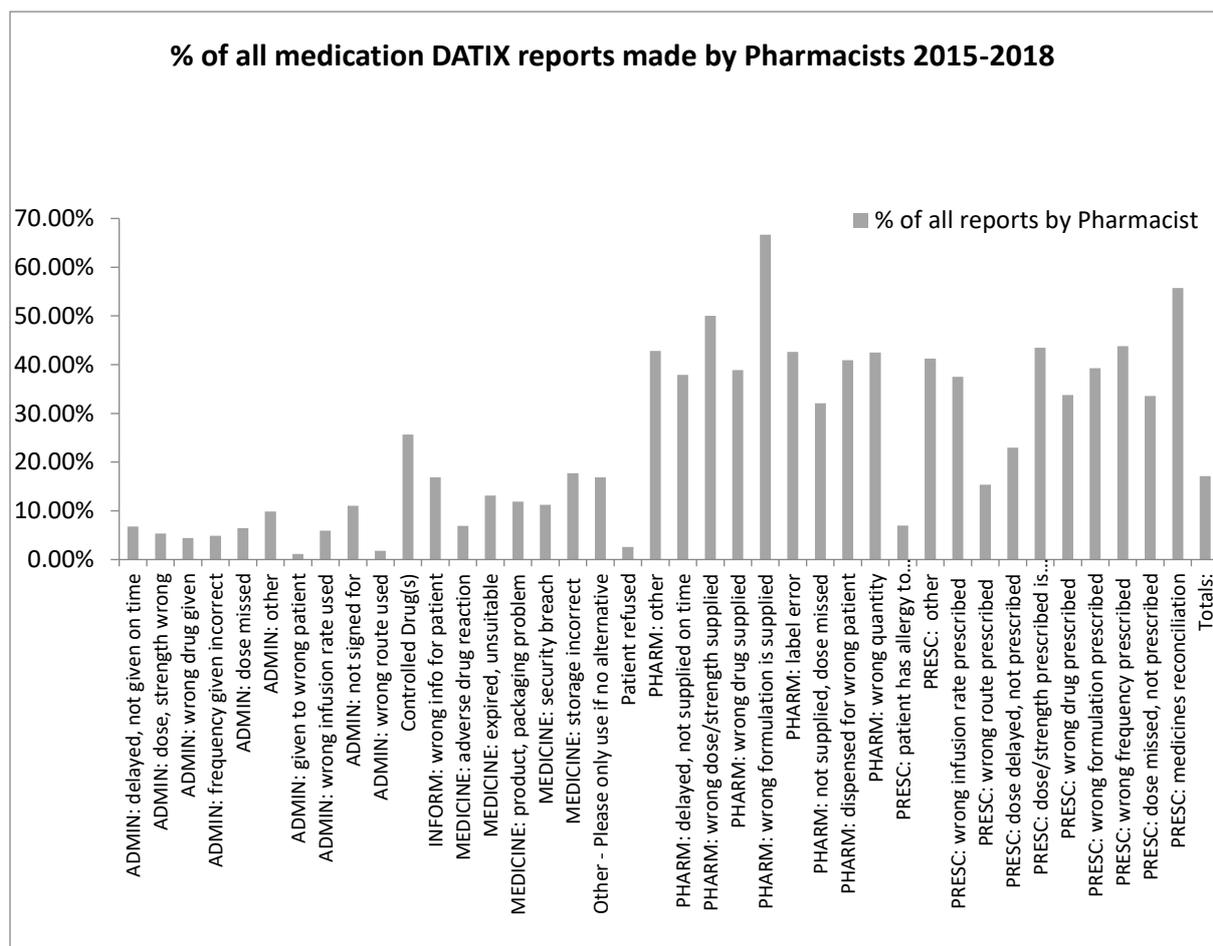


Figure 1.6 Graph showing % of all medication adverse event reports by organisations' pharmacists 2015-2018 [From DATIX risk management system, accessed by researcher Feb 2019]

In summary, the controls and monitors described within this section act as a means of managing quality and performance within the clinical pharmacy service. Formal performance review of clinical pharmacy within the quality management system includes a review of KPIs, and reporting on nonconformities and adverse events ('error reporting') at a six-monthly performance review meeting. However, as described previously, the data collected for the clinical pharmacy service for KPI's are not reflective of performance quality, and there are very few nonconformities or adverse events formally recorded that relate to clinical pharmacy activities. This leaves a gap in meeting the requirements of the quality management system, a gap in how clinical pharmacists meet their professional requirements to 'report errors and share learning' (Royal Pharmaceutical Society 2016a; Royal Pharmaceutical Society 2019), and a gap in how clinical pharmacy services can use the quality management system to drive improvement.

The thesis will now continue with a general overview of medicine safety, outlining the role of the pharmacist, and exploring possible reasons why clinical pharmacists have found it difficult to identify nonconformities and adverse events in their work practices.

1.6 Medicine safety and the role of the pharmacist

Medicine safety is a global challenge, and in 2017 the World Health Organisation (WHO) made it a priority, with the publication of their third Patient Safety Challenge, Medication without Harm (World Health Organisation, 2017). The challenge, to reduce severe avoidable medication-related harm by 50%, has been a reminder to healthcare professionals of the risks associated with medicines, particularly on the risks of harm at transitions of care, in high risk situations and with polypharmacy. Medicine safety systems rely on the reporting of adverse events with medicines, in order to understand, assess and analyse the issues and challenges (National Patient Safety Agency 2007; National Patient Safety Agency 2014; World Health Organisation 2017). In the UK, the WHO challenge built on previous targets to reduce harm with medicines, which were initiated with 'An Organisation with a Memory' (Donaldson 2000) and the subsequent development of systems and processes that were designed to help healthcare organisations to improve their reporting and learning from adverse events. (National Patient Safety Agency 2007). Studies continue to be carried out on barriers to the reporting of adverse events, since underreporting is an acknowledged issue (Keers et al 2013; Vrbnjak et al 2016; Alshehri, Keers and Ashcroft 2017).

Pharmacists in the UK have a key role in medicine safety, and it is a role expected of them as professionals (Royal Pharmaceutical Society 2014; Royal Pharmaceutical Society 2016a; Royal Pharmaceutical Society 2019). Hospital clinical pharmacists have opportunities to review patient medication at transitions of care, and within the activities of Kardex/medicines review (1.2.1.1) and medicine reconciliation (1.2.1.2) will identify and correct any discrepancies and errors.

However, as described in 1.2.1.1 there are factors (workload and stress for example), that influence the ability of pharmacists to detect prescribing errors, and there is some evidence that although pharmacists may act on and correct identified prescribing errors, reporting is less likely (National Patient Safety Agency 2014; Williams, Phipps and Ashcroft 2013). A qualitative study on the attitudes of UK hospital pharmacists to reporting medication incident (Williams, Phipps and Ashcroft 2013) concluded that whilst hospital pharmacists recognised

the importance of reporting prescribing errors, underreporting was prevalent. The study described the cognitive process by which the decision to report was made. Barriers to reporting medication incidents were identified, and included anxieties relating to interprofessional relationships, perceptions about the reporting process, time taken to report; reporting likelihood was influenced by the severity of patient harm.

Identifying, responding to and reporting on adverse events with medicines is a key skill that hospital clinical pharmacists have. It requires vigilance and attention to detail and it requires clinical pharmacists to review and assess the actions of others. As Daniel Kahneman states in 'Thinking Fast and Slow': *'it is easier to recognise other people's mistakes than our own'* (Kahneman 2011). In considering how clinical pharmacists would report on their own suboptimal pharmaceutical care, this statement was pertinent, given that their training and skill frequently focusses on identifying adverse events made by others, and may be less focussed on identifying adverse events made by themselves.

Having explored the role of the hospital clinical pharmacist in reporting medication incidents, and discussed the lack of self-reporting of adverse events within the clinical pharmacy service, the following section will explore how the reporting of adverse events has been shown to affect the behaviour of people involved. Reporting of adverse events is interpreted here as including where an individual self-reports, as well as where an adverse event has been identified by someone else, and an adverse event report is made.

1.7 Moral distress and burnout amongst healthcare professionals

This section will start by describing the impact that dealing with an adverse event has on healthcare staff, then discuss moral distress and burnout, how they develop and manifest in healthcare workers, and conclude with what this may mean to the healthcare workforce.

1.7.1 Impact of an adverse event with a medicine on healthcare professionals

It is known that being involved in an adverse event with a medicine has an impact on the member of staff involved, and those involved have been called “the second victim” of an adverse event (Wu 2000). Support for those involved in a medication error is now established within medical and nursing practice, and the support process is part of the governance processes of NHS health boards. However, there are studies that demonstrate that the reporting of adverse events holds stigma or ‘professional embarrassment’ for doctors (Wu 2000; Seys et al 2013; Bowie et al 2005), and there is a suggestion that stigma has an influence on the likelihood of adverse event reporting (Williams, Phipps and Ashcroft 2013). There is also some evidence that moral distress and burnout can arise as a consequence to involvement in adverse events (Wilkinson 1987).

1.7.2 Moral distress amongst healthcare professionals

Moral distress describes the emotional impact invoked when things do not go according to intention, whether this is because they do not go according to plan (adverse event), or cannot go according to plan (latent or environmental conditions). Moral distress was first described in nursing, to describe the gap between what nurses want to do, and what they are able to do, particularly in relation to moral conflict and ethical challenges. Jameton (1984) described moral distress as *‘the distress felt when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action’*. Wilkinson (1987) further added the dimension of a sensory experience of distress, and the negative feeling that leaves the person with. Wilkinson also, through his studies of nurse experiences, differentiated between the initial distress (characterised by frustration, anger and anxiety) and the reactive distress that occurs later (characterised by guilt, low self-esteem and feeling

powerless). Studies conducted with nurses in Australia have identified negative consequences for patients as well as the nurse (Burston and Tuckett 2013): physical symptoms of nausea, insomnia and fatigue were reported by nurses, and the resultant coping mechanisms of distancing and passivity can have an impact on patient care.

As the concept of moral distress has become more widely discussed, so has research in other healthcare professionals to explore this, as each profession has its own code of ethics and sets of legal and professional guidelines. The concept of moral distress as applied to community pharmacy in the UK has been explored by Astbury et al (2015), in a study examining the research agenda for moral distress in community pharmacy practice. In the mixed methods study, the authors used three focus groups, which were analysed using grounded theory principles. Four categories relating to moral distress were identified, namely: legislative constraints, commercial pressures, challenges to professionalism and risk taking and resilience. Fifteen individual themes were then identified and this was followed by a pilot questionnaire which was sent to fifty pharmacists to assess the validity of the tool. In the study the authors discuss how the expanding role of pharmacists to include pharmaceutical care gives rise to more opportunities for moral and ethical issues to be a factor in decision making processes. The main focus of the study was on community pharmacy, where professional isolation and commercial conflict have additional impact (Astbury et al 2015).

Moral distress in hospital clinical pharmacists has been studied in Sweden (Kälvemark et al 2004). Although Sweden has a different healthcare system from the UK, there are similarities in terms of clinical pharmacy practice. Ethical dilemmas arising from the variance between the needs of the patient and the interests of the organisations were cited as being key influences on moral distress. This mixed methods study of participant interviews followed by questionnaires, rated patient prioritisation systems and time constraints as causing the highest levels of distress. This description of clinical pharmacy service provision, where not all prioritised patients can be seen due to time constraints is familiar in UK hospitals. Even with prioritisation and screening, pharmacists may not be able see all the patients that they want to, and this had implications for this study, when contemplating the emotional impact of

suboptimal pharmaceutical care. The consequences of extended episodes of moral distress are known to have impact on healthcare professionals (Wilkinson 1987).

1.7.3 Burnout in healthcare professionals

Burnout, or occupational stress, amongst healthcare professionals is an emerging challenge to healthcare delivery (Brindley et al 2019), and one of the factors identified as being causative in burnout is a feeling of not having control over one's work, frequently described as moral distress. Burnout is now thought to be responsible for high levels of absenteeism, as well as with healthcare professionals leaving their chosen profession or changing sectors. (Austin et al 2017; Wilson and Simpkin 2019). There is a paucity of research into burnout amongst pharmacists in the UK, but emerging research from the US indicates that burnout is having an impact both on the wellbeing of pharmacists and on their retention within the profession (Hagemann et al 2020).

Sections 1.6 on medicine safety and 1.7 on moral distress and burnout in this chapter have touched on some of the psycho-social implications of being involved in adverse events in healthcare: of guilt and professional embarrassment, and of working in a stressful environment, where organisational constraints may lead to a feeling of underperforming, with associated feelings of guilt and anxiety. This was relevant to this research study, with its focus on exploring suboptimal pharmaceutical care as a concept, and the desire to understand the impact the disclosure of suboptimal pharmaceutical care may have on clinical pharmacists.

1.8 Summary of Chapter 1

This chapter has outlined the background to the research, attempted to define and describe the concept of clinical pharmacy and pharmaceutical care, and how hospital clinical pharmacists undergo training and professional development over the course of their career. Quality management principles and quality management system as relevant to the clinical pharmacy service within the organisation were described. There were descriptions of the gaps that exist in the quality management arrangements for the clinical pharmacy service, and

these were reflected by a paucity of literature on the topic of quality assurance arrangements for clinical pharmacy and pharmaceutical care. Of note there was a gap around the identification, reporting and sharing of adverse events associated with pharmaceutical care, and this has been described for the purpose of this research as suboptimal pharmaceutical care. The chapter concluded with discussion on medicine safety, and the role of the pharmacist, and an overview of the topics of moral distress and burnout in healthcare professionals, topics that is was perceived may be of relevance when considering suboptimal pharmaceutical care.

In setting out in this chapter the context of the organisation, the researcher's role, and with the introduction of the key concepts of clinical pharmacy and pharmaceutical care, as well as quality management, the thesis will now go on to describe the research that was designed, which aimed to explore what hospital clinical pharmacists perceived and understood to be optimal and suboptimal pharmaceutical care, whether and how suboptimal pharmaceutical care manifested in practice and what effect this had on those delivering the service.

CHAPTER 2 METHODOLOGY

2.1 Introduction to Chapter 2

This chapter will give an outline of key philosophical paradigms and methodology in the context of the proposed research. It will provide an overview of qualitative methodology, and describe different types of qualitative methods that have been applied in healthcare research. It will conclude with describing the rationale and justification by which the methodology for the planned professional doctorate research was adopted.

2.2 Approaches to research

Research is the rigorous, systematic process of enquiry into a phenomenon of interest (Creswell 2014). It can use different methods, but is based on observation, measurement and comparison to rules or theories, in order to understand the phenomenon in a new way. The Merriam-Webster dictionary defines research as '*investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws*' (Merriam-Webster 2018).

Research starts with a question. At the initial stage, the question can appear in the form of a thought, or series of thoughts questioning why a phenomenon occurs, or occurs in a certain way, or whether it exists at all. From these initial thoughts, research requires a plan being put into place as to how these questions can be answered. The plan will need to include elements of research design, and to identify appropriate research methods for collecting, analysing and interpreting data.

Underpinning research are the beliefs and the approach of the researcher in relation to the world as they see it, and this philosophy has been referred to in the literature in two ways. The term *worldview* (Creswell 2014), where worldview is defined following the explanation of Guba, (1990), as '*a basic set of beliefs that guide action*' (Creswell, 2014); and the term *paradigm* (Bowling 2014; Lincoln, Lynham and Guba 2011), where paradigm is defined as '*a set of ideas (hypotheses) about the phenomena under inquiry*' (Bowling 2014). Both of

these terms acknowledge the involvement of the researcher with their topic of inquiry, and acknowledge that their worldview will influence how they take the research forward through design, planning and execution.

2.2.1 Research philosophy

Understanding the philosophy behind research helps the researcher in the design, planning and execution of research. Research philosophy describes the concepts underpinning how data should be collected, analysed and used.

Creswell (2014) states that worldviews are better described in terms of their ontology, epistemology, axiology and methodology, and that by understanding and declaring these, the researcher is giving transparency and honesty to their research (Table 2.1).

Table 2.1 Research philosophy definitions (adapted from Creswell 2014)

Research term	Simplistic definition
Ontology	The reality that research aims to understand by investigation (what it means to be human, or the nature of reality)
Epistemology	The relationship between the stated reality and the person carrying out the research (how we know what we know or what counts as knowledge)
Axiology	The role of the researcher's own values on the research process (how we bring influence, and how we know that)
Methodology	The technique(s) used by the person carrying out the research to investigate the reality (how we decide how to add to the knowledge)

Donyai (2012) describes how these worldviews interconnect, and how they interact with methodology, methods and data in the research process (Figure 2.1).

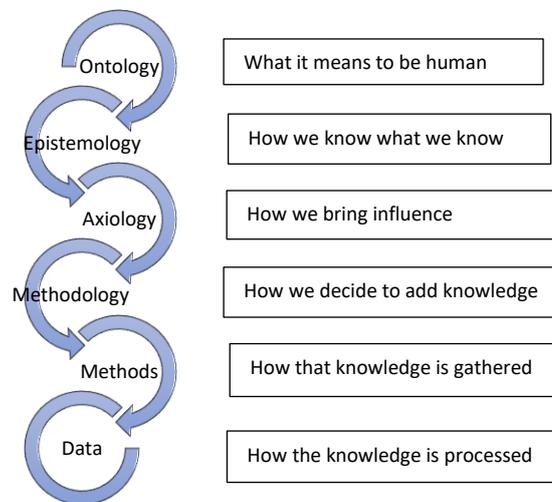


Figure 2.1 Interactions between ontology, epistemology, axiology, methodology, methods and data in the research process (Adapted from Donyai 2012)

Creswell (2014) states that research paradigms should be linked to the research methodology (strategies of inquiry) and to research methods. Behind research methodology lies the philosophical underpinning paradigm (typical model) or 'worldview'. According to Creswell (2014), there are four paradigms or worldviews: post-positivism, constructivism, transformativism and pragmatism. Table 2.2 shows how each paradigm relates to a research approach, a strategy of inquiry, the methods for achieving the strategy of inquiry, and what key features, biases and influences are involved within the paradigm.

Table 2.2 The four paradigms of research design (adapted from Creswell 2014)

Research paradigm	Research approach	Strategy of inquiry (design)	Methods for achieving	Features and influences
Post-positivism	Quantitative	Experimental design	Measuring or rating	Objectivity, validity and reliability
Constructivism	Qualitative	Ethnographic design	Field observations	Subjectivity of both participants and researcher
Transformativism	Qualitative	Narrative design	Interview	Subjectivity and interpretive by nature
Pragmatism	Mixed methods	Mixed methods	Interviews and measure/rate or observation and measure/rate	Mixed methods research combines subjectivity and objectivity

2.3 Research design

This section on research design will introduce, define and describe quantitative and qualitative research. It will describe some of the different types of qualitative research designs, and give examples from pharmacy practice research to illustrate the differences between them. It will go on to summarise some of the strengths and weaknesses of the different qualitative research designs.

2.3.1 Quantitative research

Quantitative research is the measurement and analysis of observations in a numerical way (Bowling 2014). In quantitative experimental research the researcher assesses if there is a cause and effect model, by varying the inputs and measuring the outputs, generally using statistics, mathematics or computational techniques. There are four types of quantitative research: descriptive, correlational, quasi-experimental and experimental. Randomised control trials are an example of experimental quantitative research design. Another example is survey research, which can be correlational, descriptive or quasi-experimental. Survey research may for example quantify or score a description of opinions or attitudes from a population by studying a sample, using questionnaires or structured interviews with the aim of generalising about the population from the sample studied (Creswell 2014).

2.3.2 Qualitative research

Qualitative research is social research which is carried out in the field (natural setting), and analysed largely in non-statistical ways (Bowling 2014). Qualitative research helps researchers access the feelings and thoughts of the participants, which can lead to better understanding of the meaning those participants ascribe to their experiences (Sutton and Austin 2015). Lincoln and Guba (1985) note that the natural setting is essential because the phenomena of study take their meaning not just from themselves but from their context and setting (Lincoln and Guba 1985).

There are five different types of qualitative research methodology: narrative, grounded theory, ethnographic, case study and phenomenological research

(Bowling 2014) and these are described here, using examples from pharmacy practice research for each type of research, to enhance understanding in a setting that was relevant and familiar to the researcher.

2.3.2.1 Narrative research

The term narrative research comes from the humanities, where the lives of individuals are studied and then extracted into stories by the researcher, but which are primarily derived from the participants. Kruijtbosch et al (2018) for example, used a narrative research method in a study exploring the moral dilemma of community pharmacists. In this study, an undisclosed number of early year pharmacists working in community pharmacies in the Netherlands were asked to give a written narrative review of a situation where they had experienced a moral dilemma; this was defined as being a situation where there is a choice of at least two actions that can be taken, with neither being the obvious preferred option morally. A total of 128 narratives met the criteria, and inductive content analysis gave rise to three categories (patient, doctor and involved parties) and 22 subcategories to describe the type of moral dilemma that community pharmacists face on a daily basis (Kruijtbosch et al 2018).

2.3.2.2 Grounded theory research

The term grounded theory comes from sociology, where a generalised abstract theory is produced, grounded in the views of the participants and includes a detailed description of the setting and of the individuals to provide context (Robson 2011).

A qualitative study exploring how patients with gout become engaged with their disease management and medicine compliance used grounded theory research (Howren et al 2018). The Canadian study used the patient perspective of twelve participants, using interviews, to develop an explanatory framework to understand the process by which patients become engaged in their own disease management.

Grounded theory as an approach works well to gain insight into the perception and experiences of others. Grounded theory, where the investigator develops conceptual categories from the data and makes new observations to develop

these categories further, or into subcategories (Bowling 2014), derives its hypotheses directly from the data, with the rich description of the context, setting and participants being part of the narrative.

2.3.2.3 Ethnographic research

The term ethnographic research comes from anthropology and sociology, and describes the shared patterns of behaviours of an intact cultural group in their natural setting over a prolonged period of time. Ethnographic studies give a descriptive account of social life and culture in a defined social system, based on qualitative methods like observation, unstructured interviews over a period of time, and analysis of documents (Robson 2011; Bowling 2014).

Ethnographic research in pharmacy practice can be used to look at the patterns of behaviour of pharmacists as a cultural group, or at a group of patients, and through the in-depth method of collecting data, provide a rich narrative description. For example, Lea, Corlett and Rodgers (2015) describe how interruptions, multi-tasking and task-switching in community pharmacy can be factors associated with dispensing errors. In a qualitative study in England, eleven pharmacists participated in research using unstructured observations which recorded all their activities, including interruptions, along with case study notes containing pharmacist details, workflow and staffing information. The resultant analysis used directional work maps as a technique to show how the pharmacists worked amongst the interruptions, and concluded that pharmacists did not appear to have insight of the consequences of interruptions, multi-tasking and task switching on their performance (Lea, Corlett and Rodgers 2015). In this study, the ethnographic methodology allowed the researcher to use multiple sources of data to build a picture of the way the pharmacists were working, and the problems they encountered, and used this to describe patterns of behaviours of the participants.

2.3.2.4 Case study research

Case study research is where the researcher develops an in-depth analysis of a case by collecting detailed information using a variety of data collection procedures over a sustained period of time (Robson 2011; Bowling 2014).

An example of case study research in pharmacy was described by MacLure and Stewart (2018), where they explored the e-health and digital literacy experiences of pharmacy staff in North East Scotland. The case study approach used both observations and interviews in community and hospital pharmacies with both sets of data (observation and interview) being collated and analysed using a framework approach. Four themes were inducted, namely technology, training, usability and processes. The case study approach here enabled the researchers to gain insight into the beliefs and experiences of pharmacy staff in different sectors (MacLure and Stewart 2018).

2.3.2.5 Phenomenological research

The term phenomenological research comes from fields of philosophy and psychology, and describes the study of the lived experiences of individuals (Creswell 2014). The description distils the essence of the experiences of several individuals who have all experienced the phenomena and the researcher then, invoking a constructivist paradigm, constructs meaning. Phenomenological research typically involves in-depth interviews (Bowling 2014; Creswell 2014).

An example of a phenomenological pharmacy practice research study examined pharmacist behaviour in dispensing opioids, specifically the decision-making process, incorporating ethical judgements (Russ et al 2019). The study, in the USA, used purposive and snowballing sampling to recruit seven pharmacists, who were interviewed by telephone, using a semi-structured technique. The researcher then interpreted participant experiences, which is a feature of phenomenological research: multiple people experience similar events, but when probed give different points of view. In the study, a theoretical framework, based on factors impacting ethical behaviours was used to interpret the data, and the accumulated information unified to explain the phenomena. The study described how pharmacist behaviours were influenced by patient, doctor and community knowledge, and how decision-making processes during opioid dispensing used a combination of ethical education, moral teaching and leadership experience. By using a phenomenological approach, the study was designed to interpret the interview data, using a framework, and aggregate the views of all participants (Russ et al 2019).

The strengths and weaknesses of the five different types of qualitative research design (narrative, grounded theory, ethnographic, case study and phenomenological) are summarised in Table 2.3.

Table 2.3. Strengths and weaknesses of different qualitative research designs (adapted from Creswell 2014)

Research design	Strengths	Weaknesses
Narrative research	Uses the voice of the participants, given at the time they experience the phenomenon	Using written narrative excludes some participants.
Grounded theory research	Develops a theory that can be further tested	Subjectivity of the researcher
Ethnographic research	Multiple different perspectives can be captured using observation interview and documents	Requires prolonged time period, and being part of the world being observed
Case study research	In-depth study, can bring together the views of different sectors	Dependant on selection of cases, and on the interaction of the researcher with each case being studied
Phenomenological research	Brings multiple perspectives, seeks out different view points	Interpretation may bring bias

2.4 Qualitative research – designing robust, quality-driven research.

This section will outline the parameters that need to be considered when designing qualitative research. The section will define and describe trustworthiness and reflexivity, and demonstrate how these elements can be incorporated into research design. In addition, this section will outline the different methods of sampling, sample size, question type, interview method and data analysis and presentation, and how they all need to be considered in the design of research.

2.4.1 Ensuring trustworthiness and reflexivity in qualitative research

This section will outline the ways in which trustworthiness and reflexivity should be considered during research design and planning, and further, how trustworthiness and reflexivity should be described for qualitative research studies, as a means of establishing confidence in the truth of the findings.

2.4.1.1 Trustworthiness

Processes that increase the trustworthiness of research can be embedded at the planning stage by careful consideration of the four parameters that are described as being key to trustworthiness: credibility, transferability, dependability and confirmability (Shenton 2004; Lincoln and Guba 1985); actions that can be planned to address this in research are described in Table 2.4 for each parameter.

Table 2.4 Research approaches to build in trustworthiness (adapted from Shenton 2004)

Parameter	Approach to increase trustworthiness in methodology
Credibility (whether the phenomena have been accurately represented by the study- confidence in the truth of the findings)	Choice of appropriate research method
	Being familiar with cohort of study /using "natural setting"
	Robust sampling plan
	Triangulation
	Integrity and honesty
	Reflective commentary
	Peer and supervisory support
Transferability (whether the study could be "transferred" to other situations or contexts)	Full description of the study context
Dependability (whether the study is consistent and could be repeated and get similar results)	Use of overlapping methods
Confirmability (whether the study has been carried out as objectively as possible – the results are shaped by participants and not researcher)	Triangulation
	Reflective commentary
	Acknowledgment of predisposition or bias of researcher and/or facilitators.
	Audit trail

The inclusion of details of actions and approaches taken to ensure trustworthiness should be incorporated into descriptions of the method used in research, and in the findings, and will be incorporated throughout this thesis.

2.4.1.2 Reflexivity

Reflexivity is an important consideration when undertaking qualitative methods of research, when conducting interviews to generate data, and when analysing data. Reflexivity requires the researcher to reflect on their ability to be truly unbiased when conducting the research, and to consider the effects of their bias on the study, as well as considering any subjective bias that may be present. Austin and Sutton (2014) refer to the process of reflexivity as the filters through which the research process – the way questions are asked, and data is gathered and analysed – is carried out, and emphasise the need to clearly articulate

reflexivity throughout communications (reports, presentations etc.) about the research (Austin and Sutton 2014).

However, there are also established ways to minimise bias. Reflexivity includes trustworthiness, as described above, but also includes techniques that encourage reflection, consistency of approach, equity, and fairness. Techniques and tools designed to minimise bias can be incorporated into research design. The use of topics guides and interview schedules, for example, can help consistency and can be checked for subjective bias in advance (Creswell 2014). Tools and techniques that have been used in a study should be clearly described (Austin and Sutton 2014). Reference to reflexivity, and steps taken to address this, will be included throughout this thesis.

2.4.2 Sampling strategies in qualitative research

When designing research, the strategy by which the sample is selected should be considered, and reported on. Within qualitative research, there are three main types of sampling: convenience, purposive and snowballing (Table 2.5).

Table 2.5 Sampling strategies used in qualitative research (adapted from Bowling 2014)

Sampling strategy →	Convenience	Purposive	Snowballing
Description	Sample based on easy accessibility	Sample from population with a particular goal or purpose in mind	Uses original small sample to propose/connect to others that meet criteria
Advantage	Simple, cheap	More accurate results as unsuitable cases eliminated, quick and relatively cheap	Access to difficult to reach respondents, more time-consuming
Disadvantage	Not representative, least reliable	Researcher bias in selection	More time consuming, uncertainty of response. Limits transferability

2.4.3 Sample size in qualitative research

Whilst statistical models are not generally applied in qualitative research, there must be a process by which a suitable sample size is determined. The sample size must be adequate for the research to have meaning, but not be inhibitory in terms of workload, nor of researcher and participant time.

The subject of sample size has been much discussed in the literature, with debate about whether sample size can be determined a priori or whether it is better to be adaptive, for example, using the data saturation approach (Baker, Edwards and Doidge 2012; Rosenthal 2016; Sim et al 2018).

Sim et al (2018) propose four approaches to determining sample size in qualitative research – rule of thumb, conceptual, numerical and statistical. If considering rule of thumb, then the sample size in qualitative research will depend to a certain extent on the type of research design selected (Sim et al 2018). Narrative or case studies would be expected to have an intensive study of one to five participants. Phenomenological studies involving focus groups or interviews typically three to ten. (Creswell 2014).

In phenomenological studies, where semi-structured interviews are utilised, reference is often made to reaching 'data saturation'. This is a conceptual model, and is the point at which there are no new emerging themes, findings, or concepts. So, in deciding sample size, an estimate is made of the sample size that would be expected to give an adequate sample, using 'rule of thumb' (Sim et al 2018). To assure data saturation, an estimate is then made of how many further participants will be interviewed if new themes emerge at that point. This is referred to as stopping criterion (Francis et al 2010), and can be represented as N+n sampling, where N is the initial analysis sample, obtained using the *a priori* 'rule of thumb' estimate for the sample size, and n indicates the stopping criterion.

Francis et al (2010) recommend that the initial analysis sample is set at ten for research that involves two or three stratification variables (e.g. age, gender), and states that it is necessary to describe stopping criterion in advance, by stating the number of further interviews that will take place after the initial ten (Francis et al 2010). To achieve data saturation therefore, sampling requires oversubscription of participants at recruitment, or keeping reserve participants, to avoid a time lag in recruitment of additional participants, and the potential the lag has for introducing bias. For example, there may be offline discussion about the topic, or practice or processes may have changed in the interim.

With conceptual models, there is a suggestion that the sample size should also consider the scope of the research and the quality of the data. For example, where the research has a less developed theory, the sample size may need to be larger to produce robust data (Guest, Namey and McKenna 2017; Sim et al 2108).

Reference to how sample size was determined, and the rationale for determination will be included in description of the research design for this study.

2.4.4 Data generation in qualitative research

Qualitative research involves collecting information from participants to generate data (Robson 2011). This information can be verbal or written, and is a form of inquiry using questioning. Focus groups and interviews when used as methods

will both require that the type of question used to generate data be considered in advance.

2.4.4.1 Question types used in qualitative research

There are three basic types of question used in qualitative interviews: main questions, probes, and follow up questions (Bowling 2014). A main question will begin and guide the conversation, and ask questions like '*describe how...?*' or '*what happened when...?*'. Probe questions then aim to clarify answers given to a main question, and seek further detail or clarity, and use questions like '*can you tell me more about...?*', or use pauses, or a simple enquiring '*yes...?*'. A follow up question is used to pursue the implication and meaning of a main or probe question, and might ask '*what do you mean by...?*' or '*can you tell me more about...?*'

The different question types, particularly main and follow up, frequently employ open ended questions, and then utilise follow up prompts. There are six types of open-ended question (Table 2.6); experience or behaviour, sensory, opinion or value, knowledge, feeling and background and demographic.

Table 2.6 Open-ended question types (adapted from Bowling 2014; Robson 2011)

Open ended question type	Explanation and example
Experience or behaviour	Should reflect a direct observation that could have been made by watching interviewee <i>'How would you approach this task?'</i>
Sensory	Focuses on things physically experienced (and may prompt other memories) <i>'When that happened, did you experience a physical reaction?'</i>
Opinion or value	Checks participants understanding of a phenomena or experience and provides insight into their goals and intentions <i>'Would you say that x has had a positive or negative impact on your situation?'</i>
Knowledge	Provides factual information <i>'Do you know what the policy for x is?'</i>
Feeling	Describes an emotion <i>'What emotion did that situation evoke?'</i>
Background or demographic	Characterisation of participants <i>'How long have you worked here?'</i>

Each type of open-ended question has a different function in an interview or focus group discussion, and understanding this is important when designing the topic guide or interview guide. Where a theory is used to design the topic guide or theory, there may be pre-existing interview guides or adaptable questionnaires, or the theory may lend itself to using certain types of open-ended question to obtain information.

2.4.4.2 Interviews and focus groups in qualitative research

Interviews may be conducted with an individual or with a group, for example in a focus group discussion. There are three different interview methods: structured, semi-structured, unstructured (sometimes called open).

A structured interview has the ability to incorporate a theoretical framework, but is less likely to be inductive and may be subject to framing bias. The structured interview will often use fixed wording and be delivered in a predetermined order. Structured interviews may use some open-ended questions during the interview, which distinguishes it from a quantitative survey questionnaire (Robson 2011; Bowling 2014).

Semi-structured interviews will use an interview guide, which will detail the topics that the interviewer wants to cover, and may have standardised wording. However, there will be a flexibility in approach to question order, depending on responses from the interviewee, and probe and follow up questions are asked where necessary, but may not necessarily form part of the interview guide. A semi-structured interview can incorporate a theory or theoretical framework in the design of the interview guide, allowing certain topics to be explored in some depth (Creswell 2014). A semi-structured interview will take longer to conduct than a structured interview, which may be a barrier if the sample size is large (Robson 2011; Bowling 2014). There are disadvantages to having an interview guide: if kept too rigidly it could direct and steer interviews around those topics the researcher had preconceived views on, rather than being flexible, and thus introduce bias (Robson 2011).

Unstructured interviews are generally employed when an inductive approach is desirable, and are more likely to be used in focus group discussions than structured or semi-structured interviews. An unstructured interview has the

potential to explore topics and give personal insight, and will often have a topic guide outlining the general area of interest rather than a predetermined set of questions. Unstructured interviews have been described as 'guided conversations' (Robson 2011), and have the potential to obtain in-depth and sensitive information, and, when used in one to one interviews, of uncovering an interviewee's private account of their feelings, attitudes and behaviours (Bowling 2014).

The interview process has been described as having six stages: the arrival, introduction, commencement, during, ending and afterwards stages (Ritchie and Lewis 2006). In addition, it is known that the personal attributes of the interviewer will have an impact on the conduct of the interview and the findings. Some of the attributes that make a good interviewer include being a good listener, having a logical mind, having curiosity, creating rapport, being calm and being credible. (Ritchie and Lewis 2006). In addition, there are a number of techniques that the interviewer should be cognisant of when conducting interviews in qualitative research that can help to reduce bias (Ritchie and Lewis 2006; Bowling 2014):

- Careful wording (avoiding leading questions, or influencing the response)
- Avoiding assumptions (not assuming answers will be the same to different questions)
- Avoiding misunderstandings and uncertainty (adjusting wording rather than suggesting a response)
- Using probing techniques (repeating question, pausing and expressing neutrality to allow the interviewee to reflect)
- Redirecting (bringing the interview back to topic)

Techniques used in interviews can be learned as skills, and personal attributes enhanced through consideration and reflection, in order to ensure that the interview process proceeds as intended and gives optimal data.

2.4.5 Data collection and analysis in qualitative research

This section will describe the method and purpose of data analysis. In qualitative research, the purpose of data analysis is to make sense out of text. To achieve this, data is taken apart, dissected and examined in detail. With the quantity of data collected from qualitative interviews with multiple participants, or from

focus groups, there must be some form of narrowing or 'winnowing' of the data, and a process of selecting some data and disregarding other (Creswell 2014). In this phase, the researcher must be particularly mindful of reflexivity.

Different types of qualitative research by their nature will have different outputs and this will lead to different styles of data collection, data analysis and data presentation. Table 2.7 revisits the different types of qualitative research, as described in Section 2.3, and describes the anticipated data output, which in turn dictates the way the data is presented:

Table 2.7 Anticipated data output for different types of qualitative research (adapted from Robson 2011; Bowling 2014)

Research type	Anticipated data output
Narrative research	re-tell participants' stories using structural devices (plot, setting, activities, denouement). Often includes long sections of narrative
Grounded theory research	Generates categories of information by open coding, selecting a category and positioning in a theoretical model, then selectively coding categories
Ethnographic research	Describes the setting and/or individuals and then analyses the data for themes or issues
Case study research	Describes the setting and individuals and then analyses the data for themes and issues
Phenomenological research	Analyses significant statements, generates 'meaning' units and creates 'essence' description

For qualitative research, the process of data collection and analysis has five phases: firstly, collecting the data, next becoming familiar with the data, sorting or coding the data, interpreting the data and finally representing the themes; these five phases are described here:

2.4.5.1 Data organisation: collecting, organising and transcribing data

Data is generally collected in qualitative research by interviews, either individual or group, and is collected by taking notes, audio recording or video recording, or a combination of these means (Ritchie and Lewis 2006; Robson 2011). However,

the most frequently used method is audio recording using an audio recording device to generate audio files.

The large amount of data generated by qualitative interviews needs to be organised, in order to facilitate analysis, and the first step is to transcribe audio output to the written form. There are three types of transcription – verbatim, intelligent verbatim and clean. Verbatim transcription includes hesitations, pauses, and other details of interaction, either with the interviewer or with other participants in a group setting. Alternatives to verbatim transcription include intelligent verbatim, where only relevant pauses or details like interruptions are recorded, or ‘clean’ transcript, which is merely a recording of the spoken words (Robson 2011). Transcription from a group setting interview like a focus group is complex, since there are multiple voices. In addition, the interaction between participants is an important feature of a focus group, and should therefore be noted and recorded (Robson 2011), so verbatim transcriptions are deemed most appropriate, and a clean transcript is not considered adequate. The time taken to transcribe verbatim focus group discussions can take eight to ten hours per hour of audio (Sutton and Austin 2015), depending on the skill of the transcriber, and this is a consideration when planning qualitative research.

After data transcription, data must be organised in a way that facilitates analysis and interpretation. There are different means of doing this: using Microsoft word documents or tables, using excel documents, and creating individual or linked files, or by using computer assisted qualitative data analysis software (CAQDAS), of which NVivo™ is an example.

2.4.5.2 Data analysis: initial familiarisation

Familiarisation with the data is a key stage in data analysis, and starts with accessing audio files to listen back to the interviews or focus groups discussions prior to carrying out transcription. Familiarisation continues throughout the analysis process, with reading and re-reading of transcripts to become embedded in the data, and to become familiar with key illustrative quotes and emerging themes.

2.4.5.3 Data analysis: coding data into themes

The process of coding data into themes will vary depending on what mode of analysis is being used. Bowling describes three possible methods of data analysis from gathered data: thematic, content or framework analysis (Bowling 2014).

Thematic analysis: thematic analysis focuses on examining themes or patterns of meaning within data. Thematic analysis emphasises both the organisation and the rich description of the data set, and has theoretically informed interpretation of meaning. In thematic analysis, inductive coding occurs, and the researcher will, through familiarisation, establish emerging codes and themes through examination of the transcripts, will document these codes and themes and look for relationships between them.

Content analysis: in content analysis, data are collected, coded by theme or category and the coded data analysed or presented. Content analysis is often seen as simplistic analysis.

Framework analysis: in framework analysis, a thematic framework is identified which reflects study aims as well as key themes from the data. Where a framework is used, the codes are predetermined, and sections of text can be bracketed against a code. This can be done in Microsoft word or excel documents, or using CAQDAS. Framework analysis is a useful tool to use where there are multiple researchers, where there are large data sets, and as a space where new researchers can learn and develop their skills (Gale et al 2013; Bowling 2014). Bowling claims that framework analysis is more informed by the reasoning of existing knowledge than thematic or content analysis (Bowling 2014).

2.4.5.4 Data analysis: interpreting themes

Interpretation is the process whereby broader themes are identified from the data. Interpretation may be made in relation to the framework categories, where framework analysis is used. At this stage in the data analysis process the researcher must be particularly mindful of trustworthiness and reflexivity in their interpretation of the data set, as described earlier, and seek to represent the participants voices, rather than their own.

2.4.5.5. Data presentation: representing themes

The process of gathering data which represents the findings starts with familiarisation, and the identification of key quotes, and continues throughout the coding process. The researcher will establish concordant and recurring themes, and represent these with representative exemplar quotes. In addition, the researcher may, depending on the findings, represent discordant themes, as a means of demonstrating the breadth of the findings, and the variation of the views of participants. In qualitative research, themes are generally represented and illustrated by direct participant quotes extracted from the data.

2.5 The use of theory in research

A theory, in research terms, has been described by Creswell (2013) as a scientific prediction or explanation for what the researcher expects to find (Creswell 2013). Stewart and Klein (2016) assert that researchers should consider the theoretical basis for their studies at planning: they state that the use of theory enhances robustness and rigour, as well as the relevance and the impact of the findings, when applied correctly. In addition, it is acknowledged that using theory can connect pieces of research data to other studies, and thus build impact academically, in terms of understanding, by using a common language across disciplines (Stewart and Klein 2016). However, there are challenges when selecting a theory. There are many theories to choose from, and the array can be confusing with little consensus on which theories are fit for purpose (Stewart and Klein 2016). Theory selection should be reliably informed and justified, and that requires some knowledge and awareness of the different types of theory, and how they can be used in research in different fields of science.

Nilsen (2015), within the field of implementation science, states that theory can help guide the process of translating research into practice (process models), in evaluating implementation (evaluation frameworks), or can be used to understand what influences implementation, for example of a change of practice. Determinant frameworks, classic theories or implementation theories can be used to understand factors that influence implementation (Nilsen 2015).

Changes to existing practices or new practices require changes in both individual and collective behaviour (Atkins et al 2017; Cane et al 2012) and the application of theory can be used, either to guide the change, to evaluate the change or to better understand factors influencing the implementation of the change.

Within the literature, theories can be referred to using a variety of terms: theoretical lens; theoretical perspective; theoretical framework; conceptual framework; and conceptual model (Osanloo and Grant 2016; Creswell 2014; Maxwell 2012). Nilsen (2015) attempts to explain the difference between theory, models and frameworks, with reference to implementation science, as summarised in Table 2.8, where these may be used to explain, describe or categorise variables:

Table 2.8 Differences between theory, model and framework (adapted from Nilsen 2015)

Construct	Description
Theory	Aims to explain how and why specific relationships (or variables) lead to specific outcomes. They aim to structure our understanding and explanation of the world
Model	Often described as a theory with a narrower definition of explanation. It is descriptive rather than explanatory
Framework	Consists of various constructs, concepts or variables, with the relationship between them being assumed to account for the phenomenon. Frameworks describe phenomena by fitting them into a set of categories. They do not provide explanation.

2.5.1 Theory selection

Selection of the appropriate theory, model or framework will depend on the ontological and epistemological stance of the researcher and the context and purpose of the research. It is acknowledged that in selecting a theory, model or framework, certain assumptions about the likely findings will be made that will influence the outcome of the research. For example, does the research aim to understand the behaviour of individuals, or is it the organisational climate and culture which will determine outcomes? The process of selection will start with an understanding of the research purpose: is it to understand process (process model), evaluation (evaluation framework) or understand influences (determinant frameworks)? (Nilsen 2015). Taking account of, and declaring these assumptions and considering the context and setting ensures that the theory, model or framework selected will enhance the research findings.

A theory, model or framework can be used at different stages within a research study, and Birken et al (2017) describe twelve points at which theory can be used by researchers within their particular topic of research (Table 2.9)

Table 2.9 The use of theory by researchers (adapted from Birken et al 2017)

Theory can be used:	
1	To identify key constructs that may be barriers or facilitators
2	To enhance concept clarity
3	To clarify terminology
4	To convey the wider context of the study
5	To inform data collection
6	To inform data analysis
7	To specify outcomes
8	To frame an evaluation
9	To guide an implementation plan
10	To guide the selection of implementation strategies
11	To specify the process of implementation
12	To specify hypothesised relationships between constructs

In addition to describing when a researcher might use theory, Birken et al (2017) cite various criteria used by researchers when selecting which theory to use. The criteria were developed by conducting a survey of 223 implementation scientists (Table 2.10):

Table 2.10 Criteria used by researchers when selecting theory (adapted from Birken et al 2017)

Criteria used by researchers	
1	Analytical level
2	Logical consistency/plausibility
3	Description of change process
4	Empirical support
5	Generalisability
6	Application to specific setting
7	Inclusion of change strategies/techniques
8	Outcome of interest
9	Diagrammatic representation
10	Associated research methods
11	Process guidance
12	Disciplinary approval
13	Explanatory power/testability
14	Simplicity/parsimony
15	Specificity of causal relationships among constructs
16	Familiarity
17	Degree of specificity
18	Accessibility

Understanding implementation, and the barriers and enablers or facilitators to implementation is important when designing research that is to be applied in the real world. Frameworks, specifically determinant frameworks, aim to understand and explain some of the influences on implementation, either by predicting outcomes, or by interpreting outcomes retrospectively. Barriers and enablers are independent variables; implementation outcomes are dependant variables. Examples of determinant frameworks that aid in the understanding of implementation include Diffusion of Innovation Theory, (Rogers, 2003), Promoting Action on Research Implementation in Health Services (PARiHS) (Rycroft-Malone 2010) and the Theoretical Domains Framework (TDF) (Cane et al 2012). The TDF will be discussed in detail later in this chapter.

Determinant frameworks, for example Normalisation Process Theory (NPT) (McEvoy et al 2014), TDF and the COM-B model (Michie, Van Stralen and West 2011), have been widely used as evaluation frameworks. The ability of the TDF to be used both to understand influences and to evaluate implementation makes it a good candidate to use in health service research.

2.5.2. Applications of theory in pharmacy practice

Theories used in pharmacy practice research may come from the fields of psychology, sociology, anthropology, organisational theory, implementation science and biomedical sciences (Stewart & Klein 2016; Donyai 2012, Nilsen 2015). Implementation science is concerned with the challenges associated with the translation of research into practice in healthcare. Implementation science recognises the benefits of using theoretical models and frameworks to help understand implementation, and to make interventions more likely to succeed, and uses behaviour change theories as underpinning.

Guidance from the Medical Research Council (MRC) (Craig et al 2008) on designing complex interventions has provided further support for the use of theory. The MRC guidance stresses the importance of using behaviour change theories to underpin intervention development, in order to strengthen the intervention and to enable proper evaluation of the success of implementation.

2.6 The Theoretical Domains Framework (TDF)

With the availability of many social and psycho-social theories it can be difficult for researchers to decide which would be optimal, when the data is not yet available. TDF has the advantage of being suitable for use both in design and in analysis, and having the ability to help understand behaviours and behavioural determinants, which can then be mapped to behavioural change and implementation. Additionally, TDF has been extensively validated as a research tool in healthcare research (Cane et al 2012; Phillips et al 2015). Several of the criteria cited by Birken (Table 2.10) apply to the use of the TDF, including but not limited to: description of the change process and the inclusion of change strategy techniques, accessibility, and familiarity.

2.6.1 Theoretical Domains Framework (TDF) background and applications

The Theoretical Domains Framework (TDF) is not a single theory as such, but an integrative theoretical framework developed in the fields of implementation and behaviour change research by psychology theorists (Cane et al 2012). The framework was developed from 33 different theories of behavioural change, which comprised 128 different constructs. The TDF consists of 14 domains, outlined and defined in Table 2.11:

Table 2.11 The 14 Domains of the TDF (adapted from Cane et al 2012)

	Domain	Expansion	Example or construct
1	Knowledge	Awareness of existence of something	Procedural knowledge, process or task knowledge
2	Skills	Ability or proficiency acquired through training	Competence, skills, interpersonal skills, ability
3	Social/professional role and identity	Behaviours at work	Professional confidence, professional boundaries, group identity
4	Beliefs about capabilities	Acceptance of truth, reality or validity of an ability talent or skill	Self-confidence or self-efficacy, perceived competence
5	Optimism	Confidence in system	Optimism or pessimism
6	Beliefs about consequences	Acceptance of truth, reality or validity about outcome of an action or behaviour in a given situation	Outcome expectancies, anticipated regret, beliefs
7	Reinforcement	Increasing probability of response by planning	Rewards, incentives, sanctions, punishments
8	Intentions	Conscious decision to act a certain way	Stability of intentions, stages of change
9	Goals	Mental image of outcome	Goal or target setting, action planning
10	Memory attention and decision-making	Retain information and select appropriate choice	Decision making, attention control, cognitive overload
11	Environmental context and resources	Anything that influences positively or negatively development of skills or decision making	Environmental stressors, resources, organisational culture
12	Social influences	Anything that influences changes in behaviours and actions	Social pressures, social norms, power conflict, group identity
13	Emotion	Personal influences	Anxiety, stress, fear, burn out
14	Behavioural regulation	Anything aimed at changing actions	Self-monitoring, referring to colleague/peer review, getting checked, action planning

The aim of the theorists when creating an integrative theoretical framework was to simplify the process by which behavioural change theory could be applied, and make it accessible to a wider range of disciplines across healthcare, as a means of understanding the behavioural changes that can act as barriers or facilitators when planning or implementing changes in practice. The TDF has also been used in qualitative studies to guide the development and design of, for example, interview guides (Duncan et al 2012), and has been used extensively in the analysis of qualitative data, for example audio recordings from interviews (Phillips et al 2015).

The framework has been used to identify barriers and enablers to the implementation of evidence-based interventions that require a change in behaviour since the framework identifies behavioural determinants. From this understanding of barriers and enablers, theory-based interventions can be developed that may help to achieve the desired behaviour change. In the UK, the TDF it has been used to evaluate campaigns for hand hygiene (Dyson et al 2013) and in antibiotic governance to examine the influences on the prescribing of antibiotics in general practice (Fleming et al 2012). TDF has also been applied to investigating behaviours that influence prescribing errors (Duncan et al 2012).

In pharmacy practice research, TDF has been used to explore the barriers to reporting adverse drug events by nurses and pharmacists (Mirbaha et al 2015), and to explore the beliefs' of pharmacists on their research capabilities (Stewart et al 2019); the latter study used TDF in questionnaire design, as well as in analysing free text responses. The electronic cross-sectional survey of pharmacists explored the experiences and confidence of pharmacists with research, and at the conduct, dissemination and translation of research. It found few pharmacists were involved in research conduct, nor dissemination (published research) and, using TDF during qualitative analysis, found that the domains of environmental context, and of knowledge featured dominantly in responses. TDF was then used to suggest what interventions might be successful in addressing barriers uncovered by the research. The study therefore used TDF both in design and in analysis.

As TDF is a framework, not every domain will necessarily be relevant in all research. For example, in a study on antibiotic prescribing (Fleming et al 2012)

using TDF, researchers opted to apply five pre-selected domains (environmental context and resources, knowledge, social influences, beliefs about consequences and memory attention and decision-making), to their topic of study, from the stage of development of the topic guide. In a study on prescribing errors amongst trainee doctors, Duncan et al (2012) described how they had omitted optimism, goals, emotion and reinforcement in their analysis, as there were either insufficient references made to these domains by participants or where present, the domain reference did not add to the body of knowledge (Duncan et al 2012). There is therefore the potential for the domains that are dominant to emerge from the data when using TDF, and whilst these cannot be allocated a weight or statistical significance, it can allow different populations, settings or participants to be simplistically compared.

2.6.2 Theoretical Domains Framework and behaviour change

The link between TDF and behaviour change is well documented (Cane et al 2015, Michie, Atkins and West 2014): the benefit of using TDF is that it can help guide individuals or organisations towards an optimum suite of techniques to apply to changing behaviours or making improvement. To this end, researchers in behavioural change have designed a consultative tool, the behavioural change wheel, shown as a schematic (Figure 2.2), which links theoretical aspects of behaviour change with the components needed to make sustained change. The behaviour change wheel is based on the understanding that the framework for comprehending behaviour consists of three elements – capability, opportunity and motivation. These three elements interact collectively to influence the likelihood of behaviour change, and the model is known as the COM-B model (Michie, Van Stralen and West 2011). This model of behaviour recognises that changing one or more elements puts the system or process under investigation into a new configuration, and this property can be used when designing interventions.

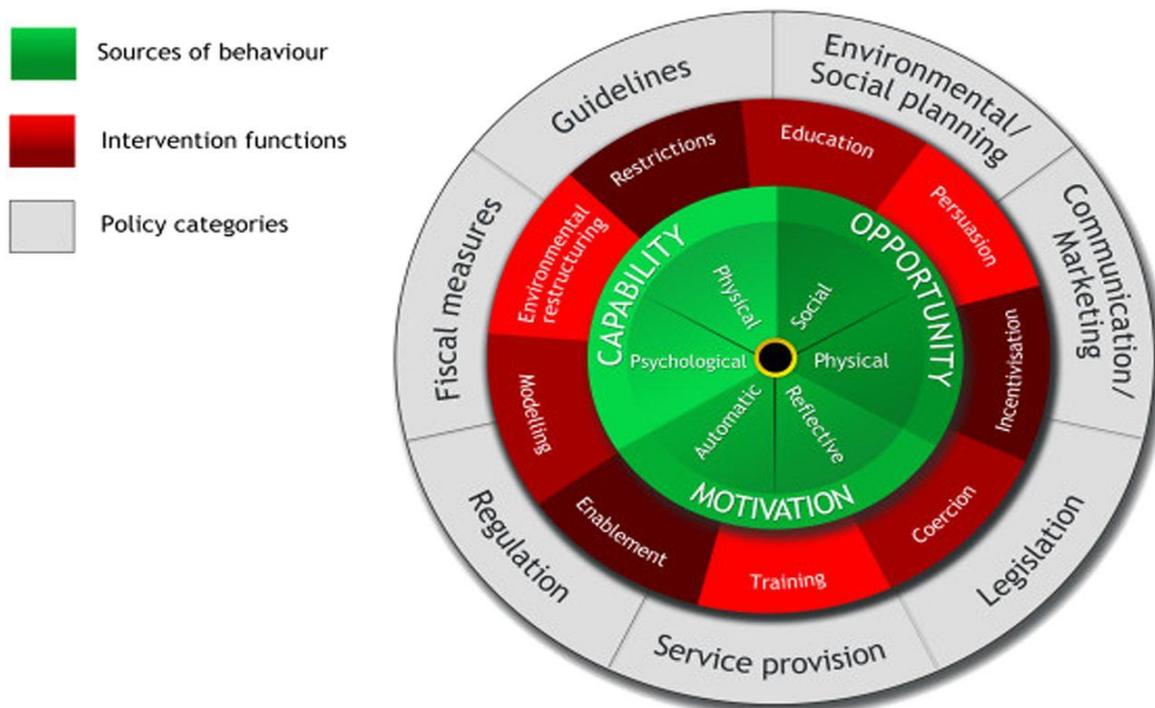


Figure 2.2. The behaviour change wheel COM-B model of behaviour change (creative commons, Michie et al 2011)

Using the schematic (Figure 2.2), the elements of behaviour change - capability, opportunity and motivation - can be evaluated and assessed, consideration made of which element (capability, opportunity or motivation) may need to change, and a suitable intervention identified. The intervention can be identified from the behaviour change wheel, using an intervention function from one of the nine interventions outlined in the red sections in the behaviour change wheel (Figure 2.2). Michie, Van Stralen and West (2011) provide definitions for the nine different behaviour change interventions (Table 2.12):

Table 2.12 Behaviour change interventions (adapted from Michie, Van Stralen and West 2011)

Intervention	Definition
Education	Increasing knowledge or understanding
Persuasion	Communicating to induce positive or negative emotions, and resultant action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment
Training	Passing on skills
Restriction	Creating rules to decrease or increase behaviour
Environmental restructuring	Change of the physical and/or social context
Modelling	Providing examples to imitate or aim for
Enablers	Reducing barriers to increase opportunity or capability

The outer (grey) wheel of the behaviour change wheel (Figure 2.2) consists of policy and fiscal changes which can be established, or amended, to support the interventions.

A corresponding behaviour change technique (BCT) taxonomy has been developed in order to standardise the content and reporting of intervention studies, and to assign BCTs to the TDF domains (Michie, Atkins and West 2014; Cane et al 2015). This taxonomy, shown in Figure 2.3, can be used to identify behavioural changes that will map to the TDF domains, to provide the most effective interventions, with the best likelihood of success when implemented.



Figure 2.3 How TDF domains relate to COM-B components (Creative commons; Michie, Atkins and West 2014)

Figure 2.3 also shows how each of the components of the COM-B model – capability, motivation and opportunity- can be further divided. Capability can be physical or psychological, opportunity can be physical or social; motivation can be reflective or automatic; opportunity can be social or physical. Not all of the sub-components will be relevant in all situations and contexts; physical skill and cognitive and interpersonal skills are grouped together as 'skills' in TDF, for example.

Using the behaviour change wheel, and with an understanding of how COM-B and TDF are related allows behaviour change interventions that are likely to be effective to be suggested for each of the TDF domains (Michie, Atkins and West 2014). The nine intervention functions are defined, and the behaviour technique(s) or policy intervention(s) that are most likely to be appropriate and effective in supporting each intervention function are described in Table 2.13.

Table 2.13 Behavioural change intervention definitions and behaviour change techniques (adapted from Michie, Atkins and West 2014)

Intervention	Definition	Suggested behaviour change technique	Policy categories for change
Education	Increasing knowledge or understanding	Information and awareness; Feedback on behaviour/outcome of the behaviour; prompts and cues; self- monitoring of behaviour	Guidelines; communication/marketing; regulation
Persuasion	Communicating to induce positive or negative emotions, and resultant action	Credible source; information about social and environmental consequences; feedback on behaviour; feedback on outcome of the behaviour	Guidelines; communication/marketing; regulation
Incentivisation	Creating an expectation of reward	Feedback on behaviour; feedback on outcome of behaviour; monitoring of behaviour by others without evidence of feedback; self-monitoring of behaviour	Guidelines, communication/marketing; regulation
Coercion	Creating an expectation of punishment	Feedback on behaviour; monitoring of behaviour of others without evidence of feedback; feedback on outcome of behaviour; monitoring outcome of behaviour by others without evidence of feedback; self-monitoring of behaviour	Guidelines; communication/marketing; fiscal measures; regulation
Training	Passing on skills	Demonstration/instruction of the behaviour; feedback on behaviour; behavioural rehearsal or practice; self-monitoring	Guidelines; fiscal measures; regulation
Restriction	Creating rules to decrease or increase behaviour	No BCT are linked because this intervention function is focussed on changing the way that people think feel and react.	Guidelines; regulation
Environmental restructuring	Change of the physical and/or social context	Adding objects to the environment; prompts and cues; restructuring the physical environment	Guidelines, fiscal measures, regulation; environmental planning
Modelling	Providing examples to imitate or aim for	Demonstration of the behaviour	Communication/marketing
Enablement	Reducing barriers to increase opportunity or capability	Goal setting; adding objects to the environment or restructuring; problem solving; action planning; self-monitoring of behaviour; review	Guidelines; fiscal measures; regulation; environmental planning

The behaviour change intervention types described in Tables 2.12 and 2.13 can be related to the 14 TDF Domains, as summarised in Table 2.14 (Michie , Atkins and West 2014). This table is a useful tool to use when making recommendations for interventions, where study findings have been mapped to the TDF domains.

Table 2.14 TDF domain and associated behaviour change techniques (adapted from Michie, Atkins and West 2014)

TDF Domain	Behaviour change intervention function
Knowledge	Education
Skills	Training
Social/professional role and identity	Education; persuasion; modelling
Beliefs about capabilities	Education; persuasion; modelling; enablement
Optimism	Education; persuasion; modelling; enablement
Beliefs about consequences	Education; persuasion; modelling
Reinforcement	Training; incentivisation; coercion; environmental restructuring
Intentions	Education; persuasion; modelling; incentivisation; coercion
Goals	Education; persuasion; incentivisation; coercion; Modelling; enablement
Memory attention and decision-making	Training; environmental restructuring; enablement
Environmental context and resources	Training; restriction; environmental restructuring; enablement
Social influences	Restriction; environmental restructuring; modelling; enablement
Emotion	Persuasion; incentivisation; coercion; modelling; enablement
Behavioural regulation	Education; training; modelling; enablement

Being able to link the findings of qualitative research to an implementation plan that has been verified and validated is advantageous. In professional practice research, with its emphasis on local implementation and impact, the behaviour change wheel/behaviour change technique process is well suited, and worthy of consideration.

Selection of methods to be used in research require careful consideration to ensure that they meet study requirements, are robust and are deliverable.

The researcher reflected on the underpinning philosophy behind research, and considered aspects of different methods, theories and techniques when considering the development of the research study. As a novice researcher, this important stage was supported by input from the research team.

2.7 Alignment of research methods to research methodology for this professional practice research

This section will outline how the philosophy of research methodology was used to develop the protocol, research question and objectives for the research undertaken.

2.7.1 Linking methodology to the aims and objectives of this research

In selecting an appropriate research methodology when conducting research (in this instance professional practice research), the philosophical viewpoint of the researcher, the required research outcomes and the research question and objectives should all be considered.

This research study is described by the title 'A theoretical exploration of hospital clinical pharmacists' perceptions, experiences and behavioural determinants in relation to provision of optimal and suboptimal pharmaceutical care'. The study has taken as its research question:

How do hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care?

The research question elicited aims, and for Phase 1 the study aim was:

1. *To explore, using focus groups, the perceptions of hospital clinical pharmacists to optimal and suboptimal pharmaceutical care.*

The objectives designed to support this aim are outlined in Chapter 3.

The aims for Phase 2 were

1. *To explore pharmacists' experiences of the provision of optimal and suboptimal pharmaceutical care within their practice*
2. *To explore the behavioural determinants relating to the provision of optimal and suboptimal pharmaceutical care using the Theoretical Domains Framework.*

The objectives designed to support these aims are outlined in Chapter 4.

Considering these aims, and taking, as a researcher, an external viewpoint on the experiences of hospital clinical pharmacists, and with a constructivist stance, a phenomenological inquiry, using a theoretical framework to understand the behaviours of hospital clinical pharmacists was selected. Phenomenological

inquiry is described as: 'A design of inquiry...in which the researcher describes the lived experiences of individuals about a phenomenon as described by participants' (Creswell, 2014)

Reflecting on the philosophical worldview of the researcher, and adapting Table 2.1. to include researcher worldview helped the researcher to understand and communicate the purpose of this research and its philosophical stance, and this is described in Table 2.15:

Table 2.15 Research philosophy and researcher worldview (adapted from Creswell 2014)

Research term	Simplistic definition	Researcher worldview
Ontology	The reality that research aims to understand by investigation	Clinical pharmacists are not recording 'errors' within pharmaceutical care delivery
Epistemology	The relationship between the stated reality and the person carrying out the research	Researcher as an outsider but 'interested party' wanting to understand the phenomenon
Axiology	The role of the researcher's own value on the research process	Researcher believes learning from error and reflective thinking important for quality management, quality improvement and professionalism
Methodology	The technique(s) used by the person carrying out the research to investigate the reality	Asking those who 'live that life' for their perspectives and experiences to better understand their world

The researcher should consider the description and communication of their research from the outset. The PICO tool (population, intervention, comparison, outcome) is useful when developing and describing quantitative research protocols (Richardson et al 1995). However, this research is qualitative and the acronym SPIDER has been suggested as a descriptive tool for qualitative research (SPIDER=Sample, phenomenon of interest, design, evaluation, research type) (Cooke, Smith and Boothe 2012). These descriptive tools have been developed to assist in literature searches or systematic reviews. It is beneficial therefore to ensure the descriptive information is easily accessible when designing or describing qualitative research, and therefore either included in the title or used as key words. The application of the SPIDER tool to this research is presented in Table 2.16.

Table 2.16 SPIDER tool application to the professional practice research study (adapted from Cooke, Smith and Boothe 2012)

S	Sample	Hospital clinical pharmacists within organisation
PI	Phenomenon of interest	Suboptimal pharmaceutical care, and why it is not being reported or shared
D	Design	Qualitative by focus group and interview
E	Evaluation	Inductive, mapping to TDF, looking for emerging themes and at the behaviours that could be modified.
R	Research type	Qualitative

2.7.2 Justification of research method choice for the professional practice research undertaken

As a professional practice doctorate student, the desire to understand the behaviour of hospital clinical pharmacists emerged from the researcher’s role within the workplace. During early literature reviews it became apparent that there was paucity of description of the specific phenomena of interest, that being, as described in Chapter 1, the delivery of suboptimal pharmaceutical care. It was also apparent that this terminology was novel, and this influenced research design.

Firstly, there was a need to consider whether hospital clinical pharmacists would perceive and understand the term suboptimal pharmaceutical care in the way that the researcher intended. Methodologies for garnering understanding of perception include qualitative interviews (Bowling 2014), and options for the type of qualitative interview are outlined in section 2.2.2. Semi-structured or open questions support the desire to understand perceptions of a concept (Bowling 2014; Kitzinger 1995), and a group setting would enable collusion and input from others in building understanding (Bowling 2014). Therefore, for Phase 1 of the study, focus group discussions was selected as the method.

Since the research was embedded within the researcher’s organisation, sampling was convenience and purposive, within the NHS Scotland organisation. The description of the methods used and the subsequent findings are described in Chapter 3.

A topic guide was designed, using the input of local clinical pharmacy experts. The proposed framework for analysis was chosen as the Theoretical Domains Framework (TDF), being a suitable framework for describing the understanding of the participants in relation to a concept.

Secondly, once understanding of suboptimal pharmaceutical care was obtained, the researcher wanted to explore the experiences of the hospital clinical pharmacists in relation to suboptimal pharmaceutical care, and understand more about their behaviours in relation to this. To achieve this, qualitative interviews were selected as a method for Phase 2, using in-depth individual interviews to allow disclosure of experiences in a safe setting, (Bowling, 2014). Since individuals are known to have both a 'public account' and a 'private account' of their views (Bowling 2014; Robson 2011), this provided further support to the use of individual interviews in this phase of the research.

Using a theoretical framework to construct a semi-structured interview schedule gives more robust data (Stewart and Klein 2016; Duncan et al 2012; Phillips et al 2015). The theoretical framework chosen as being optimal to understand behavioural determinants was the Theoretical Domains Framework (TDF), and was selected for its ability for use both in design and analysis. The description of the methods used and the subsequent findings are described in Chapter 4.

2.8 Research governance and approval

This section will briefly outline research governance principles and demonstrate how these were applied to the planned research study. Further, this section will outline the research approval processes that were required to be met, and demonstrate how approval was sought and granted.

2.8.1 Research governance principles

NHS Research Scotland (2017) describes research governance as 'the setting of standards to improve research quality and to safeguard the public'. Enhancing ethical and scientific quality, preventing poor performance and misconduct, promoting good practice, reducing adverse incidents, and ensuring lessons are learned all contribute to research governance (NHS Research Scotland 2017). Within the policy framework for health and social care research, the NHS Health Research Authority (HRA) outline principles that apply to all health and social care research, and outline the responsibilities of those involved (NHS Health Research Authority 2017). In outlining the methodology, and by the rich descriptions of the methods used in the research in Chapters 3 and 4, the researcher aimed to demonstrate that research governance principles were adhered to.

2.8.2 Research approval processes

Research approval processes act as part of the research governance arrangements for a professional practice doctorate. The researcher was required to meet the requirements both of the host university, Robert Gordon University, and their NHS Scotland organisation's workplace, within which the study took place, and the processes and requirements are described separately here:

2.8.2.1 Research approval- Robert Gordon University

Research approval is described for Robert Gordon University in the Research Governance and Integrity Policy (Robert Gordon University 2014), and includes the requirement to prepare and submit a written protocol outlining the planned research with sections relating to:

- Research team, including researcher expertise, and any training required
- Research question, aims and objectives

- Background to study
- Setting, sampling plan and inclusion and exclusion criteria
- Proposed methods
- Data collection and data analysis strategies
- Data management strategies

The preparation of the protocol assisted the researcher in structuring the study design and formed an integral part of research planning. Approval of the protocol by Robert Gordon University research ethics committee was sought. Approval was granted from the university (Ref S62; Appendix 2.1).

2.8.2.2 Research approval – NHS Scotland organisation

Approval was sought from the Caldicott guardian for the NHS Scotland organisation, and from the organisation's Research and Development department, who confirmed that ethical approval was not required for this study, as it did not involve patients. (Ref NR/2003AB6; Appendix 2.2).

To comply with the NHS Scotland organisations' requirements, the protocol, along with the consent form (Appendix 3.2) and the participant information pack (Appendix 3.1), was submitted to the organisation's Pharmacy Quality Improvement Team and approval was granted from this group (Ref QIT83: Appendix 2.3).

2.9 Summary of Chapter 2

This chapter has outlined research approaches from a theoretical perspective, and described techniques and tools used in research to generate and analyse data. Furthermore, this chapter has described in detail the purpose, selection and use of theory in research, with specific reference to the Theoretical Domains Framework (TDF). Next, the researcher reflected on the planned research and described and justified the methods that were adopted, and finally, considered research governance, and outlined how research approval was sought prior to research study commencement.

CHAPTER 3 Phase 1: Perceptions of hospital clinical pharmacists to optimal and suboptimal pharmaceutical care

3.1. Introduction to Chapter 3

This chapter will justify and describe the methods used for Phase 1 of the research, and will then present the findings from the Phase 1 study. Phase 1 was designed to explore hospital clinical pharmacists' perceptions and understanding of the concepts of optimal and suboptimal pharmaceutical care. The Phase 1 study used focus groups to generate data relating to the perceptions of participants. The findings from the focus group were mapped to the Theoretical Domains Frameworks (TDF) to identify how hospital clinical pharmacists perceived barriers and enablers that influenced behaviour in the delivery of optimal pharmaceutical care.

3.2 Research question, aims and objectives

The overarching research question for this research was:

How do hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care?

The aim of this Phase 1 study was:

To explore, using focus groups, the perceptions of hospital clinical pharmacists to optimal and suboptimal pharmaceutical care.

The supporting objectives were:

1. To determine the perceptions of focus group participants to optimal and suboptimal pharmaceutical care using a topic guide to direct discussion.
2. To determine whether the term suboptimal pharmaceutical care would be understood by participants, and represented by the findings.
3. To map the findings from the focus groups to the Theoretical Domains Framework to understand the perceptions of participants.
4. To use the theoretically mapped findings of the focus group to inform the next phase of the research.

3.2.1. Justification for use of focus groups discussions in study

Focus group discussions as a method was selected as this phase of the research was exploratory, looking to understand in particular how clinical pharmacists would perceive the term suboptimal in relation to pharmaceutical care.

The description of focus group discussions as a method was outlined in Chapter 2, and describes the advantages and disadvantages of conducting qualitative interviews with a group of participants, rather than with individuals.

The participants of a focus group are encouraged to interact with each other during discussion, and this interpersonal interaction is a feature of focus groups. Participants present their views, then listen to the contributions of others, reflect on their own views and may reframe their views in response to what they hear (Ritchie and Lewis 2006). As a group, discussions may lead to the stimulation of new ideas, and the refining of these ideas through discussion. Participants may thus identify shared concerns more rapidly than the use of the individual interview, and gain a better collective understanding of complex issues (Bowling 2014). The focus group setting allows a more naturalistic way through dialogue and conversation than an interview, and provides a way of understanding how the participants perceive, understand and experience the world around them (Ritchie and Lewis 2006). Focus group discussions can be used to examine *'not only what people think, but how they think and why they think that way, as well as what their understanding is, and what priorities they have'* (Bowling 2014).

Focus groups have been used to understand perceptions of the barriers and facilitators to implementation: a Canadian study used focus groups to determine barriers and facilitators to the implementation of clinical pharmacy key performance indicators (Minard et al 2016). In the study, three focus groups were held, with twenty-six pharmacists. Participants identified both barriers and facilitators and the findings were used to inform the wider implementation of the key performance indicators. The study authors concluded that the focus group method was successful as *'attitudes and perceptions are not developed in isolation, but through interaction with other people'*.

In the current study, the novel concept of suboptimal pharmaceutical care was being tested, to ascertain what hospital clinical pharmacists perceived the

concept to mean, when given the opportunity to discuss interactively in a focus group setting. Taking part in focus group discussions can make participants feel that they are part of the research, which can enhance the impact of the research when the purpose is to establish new practices (Robson 2011). This was an advantage in this study, as focus group discussions enabled a wider group of participants to engage with the research, who would then be aware of the research work when implementation was being proposed.

A disadvantage of focus group discussions is that there is limited in-group confidentiality, with other participants being present, and this may inhibit some responses that relate to personal feelings or actions (Robson 2011). That was not considered a barrier in this Phase 1 study, as there would be an opportunity for individual input from participants in Phase 2. It has been reported that there may also be a reluctance by participants to express a dissenting opinion in a focus group (Kitzinger 1995), but that was not considered to be a barrier, since, as above, participants would have an opportunity for individual input in Phase 2. A practical disadvantage of the focus group discussion is that the data generated are difficult and time consuming to collect, process and analyse (Ritchie and Lewis 2006), as described in Chapter 2, and this will be discussed further on in this chapter, when consideration was made to adapting the method to suit the research purpose.

The research team considered the advantages and disadvantages of focus group discussions as a method and concluded that focus group discussions were appropriate for this phase of the study.

3.2.2 Justification for use of TDF in analysis of study data

The use of a theory in the analysis of generated data was described in Chapter 2, and included description of the benefits of theory when analysing qualitative data. Additionally, framework analysis was described as a means to manage and organise the data. The process by which the data is analysed using a framework requires the researcher to obtain familiarisation with the data, coding or mapping to a thematic framework, and interpreting the data, all of which are required in qualitative data analysis; the use of framework analysis is a skill that the novice qualitative researcher should develop (Bowling et al 2014) .

The Theoretical Domains Framework (TDF), the chosen theoretical framework for this study, was described in Chapter 2. The intention of this phase of the study was not to determine individual behavioural determinants, which is the conventional use of TDF (Cane et al 2012). However, mapping of the data to TDF during analysis allows themes and subthemes to be extracted that help the researcher to understand the perceptions of participants, including barriers or enablers. Perceptions are an antecedent of, and influence behaviours, and therefore use of the TDF is justified. In Phase 1, TDF was used in data analysis.

The output from this phase of the research was intended to inform the design of the Phase 2 study. The Phase 2 study design incorporated TDF as the theoretical framework, and the research team therefore agreed that the use of TDF in Phase 1 would be beneficial to the researcher as skill development, and for mapping and interpretation of the data generated, and the use of TDF is therefore justified in this study.

3.3 Method

Having outlined the justification for the use of focus groups as a qualitative method, and of use of TDF in the analysis of the generated data, this section will describe in detail how the study was designed, and executed, to meet the key aims of this phase of the research.

3.3.1 Design of study

This phase of the study, known as Phase 1, was underpinned by a qualitative research design, since the nature of the research question and objectives necessitated the collection of rich and meaningful data. The research was grounded in constructivism, and used a phenomenological approach (see Chapter 2). The study was designed to provide data that would be used in Phase 2 of the study.

When designing focus group discussions, principles relating to group size, numbers, composition and balance of participants should be considered: (Bowling 2014; Kitzinger 1995; Côte-Arsenault & Morrison-Reedy 2005; Robson 2011):

- A focus group should not be too small or too large, 6-12 participants being deemed best.
- There should be between 5 and 20 focus group discussions in total, with separate groups, rather than serial discussions with the same group, to avoid 'groupthink'.
- There should be balance within the group in terms of age/sex/experience, with the aim being to provide a safe and comfortable environment.
- Consideration should be made whether homogenous or heterogenous groups best suit the research requirements.

3.3.1.1 Research setting

The research setting for this study was an NHS Scotland organisation pharmacy department, where the researcher and facilitator work. The researcher is a member of the pharmacy quality, risk and governance department, and the facilitator a member of the pharmacy education, research and development department. The researcher and the facilitator work closely with the clinical

pharmacy services, from which the participants were recruited, but neither work within the clinical pharmacy team. The relationship of the researcher and facilitator to the research setting has the potential to bring bias (Bowling 2014): in this research, the researcher is seeking understanding of the concept of suboptimal pharmaceutical care and a solution to a problem; the facilitator to ensuring the research has impact within the workplace. Both researcher and facilitator reflected on their biases, acted to minimise impact of bias, and this reflection formed part of an ongoing reflexive process.

3.3.1.2 Content validity: Field work

Prior to undertaking the research study, the researcher carried out preliminary field work by shadowing five experienced clinical pharmacists from acute medicine, general medicine, oncology and palliative care, at three different hospital sites between January and March 2017. The field work covered: the use of TRAK (electronic health record); the priority coding process (patient acuity or prioritisation) and the medicines reconciliation and Kardex/medicines review processes and documentation. Variation was noted across the different hospital sites and their clinical pharmacy services, and this became a consideration when planning the study. Familiarisation of the field in which the participants worked was important to build initial rapport with the participants, and understand the language they used in conversations about their work experiences.

3.3.1.3 Population and recruitment

The study was carried out using a convenience, purposive and homogenous sample of the 128 clinical pharmacists working in the five acute hospitals that are part of the NHS Scotland organisation. Participants were recruited using email sent to all clinical pharmacists, which included an information pack (Appendix 3.1). Pre-registration pharmacists were excluded as having insufficient experience of working systems to be able to participate fully in the discussions. Respondents who expressed interest in taking part in the study were sent a consent form (Appendix 3.2), and a demographic data collection form (Appendix 3.3) to complete, and a supplementary information pack introducing the topic for discussion in the focus group. (Appendix 3.4)

When planning the consent process, research governance was considered, and a statement was included on the consent form: *'I understand that any event where patient safety may have been compromised will be followed up following normal governance procedures for adverse event reporting'*. This recognised that there could be disclosure during the research of otherwise unreported adverse events. The consent form design (Appendix 3.2) would be improved by having a box to initial for each consent statement, rather than a tick box (NHS Health Research Agency 2019).

Initial recruitment resulted in 27 pharmacists expressing interest in taking part in the focus group discussions at the five hospital sites. Once the date had been established there was some attrition, with six pharmacists being on leave or not working on the date arranged for the focus group discussion at their site. Recruitment therefore resulted in 21 participants, spread across the five hospital sites.

3.3.1.4 Sampling plan

The sampling plan was to conduct five focus groups, one at each of the five acute hospital sites in the organisation, with five to seven participants at each site, with differing levels of experience. Conducting the focus groups at each site was deliberate, in part to capture variation in practice across the different sites, and in part to provide a safe and familiar environment for participants, with known colleagues. Due to attrition, the final sampling plan had four to five participants at each site, with differing levels of experience, and a total of 21 participants. One participant failed to attend on the day, resulting in 20 actual participants. The demographics of participants is described in section 3.4.1.

3.3.2 Data collection methods

Focus groups generate data in the form of discourse between participants, and traditionally this data is captured by audio recording, followed by the transcription of the audio recording into written word.

The focus group method was adapted in this study to suit the design requirements of this phase of the research. These were:

- to facilitate a rapid analysis of data to enable Phase 2 to follow.

- to obtain member checking of the output in real time.
- to engage the participants during the focus group.

To achieve this, the study design was adapted to enable participants to record written statements describing their perceptions of optimal and suboptimal pharmaceutical care during the focus group, and form a key part of the data generated. The physical activity of recording participant contributions in writing would engage participants, and provide a visual output that could be member checked.

The discussion was audio recorded to act as auditable verification, and to enable key illustrative verbal quotes to be extracted as supplementary data to support the written statements.

The data collection was therefore twofold: 1) written statements made by participants, and 2) supporting illustrative quotes extracted from audio recordings. In addition, reflective field notes were made by the researcher and the facilitator to describe the focus group setting, interactions, and level of engagement.

Using the adapted and abridged focus group method to save time, and to meet the study requirements was agreed in advance with the research team, and is a novel method of conducting focus group discussions. A review of method adaptation of focus group discussion in the literature found a single qualitative focus group study that had used written statements on post-it notes as a means of generating data (Peterson and Barron 2007). However, in that study the adaptation had a different purpose: to encourage reluctant participants rather than as a method to more efficiently capture focus group data (Peterson and Barron 2007).

The adapted study design for the focus groups is summarised in Table 3.1, showing the process for designing, conducting and analysing a typical focus group, and for the adapted focus group method.

Table 3.1 Comparison of typical focus group and adapted focus group

Typical focus group	Adapted focus group
5-10 participants	5-10 participants
Discuss topic, guided by topic guide	Discuss topic, guided by topic guide; record written statements onto post-it notes that exemplify discussion
Audio record and transcribe	Audio record; listen back & identify and extract illustrative quotes
Analysis of data from transcriptions and researcher/facilitator field notes	Analysis of data from written statements, illustrative quotes and researcher/facilitator field notes
Send to participants to member check	Participants member check during and at the end of the session

The adapted method will be discussed further throughout the chapter.

3.3.3 Data collection instruments and techniques

A focus group topic guide was established based on discussions with the research team and around clinical pharmacy processes. The topic guide was simplistic, and not theory based, relying solely on the analysis to apply the theoretical framework, and this may be perceived as a weakness in study design. The intention was for discussions to focus on patient facing aspects of pharmaceutical care, and two topics for discussion were selected. The two topics were medicines reconciliation and Kardex or medicines review, and these were described in Chapter 1.

Medicines reconciliation, in this context and setting, is the process of ensuring that a hospital patient's medication list is current and accurate. Within the organisation, this task is initiated out by the admitting doctor, with the pharmacist confirming that the process has been carried out and documented accurately.

Kardex/medicines review, in this context and setting, is the process of assessing prescribed inpatient medication by clinical pharmacists to identify and document pharmaceutical care issues, and to ensure patients receive medicines as

intended by the prescriber. The process for Kardex/medicines review is described in a procedure. Kardex is the paper based inpatient medicines prescription and administration record used in the organisation.

In preparation for the focus groups, data collection instruments were assembled and included an Olympus digital audio recorder model DS-3500 to capture the audio output, and A1 paper, pens and post-it notes to capture the written output.

Additionally, documentation was prepared to assist in the conduct of the focus groups, including reflective field notes template (Appendix 3.6), operating procedure (Appendix 3.7), an on-the-day checklist (Appendix 3.8), and focus group ground rules (Appendix 3.5).

3.3.4 Conduct of focus groups and data generation

Elements of good and of poor practice when conducting focus group discussions have been described (Bowling 2014), and these elements are summarised in Table 3.2, describing the factors that influence the likelihood of success or otherwise when conducting focus groups:

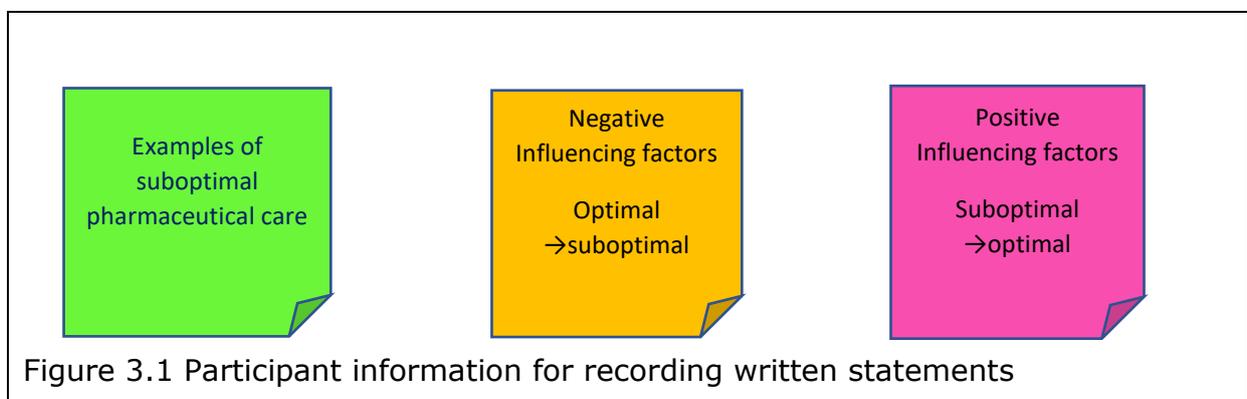
Table 3.2 Good and poor practice in focus group discussions (Adapted from Bowling 2014)

Good practice	Having a clear objective
	Being well managed/facilitated
	Having a safe environment
	Having clarity of purpose
	Being time banded
	Being accurately recorded
	Having a defined endpoint
	Stating clearly what will be done with the information
Poor practice	Poor management
	Amateur or inexperienced facilitators
	Facilitator who has vested interest (may lead to bias)
	Failure to adequately brief facilitator
	Lack of focus
	Too small or too large a group
	Scope is too ambitious for one setting
	Lack of flexibility as issues emerge

The researcher reflected on elements of focus group conduct during the planning of the Phase 1 study, conducted some self-directed study and formal training (Appendix IV). Good practice was assured by rigorous planning. The objective and purpose of the research, and the role of the focus group discussion were stated in the information pack for participants (Appendix 3.1). An experienced facilitator was recruited from the research team, their role was clarified through ongoing discussion and briefing in advance of the focus groups. The physical environment was known to participants, being on their own hospital site, and the emotional environment was made safe by assuring confidentiality in the information pack (Appendix 3.1), reinforcing at the start of the focus group, and reiterating in the focus group ground rules (Appendix 3.5). The focus group duration was stated in the information pack, and in confirmatory emails sent in advance, and time keeping was part of the planned process.

Each focus group started with an introduction by the researcher, where the plan for the focus group was described, detailing how the participants were to introduce and record their ideas using post-it notes placed onto a flipchart. Discussion was focussed on two topics as outlined in the topic guide.

Focus group participants were asked to discuss suboptimal pharmaceutical care in relation to the first topic of discussion, and write examples onto GREEN post-it notes. After 10-15 minutes on this task participants were asked to discuss influencing factors in relation to suboptimal pharmaceutical care for one or two of the examples they had described. For this participant-led stage of the task they were asked to record written statements onto two different coloured post-it notes. PINK post-it notes were to record positive influencing factors (enablers), and ORANGE post-it notes to record negative influencing factors (barriers)(Figure 3.1). This task was conducted for approximately 20 minutes, and then repeated for the second topic of discussion. The use of the different colours was deliberate, to enable participants to visualise their responses at the time (Figure 3.1). The novel presentation of the focus group data is a feature of this study.



Participants were advised that audio recording would take place to enable illustrative quotes to be extracted. It was confirmed by the researcher that all participants had completed and signed the consent form prior to commencement of each focus group. Each focus group was then read a standard introduction giving the definition of pharmaceutical care (Appendix 3.9). The focus group ground rules (Appendix 3.5) were circulated and displayed throughout the focus group. The digital audio recorder was then started and the focus group discussion commenced.

After discussing the two topics of medicines reconciliation and Kardex/medicines review, the researcher verbally summarised the content of the written statements, asking participants to confirm that their intention was recorded accurately. This step acted as member checking of the written record. The researcher kept time, and drew the discussion to a close after 45 minutes, thanking the participants for taking part. After each focus group, the researcher and facilitator met to share reflective field notes, and to discuss practical aspects of the conduct of the focus group.

3.3.5 Data processing

For Phase 1 focus groups, the data included demographics about participants, and the data generated related to individual hospital sites. Focus group and individual data were processed and stored in a manner that ensured confidentiality.

For the data generated, the written statements were transcribed verbatim into Microsoft word documents by the researcher, for each focus group, in order for extraction and analysis to take place (Appendix 3.12). The data was not merged, but treated separately for each focus group, and for each topic (medicines reconciliation and medicines review). Treating each focus group separately at the stage of transcription and data presentation was considered to be applicable and appropriate for a professional doctorate, where each focus group represented a separate hospital site, with different practices and processes, with data synthesised at a later stage to allow common themes to be determined for interpretation and discussion.

The digital audio recordings were transferred from the Olympus digital recorder to secure computer files using Olympus data management software. There was no transcription, but illustrative quotes were extracted (3.3.7).

3.3.6 Data management and storage

Data management processes were followed to ensure that individuals' and focus groups' details and data remained confidential, anonymous and privacy protected.

3.3.6.1 Protecting confidentiality

Focus group data, the output from each focus group, the audio files and the transcripts were kept securely to protect the confidentiality of participants. The written statements on post-it notes were photographed, then their content transcribed into Microsoft Word documents by the researcher. A sample was checked by the facilitator. Field notes were reviewed at the end of each focus group, any additional comments added to the form, which were then kept securely until accessed for data processing and analysis.

3.3.6.2 Anonymity

Each focus group was assigned a number, rather than using the hospital site name, when anonymising the data. The risk of individuals being identified by their handwriting on written statements was considered low, and whilst the written statements were transcribed, the photographic image of the focus group output was also deemed to be part of the data generated for the purpose of the thesis. Illustrative quotes were not assigned to individuals to assure anonymity. Identifiable information, such as the audio recording, was deleted from the audit recorder immediately after the file had been transferred to a secure computer file using Olympus data management software. Each audio file had a unique reference and a secure master file was created that matched the audio file to focus group as a numeric representation (one to five) to ensure that the data was anonymised, but could be traced back for audit or data integrity purposes.

3.3.6.3 Privacy of participants

Demographic information about participants was collected as necessary for the research and kept securely. Once transcribed, the demographic data collection that linked data to individual participants was destroyed.

3.3.7 Data extraction method

The data extraction method was agreed in advance by the research team. Firstly, the transcribed written statements from each of the five focus groups were mapped to the Theoretical Domains Framework by the researcher and a member of the research team. Interrater checking of the mapping of the

generated data between coders was ongoing, and any variance discussed and resolved. This presented a learning opportunity for the researcher.

Secondly, the audio files were accessed by the researcher for the purpose of extracting illustrative quotes to support the written statements that described participants' perceptions of optimal and suboptimal pharmaceutical care. In addition, listening to the audio output enabled the researcher to familiarise themselves with the audio recording of the focus group discussions. Input from a member of the research team verified that the illustrative quotes represented the written statements. Tables were then prepared in Microsoft word to present the data, consisting of written statement and illustrative quotes, and these are presented in Appendix 3.12.

3.3.8 Data analysis method

The data was analysed using TDF. Data analysis started after the conduct of the first focus group when the researcher and facilitator met to discuss the reflective field notes, which were collected using a template (Appendix 3.6). Abridged notes from each focus group summarised the practical aspects of each focus group (Appendix 3.11). The process of reviewing field notes with the facilitator after each focus group was beneficial as it allowed for reflection on how the conduct of the focus groups had been carried out, and enabled initial thoughts about the output from the focus groups to be captured.

Data analysis continued with the examination of the data transcribed from written statements as presented in Microsoft word tables (Appendix 3.12) to cross check the TDF coding process, to verify the domains represented, and to commence the process of analysis by identifying initial themes and subthemes. Familiarisation and immersion in the data at this early stage was an important part of the data analysis.

Data reduction – the process of filtering the data to reduce it to a manageable size - was not required at this stage of the adapted focus group method. The reduction occurred during the focus group, by the group forming consensus on the written statements. The selection of written statements for further discussion was led by participants.

The data processing and extraction are described in detail here, since the method used in this study created a novel way of data generation (written statements), data extraction (transcribing written statements and accessing audio files), and the data presentation, using captured images from the focus groups, reflects this process.

3.3.9 Data processing and extraction: medicines reconciliation and Kardex/medicines review

This section will outline the data processing and extraction processes for each focus group discussion. The two topics were treated separately during the focus group discussion in accordance with study design, and therefore ten sets of data extraction are described:

- Medicines reconciliation data extraction (3.3.9.1 to 3.3.9.5) for Focus groups 1 to 5.
- Figures 3.2 to 3.6 showing the images from discussions on medicines reconciliation for Focus groups 1 to 5, followed by explanatory notes, relating to the written statements selected by participants for further discussion.
- Summary of data processing and extraction for topic of medicines reconciliation

- Kardex/medicines review data extraction (3.3.9.7 to 3.3.9.11 for Focus groups 1 to 5.
- Figures 3.7 to 3.11 showing the images from discussions on Kardex/medicines review for Focus groups 1 to 5, followed by explanatory notes, relating to the written statements selected by participants for further discussion.
- Summary of data processing and extraction for topic of Kardex/medicines review

Full transcripts from the written statements are presented in Appendix 3.12.

[Note: the written statements made by participants relate to the clinical pharmacy service in the organisation, as described in Chapter 1; the statements

were written by participants and certain abbreviations and shorthands were used which are explained here:

IDL = intermediate discharge letter; ECS = emergency care summary; TRAK = TRAKcare, the electronic patient record used; Paperlite = a programme to reduce paper records in the organisation; med rec = medicine reconciliation, (described in Chapter 1); Kardex = a prescription and administration record; OTC = over the counter; NG = nasogastric; IV = intravenous; pod = near patient medicine storage.]

Medicines Reconciliation

3.3.9.1 Focus group 1: medicines reconciliation

The output of the discussion on medicines reconciliation was captured as a photographic image on completion of the focus group (Figure 3.2). Focus group 1 generated seven examples of suboptimal pharmaceutical care delivery in medicines reconciliation (green post-its), with seven influencing factors emerging when discussed in more depth, for the two selected examples: four negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), three positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.



Figure 3.2 Focus group 1 output: medicines reconciliation

Focus group 1 explanatory notes for participant-selected examples:

The group opted to have additional discussion on the statement:

'no clear area to document medicines reconciliation'.

The negative influencing factor, or barrier to optimal pharmaceutical care being delivered, related to the paper record of medicines reconciliation not being available:

'loose paper being lost'

The enabler for this barrier was to have an agreed location to keep a medicines reconciliation record, and to have an agreed format for completion:

'Agreed location and format'

Since the research took place, paper documentation has been replaced by an electronic record.

The second statement that was selected by participants to be discussed was:

'incomplete medicines reconciliation'

A barrier to optimal pharmaceutical care was perceived to be the lack of motivation of the junior doctors to whom this task generally falls:

'motivation to see benefit'

A second barrier was identified as being a tendency for the medicines reconciliation to focus only on those medicines that are applicable to the specialty:

'Only focussing on area of specialty rather than all medicines'

This barrier describes how medicines reconciliation sometimes focussed only on respiratory medicines on a respiratory ward, or only rheumatology medicines on a rheumatology ward for example, and this behaviour included both doctors and pharmacists.

An enabler for this barrier was perceived to be a maintenance of a generalist knowledge of medicines by pharmacists and doctors:

'maintaining generalist knowledge'

A second enabler was using appropriate sources of information for carrying out medicines reconciliation:

'Using ECS as primary source'

The ECS referred to is the emergency care summary, and is recognised as being an appropriate primary source of information about a patient's medicines on admission

3.3.9.2 Focus group 2: medicines reconciliation

The output of the discussion on medicines reconciliation was captured as a photographic image on completion of the focus group (Figure 3.3). Focus group 2 generated eleven examples of suboptimal pharmaceutical care delivery in medicines reconciliation (green post-its), with nine influencing factors emerging when discussed in more depth, for the two selected examples: five negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), four positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.



Figure 3.3 Focus group 2 output: medicines reconciliation

Focus group 2 explanatory notes for participant-selected examples:

Focus group 2 opted to have additional discussion on the statement:

'Too many resources to access – ECS, renal vital data, GP letter, patient'

This statement describes some of the sources used to carry out a thorough medicines reconciliation, and how it is not always clear which sources to use when this is not defined.

The participants perceived barriers to optimal pharmaceutical care being delivered in medicines reconciliation as relating to a lack of time, and to high patient volume, and the presence of out of date emergency care summaries in the patient record:

'Out of date ECS; lack of time; patient volume'

The suggested enabler for these perceived barriers was the availability of clinical technicians on more wards, with the technician using a referral tool available in the service, to highlight high risk patients, and with the technician having input into the management of patients:

'Clinical technician referral tool/input'

A second statement discussed in more detail by the group was:

'Asking closed questions of patient'

This referred to the practice of asking patients for information about their medicines during medicines reconciliation, and a perceived negative behaviour of using an inadequate questioning style. An enabler to asking closed questions was proposed by participants as being:

'training in open questioning skills'

This demonstrates that participants perceive that skills used in medicines reconciliation can be taught and reinforced.

Barriers to provision of optimal pharmaceutical care were perceived as being:

'Patient expectations'

'overemphasis on medicines and not seeing other factors e.g. medical history'

'time consuming task'

'Patient expectations' referred to the lack of understanding by the patient of the purpose of medicines reconciliation and the role of the pharmacist in clarifying or expanding on information already collected by the admitting doctor. The enabler to this barrier was:

'Health literacy'

Health literacy is a generic term to describe the ability of patients to understand and process health information, and here is used to describe the perceived gap between what patients currently understand about processes that pharmacists are involved in, for example, medicines reconciliation.

In describing an 'overemphasis on medicines', the participants refer to the knowledge and awareness that a complete medicines reconciliation will take account of the medical history of a patient, not just the presenting history, and current medicines. The enabler:

'holistic approach'

reflects this.

The description of medicines reconciliation as:

'time consuming task'

relates to how carrying out a complete and accurate medicines reconciliation is time consuming, and participants suggested that asking closed questions of a patient is sometimes used as a mechanism to shorten the time taken over the task.

3.3.9.3 Focus group 3: medicines reconciliation

The output of the discussion on medicines reconciliation was captured as a photographic image on completion of the focus group (Figure 3.4). Focus group 3 generated eight examples of suboptimal pharmaceutical care delivery in medicines reconciliation (green post-its), with four influencing factors emerging when discussed in more depth, for the one selected example: one negative influencing factor or barrier to provision of optimal pharmaceutical care (orange), three positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the one selected example.

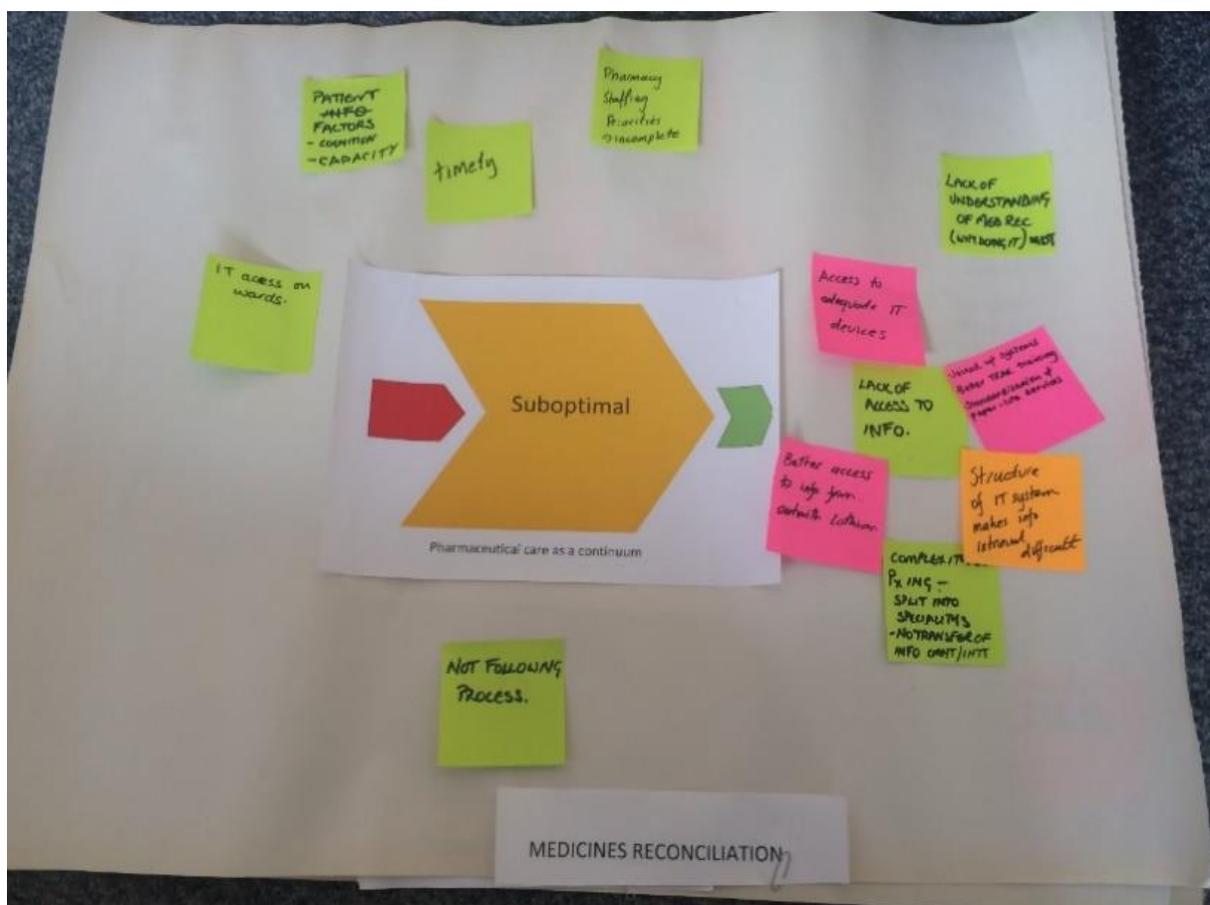


Figure 3.4 Focus group 3 output: medicines reconciliation

Focus group 3 explanatory notes for participant-selected example:

Focus group 3 opted to have additional discussion on the statement:

'Lack of access to relevant information'

The statement refers to the process of accessing information that is necessary to carry out medicines reconciliation. A barrier to provision of optimal pharmaceutical care was perceived as:

'Structure of IT makes information retrieval difficult'

This statement refers to the incompatibility of IT medical information systems in primary and secondary care making it difficult to obtain up to date information on a patients' medicines. The enablers to the incompatibility were seen as:

'Joined up IT system' and

'Better access to information from outwith [NHS Scotland organisation]'

'Access to adequate IT devices [computers]'

The latter statement relates to a shortage of computer availability, and since the research took place, this has been addressed.

A further enabler described by participants relating to IT systems was:

'Better Trak training; standardisation of paperlite system'

Better TRAK training was perceived as being needed by both pharmacists and doctors to ensure that information was recorded appropriately within TRAK. Standardisation of the paperlite system refers to perceived differences both within each hospital and across the different hospitals in the way the paperlite process was being implemented across the organisation.

3.3.9.4 Focus group 4: medicines reconciliation

The output of the discussion on medicines reconciliation was captured as a photographic image on completion of the focus group (Figure 3.5). Focus group 4 generated eight examples of suboptimal pharmaceutical care delivery in medicines reconciliation (green post-its), with six influencing factors emerging when discussed in more depth, for the two selected examples: three negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), three positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.



Figure 3.5 Focus group 4 output: medicines reconciliation

Focus group 4 explanatory notes for participant-selected examples:

Focus group 4 opted to have additional discussion on the statement:

'Communication/handover between staff e.g. Dr to Dr, pharmacist to Dr, pharmacist to pharmacist/pharmacy staff'

as an example of why suboptimal pharmaceutical care may be delivered, and outlining that multiple parties are involved in the process of medicines reconciliation, and that communication between parties is important to optimise the process. The barriers discussed included:

'Differences across different sites yet all sites access TRAK'

which refers to intra-site differences which became apparent when patients move between sites for different episodes of care. An additional barrier was described which related to perceptions of other members of the multidisciplinary team, and describes the negative perception by the team of pharmacists having a policing role:

'Lack of understanding of pharmacist/pharmacy staff role by Drs and nurses –e.g. sometimes seen as policing role'

Enablers to the discussion on communication were identified:

'Robust system in place with same terminology'

'Clear documentation on what has been done/still to do'

Clear documentation was described as the optimal method of communicating what the process status was for medicines reconciliation, both for pharmacists and doctors.

A second statement was selected for further discussion by the group, and this related to medicines reconciliation issues not being followed up by others (other pharmacists or admitting doctor):

'Medicines reconciliation issues not followed up'

However, it was acknowledged that the barriers to medicines reconciliation issues being followed up and acted on were complex and included time constraints of those involved:

'Staff time constraints'

as well as the complexity of patients' medicines and concurrent medical issues:

'Complexity of patient'

and further compounded by the lack of clarity over the pharmaceutical care issues being recorded:

'Poor documentation –unable to identify and understand issues'

Enablers to the poor practice of not following medicines reconciliation issues up were described as the need for a change of culture and attitude amongst doctors and pharmacists:

'Culture and attitude'

as well as better training in the process of medicines reconciliation:

'Training (pharmacist and doctor)'

and a clearer, standardised description of the optimal way of carrying out the process of medicines reconciliation:

'Clear processes(standardisation)'

There was a perception by participants that the barriers identified relating to IT systems were not restricted to the organisation, and that a single IT system across NHS Scotland would be beneficial, enabling sharing of patient information across health boards:

'One national single computer system through NHS'

Participants described the poor engagement of staff with the process of medicines reconciliation, and this referred both to doctors and to pharmacists:

'Staff engagement with medicines reconciliation'

3.3.9.5 Focus group 5: medicines reconciliation

The output of the discussion on medicines reconciliation was captured as a photographic image on completion of the focus group (Figure 3.6). Focus group 5 generated nine examples of suboptimal pharmaceutical care delivery in medicines reconciliation (green post-its), with eight influencing factors emerging when discussed in more depth, for the two selected examples: four negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), four positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.

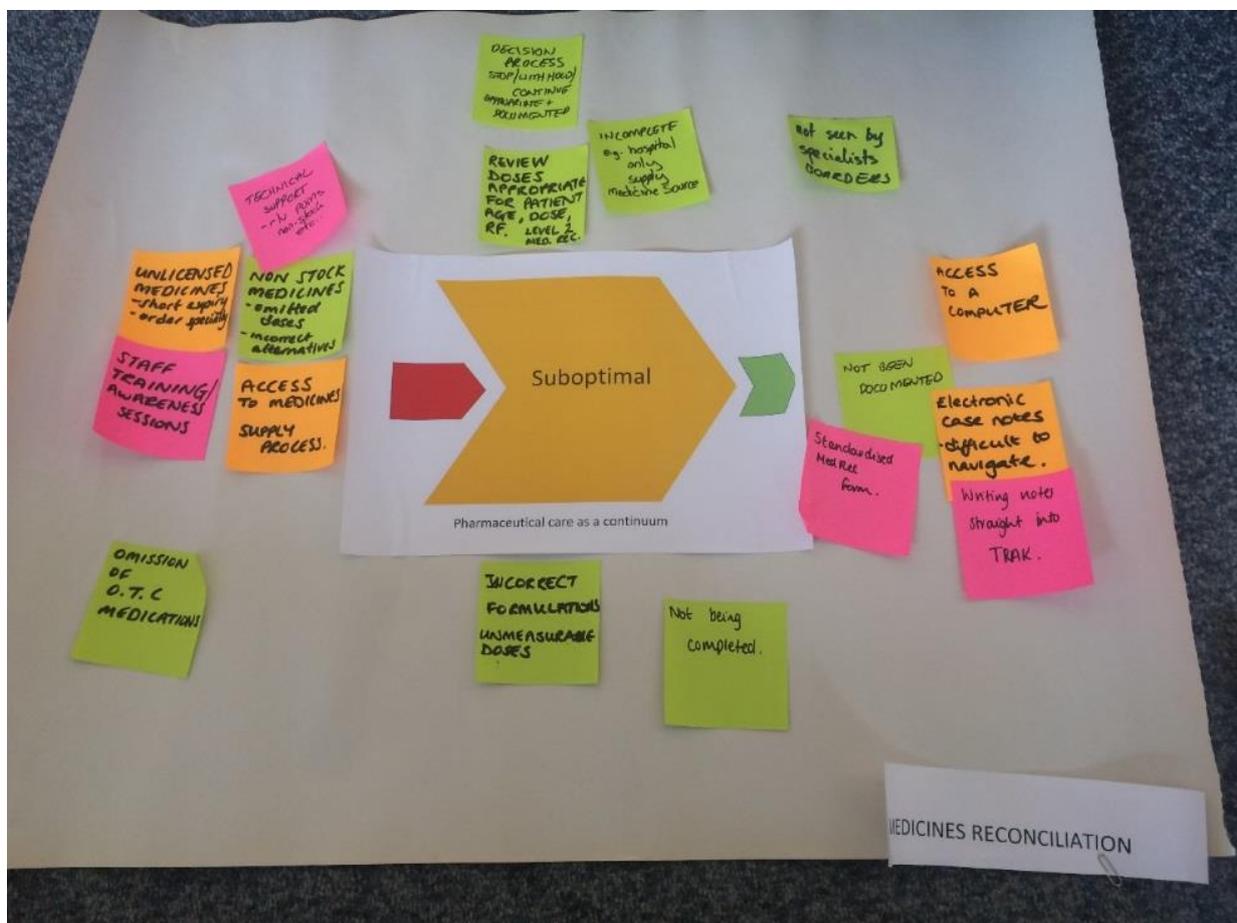


Figure 3.6 Focus group 5 output: medicines reconciliation

Focus group 5 explanatory notes for participant-selected examples:
Focus group 5 opted to have additional discussion on the statement
'Non-stock medicines – omitted doses or incorrect alternatives'

This statement describes how participants perceived that the frequent use of non-stock medicines on their wards was resulting in missed or omitted doses. Further barriers to the provision of optimal pharmaceutical care were cited, including that:

'Unlicensed medicines need ordering specially'

And that pharmacists had limited time to access the medicines supply process:

'Access to medicines/supply process'

These statements refer to additional pharmacist time being needed to source non-stock or unlicensed medicines, and to recommend substitute or replacement medicines, and therefore less time was available for pharmacists to address pharmaceutical care issues.

Two enablers were perceived for this barrier, the first being better awareness by staff, referring to the multidisciplinary team, on the role of the pharmacist:

'Staff training /awareness session'

The second enabler suggested by participants was additional resource to support in the supply of medicines, and in particular non-stock and unlicensed medicines, suggested this role could be taken on by pharmacy technicians:

'Technician support e.g. with non-stock medicines'

A second statement that the focus group opted to discuss was:

'Not being documented adequately'

This statement referred to poor practice in documenting medicines reconciliation in the patient record, and this created a barrier to provision of optimal pharmaceutical care. Specific contributory factors to this barrier were:

'Access to computer'

This statement describes how the current process requires access to a computer to access the electronic medical record, while concurrently needing access to paper records where medicines reconciliation was recorded. Access to computers on a ward is shared with other users.

In addition, participants referred to difficulty navigating electronic case notes:

'Electronic case notes difficult to navigate'

Participants discussed enablers for this difficulty and suggested:

'Writing notes straight onto TRAK'

This statement referred to the perception that the process of medicines reconciliation was not being documented adequately, participants suggested that standardised documentation would be an enabler:

'Standardised medicines reconciliation form'

3.3.9.6 Summary of data processing and extraction: medicines reconciliation

In summary, written statements of examples of suboptimal pharmaceutical care were generated from the five focus groups for the topic of medicines reconciliation (N=43). Participants then described negative influencing factors or barriers as well as positive influences or enablers to the provision of optimal pharmaceutical care for participant-selected statements. The written statements, with barriers and enablers, formed the generated data. TDF was used to analyse the generated data, and this is described within study findings.

Having described data processing and extraction for the medicines reconciliation process, sections 3.3.9.7 to 3.3.9.12 will now describe data processing and extraction for Kardex/medicines review.

Focus group 1 explanatory notes for participant-selected example:

Focus group 1 opted to have additional discussion on the statement:

'No medicines reconciliation done on admission'

This statement highlighted that there was a perceived barrier to providing optimal pharmaceutical care when there was no medicines reconciliation carried out when a patient was admitted: an example was cited of a patient not being reviewed for three weeks during an admission, as the Kardex/medicines review process would normally trigger the patient prioritisation process.

The group then identified contributory factors and discussed that high numbers of new admissions could prevent a thorough medicines review being carried out:

'Too many new patients to see to achieve proper medicines reconciliation'

A second contributory factor identified described how sometimes the balance between being thorough and being efficient resulted in inadequacies:

'Trying to do 'swoop' of kardexes to identify high risks but getting stuck (e.g. due to too much knowledge/unable to prioritise)'

Participants then discussed enablers for the issue of having too many new patients, and identified that changes would require a change of culture in how the Kardex/medicines review process is carried out, and would require management support:

'Culture and management support'

A further enabler was proposed, with pharmacy technician support suggested as a means to being able to identify and prioritise at risk patients and to support in the medicines reconciliation process:

'Pharmacy technician support'

However, additional technician support may not necessarily resolve inherent or latent problems that exist within the organisation.

3.3.9.8 Focus group 2: Kardex/medicines review

The output of the discussion on Kardex/medicines review was captured as a photographic image on completion of the focus group (Figure 3.8). Focus group 2 generated five examples of suboptimal pharmaceutical care delivery in Kardex/medicines review (green post-its), with six influencing factors emerging when discussed in more depth, for the two selected examples: three negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), three positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.



Figure 3.8 Focus group 2 output: Kardex/medicines review

Focus group 2 explanatory notes for participant-selected examples:

Focus group 2 opted to have additional discussion on the statement:

'Pharmacy/clinical team's expectations'

Participants suggested that certain contributory factors created barriers, including other staff members making assumptions about how processes are carried out:

'Making assumptions'

and that there was not always consistency between the way processes are carried out between different clinical pharmacy team members;

'Mixed messages within one team'

The participants suggested enablers to these including a consistent approach to training:

'Rotation packs for team' [a pack that includes specific training relevant for service area, available in some areas but not all]

And an improved initial induction process for each service area to ensure clarity in roles and responsibilities:

'Team specific induction to make expectations clear'

Finally, participants concluded that there was a need to improve leadership in setting clear criteria for pharmacy:

'Clear criteria for pharmacy as a whole'

A second statement was discussed by participants that referred to the wider expectations of the multidisciplinary team in relation to the purpose of the medicines review process:

'Multidisciplinary team's expectations'

Participants identified that a contributory factor for this, and a barrier to the provision of optimal pharmaceutical care was:

'Ongoing need for team specific criteria'

Indicating that communication was required to clarify roles within the multidisciplinary team, including pharmacists. No enabler was identified during discussion.

3.3.9.9 Focus group 3: Kardex/medicines review

The output of the discussion on Kardex/medicines review was captured as a photographic image on completion of the focus group (Figure 3.9). Focus group 3 generated eight examples of suboptimal pharmaceutical care delivery in Kardex/medicines review (green post-its), with six influencing factors emerging when discussed in more depth, for the two selected examples: one negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), five positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.

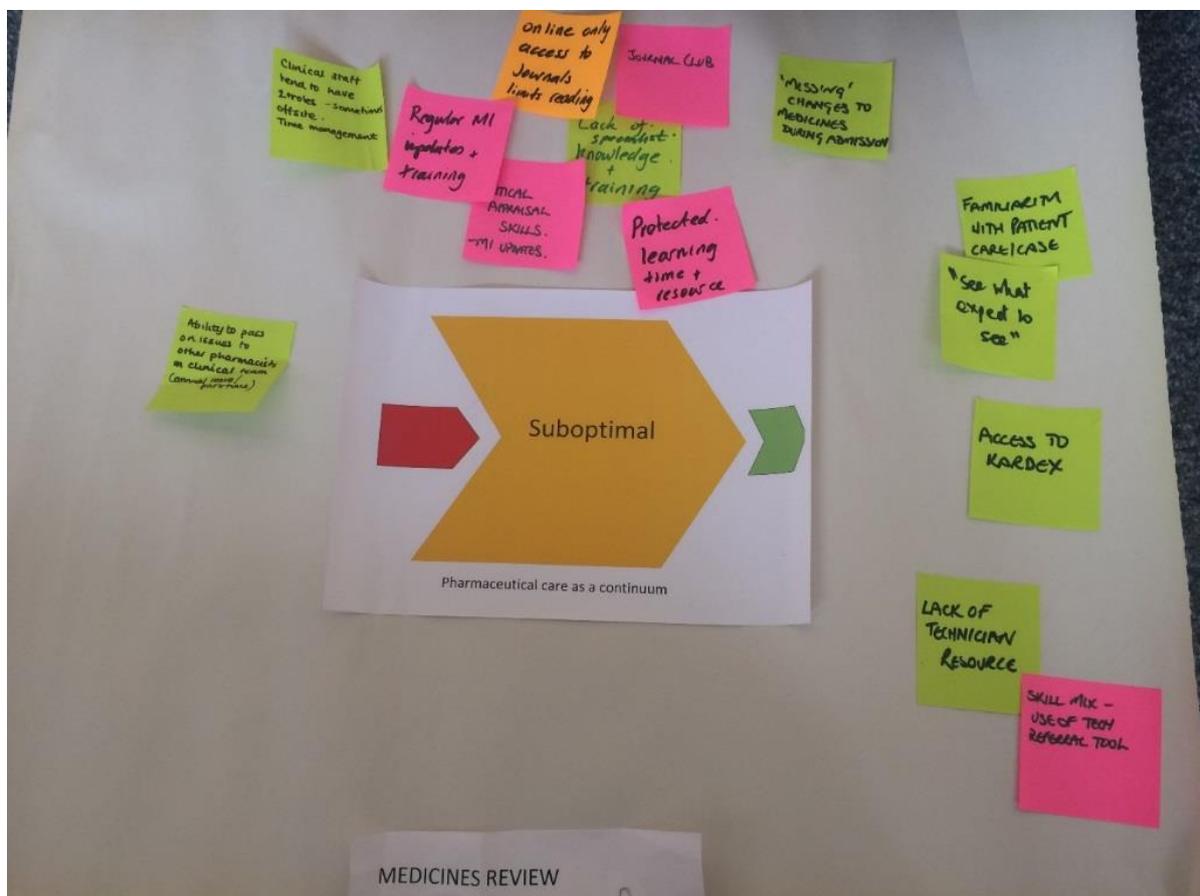


Figure 3.9 Focus group 3 output: Kardex/medicines review

Focus group 3 explanatory notes for participant-selected examples:
Focus group 3 opted to have additional discussion on the statement:
'Lack of technician resource'

This statement reflected perception by participants that a technician resource would enable at risk patients to be identified, and that some other competing tasks like supply could be managed by suitably trained technicians:

'Skill mix, use of technician referral tool'

A second statement was selected for further discussion, relating to the need for specialist knowledge to provide an adequate medicines review:

'Lack of specialist knowledge and training'

This was felt by some participants to be in part due to a lack of journal articles available in an easy to access format:

'Online only access to journals limits reading'

Participants discussed enablers to ensure specialist knowledge was shared, using local expertise:

'Regular MI updates and training'

In addition, participants discussed enablers as skills that could be developed to assist in developing specialist knowledge:

'Critical appraisal skills'

And further discussed how the skills could be acquired, by providing protected learning time and availability of resources:

'Protected learning time and resource'

Finally, participants described as an enabler, the introduction or reintroduction of a process where learning can be shared across the team:

'Journal club'

A journal club is a meeting where participants take turns to share the latest evidence within their field.

3.3.9.10 Focus group 4: Kardex/medicines review

The output of the discussion on Kardex/medicines review was captured as a photographic image on completion of the focus group (Figure 3.10). Focus group 4 generated five examples of suboptimal pharmaceutical care delivery in Kardex/medicines review (green post-its), with eight influencing factors emerging when discussed in more depth, for the two selected examples: four negative influencing factors or barriers to provision of optimal pharmaceutical care (orange), four positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the two selected examples.



Figure 3.10 Focus group 4 output: Kardex/medicines review

Focus group 4 explanatory notes for participant-selected examples:
Focus group 4 opted to have additional discussion on the statement:

'Timely review – staff availability, competing priorities'

This reflected the perception by participants that availability of staff was sometimes a barrier to the timely review of medicines, especially where there

are competing priorities on pharmacist's time. A contributory factor was identified as a lack of resource, both of Doctors and of pharmacists:

'Lack of pharmacist resource; lack of Dr's to follow up'

Without access to a doctor to follow up on issues, there can be a delay in changes being made to the Kardex.

A further factor identified referred to missing and incomplete documentation that could make the process of medicines review difficult:

'Lack of documentation to support review'

And

'Incomplete TRAK notes, time added unknown'

Enablers to the process were perceived by participants as additional resource:

'More staff would help, variety of staff grades and clinical technicians'

A second statement was discussed by participants which described how building of skills and experience, through training and supervision is required to provide optimal pharmaceutical care in the medicines review process:

'Experience of pharmacists to know what should be followed up- competence/experience/training'.

Further discussion identified barriers to gaining skills, with infrastructure of the intranet, and availability of accurate information identified as barriers:

'Access to modify available information on e.g. clinical intranet, intranet not user friendly, e.g. out of date policy, guidelines.'

A further barrier was identified that refers to understanding when additional support may be needed:

'Knowing when have reached limit of knowledge'

Participants suggested enabler for these barriers, including:

'Training/education (ongoing and on the job)'

And suggested peer review sessions on relevant topics to expand knowledge and understanding:

'Peer review on how we work-topics of interest'

Finally, participants reflected on how better use of IT could help to access relevant and pertinent information to make the process of medicines review optimal.

'Good IT resources would help – access to evidence- based information and up to date guidelines'

3.3.9.11 Focus group 5: Kardex/medicines review

The output of the discussion on Kardex/medicines review was captured as a photographic image on completion of the focus group (Figure 3.11). Focus group 5 generated seven examples of suboptimal pharmaceutical care delivery in Kardex/medicines review (green post-its), with five influencing factors emerging when discussed in more depth, for the one selected example: one negative influencing factor or barrier to provision of optimal pharmaceutical care (orange), four positive influencing factors or enablers to provision of optimal pharmaceutical care (pink) in relation to the one selected example.



Figure 3.11 Focus group 5 output: Kardex/medicines review

Focus group explanatory notes for participant-selected example:

Focus group 5 opted to have additional discussion on the statement:

'Capacity'

This reflected the participants discussion on the limited number of pharmacists available to carry out thorough medicines review. Participants went on to discuss the factors that influenced capacity, and cited occasions where other tasks take priority, with technical issues referring to medicines supply:

'Get drawn into technical issues'

Suggestions by participants of enablers to address the limited capacity included reviewing skill mix and better availability of pharmacy technicians:

'Review of skill mix, use of pharmacy technicians/upskilling'

In addition, an enabler was identified to clarify the roles that the pharmacist has within the multidisciplinary team:

'Defined role within multidisciplinary team'

A further enabler which was on a similar theme of clearer roles and responsibilities was suggested, indicating that participants did not feel that their role and purpose was always clear:

'Clinical pharmacy service aims clarified'

And finally, an enabler was suggested of improved team work and sharing learning:

'Team working -learning from each other and supporting each other'

3.3.9.12 Summary of data processing and extraction: Kardex/medicines review

In summary, written statements of examples of suboptimal pharmaceutical care were generated from the five focus groups for the topic of Kardex/medicines review (N=32). Participants then described negative influencing factors or barriers as well as positive influences or enablers to the provision of optimal pharmaceutical care for participant-selected statements. The written statements, with barriers and enablers, formed the generated data. TDF was used to analyse the generated data, and this is described within study findings.

3.3.10 Situational and environmental data

Situational and environmental data was recorded during the study. The duration of each focus group was available from the digital recorder, and the day and time of day noted in the field notes.

The duration of focus groups ranged from 45 minutes 21 seconds to 53 minutes 9 seconds, and were all completed within the planned time of one hour. Three focus groups took place in the morning and two in the afternoon. Rooms were all booked on the hospital site that the participants worked at. This meant that participants did not have to spend time travelling, and additionally increased their level of environmental comfort. Distraction and interruption was minimised by using rooms other than their normal office environment. The focus group discussions took part during June and July 2017, on working days for the participants.

By describing in detail the situational and environmental data from the study, the readership can assess the generalisability and transferability of the study, as is described below.

3.3.11. Techniques to enhance trustworthiness

Chapter 2 described how to build trustworthiness in qualitative research. The principles for building trustworthiness of credibility, transferability, dependability and conformability apply to focus group discussions.

Credibility can be assured by the way the study design is described, and when the description includes detail of setting and context, transferability can be assessed by the readership. The dependability of the study can be assessed through knowledge and awareness of the conduct of the study. Finally, confirmability can be built into design to ensure the participants voices are being heard, and this can be assessed by looking at the way data is generated, and by reviewing data, data interpretation and discussion.

The way a study design is described varies between studies, and Orvik et al (2013) have argued that the description of situational factors is important in strengthening credibility, confirmability, dependability and transferability of the findings from focus group research (Orvik et al 2013). The work of Orvik et al developed further a quality framework described by Vicsek (2010) to be used for the evaluation of focus group results (Vicsek 2010). Orvik et al suggested the addition of three further situational factors to Vicsek's original six part framework, leading to a suggested nine point quality framework (Table 3.3). This quality framework will enhance trustworthiness when considering the design of focus group methodology, and the nine points, and the action taken in this study to ensure compliance with the framework are shown in Table 3.3.

Table 3.3 Quality framework of situational factors for focus group discussions (adapted from Vicsek 2010; Orvik et al 2013)

Situational Factor	Reasoning examples	Action taken in study
Interactional factors	Social influences, conflict avoidance, 'groupthink', conformity	Recorded in field notes. Homogenous groups, all pharmacists from same site, of mixed levels of experience. Aware that juniors may be less inclined to participate and encouraged throughout session to do so. Use of a facilitator to help.
Personal characteristics	Demographics, prior knowledge of topic	Demographics collected with consent. Study was on pharmaceutical care and the participants were practitioners and had prior knowledge of topic.
Moderator/facilitator influence	Style, control, prior knowledge of topic	Facilitator well known to participants, and had previous experience, and was also a practitioner having prior knowledge of topic.
Environment	Room set up and location, interruptions, level of formality	Room details recorded in field notes, as were interruptions. Style discussed in advance.
Time factors	Time of day and duration	Recorded on field notes.
Content	Style of question, prior knowledge sent out or imparted during session	Topic guide, discussion between researcher and facilitator.
Psychological safety	Familiar setting, trust in investigator	Took place at known location, with researcher and facilitator known.
Ethical issues	Informed voluntary participation and consent, difficult topics	Consent obtained, reference made to patient safety issues at consent.
Organisational factors	Constraints, support from employer	Support obtained from organisation. Planned around work schedules.

In describing the situational factors that the study incorporated, using the quality framework (Vicsek 2010; Orvik et al 2013) the readership can ascertain the trustworthiness of the research, and assess how transferable the findings will be to their own setting.

3.4 Findings from Phase 1 focus groups

Having described in detail the study design and the methods used for the focus group discussions, this section will describe the findings of the study, including participant demographics, key findings, and the synthesis and interpretation of the findings.

3.4.1 Demographics of participants

The demographics of the participants for each of the five focus groups were collected using the demographic collection form (Appendix 3.3) and are described in Table 3.4. In the context of hospital clinical pharmacy, staff band describes the level of experience of the participants, with Band 6 being more junior pharmacists, and Band 8 more senior.

Table 3.4 Focus group participant demographics

Focus group	1	2	3	4	5	TOTAL
No of participants	3	5	4	4	4	20
M/F	3 F	5 F	1M 3F	2M 2F	1M 3F	16F 4M
Staff Band	3 x Band 8	3 x Band 8 1 x Band 7 1 x Band 6	2 x Band 8 2 x Band 7	1 x Band 8 2 x Band 7 1 x Band 6	1 x Band 8 2 x Band 7 1 x Band 6	10 x Band 8 7 x Band 7 3 x Band 6

The sample was drawn from the population of hospital clinical pharmacists in the NHS Scotland organisation. The sampling intention was for there to be a range of levels of experience in each focus group, to ensure that all experience levels of pharmacist were represented, and this was achieved. From the twenty pharmacists in the sample, eight were independent prescribers at the time of the focus groups, and this was representative. The ratio of male to female participants (1:4) was representative of the study population.

3.4.2. Data presentation: Framework analysis to TDF

Thus far, the data from each focus group and for each topic has been considered separately, to capture the input and the voice of participants; the reasons for this were outlined in 3.3.5. The generated data is presented as transcribed in Appendix 3.12, for each topic, and for each focus group, including written and verbal output.

The next two sections will present the findings from framework analysis to TDF, where themes and subthemes were generated from the data, firstly for medicines reconciliation (3.4.3) and then for Kardex/medicines review (3.4.4).

3.4.3 Findings: Framework analysis to TDF - medicines reconciliation

As described in 3.3.7, the transcribed written statements from each of the five focus groups were mapped to the TDF by the researcher and a member of the research team. For medicines reconciliation there were five dominant TDF domains representing recurrent participant comments across all five focus groups (Table 3.5). These were environmental context and resources, knowledge, social/professional role and responsibility, skills and memory, attention and decision-making.

Table 3.5 Frequency of TDF domain occurrence for Medicines Reconciliation topic

TDF Domain ↓	Knowledge	Skills	Social/professional role & identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention, decision-making	Environmental context & resources	Social influences	Emotion	Behavioural regulation
Total	13	9	10	1	0	0	0	1	0	6	34	0	0	0

The key recurring themes (TDF domains) and subthemes identified during framework analysis for medicines reconciliation are now presented, followed by description of absent and discordant themes.

3.4.3.1 Environmental context and resources domain – medicines reconciliations

Environmental context and resources

Subthemes to emerge from the environmental context and resources domain included time factors, lack of policy or procedure, lack of resources including poor IT access, and insufficient staff resource combined with conflicting priorities, and these are each described and represented by illustrative quotes:

Time factors

Focus groups discussed time factors as a barrier to providing optimal pharmaceutical care with medicines reconciliation, and this became a subtheme. There were references to difficulty in completing the task of medicines reconciliation in a timely manner:

'Timeliness' [completing within appropriate timescale] [Focus Group 3 – written statement]

Focus group 2 discussed the continual need to obtain a balance between efficiency and thoroughness, with one group participant describing their individual approach of thoroughness over efficiency:

'I always think it's better to see less patients and try and finish what you're doing with each patient' [Focus Group 2 – verbal quote]

Other participants within the same focus group, however, took a different approach of seeing more patients less thoroughly. Discussion did not find a consensus and this variation was summarised as:

'time issues-more patients less intensely or less patients done well?' [Focus Group 2 – written statement]

It was perceived by participants that there was variation across different teams, and at different sites, and that there was a lack of guidance as to what the approach should be.

Lack of policy or procedure

Focus groups described the implications of a lack of formal policy or procedure . Focus group 1 described how on occasion inappropriate sources of information were used:

'inappropriate source' [Focus Group 1; written statement]

Participants described how there was no policy or procedure to clarify, for example which sources of information are optimal for carrying out medicines. There was tacit acknowledgement that two sources were best practice:

'There's not a policy that says which sources, it just says two sources'*
[Focus Group - verbal quote] *refers to Scottish Government chief executive letter outlining requirements for medicines reconciliation (Scottish Government 2013)

On the same theme, there were several references to the ECS (emergency care summary) throughout the focus groups, either being out of date:

'Out of date ECS' [Focus Group 2 – written statement]

or being incomplete or incorrect:

'incomplete or wrong ECS' [Focus Group 1 – written statement]

Since the ECS is one of the primary sources that is used for medicines reconciliation, if the incorrect information is used at the outset, this will have compounding effects on the process. There was further discussion by participants from Focus Group 1 on the lack of definition of how and where medicines reconciliation should be documented. A statement was made as an exclamation by one individual, and was met with indications of approval by other participants:

'I mean, where do you keep a med rec?-, there's just no consensus!'
[Focus Group 1; verbal quote]

The inconsistency on the location of information will manifest when patients move between healthcare settings, and between different hospitals, and will have implications for the efficiency of the process if time is required to locate documentation. [Since the research took place, paper records of medicines reconciliation have been superseded by electronic recording of the task.]

Poor IT access

Focus group participants highlighted that there were issues carrying out the medicine reconciliation task when there was a lack of access to computers.

'Access to computers' [Focus Group 5 – written statement]

There was an understanding and awareness amongst participants that other members of the multidisciplinary team would also want to access the system, and this affected their behaviour:

'I can't sit there and do that like for every patient and hog the computer'
[Focus Group 3 – verbal quote]

The lack of access to a computer would mean that documentation of the task could not be completed at the time, but would need to be completed back in the pharmacy department:

'you can't record in real time due to lack of access' [Focus Group 3 – verbal quote]

Lack of in the moment access to a computer was described as being a factor in individuals not remembering to complete the electronic record retrospectively, and this is discussed further within the memory attention and decision-making domain. [Since the research took place, additional IT resource has been provided].

Insufficient staff resource and conflicting priorities

Focus group discussions included references to insufficient staff resource to be able to conduct medicines reconciliation. Sometimes lack of resources was perceived to be due to staff numbers or skill mix, and sometimes due to conflicting priorities on the resources:

'Pharmacy staffing – priorities' [competing priorities on time] [Focus Group 3 – written statement]

Focus group participants discussed how perceived conflicting priorities contributed to them not completing tasks:

'so, you don't actually finish the process, not through lack of following the process, or lack of skill, but because of other priorities pulling you away'
[Focus Group 3 – verbal quote]

3.4.3.2 Knowledge domain – medicines reconciliation

Knowledge

Subthemes to emerge from the theme of knowledge included knowledge of medicines, and patient health literacy.

Knowledge of medicines

When discussing the medicines reconciliation process, participants highlighted that there were occasions when medicines were missed by doctors conducting

medicines reconciliation, due to lack of recognition (knowledge) of their status as medicines:

'Health care professionals and patients not recognising medicines as medicines – e.g. patch, pill, inhaler, ointment' [Focus Group 1 – written statement]

There was further discussion between focus group participants as to why there may be incomplete or inadequate reconciliation of certain groups of medicines, particularly medicines that were less familiar within a specialty:

'maybe they don't feel as confident when it's general medical things or maybe they are happy doing their specialist area but can't be bothered with anything outwith that' [Focus Group 1 – verbal quote]

Participants indicated that taking time to correct and complete medicines reconciliation impeded delivery of optimal pharmaceutical care.

Patient health literacy

The lack of recognition of certain items being medicines was also reported for patients, and a participant described how a specialist prescribed medicine was omitted from the medicines reconciliation process as it was not included in the usual sources access for medicines reconciliation:

'the patient forgot to mention one that wasn't listed, -and it was specialist prescribed SACT!' [systemic anti-cancer therapy] [Focus Group 1- verbal quote]

Another example was given where patients needed prompted to recall non oral medicines, for example, inhalers:

'the patient was clearly on an inhaler, it was right by them, but it wasn't recorded anywhere' [Focus group 4 – verbal quote]

3.4.3.3 Social/professional role and identity domain – medicines reconciliation

Social/professional role and identity

The theme of social/professional role and identity adequately described the findings and there were no subthemes. Participants described a lack of clarity over roles and responsibilities of different healthcare professionals involved in the medicines reconciliation process:

'Lack of understanding of medicines reconciliation and why doing it within multidisciplinary team' [Focus Group 3 – written statement]

Discussion included how ownership and responsibility for the process are not shared:

'Lack of shared ownership/responsibility' [for medicines reconciliation] [Focus Group 1 - written statement]

This was described further in relation to the pharmacist's role:

'Technically the pharmacist's role should be a verification process, but it's not.' [Focus Group 1 - verbal quote]

The lack of clarity over roles and responsibilities included discussion on variation in how the process of medicines reconciliation is carried out by the admitting doctor, how medicines reconciliation issues are not always adequately followed up and how these factors impact on the ability to provide optimal pharmaceutical care:

'some doctors do a great job and others just don't seem to think it's important and then, you know, you'll have to put in more effort and time' [Focus Group 4 - verbal quote]

Discussion also included reference to nursing staff not always understanding the role and purpose of medicines reconciliation, and not being part of the process:

'nursing staff are maybe not as involved with it, maybe see it as a doctor and pharmacist thing to sort out' [Focus Group 4 - verbal quote]

3.4.3.4 Skills domain – medicine reconciliation

Skills

Subthemes within the theme of skills included skills to conduct and to document an accurate and thorough medicines reconciliation.

Conducting

Participants described deficiencies in the skills required to conduct medicines reconciliation, including where the task was incomplete:

'Incomplete medicines reconciliation' [Focus Group 1 – written statement]

Focus group 4 described specific problems that can arise when the process is not completed due to skills deficiency:

'Kardex/ECS/Med rec don't match' [Focus Group 4 – written statement]

Where the medicines reconciliation process has not been undertaken adequately, additional time is spent by the pharmacists resolving and documenting the issue. In this situation the lack of skill was interpreted as being by the admitting doctor.

Documenting

Participants further described how poor skills in documenting the medicines reconciliation process could be a barrier.

'Not being documented adequately' [Focus Group 5 – written statement]

This statement was expanded on during the discussion, with participants describing how they may be uncertain whether medicines reconciliation has been carried out, when it is not apparent from the patient's current record on TRAK:

'the process might have happened but it's not clear that it has' [Focus Group 5 – verbal quote]

This may then lead to duplication of effort, or spending time trying to establish the status of the patient's record, and there are resource implications for this.

3.4.3.5 Memory, attention and decision-making domain – medicines reconciliation

Memory, attention and decision-making

From the theme of memory attention and decision-making, subthemes emerged of distraction, and paying attention:

Distraction

Participants discussed the type of distractions that may occur when they are on the ward:

'distractions, bleeped/called away from ward' [Focus Group 1 – written statement]

In this description, participants state that they may be called away from the ward, and how this would mean they may forget to go back and complete the task, and this was also discussed in Focus group 4:

'you can be half way through a task and then another priority comes up and you're called away, and not handed over' [Focus Group 4 – verbal quote]

Being called away may leave the task, or the documentation of the task, incomplete:

'Inability to complete medicines reconciliation' [Focus group 1 – written statement]

Paying attention

Focus group participants described how sometimes the admitting doctor did not complete medicines reconciliation adequately when they did not follow a process that ensured they covered all aspects of a patient's medicines:

'the focus can be on what they get from the GP rather than everything' [Focus Group 5 – verbal quote]

3.4.3.6 Discordant and absent themes: medicine reconciliation

During analysis of the generated data, one discordant theme emerged. This included an illustrative quote from a single focus group: a perception of being judged by other pharmacists:

'I must have all this documented before he goes to the next ward otherwise that pharmacist will think I'm terrible' [Focus Group 2 – verbal quote]

This illustrative quote was selected to illustrate a behavioural response (fear), that may influence how individuals respond to the perception of being harshly judged.

Across the five focus group discussions on medicines reconciliation, there was no mapping to TDF domains of optimism, beliefs about consequences, reinforcement, goals, social influences, emotion and behavioural regulation.

3.4.4. Findings: Framework analysis to TDF - Kardex/medicines review

As described in 3.3.7, the transcribed written statements from each of the five focus groups were mapped to the TDF by the researcher and a member of the research team.

For Kardex/medicines review there were six dominant TDF domains representing recurrent participant comments across all five focus groups, and these were environmental context and resources, skills, intentions, social professional role and identity, knowledge and memory attention and decision-making (Table 3.6).

Table 3.6 Frequency of TDF domain occurrence for Kardex/Medicines review topic

TDF Domain ↓	Knowledge	Skills	Social/professional role & identity	Beliefs about capabilities	Optimism	Beliefs about consequences	Reinforcement	Intentions	Goals	Memory, attention, decision-making	Environmental context & resources	Social influences	Emotion	Behavioural regulation
Total	9	12	10	2	0	2	2	10	5	9	26	1	0	0

The key recurring themes (TDF domains) and subthemes identified during framework analysis for Kardex/medicines review are now presented, followed by description of absent and discordant themes.

3.4.4.1 Environmental context and resources domain – Kardex/medicines review

Environmental context and resources

Within the environmental context and resources domain, subthemes emerged relating to time factors, (describing a lack of time to do the task thoroughly); conflicting priorities (describing distractions on the ward, being called away to other tasks); capacity (describing the high turnover of patients relative to the staff resource available) and these subthemes are described here:

Time factors

Focus group participants cited time factors as being a barrier to conducting Kardex/medicines review:

'Time pressures' [Focus group 5 – written statement]

Also, time to complete the process thoroughly:

'You don't have time to check, like say non-formulary prescribing, there's just not time, you have to just make sure it's safe' [Focus Group 5 – verbal quote]

There were certain tasks that formed part of Kardex/medicines review that were perceived to take additional time, and impede the completion of reviews:

'sorting out unlicensed medicines and non-formulary- that all takes time' [Focus Group 4 – verbal quote]

Conflicting priorities

Focus group participants described conflicting and competing priorities for pharmacist involved in Kardex/medicines review:

'staff availability, competing priorities' [Focus Group 4 – written statement]

Other groups discussed the challenges of balancing how they spend time on medicines related activities, and whether to prioritise medicines reconciliation or Kardex/medicines review:

'depends on whether you think it is suboptimal. Say you've got half an hour to whip round, what is better use of your time – to 'med rec' two patients or to nip round 16 kardexes and make sure there are no

overdoses, drug interactions, anything that is going to cause harm' [Focus Group 2 – verbal quote]

Capacity

Participants described how capacity (the ability to carry out tasks within available resource) was a factor in being able to conduct medicines reconciliation:

'Too many new patients to see to achieve proper medicines reconciliation' [Focus Group 1 -written statement]

Other participants described how high patient turnover had an influence on task prioritisation, with high patient turnover leading to less thorough reviews:

'due to patient turnover in xx, it's maybe more risk reduction: look at Kardex, everything's fine, move on' [Focus Group 2 – verbal quote]

There is reference here to how capacity, and shortage of time leads to conflicts for participants, in knowing how and where to prioritise their time.

There was discussion within the focus groups of staffing resource shortages, influencing capacity and affecting ability to complete Kardex/medicines review, and this was described both for pharmacists:

'Lack of pharmacist resource' [Focus Group 4 – written statement]

And for technicians:

'Lack of technician resource' [to identify at risk patients] [Focus Group 3 – written statement]

3.4.4.2 Skills domain - Kardex/medicines review

Skills

Within the skills domain, subthemes emerged relating to skills in conducting Kardex/medicines review, communication skills in communicating the process, and time management skills.

Conducting

Focus group participants described some of the skills required to conduct accurate and complete Kardex/medicines review:

'Locating appropriate resources to answer questions' [Focus Group 1 – written statement]

Participants also described how the skills they used in Kardex/medicines review had evolved organically, rather than following a protocol or guideline, despite priority coding having been introduced:

'I aim to see every Kardex every day and then kind of prioritise with my own internal system' [Focus Group 5 – verbal quote]

Other participants described how there would be variation in the competence of pharmacists carrying out the task of Kardex/medicines review:

'Experience of pharmacists to know what should be followed up-competence/experience/training' [Focus Group 4 – written statement]

In this situation, it would be expected that pharmacists will bring different levels of experience and competence to the task, and clear guidance would be needed to ensure that the task could be completed adequately.

Focus group participants also described how the ability to prescribe would facilitate the Kardex/medicines review process, through the ability to resolve minor issues in the moment:

'there are issues you'd be able to sort out yourself if you were a prescriber' [Focus Group 4 – verbal quote]

Communication

Focus group participants described how communication of the process of Kardex/medicines review had challenges:

'I can't get access to a computer and I think, I'll do it later, and maybe don't, or I think I'll do it tomorrow, or half complete and then not go back' [Focus Group 4 – verbal quote]

Participants also discussed how the convention of signing a Kardex to communicate that it had been reviewed was sometimes not done, but acknowledged that the action of not signing was not as described in procedures:

'I might not be inclined to sign off a Kardex in a situation where I have 20 minutes to see 20 patients...like as a communication tool – I haven't signed off because I haven't been able to do all the checks I want to do. But this is just something I have set up for myself' [Focus Group 2 – verbal quote]

Failing to communicate what has been reviewed, and to what extent, may lead to duplication in work by other pharmacists when they encounter the Kardex. It

was perceived by participants that doctors may not comprehend the use of a signature to indicate that a review had taken place.

Time management

Participants in some groups had discussion around time management:

'Time management' [as a barrier to conducting medicine review] [Focus Group 3 – written statement]

and the discussion included challenges in finding the balance between being efficient and thorough, and this has some overlap with 'conflicting priorities' above:

'Priority review vs comprehensive' [Focus Group 5 – written statement]

And:

'as a pharmacist I find it very difficult not to get bogged down in the first Kardex' [Focus Group 1 -verbal quote]

This theme, indicating uncertainty on how to balance time and effort continued, with participants discussing their dilemmas:

'maybe sometimes I am trying to go into too much depth; I've got too much knowledge and not enough time' [Focus Group 1 – verbal quote]

Although time factors and constraints, and conflicting priorities are an organisational issue, as described above under environmental context and resources, time management is a skill, and participants describe both lacking the skills, and not knowing how the organisation wants them to manage their time in relation to tasks.

3.4.4.3 Intentions domain - Kardex/medicines review

Intentions

The theme of intentions adequately described the findings, particularly around participants expressing their intention to review Kardexes at the frequency defined by the priority coding:

'I may plan to see a patient but then don't' [Focus Group 5 – verbal quote]

Participants discussed how complying with the patient prioritisation process created concerns when they were unable to see a patient in the timescale intended:

'suboptimal is not reviewing the patient in the timescale that you think is right' [Focus Group 1 – verbal quote]

The priority coding system (described in Chapter 1) acts both as a means of prioritising activity, and prioritising patients at risk. Participants expressed that whilst the intention to comply with priority coding exists, other barriers, as described, may get in the way of meeting the target.

3.4.4.4 Social professional roles and identity domain - Kardex/medicines review

Social/professional roles and identity

Two subthemes emerged from the social/professional role and identity domain: roles and responsibilities and access to healthcare professionals.

Roles and responsibilities

Focus group participants highlighted the poor definition of the role of the pharmacist within the multidisciplinary team:

'Defined role within multidisciplinary team' [Focus Group 5 -written statement]

and a perceived expectation by the MDT that certain roles would be undertaken:

'Multidisciplinary team's expectations' [Focus Group 2 – written statement]

Participants however described how the nature of those expectations was not always clear:

'I want to know what is expected of ME!' [Focus Group 2 – verbal quote]

Discussion continued, with specific reference to the aims of the clinical pharmacy service requiring clarification, to ensure pharmacists and other members of the multidisciplinary team were aware of specific roles falling within the clinical pharmacy service.

'Clinical pharmacy service aims clarified' [Focus Group 5 – written statement]

Access to healthcare professionals

Participants described how inability to discuss issues with the prescribing doctor could lead to delays:

'lack of Dr's to follow up' [Focus group 4 – written statement]

This could mean duplication of effort, and an inability to resolve problems identified during the Kardex/medicines review process:

'sometimes you're waiting for a decision to be made, you've flagged up issues but they haven't been acted on and there's no one around' [Focus Group 4 – verbal quote]

Delays in resolving pharmaceutical care issues could lead to patients continuing to receive inappropriate medicines.

3.4.4.5 Knowledge domain - Kardex/medicines review

Knowledge

The theme of knowledge adequately described the findings, particularly in relation to lack of knowledge due to limited experience.

Participants of focus groups described how they did not always feel prepared when starting in a new speciality, lacking knowledge of how to prioritise patients who needed reviewing:

'when I started in (x ward) I kind of just had to go, had to decide what were the priorities' [Focus Group 2 – verbal quote]

One participant described this further:

'there is an assumption made that you will know what to do, maybe of your skill set and competence' [Focus Group 2 – verbal quote]

Whilst this may be expected of a less experienced pharmacist, there was also indication that more senior pharmacists were not always confident in their knowledge, especially as they started to specialise in an area.

'Lack of specialist knowledge and training' [Focus Group 3 – written statement]

'we may be better at voicing our thoughts and our knowledge with the multidisciplinary team but we maybe don't have the level of expert knowledge we'd like' [Focus Group 3 – verbal quote]

Participants indicated that the lack of knowledge affected their ability to conduct adequate Kardex/medicines review.

3.4.4.6 Memory attention and decision-making domain- Kardex/medicines review

Memory attention and decision-making

Within the memory attention and decision-making domain, two subthemes emerged: decision making, and paying attention

Decision making

Participants described some of the stages of decision making that were sometimes omitted when carrying out Kardex/medicines review:

'Not checking blood results where appropriate [for medicines the patient is on]; Not checking route of administration is appropriate; Not actually seeing patient to assess risk factors e.g. NG tube, weight (high or low) IV cannula' [where review carried out remotely] [Focus Group 1 – written statement]

Paying attention

Focus group 3 participants described how the process of Kardex/medicines review could sometimes become overfamiliar with longer stay patients, leading to less thorough review, and how this can lead to missing errors:

'so, you know the patient really well, and you look at a Kardex and you see what you expect to see, and you miss the glaringly obvious transcription error' [Focus Group 3 – verbal quote]

Participants also described some of the challenges in remembering to go back and complete an interrupted task:

'I can't get access to a computer and I think, I'll do it later, and maybe don't, or I think I'll do it tomorrow, or half complete and then not go back' [Focus Group 4 – verbal quote]

3.4.4.7 Discordant and absent themes – Kardex/medicines review

During analysis of the generated data, one discordant theme from a single focus group discussion was identified, relating to perceived criticism from other pharmacists if the Kardex/medicines review task not completed thoroughly:

'I was told – you saw this patient and you missed this – and it might have been for a million different reasons and I found that very difficult' [taken as criticism] [Focus Group 1 – verbal quote]

Although this theme was not discussed in other focus groups, it mirrors the discordant theme identified in a different focus group for medicines reconciliation – a fear of being negatively judged by colleagues.

Across the five focus group discussions on Kardex/medicines review there was no mapping to the TDF domains of optimism, emotion and behavioural regulation.

3.5. Discussion

Having outlined the findings of the study, the discussion section will outline the key findings for each topic discussed: medicines reconciliation and Kardex/medicines review, and start to interpret those key findings in relation to the literature.

3.5.1 Key findings

This qualitative study aimed to explore how pharmacists perceive optimal and suboptimal pharmaceutical care. Not all TDF domains were mapped to, for either topic, and this was appropriate. It would be possible to artificially assign quotes to domains, as it is an iterative and interpretive process, but there is a possibility of introducing bias if the mapping process focuses on the process and not on the data generated.

Medicines Reconciliation

3.5.1.1 Key findings: medicines reconciliation

Focus groups participants identified behaviours that they perceived impeded the delivery of optimal pharmaceutical care for medicines reconciliation. The findings from the five focus groups were synthesised to determine key findings. The five dominant domains, or themes, and the emerging subthemes are described here:

Within the strongly represented environmental context and resources domain, subthemes emerged relating to time factors (lack of time to carry out medicines reconciliation thoroughly); lack of policy and procedures (to accurately describe the process); poor IT access (lack of access to computers), insufficient staff resource and conflicting priorities (including uncertainty over how the organisation wants resource to be directed).

Within the knowledge domain, a subtheme emerged relating to poor knowledge of medicines by admitting doctors when documenting medicines reconciliation, and a further subtheme of poor patient health literacy.

Within the social/professional role and identity domain, a theme emerged relating to lack of clarity of roles of different members of the multidisciplinary team, and of other pharmacists.

Within the skills domain, a subtheme emerged relating to a lack of skills required to conduct medicines reconciliation thoroughly, including skills in accessing all the appropriate information relating to the patient and their medicines; a second subtheme related to documenting the activity appropriately. There was perceived variation in competency in these skills across both doctors and pharmacists.

Within the memory, attention and decision-making domain, subthemes emerged relating to distractions (forgetting to complete the task if distracted or pulled away to other tasks), and to paying attention (whilst conducting task – by doctors).

Kardex/Medicines Review

3.5.1.2 Key findings: Kardex/medicines review

Focus groups participants identified behaviours that they perceived impeded the delivery of optimal pharmaceutical care for Kardex/medicines review. The findings from the five focus groups were synthesised to determine key findings. The six dominant domains or themes and the emerging subthemes are described here:

Within the environmental context and resources domain, subthemes emerged relating to time factors, (describing a lack of time to do the task thoroughly); conflicting priorities (describing distractions on the ward, being called away to other tasks); capacity (describing the high turnover of patients relative to the staff resource available).

Within the skills domain, subthemes emerged relating to lack of competency (in carrying out and documenting the process), communication skills (of communicating the outcome of the process in an understandable way), and time management skills (the ability to balance time and efficiency).

Within the intentions domain, a theme emerged relating to having intention to see patients but failing (intention prompted by priority coding process, but failing due to environmental factors of time, capacity, and other priorities).

For the social/professional role and responsibility domain, subthemes emerged relating to lack of clarity of roles and responsibilities relating to the activity, and a lack of access to other healthcare professionals to resolve issues relating to the task.

Within the knowledge domain, a theme emerged relating to lack of knowledge of other pharmacists, or of self (due to lack of experience), and how this could mean inadequate Kardex/medicines review.

Within the memory, attention and decision-making domain, subthemes emerged relating to the decision making of others (when waiting for a decision on pharmaceutical care issues by prescribers); and of paying attention, to multiple sources of information, for example, when making decisions (both for doctors and pharmacists).

3.5.2 Interpretation

Interpretation of the data will be related to the objective for this phase of the study, namely how hospital clinical pharmacists perceive optimal and suboptimal pharmaceutical care.

The intention of this phase of the study was to understand perceptions of optimal and suboptimal pharmaceutical care within the group setting. Mapping of the data to TDF allowed themes to be extracted that help to understand the perceptions that clinical pharmacists had when discussing the focus groups topics of medicines reconciliation and Kardex/medicines review, and the interpretation of these topics are described separately.

Medicines Reconciliation

3.5.2.1. Interpretation: optimal and suboptimal medicines reconciliation

Medicines reconciliation, as described in Chapter 1, is a complex activity, with responsibility shared across the multidisciplinary team, and with implications for the safety of the patient (Scottish Government 2013; National Institute for Health and Care Excellence 2015; Royal Pharmaceutical Society 2013). The complexity of medicines reconciliation, and the multidisciplinary input was reflected by discussions in the focus groups in this study around the delivery of suboptimal pharmaceutical care in medicines reconciliation. The paucity of qualitative research in medicines reconciliation in the UK is reflected by the low number of comparator studies.

Frequent references were made by study participants to a lack of staff resource and to insufficient time to conduct medicines reconciliation. The complexity of the task, including accessing multiple sources of information required to conduct a thorough medicines reconciliation can mean that the process of medicines reconciliation can be time-consuming, and be a resource-intensive task. Al-Hashar et al reported that 47% of pharmacists in their qualitative study in Kuwait perceived that time and staff resource would be a barrier to the implementation of medicines reconciliation (Al-Hashar et al 2017), and this is supported by the findings in this study. Whilst in the current study, in contrast to the Kuwait study, medicines reconciliation has already been implemented in

the organisation, participants of focus groups identified time and resource as barriers that impede the delivery of optimal pharmaceutical care within the medicines reconciliation process.

The findings of the current study are similar to those identified in a study on barriers to medicine reconciliation in Ireland (Redmond et al 2020), where lack of description of process, and poor IT systems to support the process were described as barriers. In addition, studies in the USA have shown that the complexity of the medicines reconciliation process, and the multiple steps involved, can be a barrier to its implementation (Van Sluisveld et al 2012). This was reflected by the findings in this study, with participants describing lack of consistency of approach within teams, and shortcomings in the documentation supporting the multi-step process as barriers to optimal medicines reconciliation.

The absence of policy or comprehensive process description was cited by participants as creating uncertainty in roles and responsibilities both for participants as pharmacists, and for other healthcare professionals. Although high level policy direction on medicines reconciliation exists in Scotland in the form of a Chief Executive Letter (CEL) (Scottish Government 2013), local policies and procedures that describe roles, responsibilities and local arrangements across all disciplines were perceived as being absent within the organisation. Participants in the current study referred to unclear professional role definition as causing barriers to the delivery of optimal pharmaceutical care with medicines reconciliation. Poor definition or agreement on roles of different member of the multidisciplinary team has been cited as a barrier for the implementation of medicines reconciliation in other studies (Al-Hashar et al 2017; Lee et al 2015).

Study participants described how lack of knowledge about medicines by some doctors created a challenge for pharmacists when conducting medicines reconciliation. Lack of knowledge of medicines by doctors, and particularly junior doctors, has often been cited in literature about the causes of prescribing errors (Ross et al 2013; Avery et al 2012). Poor health literacy of patients was also cited in this study as being a barrier to optimal medicines reconciliation, and health literacy has previously been reported as a barrier in relation to medicines reconciliation (Persell et al 2007).

Poor knowledge and low self-reported self-efficacy in the medicines reconciliation process were described in a US qualitative study of doctors and pharmacists (Boockvar et al 2011), and the findings of this current study also reflect a perceived lack of knowledge and awareness in relation to the medicines reconciliation process. The current study did not find examine self-efficacy, as self-reporting is not a feature of a focus group discussion.

During the focus group discussions, it became apparent that there were different approaches between pharmacists, and between clinical pharmacy teams, in how medicines reconciliation was conducted. Some opted for efficiency, and seeing more patients less thoroughly, and others opted for thoroughness, seeing fewer patients more thoroughly. Striking a balance between efficiency and thoroughness has been described for the process of medication reviews in GP practices (Duncan et al 2019). The qualitative study in three practices, with GPs and GP practice pharmacists, described how both GPs and pharmacists perceived that pharmacists were more thorough but less time efficient than GPs when conducting medicine reviews. The current study reflects a similar theme of efficiency vs thoroughness, albeit in a different setting, and with a different process (medicines reconciliation); in the current study there was discrepancy between participants, and a lack of agreement as which approach was preferable. The balance between thoroughness and efficiency is often discussed in relation to safety (Hollnagel 2009). Hollnagel describes how, in accordance with the efficiency thoroughness trade off (ETTO) principle, demands for productivity tend to reduce thoroughness while demands for safety reduce efficiency. Organisational clarification for pharmacists, within their teams or across the service, on how the balance should be achieved could ensure less variation in how medicines reconciliation is delivered.

In summary, there is little in the literature, particularly from the UK, regarding clinical pharmacists' perceptions of the barriers and enablers to delivering optimal pharmaceutical care in medicines reconciliation in the UK, and the current research therefore adds to the knowledge on this topic.

3.5.2.2. Interpretation: optimal and suboptimal Kardex/Medicines review

The process of Kardex/medicines review, in contrast to medicines reconciliation, is entirely carried out by clinical pharmacists in the organisation, but relies on accurate medicines reconciliation, and accurate prescribing by the admitting doctor. The aim of the Kardex/medicines review is to reduce harm with medicines and improve the effectiveness of medicines. Within the clinical pharmacy service the process for conducting a review is described in a standard operating procedure. As with medicines reconciliation, there was a paucity of qualitative research on the topic of Kardex/medicines review, particularly in the UK, to use as comparator studies.

In the current study there were frequent participant references to organisational and environmental factors, as barriers to the delivery of optimal pharmaceutical care with Kardex/medicines review. These factors included a lack of time to conduct a thorough Kardex/medicines review, conflicting priorities and capacity.

The lack of time to conduct thorough Kardex/medicines review identified in the current study concurs with the findings of a Swedish study: the study, using semi-structured interviews with sixteen hospital doctors and seven hospital pharmacists in Sweden, identified similar themes of a lack of resources (including time), and of unclear roles and responsibilities as being barriers to conducting thorough medicines review (Kempen et al 2020).

Participants described the conflict between carrying out a thorough Kardex/medicines review and being able to see multiple patients, or carry out other tasks. This dilemma was described for the topic of medicine reconciliation above as the *efficiency thoroughness trade off* (ETTO) (Hollnagel 2009). The findings of the current study in part reflect those of Duncan et al, described above, where pharmacists were more thorough but less time efficient when conducting medication reviews in GP practices. In the current study there was variation identified across participants, with some participants expressing a favour for efficiency, and others for thoroughness, and there did not appear to be organisational guidance to support either approach.

A lack of skills was identified by participants in the current study, describing poor competency in completing, documenting and communicating the activity. Poor competency in completing and documenting Kardex/medicines review, and of communicating the activity, will be detected when the patient moves downstream to another ward and a second pharmacist may observe discrepancies in the process. Within the organisation the process is currently described in operating procedures, and these may benefit from review.

It was recognised during focus group discussion that variation in knowledge impacts on ability to conduct Kardex/medicines review. In particular, discussions identified that inexperienced pharmacists will have less knowledge and fewer skills relating to the task, and may therefore be less effective. Studies that explored effectiveness of pharmacy interventions from medicines review (Graabaek and Kjeldsen 2013) and cost-effectiveness of medicines review (Gallagher et al 2014) did not report on qualitative aspects of pharmacist input, and cannot be used as comparators to this study.

Participants in the focus group discussions on Kardex/medicines review described how the priority coding system in use provided a framework that gave them an intention to see priority patients. However, environmental factors, like time constraints, and conflicting priorities, meant that they did not always get to see those patients prioritised by themselves or by other pharmacists. The findings in this study echo those of Falconer, Barras and Cottrell, in their two-phase study using focus groups (N=20) and a cross sectional survey (N=231) with Australian hospital pharmacists. The study explored attitudes and perceptions to methods for prioritising patients for pharmacist review. Participants in the study identified barriers to meeting the requirements of the prioritisation process, including organisational demands, for example patient discharge and medicines supply (Falconer, Barras and Cottrell 2019), and this was reflected by the findings of the current study, where conflicting priorities was cited as a barrier.

In summary, there is little in the literature, particularly from the UK, regarding clinical pharmacists' perceptions of the barriers and enablers to delivering optimal pharmaceutical care in Kardex/medicines review in the UK, and the current research therefore adds to the knowledge on this topic.

3.6 Recommendations

Recommendations are now made for each topic discussed in the focus groups: medicines reconciliation and Kardex/medicines review. In the context of the organisation, the two topics are treated independently: medicines reconciliation is a shared task, and recommendations are not restricted to the pharmacy service.

Recommendations are made based on established behaviour change techniques, described in Chapter 2. Chapter 2 also described the link between TDF domains and behaviour change techniques (Table 2.14). The behaviour change wheel and the COM-B model (Michie Van Stralen and West 2011) can be used to identify behaviour change techniques to address barriers which are identified when using TDF as a framework (Michie, Atkins and West 2014). Definitions and descriptions of behaviour change techniques, as interventions, were described in Table 2.12 and Table 2.13 within Chapter 2.

3.6.1 Recommendations – medicines reconciliation

For the topic of medicines reconciliation there were five dominant behavioural domains, and participants expressed their thoughts through discussion of roles and responsibilities, competence related to the task, and time constraints and staff capacity and availability. The recommended behaviour change technique for each of the dominant domains is described in Table 3.7

Table 3.7 Suggested behavioural change techniques: medicines reconciliation (adapted from Michie, Atkins and West 2014)

Key domains identified	Suggested behavioural change techniques
Environmental context and resources	Training; restriction, environmental restructuring; enablement
Knowledge	Education
Social/professional role and identity	Education; persuasion; modelling
Skills	Training
Memory attention and decision-making	Training; environmental restructuring; enablement

The findings of this part of the study, along with the suggested behaviour change techniques can be used by the organisation to generate improvements to the process of medicines reconciliation. Due to the complex nature of the medicines reconciliation process, some of the barriers identified are outwith the control of the clinical pharmacy service, and this may create challenges. The findings were available for each hospital site, as a result of the way the data was processed and analysed, and this was of benefit when the data was shared with senior management.

3.6.2 Recommendations – Kardex/medicines review

There were six predominant TDF domains identified for the topic of Kardex/medicines review, and participants expressed their thoughts through discussions on a lack of time to carry out the task properly, conflicting priorities, capacity, staff resource and experience, skills, and clarity around roles and responsibilities.

The suggested behaviour change techniques that articulate with the six predominant TDF domains are described in Table 3.8.

Table 3.8 Suggested behavioural change techniques: Kardex/medicines review (adapted from Michie, Atkins and West 2014)

Key domains identified	Suggested behavioural change techniques
Environmental context and resources	Training; restriction; environmental restructuring; enablement
Skills	Training
Intentions	Education; persuasion; modelling; incentivisation; coercion
Social/professional role and identity	Education; persuasion; modelling
Knowledge	Education
Memory attention and decision-making	Training; environmental restructuring; enablement

The findings from this part of the study, along with the suggested behaviour change techniques, can be used by the organisation to generate improvements to the process of Kardex/medicines reconciliation. The findings were available for each hospital, due to the way the data was processed and analysed and this was of benefit when the data was shared with senior management.

3.7 Strengths and limitations of Phase 1

This section will discuss the strengths and limitations of the Phase 1 study, in relation to the study design and conduct, and the analysis of study findings and interpretation.

This qualitative initial phase of the research has addressed the paucity of literature relating to suboptimal pharmaceutical care. The novel approach taken in the study ensures the content is original, providing a unique exploration of pharmacists' understanding of the concept of suboptimal pharmaceutical care. In addition, the theoretical foundation used enhances the evidence, and provides the knowledge required to move forward with developing interventions.

3.7.1 Study design and conduct

The flexibility of the focus group discussions, by using a topic guide and allowing participants to identify for themselves the aspects of suboptimal pharmaceutical care they wanted to discuss, means the discussions had breadth and depth. The use of a skilled facilitator ensured that all participants took part, and that all participants voices were part of the data generated. The adapted method, whereby written statements formed part of data generation, meant that participants had the opportunity to 'member check' the output, and this was a strength of the method design.

By conducting focus group discussions at five separate hospital sites, participants were able to discuss the novel topic of suboptimal pharmaceutical care in a safe environment with colleagues, and with trust in the researcher and facilitator created during the recruitment stage. Participants were thus able to share concerns openly, as was evidenced by the findings, and this was a strength of the study design.

The setting for the study was a single health board in Scotland, and clinical pharmacy practices in other settings may vary. In describing in detail these practices, the readership can consider whether findings will be transferable to their own setting.

When planning the focus groups, the researcher was conscious of participants taking time away from their work. The focus groups were therefore booked for one hour. Participants were advised of this in the information pack, and focus group discussions were terminated within this time frame. The limited duration of the focus group discussions, however, meant that not all written statements had negative influencing factors and positive influencing factors identified, and this was a weakness of the method. Additionally, it was not possible to extract illustrative quotes for all written statements in the adapted focus group method. Whilst this did not affect the analysis, as the written statements generated the data that mapped to the TDF, the presentation of the findings is not uniform, and is not consistent with typical qualitative data presentation that use exclusively illustrative quotes, and this could be perceived as a limitation of the study. Had the focus groups been video recorded, the process for matching the verbal illustrative quote to the written statement would have been easier.

The focus groups varied in the quality of their output, and some group participants were better at articulating their collective thoughts and ideas onto post-it notes. This was not an anticipated outcome, and could have been improved by better facilitation or clearer instructions at the outset. It was difficult to assess if data saturation was achieved, and this was a limitation of the study design. Although there was a topic guide for the overarching topics of medicines reconciliation and Kardex/medicines review, individual focus groups varied in the topics they wanted to discuss in more depth, and this meant that data saturation could not be easily assessed. A more detailed topic guide, better facilitation, and ongoing discussion with the research team after each focus group may have mitigated this.

The study utilised an adapted focus group method as described. The brief written statements on post-it notes were adequate for participants, facilitator and researcher to understand, as they understood the context and setting for the study. However, in the context of a research study, extensive explanation was needed for many of the written statements to create generally understandable data, and the time required for this was not considered in the study design. As a method of rapidly assimilating the data however, the transcription of written statements, and the subsequent extraction of illustrative quotes was successful.

The time taken for transcription was reduced from 50 hours to 20, with approximately half of the time being used to transcribe the written statements and half to extract the illustrative quotes. The extraction of illustrative quotes from the audio recordings enabled the researcher to immerse in the data in a way that the straightforward transcription of written statements did not. Overall, the adapted focus group method was beneficial to the study, and is a novel adaptation.

3.7.2 Data analysis

The study used deductive methods to analyse data using a set framework. There are known weaknesses associated with using deductive methods to analyse data, such as mapping to TDF. Coding may be restrictive and there is considerable overlap between some of the domains in the TDF (Atkins et al 2017). In addition, individual domains may be perceived differently by coders. Efforts were made to minimise this variation by the frequent comparison of coding between coders during the process. In this study the purpose was not to examine the individual behavioural determinants of participants with the aim of changing behaviour, but rather to gain insight into participant's understanding of the concept, and to explore their perceptions of suboptimal pharmaceutical care.

3.7.3 Trustworthiness and reflexivity

Research trustworthiness was assured via a number of strategies, as described within this chapter, and is considered a strength of the study. Steps were taken to promote credibility, transferability, dependability and confirmability. Strategies included: utilising methods with a favourable evidence base and deemed fit for purpose; previous experience of the researcher in audit interviews, and additional self-guided training in conducting focus groups. The detailed and accurate reporting and recording of research procedures allows these actions to be appraised by the readership. Reflexivity was enhanced through the presence of a facilitator, and the review process that took place after each focus group, where researcher and facilitator identified opportunities to improve future focus group discussions ensured that the voice of participants was represented in the generated data. In addition, reflexivity was assured

through reflective processes the researcher undertook to be aware of the effects that personal beliefs have on interpretation of data.

3.8 Conclusions

Evidence from this Phase 1 study demonstrated that focus groups were an appropriate method to use to understand the perceptions of hospital clinical pharmacists to optimal and suboptimal pharmaceutical care. Use of a topic guide that directed discussion to two patient facing pharmaceutical care tasks of medicines reconciliation and Kardex/medicines review meant that the five focus groups could have their findings explored separately, to reflect minor differences in process. This was helpful to the organisation, and highlighted differences in approach across the five hospital sites. In addition, the findings could be synthesised across the five focus groups, for each topic, to identify recurring themes.

Participants of the focus groups were able to identify aspects of medicines reconciliation and of Kardex/medicines that they perceived as being suboptimal pharmaceutical care. Participants used the phrase suboptimal in relation to pharmaceutical care, and this was perceived by the research team to be an expression of understanding and accepting the terminology, and met one key objective of this study.

With medicines reconciliation, which is a shared task, relying on the input of the admitting doctor, participants in all five focus groups identified barriers to the delivery of optimal pharmaceutical care, described within key findings.

Interventions to address the barrier of a lack of clarity of roles and responsibilities between professions include education, persuasion and modelling to encourage motivation.

With Kardex/medicines review, where the pharmacist's role is clearer, participants in all five focus groups identified barriers to the delivery of optimal pharmaceutical care, described within key findings. The barrier of poor skills in documenting and communicating Kardex/medicines review can be addressed through skills training to increase capability. Time management and resource barrier can be addressed through environmental restructuring, enablement and training to create opportunity.

In addition, for both topics, participants described personal conflict in achieving the balance between efficiency and time, and a lack of resources - of time, of people and of access to computers - as being barriers to providing optimal pharmaceutical care. These barriers can be addressed using environmental restructuring, enablement and training, to create opportunity.

The findings from Phase 1 were intended to inform the study design for Phase 2, and in preparation, an information pack for Phase 2 was prepared using key examples from the Phase 1 study (Appendix 3.10). The use of the theoretically mapped findings of the focus group to inform the next phase of the research was an objective of this study, and how this worked will be described further in Chapter 4.

Chapter 4 Phase 2: Experiences of hospital clinical pharmacists of suboptimal pharmaceutical care

4.1 Introduction to Chapter 4

This chapter will justify and describe the methods used in Phase 2 of this research, and will then present the findings from the Phase 2 study. The Phase 2 study was designed to understand hospital clinical pharmacists' experiences of suboptimal pharmaceutical care. The Phase 2 study used one to one, in-depth interviews using a semi-structured interview guide designed using the Theoretical Domains Framework (TDF). The generated data was mapped to (TDF) during analysis to identify the behavioural determinants that affect how hospital clinical pharmacists experienced barriers and enablers to delivery of optimal pharmaceutical care. Throughout this chapter, the one to one, in depth interviews conducted will be referred to generically as interviews.

4.2 Research question, aims and objectives

The overarching research question for this research was:

How do hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care?

Aims: The specific aims for this phase of the research were:

1. To explore pharmacists' experiences of the provision of optimal and suboptimal pharmaceutical care within their practice.
2. To explore the behavioural determinants relating to the provision of optimal and suboptimal pharmaceutical care using the Theoretical Domains Framework.

The supporting objectives for this phase of the research were:

1. To determine the experiences of participants with suboptimal pharmaceutical care using semi-structured interviews designed around the Theoretical Domains Framework.
2. To map the findings from the interviews to the Theoretical Domains Framework to determine behavioural determinants of participants.

3. To interpret the findings and draw conclusions of participants experiences with suboptimal pharmaceutical care.
4. To interpret the findings in relation to quality management principles, and draw conclusions relevant to the organisation.

4.2.1 Justification for use of in-depth interviews in study

The Phase 2 study built on the findings of the focus groups. In-depth interviews were selected as a method for Phase 2. The interview method has been extensively described in Chapter 2, and included interview styles, question types, and data processing and analysis methods. The use of interviews as a qualitative method in this phase of the research provided the opportunity for participants to discuss experiences that they did not feel able to in a group setting (Dejonckheere and Vaughn 2019; Bowling 2014). Participants are more likely to relate personal feelings or actions in one-to-one interviews (Robson 2011), and this was relevant to this study. It was anticipated that there would be disclosure of personal experiences with suboptimal pharmaceutical care that participants were reluctant to discuss in the focus group setting. The opportunity to obtain rich data from in-depth interviews, without the constraint that a group setting might introduce, was key to understanding the experiences of participants with relation to the provision of suboptimal pharmaceutical care and was therefore justified in this study.

4.2.2 Justification for use of Big 5 personality test in study

The personality test used in this phase of the research was intended to act as an ice-breaker, a suggested mechanism for use in interviews (Kitzinger 1995), and additionally to give insight into participant's personality. Personality type has an influence on an individual's perceptions and this was of interest in this study. Ferguson and Lievens (2017) describe how personality tests pick up on typical behaviour tendencies, particularly for those who score high on a particular personality trait. Since this research was looking at behavioural determinants, it was considered appropriate to include this step in the research at this stage. There are many personality tests available, but for the purpose of this research, with the requirements of an easy to administer, easy to analyse, self-reporting, short personality test that would give descriptive elements of personality, the

Big 5 Inventory personality test was selected by the research team (Goldberg 1990; John and Srivastava 1999).

4.2.3 Justification for use of Theoretical Domains Framework (TDF) in analysis of study data

The use of a theory in the analysis of generated data was described in Chapter 2, and again in Chapter 3 and included description of the benefits of theory when analysing qualitative data. There are additional benefits when using a theoretical framework to manage and organise the data, and when designing research tools and instruments, such as interview schedules.

Given that the focus of this phase of the study was to explore participants' experiences relating to suboptimal pharmaceutical care, it is appropriate that the underpinning for the research comes from a theoretical framework that encompasses a number of validated domains influential in behaviour and behaviour change at an individual level. The theoretical framework selected was the Theoretical Domains Framework (TDF). The application of TDF was described in Chapter 2 and again in Chapter 3. TDF is designed to determine individual behavioural determinants (Cane et al 2012), and, through the findings, to support the development of appropriate interventions (Michie et al 2014). It was the intention to use the TDF to inform the design of the semi-structured interview schedule, to create an initial framework for data analysis, and for the reporting and discussion of findings. The use of TDF was therefore justified for use in this study.

4.3 Method

4.3.1 Design of study

Phase 2 was underpinned by a qualitative research design, since the nature of the research question and aims necessitated the collection of rich and meaningful data. The research was grounded in constructivism, and used a phenomenological approach, as described in see Chapter 2.

4.3.1.1 Setting

The setting for the research study was the clinical pharmacy service in an NHS Scotland organisation, as described in Chapter 1.

4.3.1.2 Participant identification

Interviews were conducted with participants who had previously participated in the focus group discussion phase of the study, who had consented, and who had shown interest in participating in the interview phase (Figure 4.1). Phase 1 focus group discussions had explored the term suboptimal pharmaceutical care.

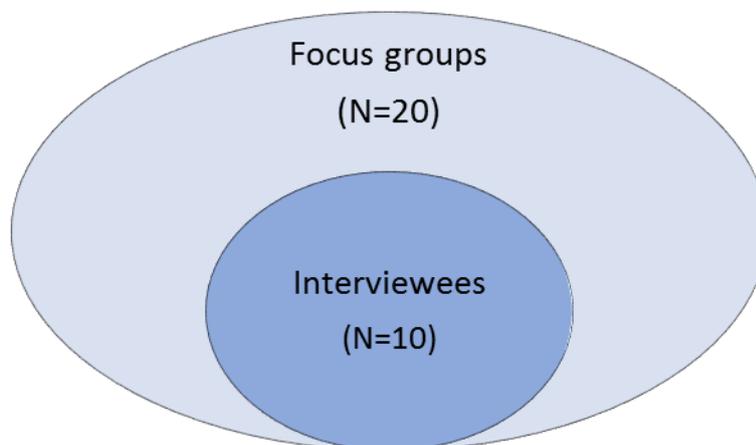


Figure 4.1 Participant sampling

4.3.1.3 Sampling plan

All participants (n= 20) from phase 1 (focus groups) were contacted by email to invite them to take part in the interviews. The sampling plan was designed around a 'rule of thumb' initial sampling plan, with data saturation, as described in Chapter 2. The initial sampling plan aimed to recruit ten participants, with a

stopping criterion of three. This is in accordance with known methods of reaching data saturation in qualitative research (Francis et al 2010). Data saturation would be determined by the interviewer and the stopping criterion identified through a review of the collected data on an ongoing basis.

There was an unplanned delay between Phase 1 and Phase 2. Two participants had left, and six participants did not respond to the first or to follow up email, leaving 12 potential participants. One potential participant then became unavailable for interview for health reasons. One participant was selected (by dates of availability) to be the stopping criterion, to be interviewed if data saturation was not achieved after ten interviews. The remaining ten participants formed the study sample (Figure 4.1)

4.3.1.4 Participant information

Interview participants were sent information in advance of the planned interview by email (Appendix 3.10). The participant information consisted of examples of suboptimal pharmaceutical care from Phase 1 focus group discussions, which had been mapped to TDF domains, as described in Chapter 3. The purpose of the advance information was to remind participants of the previous phase of the research, and to provide them with an abbreviated synthesis of the findings from across the five focus groups, in preparation for the interview phase. The extracts given in the information for participants were selected by the researcher, and confirmed by the research team as being representative of the focus group output.

4.3.2 Data collection methods

The data collection in this phase of the research was from in-depth, one to one interviews. Interviews generate data in the form of a discussion between interviewer, in this case, the researcher, and the interviewee. The data was collected using audio recording, supported by reflective field notes made by the researcher, using a template (Appendix 4.1)

4.3.3. Data collection instruments and techniques

A semi-structured interview schedule was designed, using the TDF, and informed by the findings of Phase 1. In Phase 1, participant discussion on perceptions was predominantly within the environmental context and resources domain, and the interview schedule for Phase 2 was intended to expand discussion across multiple TDF domains to capture the true experiences of participants. The interview schedule was tested on a pharmacist colleague and minor changes made to wording (Appendix 4.2)

It was not known at the planning stage if all fourteen TDF domains would be relevant to the target output as 1) there was no prior research looking at pharmacist's experiences of suboptimal pharmaceutical care and 2) there was no target output in the semi structured interview guide. Although the interview schedule (Appendix 4.2) included suggested questions for each domain, it was the aim of the interviews to enable a free-flowing dialogue, with a neutral stance by the interviewer, generating a richness of data, and thus asking all the guide questions, and covering all the TDF domains in doing so, was not seen as a priority.

In addition to the interview schedule, a personality test was prepared, which was to be administered prior to the interviews. The personality test used was the Big 5 Inventory (Appendix 4.3)

An operating procedure was prepared, to ensure all good practice elements were included for the researcher, to ensure consistency and to provide transparency in the procedure (Appendix 4.4).

A template was prepared for collecting field notes (Appendix 4.1), and included demographic information about participants, as well as space for reflective notes to be collected by the researcher during and after the interview.

4.3.4. Conduct of interviews and data generation

Having prepared the instruments for use, the researcher reflected on their personal attributes and skills in relation to conducting interviews, and carried out some self-directed learning and formal training (Appendix IV).

Communication between interviewer and interviewee was maintained via email and telephone to create rapport, and to ensure the interview would go according to plan, at the date, time and place arranged. Interviews were booked with participants at a time and place convenient for them, in locations with adequate privacy to assure confidentiality.

A standardised introduction was prepared (Appendix 4.5), intended to reduce variation, and to ensure all necessary information would be provided to participants; this stage also included confirming that consent had been given. Interviews were conducted as planned and according to the operating procedure (Appendix 4.4): The interviewees were greeted at arrival. During the standardised introduction (Appendix 4.5) interviewees were handed a Big 5 inventory personality test to complete (Appendix 4.3). Although written consent was not specifically obtained for the personality test, participants were given the opportunity to decline. On completion of the personality test, the audio recording of the interview commenced.

The interviews were audio recorded using an Olympus digital voice recorder model DS-3500, with Olympus dictation management software to transfer the files to a computer.

Interviews were conducted according to the sampling plan of 10+1 (ten interviews booked and one held as reserve), as described in 4.3.1.3. In accordance with the plan, the researcher reviewed emerging themes after interview 3,6 and 10, (Figure 4.2) using field notes.

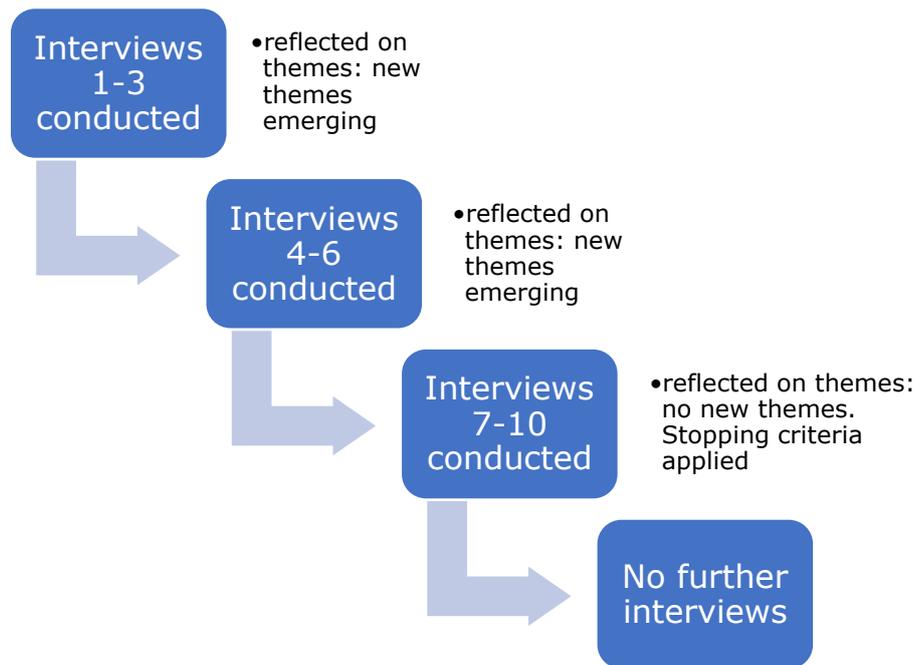


Figure 4.2 Sampling plan for interviews

The ongoing recording of field notes after each interview was conducted to allow data saturation to be determined, by enabling reflection on emerging themes, and was included as generated data (Appendix 4.8).

4.3.5 Data processing

The primary data was generated in the form of digital audio files, and these were transferred to a secure computer location using the Olympus dictation management software (ODMS), and then deleted from the digital audio recorder. The interviews ranged in duration from 19 minutes 14 seconds to 35 minutes 26 seconds: this information was available from the digital audio files. Stored audio files were accessed for transcription. Seven audio files were transcribed, using intelligent verbatim method, by the researcher and three by an external agency. The transcripts from the three externally transcribed interviews were checked against the audio file for accuracy once received and any corrections, amendments or gaps (for example, the names of drugs) completed.

Data in the form of personality test scores was generated by the completion of the Big 5 inventory personality test (Appendix 4.3) by individuals at the start of the interview. The forms were stored securely until accessed to calculate the personality test scores. In this study, scores were calculated and compared to

the participant cohort. For the Big 5 personality test, scores were calculated using the Big 5 inventory scale scoring schedule (Appendix 4.6)

4.3.6 Data management and storage

This section will describe how data management procedures were followed to ensure that individuals' details and data remained confidential, and how participant privacy and anonymity were protected.

4.3.6.1 Protecting confidentiality

Interview data, the audio files, the personality test forms and the transcripts were kept securely to protect the confidentiality of participants.

4.3.6.2 Anonymity

The data was anonymised by referring to the interviewee by numbers one to ten. Identifiable information, such as the audio recording, was deleted from the audio recorder immediately after the file had been saved to a secure location.

Three of the audio-recorded interviews were transcribed by an external agency, and these were sent as encrypted password protected files.

Each audio file had a unique reference and a secure master file was created that matched the audio file to the interviewee as a numeric representation (1-10) to ensure that the data was anonymised but could be traced back for audit or data integrity purposes.

Each personality test result was matched with the transcript for the interviewee and numbered one to ten. Names of participants were not recorded on the personality test forms.

4.3.6.3 Privacy of participants

Demographic information about participants was collected as necessary for the research, and kept securely. Once transcribed, the demographic data collection that linked data to individual participants was destroyed. Personality test information was collected for the research, the personality test score calculated for each interviewee, and the forms were then destroyed.

4.3.7 Data extraction

The data extraction method was protocol driven and agreed in advance by the research team.

4.3.7.1 Data extraction – interviews

Firstly, the transcribed interviews were mapped to TDF by the researcher and two members of the research team. To ensure consistency and objectivity in coding to the TDF, transcripts were coded, as shown in Table 4.1. The researcher coded ten interview transcripts, one team member coded five transcripts and the other team member coded six to allow a three person interrater reliability and verification process for interview 6 (4.4.2). There was agreement within the team that an illustrative quote could be mapped to multiple TDF domains.

Table 4.1 Coding schedule for mapping of interviews to TDF

Interviewee	1	2	3	4	5	6	7	8	9	10
Researcher	√	√	√	√	√	√	√	√	√	√
Coder 1						√	√	√	√	√
Coder 2	√	√	√	√	√	√				

4.3.7.2 Data Extraction -personality test data

Secondly, the personality test scores were calculated and recorded as described in 4.3.6 using the Big 5 inventory scale scoring schedule (Appendix 4.6). The scoring was carried out by the researcher, and a sample checked by a colleague.

4.3.8 Data analysis

Data analysis was conducted, commencing with familiarisation of data and mapping to TDF for interviews, and with calculation of personality test data and these steps are now described.

4.3.8.1. Data analysis - interviews

The interview transcripts were analysed using a framework approach, using TDF as the main theoretical underpinning framework. In addition, the whole

transcript was checked frequently to determine if further data extraction to the TDF domains, themes or subthemes could be made. This 'checking back' was done repeatedly as the findings were analysed, and ensured that participants' voices were adequately represented.

After mapping to TDF, the process of data extraction continued, grouping themes and subthemes together from within and across the TDF Domains. This step was done by the researcher, with ongoing verification by the research team that the themes and subthemes were clear and appropriate. This step is conventional when using a theoretical framework. The data extraction and initial analysis method is summarised in Figure 4.3.

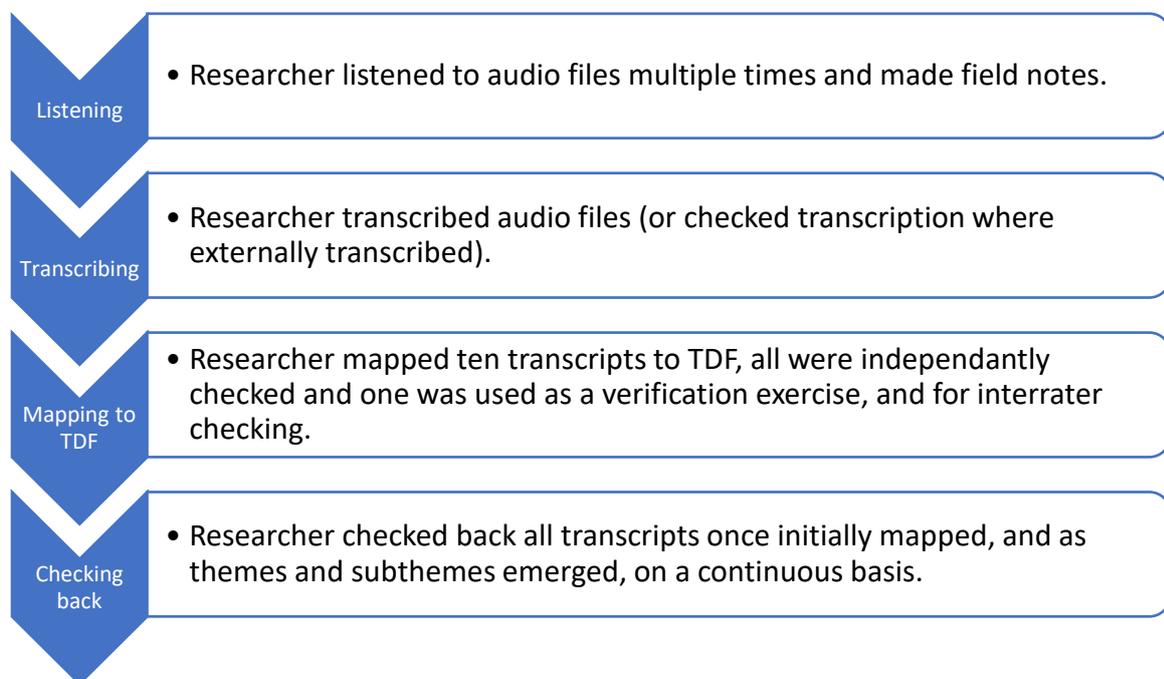


Figure 4.3 Schematic of data extraction and analysis process

4.3.8.2 Data analysis: personality tests

As described (4.3.5), personality test scores were calculated for each interviewee (Table 4.2). For purposes of this study, the scores were compared across the cohort to ascertain personality types for participants (Figure 4.4), and the scores and the comparison were used in creating individual profiles for participants (4.4.1). A report of individual personality test scores was sent to each participant using a template (Appendix 4.7).

Table 4.2: Big 5 inventory personality test scores for interview participants.

Interviewee / Score	1	2	3	4	5	6	7	8	9	10	Ave	Max	Min
Extroversion	33	27	24	21	29	37	28	38	30	26	29.3	38	21
Agreeableness	42	32	43	37	39	39	37	37	39	31	37.6	43	31
Conscientiousness	25	33	33	24	41	41	29	30	43	35	33.4	43	24
Neuroticism	13	31	19	21	20	25	29	23	16	33	23	33	13
Openness	41	27	35	24	31	45	31	33	33	42	34.2	45	24

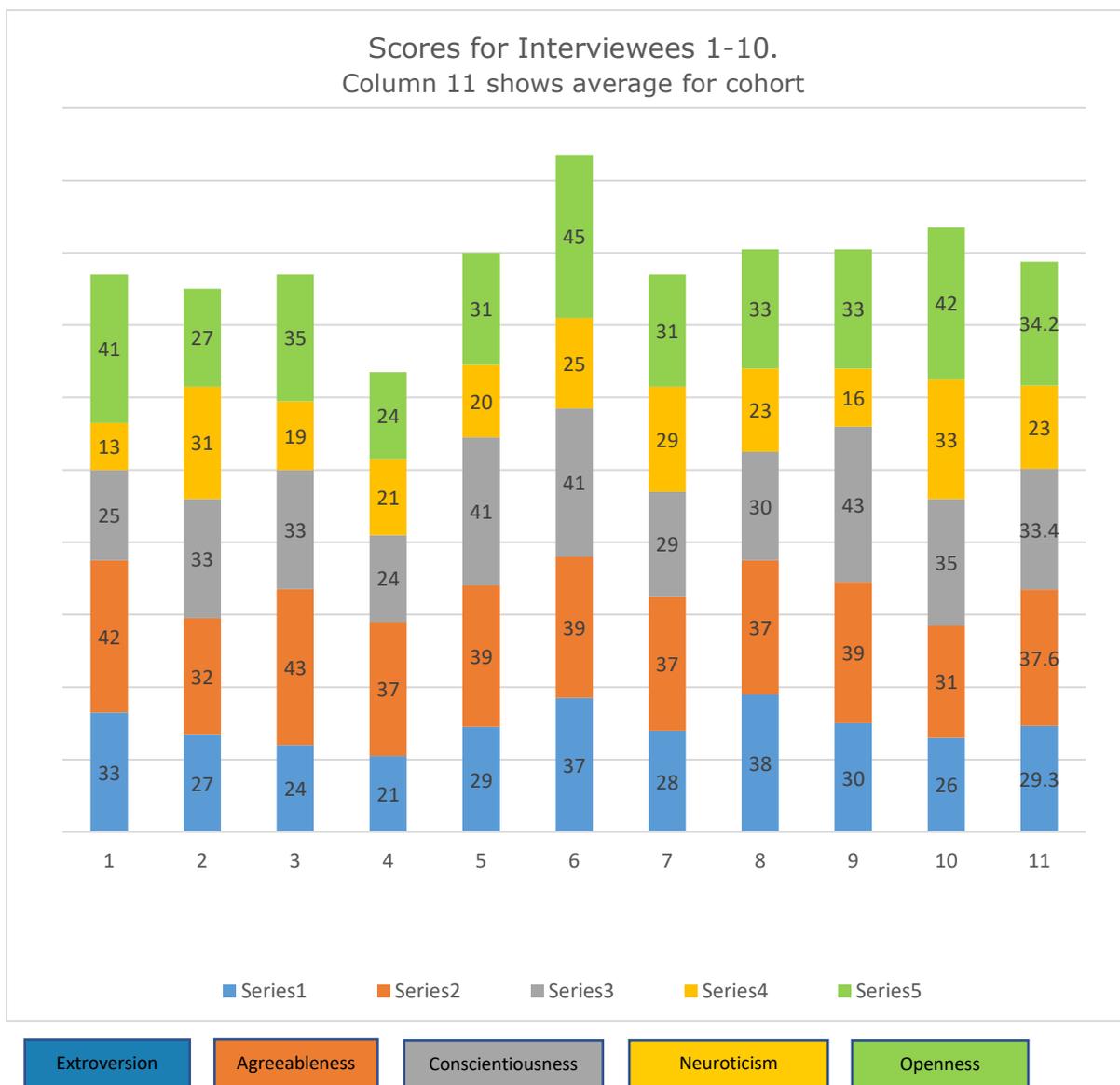


Figure 4.4 Personality test scores for interviewees

4.3.9 Situational and environmental data

Situational and environmental data was recorded during the study. The duration of each interview was available from the digital recorder, and the day and time of day noted in the field notes. The interview duration ranged from 19 minutes 13 seconds to 35 minutes 9 seconds, with up to ten minutes spent on introduction and carrying out the personality test, and were all therefore completed within the planned time of 45 minutes. Five interviews took place in the morning and five in the afternoon. Rooms were all booked on the hospital site that the participants worked at. This meant that participants did not have to spend time travelling, and additionally increased their level of environmental comfort. Distraction and interruption was minimised by using rooms other than their normal office environment. The interviews took place during March and April 2018, on working days for the participants.

4.3.10 Techniques to enhance trustworthiness

The four key components of trustworthiness are credibility, transferability, dependability and confirmability (Shenton 2004), as discussed in Chapter 2. Each component should be considered during study design to maximise trustworthiness.

Credibility describes whether the phenomena have been accurately represented by the study, giving confidence in the truth or credibility of the findings. Credibility can be increased during planning of interviews by defining and explaining the method and sampling. In this study, the method and sampling plan have been described. This study used a theoretical framework (TDF) in the design of the interview schedule, and in data analysis; the use of theory adds to the credibility of the findings.

Transferability describes whether the study could be “transferred” to other situations or contexts. Describing the study in sufficient detail to facilitate transferability, or to allow adequate understanding of the context and setting, will increase transferability. In this study, detailed descriptions of the method used, including the context, setting and participant profiles, have been described.

Dependability describes whether the study is consistent, and could be repeated, getting similar results in a dependable manner. The conduct of the interviews has been described, and detail provided on data generation and analysis. These details have allowed dependability to be assessed by the readership, to evaluate whether the study could be repeated in another setting.

Confirmability describes whether the study has been carried out as objectively as possible, so the results are shaped by participants and not researcher. Details have been provided of the conduct of the interviews, and generated data has been presented to allow readership to assess how well the voice of the participant has been represented. By describing reflexivity and biases at all stages of the research, the researcher can maximise confirmability. Reflexivity is described throughout the thesis and a summary provided in Chapter 5.

4.4 Findings of Phase 2 interview study

This section will describe the findings of the Phase 2 study. The findings included information about participants as demographic information, and as personality test scores. Data was generated from mapping of interview transcripts to the Theoretical Domains Framework, which was then analysed.

This section will first describe participant demographics, then interrater reliability, next, the findings from content and framework analysis of the generated data and finally the findings from the personality tests.

4.4.1. Demographics of participants

The demographics of all participants in Phase 2 in-depth interview are shown in Table 4.3, and additionally by individual personality profiles for each participant (Figures 4.5-4.14). Demographic and descriptive information is relevant when considering the transferability and dependability of the study. The site numbering reflects the numbering used in Chapter 3 focus groups.

Table 4.3 Demographics of participants for Phase 2 interviews

Interviewee	1	2	3	4	5	6	7	8	9	10
Site	4	1	2	1	1	2	2	1	4	5
Age band	45- 55	25- 35	25- 35	35- 45	35- 45	25- 35	35- 45	25- 35	35- 45	45- 55
Grade/Band	8	8	6	8	8	7	8	8	7	7
Gender	F	F	F	F	F	F	F	F	M	F

The study was conducted across the five acute hospital sites. In Phase 1, one focus group discussion was held at each of the five sites, and this was considered an important part of the sampling plan. For the Phase 2 interviews, none of the focus group participants from site 3 responded to the request to participate in interviews, at initial or follow up request. Therefore, there was no representation from site 3, which was the single site that did not participate in the interview phase of the study, and this could have introduced bias.

Participants for interviews were selected from the initial cohort of 20 pharmacists that had taken place in Phase 1 focus group discussions, where the male/female

ratio was four males to sixteen females. This is reflective of the ratio across the organisation. Having only one male participant for Phase 2 interviews is less than this 1:4 ratio, and may have had an influence on the results.

4.4.1.1 Demographics of participants – personality test results

Individual profiles of participants were created to describe the demographics of participants, incorporating the information from the Big 5 inventory personality test results (Figures 4.5-4.14). The use of the personality test scores in the individual profiles is believed to be a novel form of presenting demographic information about participants taking part in qualitative research.

Each personality trait used in the Big 5 inventory is described here (Benet-Martinez and John 1998; John and Scrivastava 1999):

Extroversion as a personality descriptor describes the spectrum from extroversion to introversion. Extroversion manifests in how an individual interacts with others: in general, extroverts draw energy from interacting with others, while introverts get tired from interacting with others and replenish their energy from being alone. In the Big 5 personality test, the higher the score the more extrovert the person. People high in extroversion tend to seek out opportunities for social interaction. They are comfortable with others, gregarious, and prone to 'doing' and being active rather than being contemplative. People low in extroversion, or introverts, are more likely to be quieter, introspective, reserved, and thoughtful.

Agreeableness describes how well people get along with others. While extroversion concerns sources of energy and the pursuit of interactions with others, agreeableness concerns orientation to others. It is a descriptor of how well individuals interact with others. People high in agreeableness tend to be well-liked, respected, and sensitive to the needs of others. They have few enemies, are sympathetic, and affectionate to their friends and loved ones, as well as sympathetic to the plights of strangers. People on the lower end of the agreeableness spectrum are less likely to be trusted and liked by others. They tend to be more callous, perhaps blunt or rude, ill-tempered, antagonistic, and sarcastic. People who are low in agreeableness are not likely to leave others with a feeling of warmth.

Conscientiousness is a trait that can be described as the tendency to control impulses and act in socially acceptable ways, displaying tendencies that facilitate goal-directed behaviour. Conscientious people excel in their ability to delay gratification, work within the rules, and plan and organize effectively. Someone who is high in conscientiousness is likely to be successful in school and in their career, to excel in leadership positions and to doggedly pursue their goals with determination and forethought. A person who is low in conscientiousness is much more likely to procrastinate, to be flighty, impetuous, and impulsive.

Neuroticism is a factor of confidence and being comfortable in one's own skin. It encompasses emotional stability and general temper. Those with high scores in neuroticism are generally given to anxiety, sadness, worry, and low self-esteem. They may be temperamental or easily angered, and they tend to be self-conscious and unsure of themselves. Individuals who score on the low end of neuroticism are more likely to feel confident, sure of themselves, and adventurous. They may also be brave and appear unencumbered by worry or self-doubt.

Openness to experience has been described as the depth and complexity of an individual's mental life and experiences. It is also sometimes called intellect or imagination. Openness to experience concerns an individual's willingness to try new things, to be vulnerable, and the ability to think outside the box. An individual who scores high in openness to experience is likely to be someone who has a love of learning, enjoys the arts, engages in a creative career or hobby, and likes meeting new people. An individual who is low in openness to experience probably prefers routine over variety, sticks to what they know, and prefers less abstract styles of arts and entertainment.

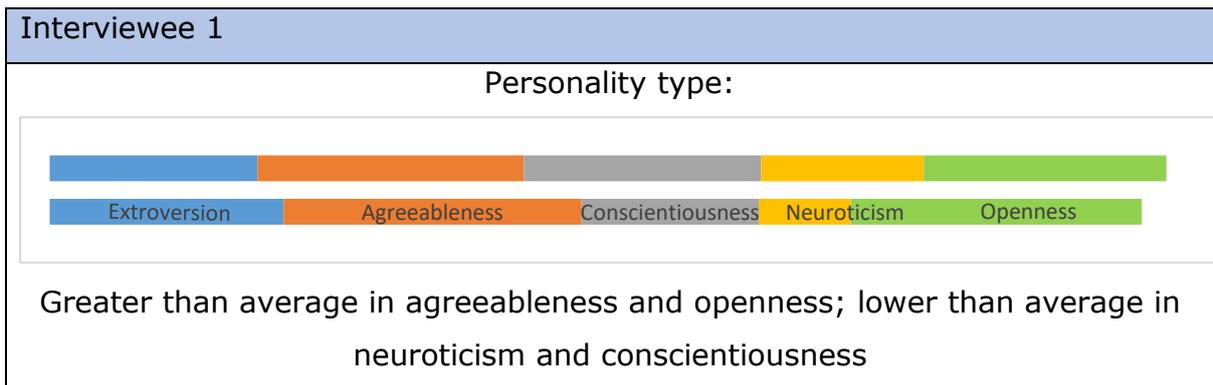


Figure 4.5 Interviewee 1 profile

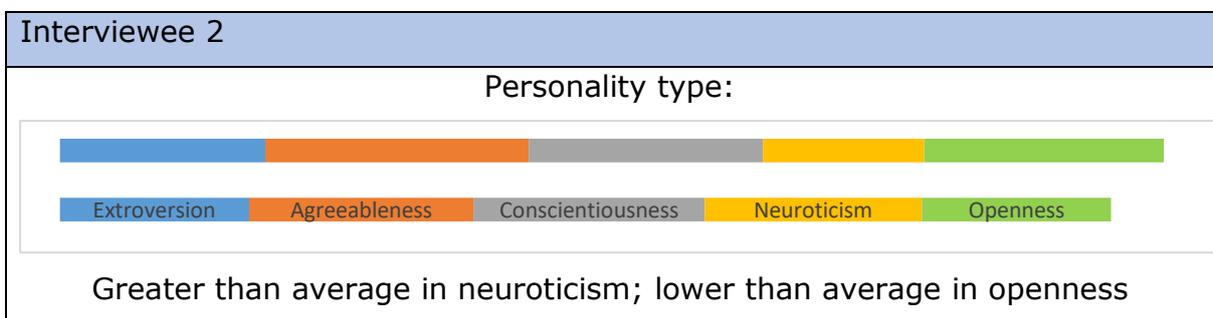


Figure 4.6 Interviewee 2 profile

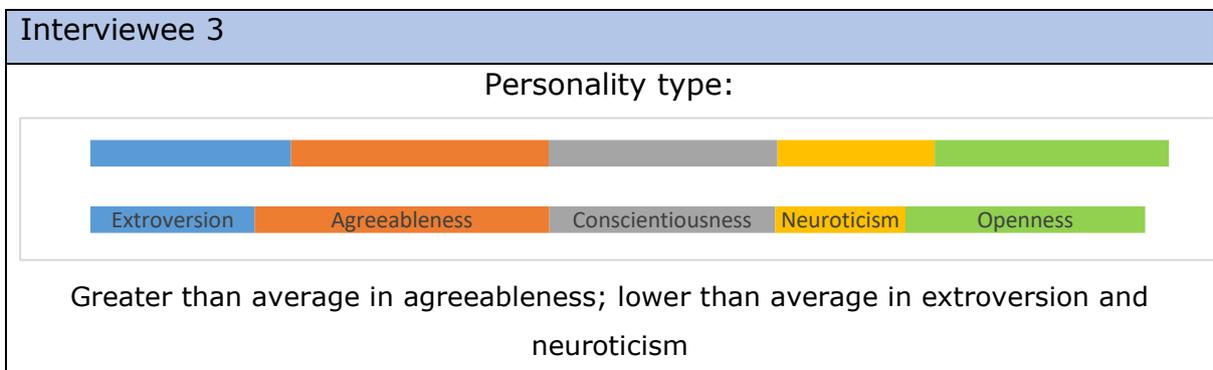


Figure 4.7 Interviewee 3 profile

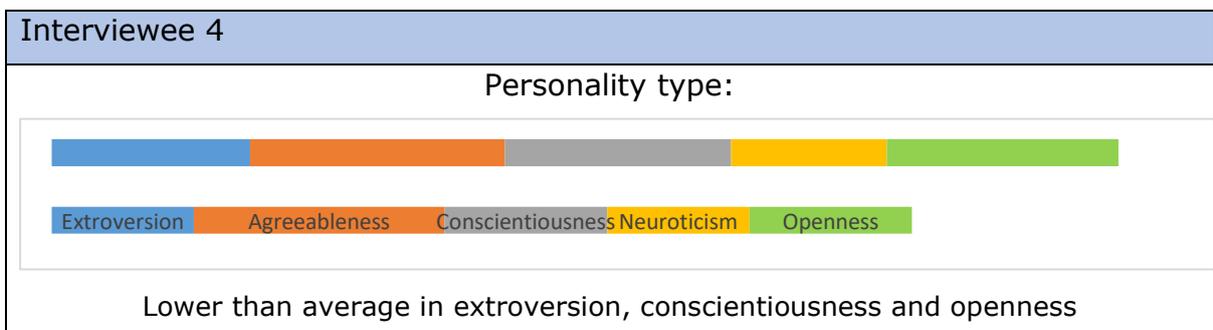


Figure 4.8 Interviewee 4 profile

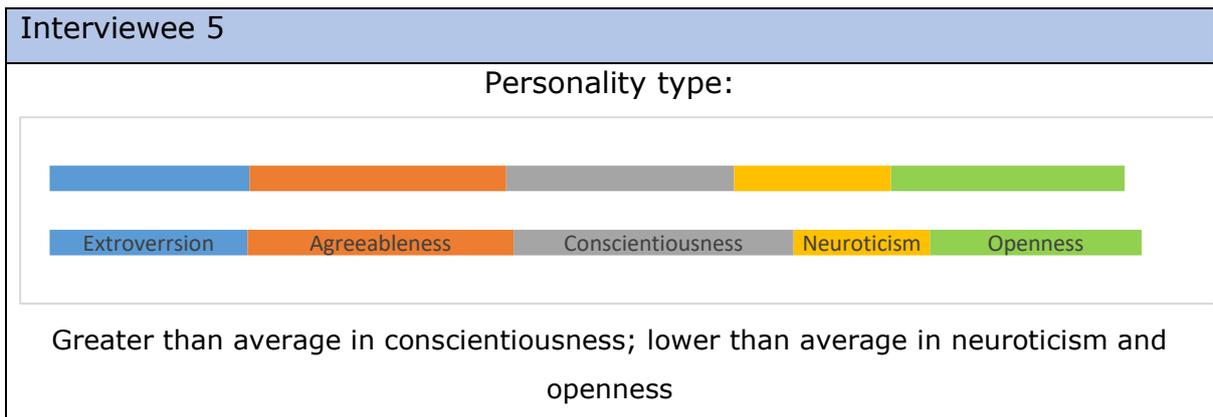


Figure 4.9 Interviewee 5 profile

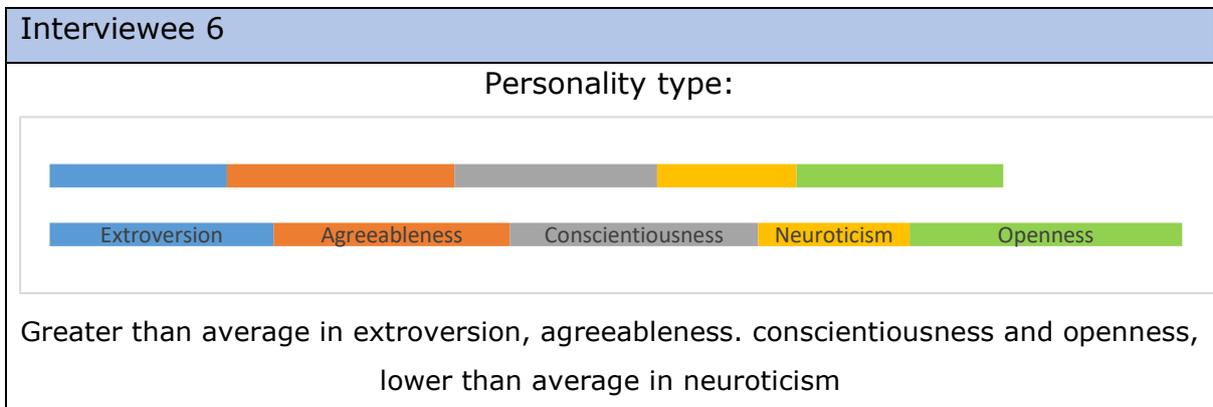


Figure 4.10 Interviewee 6 profile

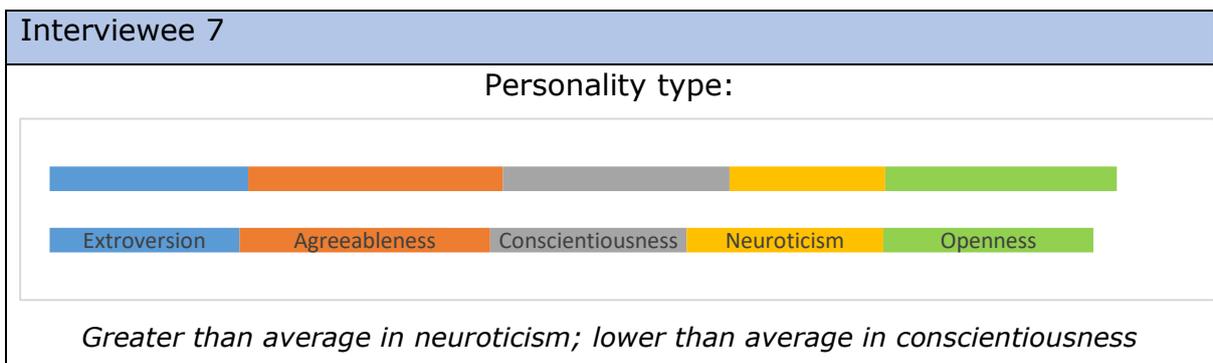


Figure 4.11 Interviewee 7 profile

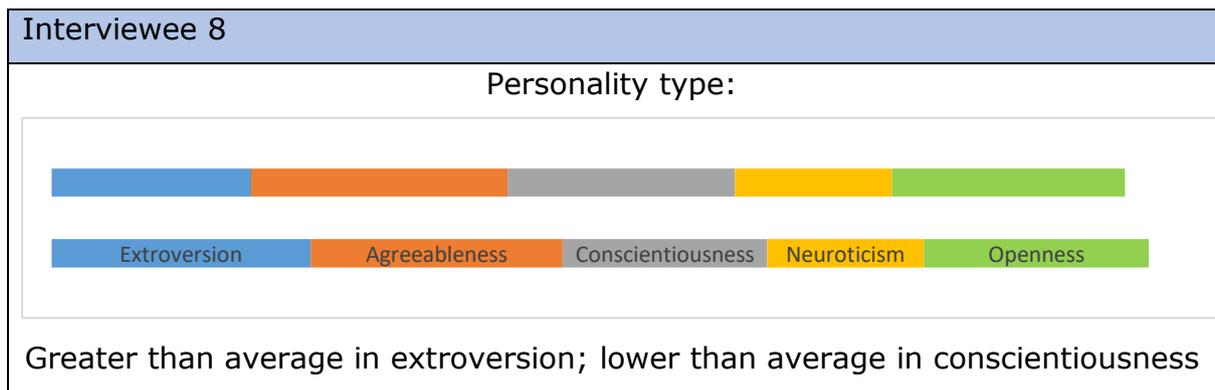


Figure 4.12 Interviewee 8 profile

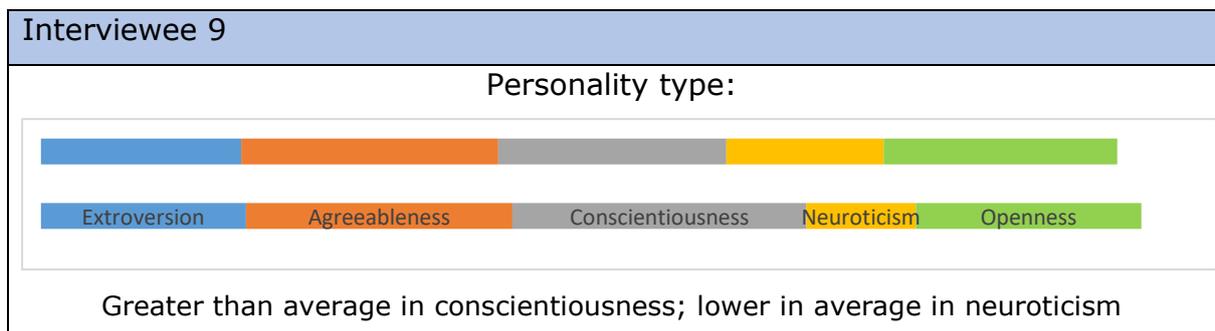


Figure 4.13 Interviewee 9 profile

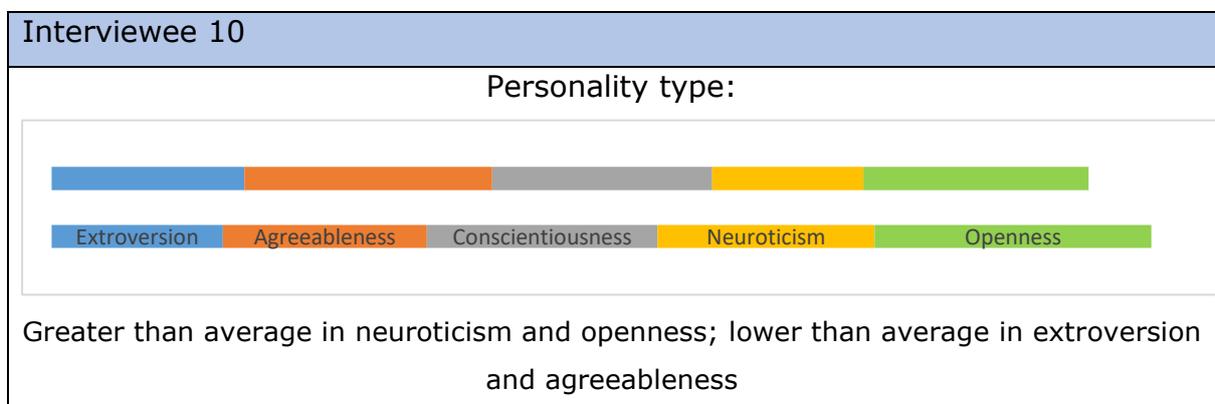


Figure 4.14 Interviewee 10 profile

4.4.2. Interrater reliability

An interrater exercise was conducted using the interview transcript that all three coders had coded to TDF, (interview 6), as described. A total of 54 quotes were extracted from the interview transcript of interview 6 by the three coders: 19 had a three from three match at first mapping; 21 had a two from three match at first mapping and the remaining 14 quotes were discussed and TDF domain(s) agreed following discussion. On discussion between the coders, it was agreed that the variation came from inexperience with the TDF (researcher), or

unfamiliarity with the process that was being described in the transcript (research team). The interrater exercise was of benefit to the researcher, and adds to the trustworthiness of the study.

4.4.3. Findings – content analysis

Content analysis of the data generated by mapping the interviews to the TDF demonstrated that there was a range in the frequency with which each domain occurred, from two instances for the domain 'reinforcement' to 75 instances for the domain 'social/ professional role and identity' (Table 4.4).

There was also variation in how many quotes were extracted for individual participants, from twenty for interviewee 3 to sixty for interviewee 6. All TDF domains were represented in the data extraction phase, although this had not been a prior requirement.

Although there is no significance attached to the frequency with which a domain is represented, content analysis may indicate which domains have provided the richest data. However, it is noted that this may be influenced by the interviewer, by the interview schedule or by the participants.

The process of coding data and extracting meaning is subjective. As a naïve researcher, starting with the TDF as an a priori framework was beneficial as it gave the process an initial structure and allowed TDF domains to be established as themes, with subthemes emerging as the data was continually reviewed.

Table 4.4: Frequency TDF domain mapped to for each interviewee

sum																
← Interviewee	TDF Domain ↓	Knowledge	Skills	Social/professional Role and identity	Beliefs-capabilities	Optimism	Beliefs-consequences	Reinforcement	Intentions	Goals	Memory, attention, decision-making	Environmental context and resources	Social influences	Emotion	Behavioural regulation	
1	Count	1	9	11	5	1	4	0	3	1	3	3	2	6	1	50
2		4	8	5	1	0	2	1	1	0	2	1	1	5	1	32
3		1	3	0	1	0	4	0	0	0	2	3	1	5	0	20
4		1	3	6	5	1	1	1	2	1	4	1	1	2	3	32
5		4	4	6	4	3	2	0	2	1	1	3	2	2	5	39
6		1	6	15	6	0	2	0	3	1	2	7	2	9	6	60
7		3	4	6	1	0	4	0	0	0	1	3	7	5	6	40
8		3	4	9	1	0	3	0	0	0	1	1	4	6	11	45
9		7	2	9	0	0	1	0	0	0	2	3	7	1	3	35
10		1	1	8	2	1	0	0	0	0	3	8	3	2	9	38
	Totals	26	44	75	26	6	23	2	11	4	23	33	30	43	45	391

Note: Count = number of times illustrative quotes were identified and mapped to each TDF domain, for each interviewee

4.4.4 Findings – framework analysis

As described, the transcripts were individually mapped to the TDF, as the underpinning theoretical framework for Phase 2, using framework analysis techniques. During this exercise, the research team conferred on the process for mapping, and agreed that the purpose of the data extraction was to identify key statements that related to how clinical pharmacist experienced suboptimal pharmaceutical. It was noted that there were four areas where suboptimal pharmaceutical care could be experienced, and these are described here:

- 1) Identifying suboptimal pharmaceutical care is used as a description of the process that may happen with an individual realising that a clinical decision they have made, or a prescription they have written has an error; or where an individual observes an error in the clinical decision making or prescription writing that another pharmacist has done.
- 2) Responding to suboptimal pharmaceutical care describes the process that follows the detection of suboptimal pharmaceutical care in self or others, and may take the form of 'fixing' the identified error.
- 3) Reporting suboptimal pharmaceutical care is used as a description that covers: informal feedback between colleagues who are peers, informal feedback from a senior to a more junior colleague, or reporting or self-reporting using formal means (for example DATIX reporting system).
- 4) Reflecting on suboptimal pharmaceutical care describes the process by which individuals reflect on their own experiences of suboptimal pharmaceutical care. This may be within their own or other's practice

The findings from the data are presented initially using the TDF as a framework, and with any emerging subthemes described within each domain. All 14 TDF domains were represented by the gathered data (Table 4.4), and are presented. Specific examples of suboptimal pharmaceutical care as described by interviewees were extracted from the transcripts and anonymised and are presented in Appendix 4.9 as supplementary data.

4.4.4.1 Knowledge domain

Knowledge

There were 26 quotes from participants in the knowledge domain. The quotes were captured within the theme of 'knowledge' and two subthemes:

- 1) Lack of knowledge of what constitutes suboptimal pharmaceutical care
- 2) Lack of knowledge – expected as in training

Lack of knowledge of what constitutes suboptimal pharmaceutical care

The first subtheme emerged from recurring reference to individuals' knowledge and understanding of what would be classified as suboptimal pharmaceutical care:

'what you're providing is the, the best pharmaceutical care provision you can but, it could be suboptimal in others experience or views and that, potentially, could be due to limited experience you have or that, or could be due to lack of knowledge' [Interviewee 9 Band 7 Pharmacist]

This participant referred to lack of knowledge or experience as being an influence on whether something would be perceived as suboptimal. Other participants reiterated that it was difficult to define what was suboptimal in terms of pharmaceutical care:

'I guess it's quite difficult sometimes to define suboptimal pharmaceutical practice' [Interviewee 9 Band 7 Pharmacist]

An exception to this uncertainty appeared to be for pharmacist independent prescribers, where there was more certainty that making a prescribing error would be classed as suboptimal pharmaceutical care:

'I feel more responsible when it's my pen and it's more obvious that it would be a suboptimal pharmaceutical care issue, and it was me' [Interviewee 2 Band 8 Pharmacist]

The subtheme 'lack of knowledge of what constitutes suboptimal pharmaceutical care' also included several participants' discussions around the priority coding process being used (described in Chapter 1):

'...then it's all subjective. One person's high priority patient is another person's slightly lower priority patient. So, there is that inter-variability on how people code' [Interviewee 1 Band 8 Pharmacist]

A number of participants highlighted that the process for prioritising patients had perhaps inadvertently lead to a new area for identifying suboptimal pharmaceutical care. Priority coding has been introduced as a tool to help pharmacists prioritise how they direct their skills, and manage workload by identifying at risk patients. The tool has changed how pharmacists work but has also potentially created a feeling of poor performance, with several interviewees citing the inability to see priority patients as an example of suboptimal pharmaceutical care:

'If we or a professional colleague has reviewed a patient, screened a patient for care issues, and in their judgement, feel there are enough issues going on with that patient that we should check their status every day, check their prescription regularly, ensure that they are appropriately monitored... So, if we're not doing that? It's suboptimal' [Interviewee 1 Band 8 Pharmacist]

And:

'If there are code 1 patients, I will try my best to do it, but some days you can't. When I don't get to them I feel it is suboptimal pharmaceutical care' [Interviewee 6 Band 7 Pharmacist]

However, one participant was more circumspect, pointing out that, when at work, prioritisation is continually changing, and other tasks may become more important:

If you don't get to see them (priority 1 patients) because you've literally had so much to do that you considered to be as much a priority in your opinion, then no, I don't think that it's suboptimal. [Interviewee 7 Band 8 Pharmacist]

Lack of knowledge – expected as in training

The second subtheme emerged where some participants reported that they would sometimes identify suboptimal pharmaceutical care in others, where it appeared to be because the other person (often a trainee) did not have adequate knowledge of work practices in the area:

'She'd not been qualified that long, and she hadn't followed up something as well, and, well, I was the same, after I'd qualified' [Interviewee 3, Band 6 Pharmacist]

The benefit of this informal feedback was acknowledged by a recipient:

'when you're a junior you really benefit from that informal peer review, sort of feedback session' [Interviewee 7 Band 8 Pharmacist]

Another participant referred to a point at which you might be expected to have the required knowledge, and this is captured by the main theme of knowledge:

'probably there's a kind of middle grade where you think you should know things' [Interviewee 2 Band 8 Pharmacist]

It appears that participants felt that there was a level of experience – 'a kind of middle grade'- where they would expect colleagues to have the required knowledge to be able to deliver optimal pharmaceutical care. Beyond this level of experience, as will be indicated later in this section, 'hierarchy' and 'personal and professional barriers' may become more prevalent as determinants of behaviour that affect reporting of suboptimal pharmaceutical care.

4.4.4.2 Skills domain

Skills

There were 44 quotes identified from participants in the skills domain. The quotes were captured within two subthemes:

- 1) skills for reporting on suboptimal pharmaceutical care
- 2) skills in giving feedback

Skills for reporting on suboptimal pharmaceutical care

The first subtheme related to the skills involved in reporting on suboptimal pharmaceutical care, and participants stating that they did not have the skill set to report:

'Yeah, it's something on reflection that we probably aren't very good at and probably still aren't very good at, in terms of reporting erm incidents' [Interviewee 1 Band 8 Pharmacist]

There was reference to the practicalities of reporting suboptimal pharmaceutical care being difficult, as a skill:

'I think the practicalities of actually doing it might be difficult' [Interviewee 2 Band 8 Pharmacist] (referring to reporting of suboptimal pharmaceutical care being difficult)

These illustrative quotes demonstrate that there is an awareness amongst participants that there are occasions when suboptimal pharmaceutical care occurs, but is not reported.

Skills in giving feedback

The second subtheme identified that skills are needed to be able to give feedback to other pharmacists when you have observed suboptimal pharmaceutical care in their practice. One participant identified that they lacked skills in giving feedback or having 'difficult conversations':

'I suppose, lacking the skills to have difficult conversations...[Interviewee 4 Band 8 Pharmacist]

And another identified that they lacked the skills, felt uncomfortable crossing the professional barrier, and invoked an emotional reaction:

'I find it very difficult to feedback directly to my colleague, I don't feel comfortable to do that, emotionally' [Interviewee 6 Band 7 Pharmacist]

In these two examples, participants describe an absence or lack of skills. This is in contrast to an example given where the presence of skills to provide feedback was perceived as an enabling determinant to developing others in the team:

'although she'd covered quite a lot of the common policies in her training this one seemed to be omitted for whatever reason. So, I just caught her the next day, and showed her the protocol, and she said she'd not seen it before' [Interviewee 5 Band 8 Pharmacist]

Therefore, the 'skills in giving feedback' subtheme can be either a positive or a negative influence on behaviour.

4.4.4.3 Social/professional roles and identity domain

Social/professional roles and identity

There were 75 quotes identified from participants in the social/professional roles and identity domain. The quotes were captured within two subthemes:

- 1) personal and professional barriers
- 2) professional embarrassment

Personal and professional barriers

Participants reflected on what it meant to be a pharmacist, and expressed how they felt pharmacists were perceived as paying attention to detail. This created a barrier to disclosing suboptimal pharmaceutical care, captured by the subtheme 'personal and professional barriers':

'It would be very difficult (to disclose suboptimal pharmaceutical care), as I think as pharmacists we're known for our attention to detail'

[Interviewee 1 Band 8 Pharmacist]

This related to disclosure to the wider community of the multidisciplinary team or to pharmacy senior management.

Other participants described in their interviews how the pharmacy profession is viewed by others within the MDT, with the subtheme of 'personal and professional barriers' describing how the pharmacist may not be held accountable by other members of the MDT, and how other professions were unlikely to report on suboptimal pharmaceutical care:

'I feel like pharmacy is not judged as harshly as maybe the other professions are. Like doctors' [Interviewee 2 Band 8 Pharmacist]

and

'I don't think other professionals are very critical of us' [Interviewee 3 Band 6 Pharmacist]

Participants gave examples of why they thought there were professional barriers, and the difficulty other professions may have in identifying whether care provided was suboptimal pharmaceutical care:

'I don't think many people understand what a pharmacist truly does, I think that's the key thing' [Interviewee 6 Band 7 Pharmacist]

These two illustrative quotes are captured within the 'personal and professional barriers' subtheme, and relate to the unlikelihood of other professions identifying suboptimal pharmaceutical care.

Professional embarrassment

A second subtheme was identified that captured discussions around feelings of shame as barriers to reporting:

'I think that it (professional embarrassment) is a barrier in lots of ways to reporting' [Interviewee 4 Band 8 Pharmacist]

Professional embarrassment was also expressed by a participant when describing the disclosure of a 'silly' mistake:

'the embarrassment of admitting to the team that you've done something really silly' [Interviewee 4 Band 8 Pharmacist]

Another participant discussed their experience of disclosure, and suggested that if they had made an error, they would be selective about who they shared that with, due to professional embarrassment:

'you might sort of tell people you know well and trust, but you don't necessarily want to, won't necessarily tell everyone...' [Interviewee 4 Band 8 Pharmacist]

Professional embarrassment therefore appears to create a barrier to reporting on suboptimal pharmaceutical care, however one participant pointed out that they would overcome professional embarrassment in order to fix something that may harm a patient, or to act on suboptimal pharmaceutical care:

'did I do something wrong for those patients?... and that overrides the embarrassment that I'm like, I'm trying to fix this' [Interviewee 2 Band 8 Pharmacist]

4.4.4.4 Beliefs about capabilities domain

Beliefs about capabilities

There were 26 quotes identified within the beliefs about capabilities domain. All quotes were captured within beliefs about capabilities as a main theme and there were no subthemes.

Participants reflected on their ability and competence to identify and to report on suboptimal pharmaceutical care. However, there did not appear to be a consensus amongst participants. Some participants felt they, and other pharmacists would be competent and able to identify instances of suboptimal pharmaceutical care:

'I think we all, all pharmacists, junior and senior, have the ability to identify suboptimal pharmaceutical care. It's how comfortable people are then to report that then.' [Interviewee 6 Band 7 Pharmacist]

However, other participants were more reticent:

'I think before we find suboptimal pharmaceutical care we have to identify optimal pharmaceutical care and I don't think we've really got that yet.'

[Interviewee 4 Band 8 Pharmacist]

The quote is used here to illustrate how the lack of clarity of optimal and suboptimal in terms of pharmaceutical care can be a barrier to the capability of individuals to identify instances of suboptimal pharmaceutical care.

Some participants were unclear on their capability of being able to report. This included references to reporting by self:

'I suppose self-reporting is very difficult. That you have to blame yourself kind of' *[Interviewee 2 Band 8 Pharmacist]*

As previously described, in this situation subthemes from the social/professional role and identity domain, namely 'personal and professional barriers' and 'professional embarrassment' are determinants of whether self-reporting is likely.

Other participants referred to barriers in the reporting of others:

'to be honest unless it was something I suppose, a near miss or something very serious, generally you wouldn't feedback to the person who had seen the patient before you.' *[Interviewee 7 Band 8 Pharmacist]*

In this situation the participant appears to be using their own criteria to determine whether the instance of suboptimal pharmaceutical care that they had observed in another's practice should be fed back on, or just fixed, and this is discussed further as a subtheme (fix and forget) under the memory attention and decision-making domain.

4.4.4.5 Optimism domain

Optimism

There were six quotes in the optimism domain, and all were contained within the theme of optimism, with no subthemes.

Some participants did not feel optimistic that reporting on suboptimal pharmaceutical care would be carried out, with one participant describing their perception that there would be a reluctance by other people to report on

suboptimal pharmaceutical care, and with individual or collective attitude having an influence:

'I think it's a lot to do with attitude, erm and I think we could, but I think some, some of them (other pharmacists) would probably have excuses'
[Interviewee 6 Band 7 Pharmacist]

A further participant reflected on the unlikelihood of reporting of suboptimal pharmaceutical care, perceiving overload as being a barrier, with some suggestion of defeatism in their statement:

'you could report suboptimal pharmaceutical care all day 'cause there's always going to be something that we're going to miss.' [Interviewee 2 Band 8 Pharmacist]

The theme of optimism captured perceptions by participants that reporting on suboptimal pharmaceutical care was unlikely unless changes in attitude and behaviour took place.

4.4.4.6 Beliefs about consequences domain

Beliefs about consequences

There were 23 quotes identified in the beliefs about consequences domain and all were captured within beliefs about consequences as a main theme with no subthemes.

Participants had contrasting views on whether the consequence of reporting on suboptimal pharmaceutical care would be negative or positive, with one participant being negative about the consequences for them as an individual:

'it would require a culture shift, or a culture change for it to be accepted, I suspect like everything, I mean it's just nature isn't it, everyone's individual reaction is you know, oh I'm getting told off or I've done something wrong and you're having to disclose and you're airing your dirty laundry' [Interviewee 1 Band 8 Pharmacist]

In this example, the previously described subtheme of 'professional embarrassment' can be seen to be a barrier to reporting, unless there was a change in culture.

However, other participants felt the consequence of reporting on suboptimal pharmaceutical care would be positive:

'I think there could be some good learning from it' [Interviewee 2 Band 8 Pharmacist]

whilst another participant acknowledged that 'personal and professional barriers' could be overcome by the recognition that there would benefit overall:

'I think initially I'd be quite nervous about it, because then like everyone's basically seeing your mistake essentially, but then in the long run it would be better overall' [Interviewee 3 Band 6 Pharmacist]

Other participants discussed how senior management might view reporting on suboptimal pharmaceutical care. One participant had concerns that there may be criticism from senior management, and this reflected the 'personal and professional barriers' subtheme:

'it might just be difficult for them (senior management team) to understand how that could happen, a suboptimal episode of care for a patient. So, it might turn like a little bit too critical, when actually it's just reality' [Interviewee 8 Band 8 Pharmacist]

whilst another participant acknowledged that information on instances of suboptimal pharmaceutical care should be something that senior management know about, but were not clear how this could be achieved:

'It's quite difficult to know how to report them isn't it though? And I think probably it's vital that senior management do know that, because then the strategy, if that's what needs changed, like the pharmacy strategy, can kind of be tweaked to fit better with that, so that's what the advantages of senior management knowing these things are, that support can be from the top down' [Interviewee 8 Band 8 Pharmacist]

4.4.4.7 Reinforcement domain

Reinforcement

There were two quotes identified in the reinforcement domain, and both were captured within 'reinforcement' as a theme with no subthemes. One interviewee described how they had used their personal experience of suboptimal pharmaceutical care to provide knowledge to others, as an example of reinforcing the learning they had received themselves:

'I definitely use what I have learnt to give examples to people' [Interviewee 2 Band 8 Pharmacist]

4.4.4.8 Intentions domain

Intentions

There were eleven quotes identified in the intentions domain, and these were captured within the theme of 'intentions' with no subthemes. The TDF domain for intentions included those instances where the interviewee intended to see patients as planned, and did not or could not:

'I may have a plan that goes completely by the wayside of what I will be doing that day because of the reactive nature of the job, the bleep goes off, things change, patients change, discharges happen and, yes, ah ha, I do see that as suboptimal, if I've planned to go and see a certain patient and I don't see them, I'd see that as suboptimal. [Interviewee 4 Band 8 Pharmacist]

4.4.4.9 Goals domain

Goals

There were four quotes in the goals domain, and no subthemes; it was noted that there was some overlap between the goals domain and the intentions domain.

Participants discussed how their overall goal of seeing patients was sometimes impeded:

'I guess because I'm quite conscientious it does kind of, I do think, oh that's quite annoying I didn't get to that' [Interviewee 5 Band 8 Pharmacist]

This was sometimes described as being due to distractions or other tasks taking priority:

'Where you may have a plan of erm you know the next two hours this is what I'm going to do, you get bleeped or called for something else' Interviewee 1 Band 8 Pharmacist]

4.4.4.10 Memory, attention and decision-making domain

Memory attention and decision-making

There were 23 quotes identified by participants in the memory, attention and decision-making domain. Quotes were captured within memory attention and decision-making as a theme, and with one subtheme:

1) Fix and forget

In the theme 'memory, attention and decision-making', participants described how lapses in memory or attention contributed to an episode of suboptimal pharmaceutical care, (in this example, not providing timely counselling on warfarin), which may result in additional unscheduled work for another member of the team:

'It might be things like I've forgotten to...say...someone needs to be warfarin counselled and then it'll be a few days later and someone will have to do it in a mad rush.' [Interviewee 10 Band 7 Pharmacist]

Other participants describe how the lack of attention or remembering to go back and complete a task are behaviours that can create the environment in which suboptimal pharmaceutical care can occur:

'Sometimes there's a complete forget and you think, oh, I never ever, ever came back to that and you're too late now or, it doesn't, just gets pushed to the bottom of the list.' [Interviewee 2 Band 8 Pharmacist]

And one participant described how other, more urgent tasks, can take priority and lead to a situation where suboptimal pharmaceutical care is invoked:

'I am doing what is urgently needing my attention and, in doing so that might have slipped your mind or, you might have put at the back of your mind that I can deal with it later on and then that didn't happen for whatever reason...' [Interviewee 9 Band 7 Pharmacist]

Fix and forget

A subtheme of 'fix and forget' emerged when discussing the process of providing feedback to someone else who has delivered suboptimal pharmaceutical care

'...feeding that back to people, there could be a time constraint of actually having to, you see something, you fix it and you've got to remember to go back to somebody.' [Interviewee 4 Band 8 Pharmacist]

In this situation, the participant described memory failure as a barrier, and instead, acted to fix the issue. In the subtheme of 'fix and forget', participants described how identifying suboptimal pharmaceutical care, and acting in the moment to fix the error were dominant behaviours, but that reporting was less likely where there were time constraints, and the error would then be forgotten. Another participant however, described that if there was a more serious error then they would take time to provide feedback.

I would probably go and fix it, and then I'd just catch them whenever I next saw them and just kind of say, well if it was something that would harm the patient I would definitely highlight it to them [Interviewee 3 Band 8 Pharmacist]

The description of 'fixing' something that was observed in another's practice was referred to several times, and included 'fixing' across multiple grades and experience of pharmacist.

4.4.4.11 Environmental context and resources domain

Environmental context and resources

There were 33 illustrative quotes extracted from participants in the environmental context and resources domain. The quotes were captured within the theme 'environmental context and resources' with three subthemes:

- 1) Time constraints
- 2) Lack of access to computers
- 3) Lack of formal mechanisms for reporting on suboptimal pharmaceutical care

Time constraints

For the first subtheme, several participants referred to 'time constraints' as an issue that may lead to suboptimal pharmaceutical care being delivered, for example, not following up a pharmaceutical care issue as planned and intended:

'suboptimal- I mean a lot of it's about time pressure, it's not following up on something that you know really you should have done, and you're kind of like ach I'm sure it will be fine' [Interviewee 1 Band 8 Pharmacist]

Another participant described time constraints as a barrier to completing tasks:

'Time is always an aspect and I think that would be for me, that would, that would be the biggest one' [Interviewee 2 Band 8 Pharmacist]

Time constraints were also cited as a barrier to formal reporting on suboptimal pharmaceutical care:

'I think because of time constraints I probably wouldn't do it. I think documenting on DATIX is poorly done, people just think I'll do it later, and never do it. So, I think something else to complete, it sounds a bit pessimistic, but I just don't think it would work' [Interviewee 6 Band 7 Pharmacist]

Lack of access to computers

A second subtheme emerged, where participants cited a lack of access to computers as being a barrier, and described the consequences of this as being duplication of effort, and impact on others:

'in the course of the day, I've been really busy and I've done the discharge letter and I'm still trying to see code 1's and I've not always put it on (TRAK), because there's still issues or there's no access to computers, and of course that has an impact on someone's work the next day because they don't know it's been done' [Interviewee 10 Band 7 Pharmacist]

Lack of formal mechanisms for reporting on suboptimal pharmaceutical care

The third subtheme emerged since mechanisms for reporting are an organisational issue, and are not currently described. Whilst the lack of formal mechanisms for reporting on suboptimal pharmaceutical care was a barrier for some participants:

'I think if you do it in a more formal way, people do feel picked on, because pharmacists like to get everything right' [Interviewee 7 Band 8 Pharmacist]]

or saw that the presence of a formal process itself could become a barrier:

'if you had to do it in a formal way, as a reporter you might feel less inclined to do it. It's like DATIX, oh I don't want to get anyone into trouble, don't want to be that person that's told a tale' [Interviewee 7 Band 8 Pharmacist]

The participant here was contrasting formal means of reporting on suboptimal pharmaceutical care with informal means of providing feedback. There were multiple references to 'feedback' given during the interviews. The term 'feedback' has differing meanings in different contexts, but use here is interpreted as meaning '*giving information about performance, as a basis for improvement*' (Oxford Dictionary 2020c). As discussed previously, informal feedback may be given to more junior pharmacists, acknowledging that they will have less knowledge and experience.

Some participants expressed concern that there were no formal processes in place to provide feedback to pharmacists – particularly more experienced, senior pharmacists:

'I do sometimes worry about that, that we don't get the feedback for our own work' [Interviewee 2 Band 8 Pharmacist]

Participants also discussed means of getting more formal feedback on their performance, with two participants referring to a method used for trainees and considering that it might be of benefit for senior pharmacists too:

'But I don't have that (feedback). I remember when we first did the mini-CEX training thinking I should get (the tutor) to come and do mini-CEX with me' [Interviewee 4 Band 8 Pharmacist]

'The Mini-Cex training, the way that the juniors, for want of a better word, the way they have to demonstrate... I think that provides a much better forum for discussing these types of things. I think that would have value' [Interviewee 7 Band 8 Pharmacist]

The mini-CEX (mini clinical evaluation exercise) is a type of supervised learning event, where an individual carries out a task whilst being observed.

4.4.4.12 Social influences domain

Social influences

There were 30 illustrative quotes identified in the social influences domain.

Quotes were captured within the theme of social influences and one subtheme:

- 1) hierarchy

One participant reflected on social influences that had affected them, and how the interactions they had had with colleagues had influenced the way they now felt about giving feedback on suboptimal pharmaceutical care:

'I think that's important, from when you're a junior, having been a junior, not to feel like you're being picked on, or pulled up, because it's ok to make mistakes. We are all learning'. [Interviewee 7 Band 8 Pharmacist]

This quote illustrates the role the participant felt they now had in being a positive social influence on a more junior member of staff, and is also reflected by the previously identified 'skills in giving feedback' subtheme.

Two other participants described variation in, and barriers to, giving and receiving feedback. The first participant indicates the positive social influence that giving feedback on suboptimal pharmaceutical care can have:

'that's why I think it's such an important thing that people do receive feedback on these things. Certain people are better at giving feedback than others. I can imagine that there would be some people that would have just come and been like...(shrugs)... or like not even have told me' [Interviewee 8 Band 8 Pharmacist]

This quote also revisits the subtheme of 'skills in giving feedback'. However, a second participant identified that there were barriers involved as a determinant of behaviour in the reporting of suboptimal pharmaceutical care:

'So, then that's subjective, and you feel, well the implications of you reporting a colleague, from both a professional and from a personal issue, that's very difficult' [Interviewee 7 Band 8 Pharmacist]

This second quote also reflects how the subtheme 'personal and professional barriers' has influence.

Hierarchy

The subtheme of 'hierarchy' was created to capture a specific area of discussion that related to the influence of the relative grades of the pharmacists involved on the likelihood of giving feedback on suboptimal pharmaceutical care:

'I think when it comes to probably giving feedback to others, thinking about it, now I think I will say it will be probably easier to do that with the people who are junior compared to someone who has a lot more experience than you, because people can sometimes see it as a criticism' [Interviewee 9 Band 7 Pharmacist]

The subtheme of 'hierarchy' as a barrier when providing feedback on suboptimal pharmaceutical care was echoed by other interviewees:

'Yes, I would feel more comfortable feeding back more junior colleagues than more senior, or my peers' [Interviewee 6 Band 7 Pharmacist]

Of note is that these two illustrative quotes relating to hierarchy were from middle grade (Band 7) pharmacists. Interviewee 6 gave some insight into the reason for this behaviour:

'I think it might be perceived in the wrong way. They may feel I am judging on how they are performing their tasks' [Interviewee 6 Band 7 Pharmacist]

Not wanting to provide negative feedback on suboptimal pharmaceutical care to a more senior colleague because of hierarchical boundaries was established as a barrier. This was also reported from the recipient's perspective, in this case a more senior grade pharmacist:

'I do find that often people are reluctant to give negative feedback, so it's not always helpful. I just think they don't want to upset you or...yeah, it can be quite awkward for them' [Interviewee 8 Band 8 Pharmacist]

Whilst representing the subtheme of 'hierarchy, this quote, and others above, also reflects the 'skills in giving feedback' subtheme, for both giver and recipient of feedback.

4.4.4.13 Emotion domain

Emotion

There were 43 quotes identified from participants in the emotion domain.

Quotes were captured within two subthemes:

- 1) emotional reaction to provision of suboptimal pharmaceutical care
- 2) moral distress

Emotional reaction to provision of suboptimal pharmaceutical care

The first subtheme emerged from several participants expressing emotion when disclosing episodes of suboptimal pharmaceutical care. Emotions expressed included 'feeling terrible' when discovering they have made an error:

'I felt terrible, I felt...I felt like I hadn't paid enough attention to the patient and that could've caused them serious harm' [Interviewee 2 Band 8 Pharmacist]

And similarly, feeling 'terrified' that there would be harm to a patient:

'I was terrified! I mean oh my goodness, I made that error quite early on when I was prescribing [Interviewee 6 Band 7 Pharmacist]

There were similar negative emotions of guilt and fear of wrong doing expressed by participants when they described instances that they perceived as being suboptimal.

'And I was like ugh, god, it just makes you feel sick' [Interviewee 8 Band 8 Pharmacist]

Moral distress

One participant expressed an emotional response of dissatisfaction, when feeling unable to provide optimal pharmaceutical care when resources are lacking, and a subtheme of 'moral distress' emerged, describing the inability to do the job properly due to organisational constraints:

'I find it very emotionally wearing. I find it causes a lot of dissatisfaction with the job because you feel like you should be doing a job properly' [Interviewee 10 Band 7 Pharmacist]

Although this was a single illustrative quote, it reflected discussions by other participants of how emotions influenced their behaviour, and how anxieties about suboptimal pharmaceutical care may be taken home with them:

'Yeah I'm told oh you need to leave work at work, I mean it's getting better, but I do spend time thinking, oh goodness I haven't done this' [Interviewee 6 Band 7 Pharmacist]

'you'd go home and think oh did I do that right, and not sleep, and worry...' [Interviewee 7 Band 8 Pharmacist]

Whilst these interviewees did not express dissatisfaction, the emotions expressed indicate that participants sometimes take work concerns home with them.

4.4.4.14 Behavioural regulation domain

Behavioural regulation

There were 45 quotes identified from participants in the behavioural regulation domain. Quotes were captured in the theme of behavioural regulation and one subtheme:

1) suboptimal pharmaceutical care as a learning opportunity

Participants referred to behavioural regulation as a means of using their personal experiences of suboptimal pharmaceutical care, and taking the opportunity to promote behavioural regulation in others:

'I would definitely do it from a training point of view. Definitely. I would see that as a priority, because if they start developing habits, not intentionally, but missing that sort of thing they're never gonna learn unless someone picks up on it' [Interviewee 5 Band 8 Pharmacist]

This also reflects the previously identified subtheme 'lack of knowledge – expected as in training', with the interviewee understanding that that is a behaviour that is required for the development of others

Suboptimal pharmaceutical care as a learning opportunity

Participants described how they used their experiences of suboptimal pharmaceutical care to change their own practice:

'certainly, after that I was incredibly careful when I was checking' [Interviewee 1 Band 8 Pharmacist]

Or, that reflecting on suboptimal pharmaceutical care made them realise that internal process checks were flawed:

'it made me realise that maybe some of my subconscious warning systems were not working' [Interviewee 4 Band 8 Pharmacist]

The sentiments here are captured by the subtheme 'suboptimal pharmaceutical care as a learning opportunity' – and this can be an opportunity for learning as an individual or as an opportunity for learning for the wider community.

The opportunity for sharing experiences within the wider community was further discussed in relation to suggestions for how sharing the learning from reporting of suboptimal pharmaceutical care might translate into practice:

'and it just sort of prompts everyone to maybe be that little bit tighter in their care or approach to care and maybe change their practice a little bit'
[Interviewee 8 Band 8 Pharmacist]

'But it would be worthwhile, because then it would identify if everyone was having the exact same problem' [Interviewee 3 Band 6 Pharmacist]

'I think it could have a positive impact, in terms of especially with topics, it might identify topics for learning' [Interviewee 9 Band 7 Pharmacist]

These participants were able to describe benefits to individuals and teams of more formal reporting and of shared learning opportunities.

4.4.4.15 Summary of findings: framework analysis

To summarise the findings from Phase 2 interviews: there was uncertainty amongst participants as to what, when, whether, how or why to report on suboptimal pharmaceutical care and Table 4.5 summarises the findings. Themes and subthemes (behavioural determinants) were identified from the generated data, and the behaviours that were demonstrated by the findings are described.

Table 4.5 Key themes and subthemes from generated data from interviews

TDF Domain/theme	Subtheme	Behaviour
Knowledge	Lack of knowledge of what constitutes suboptimal pharmaceutical care	Not knowing what constitutes suboptimal pharmaceutical care means cannot report on it
	Lack of knowledge – expected as in training	Fixing of suboptimal pharmaceutical care, may or may not provide feedback (reporting) to trainee
Skills	Skills for reporting on suboptimal pharmaceutical care	Lack of process for reporting means can identify but not report; reluctance to report
	Skills in giving feedback	Other determinants impact, for example hierarchy, personal and professional barriers.
		Good feedback skills ensure lessons are learned
Social/professional role and identity	Personal and professional barriers	Other professions unlikely to identify and report on suboptimal pharmaceutical care
	Professional embarrassment	Unlikely to self-report
Beliefs about capabilities	No specific subthemes – includes overlap with others	Positive and negative beliefs that capable of identifying, (influenced by lack of knowledge of what constitutes suboptimal pharmaceutical care); lack of belief that capable of reporting (influenced by time constraints)
Optimism	No specific new subthemes	Pessimism about reporting

TDF Domain/theme	Subtheme	Behaviour
Beliefs about consequences	No specific subthemes	Positive and negative beliefs about consequences of reporting
Reinforcement	No specific subthemes	Using personal experiences to reinforce learning in others
Intentions	No specific subthemes	Intention hampered by organisational and environmental factors
Goals	No specific subthemes	Goals hampered by organisational and environmental factors
Memory attention and decision-making	Fix and forget	Likely to act on suboptimal pharmaceutical care in others but may forget to feedback
Environmental context and resources	Time constraints	Time may be a factor in providing feedback or self-reporting
	Lack of computer access	Lack of access to computers may inhibit reporting
	Lack of formal feedback process	Lack of formal process inhibits reporting
Social influences	Hierarchy	Unlikely to report more senior colleagues
Emotion	Emotional reaction to suboptimal pharmaceutical care	Distress and guilt may inhibit reporting.
	Moral distress	Reflection on inability to deliver optimal pharmaceutical care due to organisational and environmental factors causes anxiety and distress
Behavioural regulation	Suboptimal pharmaceutical care as a learning opportunity	Learning opportunity for self, on reflection, or for responding to and reporting, for others

4.4.5 Findings: personality tests

The personality test data was not collected with the intention of using in primary data analysis, as the study sample was too small to make meaningful comparisons. Personality test data was however used to profile the participants, and understand more about their personality traits. Personality traits are linked to the likelihood of adoption of behaviours, and perception (the way something is understood or interpreted (Ferguson and Lievens 2017)). Perception will differ depending on the worldview of the participant, and is influenced by personality type. Perception and the adoption of behaviours were of interest in this study.

The personality test results revealed that there was variation in expression of the five personality traits across the participants (Figures 4.5 to 4.14), and indicated that different personality type were represented by the findings. The five traits are openness, conscientiousness, extroversion, agreeableness and neuroticism (John and Srivastava 1999). Each personality trait is a spectrum: from openness to closedness, from conscientious to non-conscientious, from extrovert to introvert, from agreeable to antagonistic, from neurotic to emotionally stable. Indicative quotes revealed that personalities from opposing ends of the personality spectrum responded differently to a similar line of questioning (Table 4.6).

Table 4.6 Indicative quotes for personality traits of interviewees

Personality trait	Indicative quote	Personality trait	Indicative quote
Openness	<i>'I think it's a good thing, that we are all comfortable enough to be able to share with each other what we've done well and what we've not done so well' [Interviewee 6]</i>	Closedness	<i>'I think pharmacists are quite, as a profession, critical of themselves and each other' [Interviewee 4]</i>
Conscientiousness	<i>'I kind of know what I should be prioritising and I know that I've addressed the serious ones [Ph 5] I would definitely do it from a training point of view' [Ph 5]</i>	Unconscientious	<i>'...and you're kind of like ach I'm sure it will be fine' [Interviewee 1] 'Yes, almost like making an assumption because it's slightly easier to do that' [Interviewee 8]</i>
Extroversion	<i>'I quite like feedback and I quite often search it out, which I don't know that everybody does' [Interviewee 8]</i>	Introversion	<i>'I think within pharmacy we're maybe not good at sharing our negative experiences' [Interviewee 4]</i>
Agreeableness	<i>'I am comfortable with people telling me I have made a mistake' [Interviewee 6]</i>	Antagonistic	<i>'I'm aware of that because I can be a quite brusque person' [Interviewee 10]</i>
Neuroticism	<i>'I suppose self-reporting is very difficult. That you have to blame yourself kind of' [Interviewee 2]</i>	Emotional stability	<i>'if you have learnt something then share that with the team' [Interviewee 9] '.. and we have to let that go' [Interviewee 9]</i>

4.5 Discussion

The discussion section will outline the key findings from the data analysis, and provide interpretation of the data in relation to the aims and objectives for this study.

4.5.1 Key findings from Phase 2 interviews

Key findings will be presented for the four different areas of suboptimal pharmaceutical care that participants described: identifying, responding to, reporting and reflecting on suboptimal pharmaceutical care.

4.5.1.1 Identifying suboptimal pharmaceutical care

Participant interviews revealed determinants of behaviour that influenced how individuals identified suboptimal pharmaceutical care. A subtheme emerged from the knowledge domain of 'lack of knowledge of what constitutes suboptimal pharmaceutical care' and this subtheme expressed how participants lacked clarity in what they would consistently identify as suboptimal pharmaceutical care in their own or in other's practice. In addition, participants described a lack of definition, and the absence of a process, or of documentation that would drive the process of identifying suboptimal pharmaceutical care.

Secondly, the subtheme of 'personal and professional barriers' in the social/professional role and identity domain described how other professions would be unlikely to identify what was suboptimal pharmaceutical care. A reason given for this was that other professions were not fully aware of the role of the clinical pharmacist.

There was indication that some of the participants would view the identification of suboptimal pharmaceutical care in junior pharmacists from a different perspective than they would in a colleague or more senior pharmacist. Participants expressed a desire to provide useful feedback (reporting) when identifying suboptimal practice in a trainee. However, there was not sufficient information from the data to assess whether these participants were actively providing feedback because they were in a supervisory role, or if it was a practice they had developed from their own experiences, and used for multiple

individuals. This appears to be informal arrangement, and many episodes of pharmaceutical care take place without checking or review by another pharmacist.

Participants recognised that there was a certain level of experience that was needed before you could recognise suboptimal pharmaceutical care in others.

4.5.1.2 Responding to suboptimal pharmaceutical care

Discussions on how participants would respond to suboptimal pharmaceutical care were focussed mainly on suboptimal pharmaceutical care as identified in other's practice. The majority of participants stated that they would 'fix' something that they identified as being suboptimal. One barrier identified for responding to suboptimal pharmaceutical care was failing to remember to go back to address an issue that was observed earlier. This barrier was in the memory, attention and decision-making domain.

Participants described how they may or may not change behaviours when suboptimal pharmaceutical care was identified in their practice and they were informed. Some participants described how behavioural regulation meant that they were likely to carry out checks on their own work more carefully, if they were made aware of an episode of suboptimal pharmaceutical care, whilst others were pragmatic in stating that occasional informal feedback was unlikely to make them change behaviour.

There was limited discussion that referenced to how participants acted when detecting suboptimal pharmaceutical care in their own practice.

4.5.1.3 Reporting suboptimal pharmaceutical care

There was more expansive discussion on the topic of reporting of suboptimal pharmaceutical care than other areas. Behavioural determinants included themes and subthemes across several TDF domains. Reporting is interpreted here as including the giving of informal feedback, as well as formal feedback and/or reporting. Informal feedback was mainly described as giving verbal feedback to an individual, or occasionally of leaving a written note. Formal feedback was interpreted as reporting using the DATIX risk management

system. Again, participants referred to reporting suboptimal pharmaceutical care in terms of their own, or in other's practice.

Participants identified that lack of certainty of what constitutes suboptimal pharmaceutical care was a barrier to reporting. Exceptions included where reporting would benefit a trainee, or where there was a pharmacist prescribing error. Participants also indicated that there was an absence of formal reporting mechanisms, and a lack of definition, and that this created a barrier to reporting. Although participants expressed their intention of feeding back informally to junior pharmacists on practice they identified as suboptimal, lack of time was identified as a barrier to carrying out that intention. Other barriers that impeded the giving of feedback, informal or formal, to peers or more senior colleagues were identified as personal and professional barriers, and barriers due to hierarchy.

Participants also identified that there were personal and professional barriers to their own reporting, with professional embarrassment being given as a reason why they would be reluctant to report on an error they had made. Participants however expressed that if there was a risk to patient safety, they would be more inclined to report, and to share lessons learned.

Participants differed in their perception of whether formal reporting of suboptimal pharmaceutical care would be beneficial to the organisation, with some interviewees feeling they could overcome professional embarrassment and other barriers if the culture was different, and others being less positive about the consequences of reporting. Influence from senior management was deemed important. The potential benefits of reporting suboptimal pharmaceutical care were perceived as being for the team, to build awareness of areas for improvement, and for the senior management team, to understand the challenges faced by the team.

However, participants expressed pessimism regarding the likelihood of formal reporting being carried out, citing time constraints and the lack of a formal reporting process as barriers.

4.5.1.4 Reflecting on suboptimal pharmaceutical care

Participants described how reflecting on suboptimal pharmaceutical care in their own practice could lead to them making improvements to their own practice. Participants also indicated that they considered sharing their experience with others. This appeared to incur less professional embarrassment once time had elapsed and if the episode could be used as a learning opportunity.

However, reflecting on episodes of suboptimal pharmaceutical care was also described as invoking emotional reactions, and cumulatively, leading to dissatisfaction, and these are known antecedents to moral distress (Monrouxe et al 2015).

4.5.2 Interpretation

Interpretation of the data will be related to the aims for this phase of the study, namely to explore pharmacists' experiences of the provision of optimal and suboptimal pharmaceutical care, and to explore the behavioural determinants that relate to the provision of optimal and suboptimal pharmaceutical care.

4.5.2.1 Pharmacists' experiences of the provision of optimal and suboptimal pharmaceutical care

The interviews focussed more on suboptimal pharmaceutical care, than on optimal pharmaceutical care, in accordance with the semi-structured interview schedule (Appendix 4.2). The interviews were successful in achieving their aim of enabling in-depth discussion on the topic of suboptimal pharmaceutical care. There is a paucity of literature on suboptimal pharmaceutical care, and this study adds to knowledge. However, the lack of comparator studies mean that interpretation relies on opinion and review studies, and comparison with studies on patient safety incident reporting and error disclosure from other healthcare professions.

A key finding from the interviews was that participants were uncertain of how to define optimal pharmaceutical care, meaning that defining suboptimal pharmaceutical care was also difficult. This particularly affected the identification and reporting of suboptimal pharmaceutical care. Other authors have described a lack of agreement and definition of which components of pharmaceutical care are the most important, (Onatade et al 2018) and this was reflected in the current study.

Participants in this study stated that they did not know what or how to report, when discussing the reporting or provision of feedback on suboptimal pharmaceutical care. These findings are supported by the findings of a systematic review of the reporting of medical device adverse events, (Polisena et al 2015) where lack of awareness of what and how to report were cited as reasons for the underreporting of adverse events. Similarly, a barrier of lack of knowledge of what to report was described in a study examining barriers to

reporting adverse drug reactions through pharmacovigilance routes (Mirbaha et al 2015), and was supported by the findings of the current study.

However, despite interviewees expressing doubt at knowing what to report, and what constituted suboptimal pharmaceutical care, this was not borne out by their individual responses. During interviews, participants were able to identify and describe examples of suboptimal pharmaceutical care in their own and in other's practice (Appendix 4.9). Thus, their perception that they lack knowledge of what constitutes suboptimal pharmaceutical care can be disputed, and may instead refer to a lack of a set of definitions, or a framework, or direction from the organisation on what constitutes suboptimal pharmaceutical care, rather than lack of individual knowledge. This finding supports those of Quirke, Coombs and McEldowney, who described how a lack of definition of suboptimal care in nursing was a barrier to understanding how and when suboptimal care arises, and the antecedents that may be involved (Quirke, Coombs and McEldowney 2011). In the current study, the lack of a formal defined process for reporting suboptimal pharmaceutical care added to the uncertainty of what or how to report.

Participants described how time constraints were a factor in not reporting instances of suboptimal pharmaceutical care. This supports the findings of two UK studies investigating the provision of feedback to junior doctors on prescribing errors. In a UK study on pharmacists' attitudes towards giving feedback to junior doctors, recruits to focus groups described barriers of time and workload as influencing the likelihood that they would provide feedback on a prescribing error to a doctor (Lloyd et al 2016). Other influences were the severity of the error, with the likelihood of providing feedback increasing with the perceived severity of the error, and the availability and accessibility of the prescriber. In another UK study, Bertels et al examined the views of both pharmacists and junior doctors on feedback by pharmacists on junior doctors' prescribing errors, using a self-administered questionnaire. Doctors perceived feedback from pharmacists as constructive but irregular. Pharmacists acknowledged they were inconsistent with feedback, and cited time constraints and lack of availability of the prescriber as barriers (Bertels et al 2013). The current study did not investigate whether lack of availability of the person

receiving feedback was a barrier, and this would have been a useful addition to the interview schedule.

Senior pharmacists acknowledged that responding to and reporting back to junior members of the team on instances of suboptimal pharmaceutical care was important for the junior pharmacist's development. However, senior pharmacists expressed that they were aware that they did not have an equivalent process for themselves as senior pharmacists. Senior pharmacists also identified that they were aware that there were inconsistencies in the process of providing feedback to junior pharmacists, citing time constraints as leading to a 'fix and forget' culture. 'Fix and forget' has previously been described (Hewitt and Chreim 2015), in relation to patient safety incident reporting: the qualitative case study designed research found that most of the doctors interviewed fixed patient safety incidents themselves, and rarely reported on incidents unless there was actual harm (Hewitt and Chreim 2015). The authors concluded that better criteria could be set to guide practitioners about what and how to report, and this was reflected by the findings of this study, with lack of knowledge of what and how to report being frequently cited by participants as barriers to reporting, as previously described.

Participants in this study described that they were less likely to report back on instances of suboptimal pharmaceutical care to those more senior than themselves, although they may still act on those instances, to 'fix' them. This was described as a hierarchical barrier. In a systematic review of barriers to reporting of adverse events by nurses (Vrbnjak et al 2016), personal and professional barriers, including the power hierarchies that exist in healthcare, for example between professions, or within professions, were reported as barriers to reporting, and is supported by the findings of this study.

Participants in this study expressed barriers to the self-reporting of episodes or incidents in their own practice. Professional embarrassment was cited as a factor. In a study looking at barriers to the reporting of adverse events by doctors, embarrassment was cited as a critical barrier (Smith et al 2014). The study suggested that the embarrassment barrier could be overcome by case reporting, regularly, in a non-threatening environment, and getting feedback. In the current study participants also expressed that they would disclose

suboptimal pharmaceutical care if there was perceived benefit, and if there was an established process to follow. A further study with doctors (O'Connor et al 2010), on the disclosure of adverse events and perceived barriers, cited professional embarrassment, a lack of training, and the emotional impact of reporting as being barriers to disclosing and reporting adverse events. Professional embarrassment was also a barrier identified in a Scottish study examining the significant event analysis (SEA) process that GPs use, where GPs also expressed a reluctance to share events that may expose them to professional embarrassment (Bowie et al 2005). There was a paucity of studies from within the pharmacy profession to act as comparators. The reluctance to share events that would expose participants was a conflicting factor in the current study, with contrast between those who stated that they could overcome embarrassment, if there was benefit to the service, and those who stated they were reluctant to disclose and share events. This reluctance was expressed in the interviews, with participants stating they would be selective about what they would be willing to share with colleagues.

4.5.2.2 Behavioural determinants that relate to the provision of optimal and suboptimal pharmaceutical care

The use of the TDF to analyse the results meant that behavioural determinants were identified from the interviews. All fourteen domains of the TDF domains were identified as having influence on participant behaviours, with some domains perceived as having greater influence than others. Awareness and examination of the behavioural determinants that influenced participants means that behavioural change interventions can be proposed.

There are nine available behavioural changes interventions that articulate with the TDF: education, persuasion, incentivisation, coercion, training, restriction, environmental restructuring, modelling and enablement (Michie, Atkins and West 2014). The behavioural change intervention types, and their definitions were described in Chapter 2, in Tables 2.12 and 2.13.

Chapter 2 also described the link between TDF domains and behaviour change techniques. The behaviour change wheel and the COM-B model (Michie, Van Stralen and West 2011) can be used to identify behaviour change techniques to

address barriers which are identified when using TDF as a framework. The behaviour change techniques that articulate with the TDF domains were described in in Table 2.14 within Chapter 2. From this, recommendations can be made in the form of recommended interventions that are underpinned by implementation science, and thus have likelihood of successful when implemented, and these are described in 4.6.

4.5.2.3 Interpretation of personality tests

This small study used personality tests to create profiles for interviewees (Figures 4.4 to 4.13), and the results demonstrated that there were a range of personality traits across the participant cohort. Personality traits were reflected in participants' responses (Table 4.6), and will affect the behaviours they display at work. For example, certain personality traits have been seen as an influence on performance in medical training (Doherty and Nugent 2011), with conscientiousness seen as a significant predictor of good performance amongst medical students. Doherty and Nugent also observed a link between the personality trait of neuroticism and an individual's vulnerability to stress, and to psycho-social tendencies associated with stress such as moral distress. Personality traits have also been linked to work performance (Neal et al 2011), with openness positively predicting adaptability to change and proactivity, and agreeableness predicting good team workers, as does extroversion. Conscientiousness was found to predict individual rather than team proficiency, and high levels of neuroticism found to negatively predict work performance. The findings from the personality test are of interest to the study when considering the suitability of planned interventions (requiring change and proactivity). Some personality types are likely to respond well to change, whilst others may not, and this may be considered by the organisation, and interventions adjusted to reflect different personality types. In addition, personality traits have been demonstrated to influence behaviours in relation to the giving and receiving of feedback (Krasman 2010; Robison, McQuiggan and Lester 2010), and this may be of consideration when developing interventions that involve the giving and receiving of feedback.

4.6 Recommendations

Recommendations in the form of described interventions are detailed for each of the identified behavioural determinants from the findings. The behavioural determinants are clustered within the overarching TDF domain, and summarised in Table 4.7. The recommendations include both those specific to the organisation, as befits a professional practice doctorate, and recommendations for the wider pharmacy profession. Recommendations specific to the organisation include those relating to quality management system requirements.

Knowledge

4.6.1 Lack of knowledge of what constitutes suboptimal pharmaceutical care

Education strategies may be utilised to increase knowledge and awareness of what constitutes suboptimal pharmaceutical care. There could be local and wider National, and professional discussions on whether there are elements of suboptimal pharmaceutical care that can be described and defined, and that are reportable. There are existing frameworks and guidance that describe reportable adverse events for pharmacists (Royal Pharmaceutical Society 2016a), including under duty of candour (General Pharmaceutical Council 2014), but currently, reporting on suboptimal pharmaceutical care is not included.

Within the context of the organisation, the lack of clarity of what constitutes suboptimal pharmaceutical care means that the requirement to describe what constitutes a nonconformity, and what action should be taken is missing (British Standards Institute 2015), and this should be addressed. The medical profession has attempted to address lack of awareness of how to deal with prescribing error amongst junior doctors, for example, by provision of training using simulation, and by experiential placement learning (Klein et al 2017; Ryder et al 2019), and these methods may be considered.

4.6.2 Lack of knowledge – expected as in training

Education strategies may be utilised to ensure both trainer (or supervising pharmacist) and trainee acknowledge that provision of feedback on suboptimal

pharmaceutical care should form part of the knowledge development that takes place during the training period.

Education could be used in conjunction with the development of skills in giving feedback by trainers and supervisors (4.6.4). Within the study setting, awareness may be raised by incorporating guidance into local learning agreements, and promulgating through foundation tutor support sessions. Foundation training includes scope for discussion between trainer and trainee on trainee performance, through mini-CEX and case based discussion and these could be further developed; in addition, there are opportunities for the trainee to reflect on their experiences through reflective accounts (NHS Education Scotland 2019).

Skills

4.6.3 Skills for reporting on suboptimal pharmaceutical care

A training intervention may be utilised to develop skills around reporting, but only once a formal feedback or reporting process has been established (4.6.16).

4.6.4 Skills in giving feedback

A training intervention may be utilised to develop skills relating to giving feedback. The skills training should encompass giving feedback across hierarchies, in receiving feedback (for recipients) and in giving feedback to trainees that helps develop their knowledge (4.6.2). Skills training may start with undergraduates and continue throughout professional development. Skills training may improve competence and thus confidence in the provision of feedback (Duffy 2013). Skills in giving feedback is included in the training of tutors and supervisors (NHS Education Scotland 2017), and aspects of the training could be shared within the organisations' clinical pharmacy teams, to ensure all pharmacists understand the principles of giving good feedback.

4.6.5 Personal and professional barriers

An education and modelling intervention may be utilised to raise awareness of personal and professional barriers, using modelling to give examples of behaviours in overcoming personal and professional barriers where these are a barrier to the provision of optimal pharmaceutical care (Vrbnjak et al 2016).

Modelling may include sharing learning from episodes of suboptimal pharmaceutical care by more senior clinical pharmacists; this approach has been described in medical teams (Millwood 2014) to help junior doctors overcome personal and professional barriers. Barriers to the reporting of medication errors, where professional barriers have been implicated, has been widely described in literature and lessons may be learned from these studies (Williams Phipps and Ashcroft 2013; Keers et al 2013); suggestions from the studies include easier reporting, and addressing concerns about interprofessional relationships.

4.6.6 Professional embarrassment

An education, modelling and persuasion intervention may be utilised to raise awareness of professional embarrassment as a barrier, using persuasive commentary to highlight the negative effect of the barrier; education could use model examples or strategies for overcoming professional embarrassment. For example, a study by Smith et al (2014) suggested that professional embarrassment may be overcome by case reporting regularly, in a non-threatening environment, and would be a means of applying the true principles of peer review (Al-Lamki 2009). Peer review should aim to improve the quality of care for patients, by allowing participants to reflect on their practice compared with that of others. It requires a skill set, depends on the openness and transparency of participants, and relies on the presentation of a case that can be thoroughly examined. The mitigation of professional embarrassment may also reduce the impact of an emotional reaction to suboptimal pharmaceutical care (4.7.19) (Smith et al 2014).

Beliefs about capabilities

4.6.7 Beliefs about capabilities

Modelling and enablement of reporting may be an intervention that would increase pharmacist's confidence in their own ability to provide feedback and report on suboptimal pharmaceutical care. Gaining skills in giving feedback (4.6.4) will increase confidence (Duffy 2013). In addition, addressing the perception that time constraints (4.6.14) influence individual capability of providing feedback and reporting on suboptimal pharmaceutical care will increase confidence and self-efficacy.

Optimism

4.6.8 Optimism

Education and modelling interventions, demonstrating the gains from reporting, and using persuasion to encourage reporting are interventions that may reduce pessimism associated with reporting or providing feedback on suboptimal pharmaceutical care. Similar interventions have been used to encourage the reporting of medication adverse events (Healthcare Improvement Scotland 2019).

Beliefs about consequences

4.6.9 Beliefs about consequences

Educational and persuasive interventions that focus on the positive outcomes associated with engagement with reporting or providing feedback on suboptimal pharmaceutical care may reduce concerns about consequences. The negative consequences of failing to engage with the process may also be highlighted. For example, the positive outcomes, e.g. shared learning, opportunities to learn from suboptimal pharmaceutical care (4.6.21), ensuring that others do not make similar errors, and targeting areas for future training may be addressed in an educational intervention. Similar interventions have been made with prescribers

to encourage reporting on, and sharing the learning from, prescribing errors (Dornan et al 2009; Avery et al 2012; Bertels et al 2013).

Reinforcement

4.6.10 Reinforcement

Engaging strategies which enhance the positive rewards and outcomes from providing feedback and reporting on suboptimal pharmaceutical care, for example where changes in individual or team actions create a safer environment for patients, may be used. Coercive techniques, using a trusted clinical pharmacy lead, to demonstrate as an educational intervention the advantages that providing feedback and reporting on suboptimal pharmaceutical care have may be beneficial.

Intentions

4.6.11 Intentions

The use of strategies which promote motivation to engage in reporting or provision of feedback on suboptimal pharmaceutical care should be encouraged. For example, outlining optimal methods and ensuring reporting structures exist may be used as both an educational and a skills training intervention.

Goals

4.6.12 Goals

Having goal and target-setting strategies may aid pharmacists in facilitating and maintaining a behaviour change around reporting and providing feedback on suboptimal pharmaceutical care (Michie, Atkins and West 2014). For example, pharmacy teams may be encouraged to set goals and targets to increase the level of reporting and providing feedback, using incentivisation and persuasion; in addition, modelling can be applied, through asking recipients of the feedback process to give their perceptions, to ensure the process of reporting is having the perceived benefits

4.6.13 Fix and forget

Environmental restructuring, ensuring that pharmacists have the ability to provide feedback or report on suboptimal pharmaceutical care 'in the moment' may be beneficial as an intervention (Dearnley et al 2013). This may require additional IT access (4.6.15). This, along with other interventions that raise awareness of the benefits and gains of providing feedback (Hewitt, Chreim and Forster 2013), and reporting on suboptimal pharmaceutical care may reduce the tendency towards fixing suboptimal pharmaceutical care but not reporting on, or providing feedback.

4.6.14 Time constraints /lack of staff resource

Environmental restructuring, ensuring that there is the ability to rapidly provide feedback or report on suboptimal pharmaceutical care 'in the moment' may ensure that time constraints do not have impact on the ability to provide optimal pharmaceutical care, nor on the ability to provide feedback and report on suboptimal pharmaceutical care (Dearnley et al 2013). Addressing lack of staff resource, which is linked to perceptions of time constraints may reduce impact of this barrier. In addition, training interventions that address time management may be beneficial. Time constraints and low staff levels are known contributory factors in moral distress in nurses (Burston and Tuckett 2013), and this may be the case with pharmacists too (Kälvemarm et al 2004).

4.6.15 Lack of computer access

Enablement, through environmental restructuring that facilitates the provision of improved computer access may improve the ability to self-report on suboptimal pharmaceutical care; provision of feedback currently is predominantly done face to face (although that may change) and is therefore not affected by lack of computer access.

4.6.16 Lack of formal described process for reporting/feedback

Environmental restructuring, by ensuring a defined, process exists for formal reporting, for example outlining the type or nature of suboptimal pharmaceutical care that is reportable may be beneficial. Also, enabling reporting by provision of training in how reports should be made, for example, via existing systems, such as the DATIX risk management system.

4.6.17 Conflicting priorities

Environmental restructuring and enabling interventions may allow pharmacists to address conflicting priorities, and skills training in task prioritisation and time management may be beneficial. Better understanding of the source of conflict is required, and this could be assessed through data collection. The priority coding process should be reviewed to ensure that priority setting is not creating an additional burden of distress, since conflicts in ethical decision making is a contributory factor in moral distress (Kälvemark et al 2004).

Social Influences

4.6.18 Hierarchy

Enablement through skills training (4.6.4) to ensure pharmacists are comfortable with the provision of feedback and reporting suboptimal pharmaceutical care identified in more senior colleagues may be beneficial (Vrbnjak et al 2016). Also, ensuring through awareness and educational sessions that the advantages of reporting and providing feedback are understood across all grades of staff may be of benefit; this may require a culture change. Studies in medicine and in nursing have attempted to describe and address this barrier (Hooper et al 2015; Vrbnjak et al 2016).

4.6.19 Emotional reaction to suboptimal pharmaceutical care

Modelling and educational interventions may be utilised to assure pharmacists that an emotional reaction to an episode of suboptimal pharmaceutical care is appropriate, and recognising that the emotional reaction will be different for different people. Using techniques to manage emotional reaction to suboptimal pharmaceutical care may reduce likelihood of negative feelings becoming overwhelming and contributing to moral distress (4.6.20). Support mechanisms, such as exist for other professions when involved in medical error, could be utilised in an enabling intervention (Cabilan and Kynoch 2017; Klein et al 2017; Austin, Saylor and Finley 2017).

4.6.20 Moral distress

Modelling and persuasion interventions may be utilised to assist pharmacists who experience emotional reactions to an episode of suboptimal pharmaceutical care (4.6.19), as 'exposure to dilemmas' may be a contributory factor in moral distress (Monrouxe et al 2015). Raising awareness of the features and consequences of moral distress by educational intervention may be supportive of this. The use of coercive techniques and persuasion by line managers may allow pharmacists to disclose areas of concern they have in their own ability to provide optimal pharmaceutical care to their patients. The negative feeling arising from an inability to perform work as desired is a contributory factor in moral distress (Jameton 1984). Studies have shown that feeling supported increases the likelihood of disclosure of areas of concern (Cabilan and Kynoch 2017; Sporrang et al 2005), and that reducing distress and anxiety can mitigate the tendency towards behaviours that manifest as moral distress; there is some evidence that moral distress affects junior staff more than senior (Wilkinson 1987; Sporrang et al 2005). Recognition of the effects moral distress has on workforce should be recognised by the profession and requires further research (Astbury, Gallagher and O'Neill 2015), particularly in hospital clinical pharmacy.

4.6.21 Suboptimal pharmaceutical care as a learning opportunity

Educational interventions to ensure that there is awareness of suboptimal pharmaceutical care as a learning opportunity rather than as a threat to individuals or the profession may be beneficial. Modelling by senior pharmacists, and templates or proformas that capture learning opportunities may enhance this intervention. Similar interventions have been applied to the reporting of medication incidents (Williams, Phipps and Ashcroft 2013)

4.6.22 Summary of recommendations

In summary, there are a number of interventions that may be implemented to facilitate the identification, responding to, reporting and feedback of suboptimal pharmaceutical care. Interventions include educational interventions, skills training, modelling, enablement, restriction, persuasion, incentivisation, coercion and environmental restructuring as behaviour change techniques (Michie, Atkins and West 2014), and these are summarised in Table 4.7:

Table 4.7 Suggested behaviour change technique for identified behavioural determinants

TDF Domain/theme	Subtheme	Suggested Behaviour change technique
Behavioural determinants		Intervention
Knowledge	Lack of knowledge of what constitutes suboptimal pharmaceutical care	Education
	Lack of knowledge – expected as in training	Education
Skills	Skills for reporting on suboptimal pharmaceutical care	Training
	Skills in giving feedback	Training
Social/professional role and identity	Personal and professional barriers	Education; persuasion; modelling
	Professional embarrassment	Education; persuasion; modelling
Beliefs about capabilities	No specific subthemes – includes overlap with others	Education; persuasion; modelling; enablement
Optimism	No specific subthemes	Education; persuasion; modelling; enablement
Beliefs about consequences	No specific subthemes	Education; persuasion; modelling
Reinforcement	No specific subthemes	Training; incentivisation; coercion; environmental restructuring
Intentions	No specific subthemes	Education; persuasion; modelling; incentivisation; coercion

TDF Domain	Subtheme	Suggested behaviour change technique
Goals	No specific subthemes	Education; persuasion; incentivisation; coercion; modelling; enablement
Memory attention and decision making	Fix and forget	Training; environmental restructuring; enablement
Environmental context and resources	Time constraints	Training; restriction; environmental restructuring; enablement
	Lack of computer access	Training; restriction; environmental restructuring; enablement
	Lack of formal feedback process	Training; restriction; environmental restructuring; enablement
Social influences	Hierarchy	Restriction; environmental restructuring; modelling; enablement
Emotion	Emotional reaction to suboptimal pharmaceutical care	Persuasion; incentivisation; coercion; modelling; enablement
	Moral distress	Persuasion; incentivisation; coercion; modelling; enablement
Behavioural regulation	Suboptimal pharmaceutical care as a learning opportunity	Education; training; modelling; enablement

Although the suggested behavioural technique interventions and recommendations are described separately in 4.7.1 to 4.7.21, there may be overlapping strategies, particularly around educational interventions, and synergistic opportunities to combine interventions. For instance, skills training could focus around skills in giving feedback, both to junior staff, and to more senior colleagues to address skills, hierarchy and personal and professional barriers. Educational interventions may address multiple behavioural determinants, including the advantages of feedback, overcoming professional barriers, awareness of, and means of overcoming professional embarrassment, and awareness of moral distress and antecedent behaviours. Environmental restructuring may be commissioned to address IT access, staff shortages and the design of a process of formal reporting.

Additionally, the design and the most appropriate mode of delivery for the intervention should be identified to assure impact. For example, educational interventions are not limited to face to face delivery but may also include written material (posters, procedures etc.). The mode of delivery of interventions should be designed based on APEASE criteria (Michie, Atkins and West 2014) to enhance likelihood of success (Figure 4.15):

A	Affordability
P	Practicality
E	Effectiveness (including cost effectiveness)
A	Acceptability (to those delivering and receiving)
S	Side effects or unintentional outcomes minimised
E	Equity

Figure 4.15 APEASE criteria (adapted from Michie, Atkins and West 2014)

In this study, personality tests were used to profile participants, and exploration of personality type in intervention uptake may be a consideration (Eccles et al 2005).

4.7. Strengths and limitations of Phase 2 study

This qualitative study has addressed the paucity of literature relating to suboptimal pharmaceutical care. The novel approach taken in the study ensures the content is unique, providing a unique exploration of pharmacists' experiences of suboptimal pharmaceutical care. In addition, the theoretical foundation used enhances the evidence and provides the knowledge required to move forward with developing interventions.

4.7.1 Participants, recruitment and setting

Prior to the interviews, participants had been involved in focus group discussions as described in Chapter 3. This ensured participants were familiar with the research topic. Participants received information prior to the interview that summarised key findings from the focus groups (Appendix 3.10). The examples used were selected by the researcher as indicative of discussions, however, a different researcher may have selected a different set of examples and as such this could have introduced bias by influencing the thought processes for participants in advance of the Phase 2 interviews.

The setting for the study was a single health board in Scotland, and clinical pharmacy practices in other settings may vary. In describing in detail these practices in Chapter 1 and throughout the thesis, the readership can consider whether findings will be transferable to their own setting.

In terms of representation, the participant demographic had spread in terms of age, but less so in terms of grade or band of staff, nor of gender. This may have been because junior staff (Band 6) were less able to commit to time away from their schedule, or were less inclined to be involved in research, or were not interested in the topic area, and this may have introduced bias (Bowling 2014), as may the low level of male participants in the study. However, by including detailed descriptions of study participants' demographics, including personality profiles, the readership can consider whether the findings would be applicable within their own setting. The novel use of personality profiles demonstrates originality in study design.

4.7.2 Study design and conduct

The interview schedule was developed in accordance with the TDF, and is a strength of this study. Until recently, theoretical underpinning has been less common in pharmacy practice research compared to other disciplines (Stewart and Klein 2016). Theoretical underpinning is recognised as promoting quality and relevance in research (Stewart and Klein 2016). Dyson and colleagues, for example, compared the effectiveness of qualitative and quantitative research underpinned by the TDF with similar research in the absence of any theoretical basis. They found some overlap in effectiveness, but that TDF-informed research elicited more relevant information (Dyson et al 2011). The domains of the TDF were also used to prepare an initial coding framework for data analysis in this study, and this was a strength of study design.

Identification of the mechanisms driving behaviour is important in the context of intervention development since behavioural determinant identification enables interventions to be targeted accordingly (Michie, Aktins and West 2014; Atkins et al 2017). It is anticipated that development of recommendations as interventions that relate to evidenced behavioural determinants will enhance the effectiveness and sustainability of behaviour change. Findings from personality tests could be applied to behaviour change techniques to strengthen uptake (Eccles et al 2005; O'Connor et al 2020), and the use of personality tests in the study is therefore justified.

The coding process included mapping to all 14 TDF domains in this study, and analysis and recommendations were made across all domains; an alternative approach, where there was focus on the more influential behavioural determinants (Atkins et al 2017) may have strengthened the study

The flexibility of the interviews, by using a semi-structured interview schedule and allowing participants to identify for themselves the aspects of suboptimal pharmaceutical care they wanted to discuss, means the topic area had breadth and depth. The behavioural determinants were obtained from across all interviewees, and this is a strength of the study.

There was emphasis in the interviews on mechanisms for reporting suboptimal pharmaceutical care and it is recognised that this was an area where the

reflexivity of the researcher was weak; the researcher should have been more aware of their bias on this topic, and used more open questions, and less focussed probing. Given the naivety of the researcher, more interaction with the research team between interviews, and better reflection could have minimised the impact that this bias may have had, and is a lesson to be learned.

There are known weaknesses associated with using deductive methods to analyse data, such as mapping to TDF. Coding may be restrictive and there is considerable overlap between some of the domains in the TDF. In addition, individual domains may be perceived differently by coders (Cane, O'Connor and Michie 2012). However, efforts were made to minimise this by including an interrater comparison step, and by the frequent comparison of coding during the process.

Research trustworthiness was assured via a number of strategies, as have been described earlier in this chapter. Steps were taken to promote credibility, transferability, dependability and confirmability. Strategies included: utilising methods with a favourable evidence base and deemed fit for purpose; previous workplace experience of the researcher, and additional training in conducting interviews; the detailed and accurate reporting and recording of research procedures, and the reflexive processes the researcher undertook to develop an awareness of the effect that personal beliefs have on interpretation of the data.

In summary, the study has strengths in terms of study design and the use of a theoretical framework, and some limitations which include the naivety of the researcher and the limitations of the study setting.

4.8 Conclusions

Evidence from the Phase 2 study demonstrated that the use of interviews allowed in-depth exploration of the experiences of hospital clinical pharmacists with optimal and suboptimal pharmaceutical care, and was an appropriate method to use in the study. The use of a semi-structured interview schedule, designed around the TDF, ensured that the study was robust in design and that recurring themes and subthemes could be readily identified. Participants were able to describe their experiences of suboptimal pharmaceutical care, both in their own practice and in that of others. It was identified that there were different areas where which barriers and facilitators could be described, and these were identifying, responding to, reporting on and reflecting on suboptimal pharmaceutical care.

There were behavioural influences from all 14 domains of the TDF, and with significant influence from some domains, such as social/professional role and identity, behavioural regulation, skills and emotion. Subthemes were also identified and described. Recommendations were made using acknowledged behavioural change techniques, for the behavioural determinants identified from the findings, using the behavioural change wheel and the COM-B model. Behaviour change techniques suggested that address the influential behavioural domains include education, skills training, modelling, enablement, persuasion, modelling, coercion incentivisation, enablement and environmental restructuring.

CHAPTER 5 DISCUSSION

5.1 Introduction to Chapter 5

The final chapter of the thesis will revisit the overall aims of the research, and highlight the key findings associated with each phase. It will emphasise the originality of the research, and consider the strengths and limitations of the research study. Areas for future research will be identified along with consideration of the impact of this research - for the researcher, for the work environment the study took place in, and for the pharmacy profession. Finally, the main conclusions will be outlined.

5.2 Thesis review

This research study was described by the title '*Exploring hospital clinical pharmacists' perceptions, experiences and behavioural determinants relating to provision of optimal and suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework*'. It took as its overarching research question: '*How do hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care?*'

The research study was qualitative, with a phenomenological worldview, and was conducted in two phases, with the second phase building on the findings of the previous phase. The first phase used focus group discussions, and the second phase used a semi-structured interview schedule to conduct in-depth interviews.

5.2.1 Key findings from Phase 1 focus groups

Findings from Phase 1 suggest that participants of focus groups were aware of instances of suboptimal pharmaceutical care in the services they provided. A definitive definition of suboptimal pharmaceutical care was not elicited, and was not an aim of this phase of the study, but participants were able to describe how suboptimal pharmaceutical care manifested within the clinical pharmacy processes of medicines reconciliation and Kardex/medicines review. Participants described the challenges they faced when conducting the tasks associated with these two processes, and cited time constraints, conflicting priorities (including

uncertainties over efficiency vs thoroughness) and capacity (staff resources available relative to patient numbers and turnover) as being barriers to the provision of optimal delivery of medicines reconciliation and of Kardex/medicines review. For medicines reconciliation additional barriers were identified, for example, role uncertainty within the multidisciplinary team, and for Kardex/medicines review, additional barriers were identified including, for example, poor competency in conducting and documenting the task.

5.2.2 Key findings from Phase 2 interviews

The findings from the in-depth interviews suggested that participants were able to identify suboptimal pharmaceutical care in their own and in other's practice. Participants described challenges in knowing how, and whether to report on instances of suboptimal pharmaceutical care, as well as uncertainty as to what would constitute 'reportable' suboptimal pharmaceutical care. The majority of participants would opt to 'fix' an episode of suboptimal pharmaceutical care, but the likelihood of going on to report or provide feedback was influenced by hierarchy and time constraints, with participants expressing a tendency towards reporting or providing feedback when the other person was at the same, or at a more junior level than them. The likelihood that a participant would self-report instances of suboptimal pharmaceutical care identified was influenced by professional embarrassment, as well as time constraints, and opportunity.

5.3 Interpretation of findings from Phase 1 and Phase 2 studies

In this section, the findings from both studies will be integrated and interpreted. Both studies utilised TDF as a framework for analysis, and different TDF domains featured dominantly across the two phases. Not all TDF domains were represented by the findings from Phase 1 focus groups, and this was as expected. The focus group discussions were participant-led, whilst the interviews followed a semi-structured interview schedule designed around the TDF. The interview schedule included questions relating to each domain (Appendix 4.2), hence all TDF domains were predicted to be represented by the findings from the interviews, and this was found to be the case.

The findings of Phase 1 and Phase 2, when integrated, identified a number of common themes that described barriers to the provision of optimal pharmaceutical care: time constraints and a lack of staff resource in relation to patient volume and turnover, conflicting priorities, a lack of IT access, and a lack of defined policy or guidance. The findings will be triangulated with the requirements of the quality management system for interpretation in the next section, since meeting the requirement of the quality management system was a driver for the research.

In both phases of the research, time constraints were referred to as a challenge to providing optimal pharmaceutical care. In particular there was discussion on time management skills, and on finding the balance between being efficient and being thorough. Participants from focus groups described a lack of agreement as to which approach to take, and this theme was repeated in some of the interviews. This dilemma has been described as the *efficiency thoroughness trade off* (ETTO), (Hollnagel 2009) and has been previously described in the healthcare setting (Duncan et al 2019; Hollnagel 2009; McNab et al 2016). McNab et al (2016) describe how when things go well, healthcare practitioners are judged on efficiency, but when things go wrong they are judged on thoroughness. The authors conclude that there is no right or wrong approach, especially within organisations as complex as healthcare settings, and that instead, the focus should be on managing variation through protocol, rather than through policy (McNab et al 2016). Provision of an efficient and effective service is required within the quality management system requirements of control of service provision, and monitoring and measuring of the delivered service (British Standards Institute 2015). Therefore, in the context of the study setting, definition of how to achieve the correct balance for the organisation should be described.

Participants across both phases described a lack of policy, procedure or guidance as being barriers to provision of optimal pharmaceutical care. Lack of local policy was described for the task of medicines reconciliation, and the consequences of this have been described. In addition, participants described how a lack of definition or guidance as to what constitutes suboptimal pharmaceutical care prevented reporting. Better description of processes through policy, procedures

or guidance would enable the clinical pharmacy service to ensure that knowledge of the correct procedure, and training in the correct procedure would be part of training programmes, and thus enhance and assure competence. This is in accordance with quality management principles where the ongoing assurance of competency is a requirement (British Standards Institute 2015).

Improving the delivery of the two processes of medicines reconciliation and Kardex/medicines review will be beneficial to the clinical pharmacy service, and fulfil some requirements of the quality management system, namely: control of service provision and monitoring and measuring of the delivered service (British Standards Institute 2015). In addition, definition of what constitutes suboptimal pharmaceutical care will be beneficial to the clinical pharmacy services and fulfil in part the quality management system requirements relating to nonconformity and corrective action; describing what constitutes a nonconformity within clinical pharmacy services is a key requirement of the organisation. Nonconformity and corrective action processes have key roles within the continuous improvement clause within the quality management standard (British Standards Institute 2015).

5.4 Strengths and limitations

This section will outline the known strengths and limitations of the research, highlighting the originality of the research, aspects of study design, trustworthiness of the research, and reflexivity of the researcher

5.4.1 Originality

As far as is known, this is the first research study to have explored suboptimal pharmaceutical care as a concept, and to identify barriers to the provision of optimal pharmaceutical care. Suboptimal pharmaceutical care is an unexplored area of research, and this is, as far as is known, original research on this topic.

The use of personality tests to provide enhanced participant profiles is unique, and adds to the originality of the presentation of findings, and to the description of participants.

The use of an adapted focus group method in Phase 1 focus groups enabled a rapid assimilation of the findings, which were then used to inform the design and conduct of the Phase 2 in-depth interviews, and this was, as far as is known, a novel approach.

These examples from the research conducted meet originality criteria: undertaking empirical research that has not been done before, researching unexplored areas in a discipline and using techniques (focus group; personality test results) in a new way (Edwards 2014; Phillips and Pugh 2010).

5.4.2 Study design

The phenomenological approach to this research was appropriate, given the overarching aim, which was to explore perceptions and experiences of study participants. The qualitative methodology of focus groups allowed for collective exploration of perceptions of optimal and suboptimal pharmaceutical care. Focus groups and interviews took place across a range of settings (different hospital sites), and across a range of participant levels of experience. The qualitative methodology of interviews allowed for in-depth exploration of participants experiences, particularly in relation to suboptimal pharmaceutical

care, the interview setting facilitating openness and candour (Dejonckheere and Vaughn 2019; Bowling 2014). Participants in Phase 2 were drawn from the population from Phase 1, and this ensured interview participants had previously been involved in discussions about suboptimal pharmaceutical care. Using the same participants for both phases offered both strengths and limitations for the research: participation in focus groups had allowed those taking part in interviews the opportunity to reflect on the topic, and to consider aspects of pharmaceutical care that they considered to be suboptimal. However, this may have inadvertently led to bias, and input from naïve participants may have provided new insight into the concept.

The use of TDF as theoretical underpinning in the research design, and additionally in the development of the semi-structured interview schedule for Phase 2 provided a theoretically driven foundation for the research. The use of theory is likely to enhance the strength of the study design (Stewart and Klein 2016), and benefit the development of interventions (Craig et al 2008), and is a strength in study design. Craig et al (2008) suggest that integration of theory is critical in ensuring robustness in research since it permits determinants of behaviour to be reliably mapped, and intervention content to be tailored accordingly; there is however a lack of specific guidance of how to achieve this.

As a phenomenological study, the research asked participants to reflect on their experiences retrospectively, and this relied on their recall of events. This may be a limitation of study design, since recall bias is a known factor of influence in qualitative research (Bowling 2014; Robson 2011).

5.4.3 Data saturation

Phase 1 focus groups did not apply data saturation techniques but instead relied on recognised principles of conducting focus groups in terms of numbers of participants per group, and the total number of groups (Bowling 2014), as described in Chapter 2. For Phase 2 interviews, data saturation techniques were applied and met, but representation was limited by the availability of participants across the range of experience, location and gender. Wider participation may have allowed for additional subthemes, and may have enhanced the transferability of findings.

5.4.4 Generalisability

Conducting the study in a single health board in Scotland is appropriate for a professional doctorate research study, but may limit generalisability. The rich detail around study design description, and around setting and participant details, including personality profiles, allows the readership to assess whether the findings from the study are applicable to another setting.

5.4.5 Trustworthiness

Reference to trustworthiness of research has been referred to throughout the thesis: in the methodology chapter, and in each of the studies described for Phase 1 and Phase 2.

Various steps were taken to augment the trustworthiness of the research and are described under the four tenets of trustworthiness as described by Shenton et al (2004), of credibility, transferability, dependability and confirmability, and these are described:

Credibility was enhanced by the use of an appropriate methodology and methods, a reflexive approach, knowledge of and attention to the background and culture of clinical pharmacy practice locally, and the involvement of relevant experts in the study design.

Transferability was promoted by description in this thesis of background contextualising data and detailed descriptions of what was done, while at the same time protecting the anonymity of participants.

Dependability was engendered by the use of overlapping methods, the use of two phases of study, and by inclusion of detailed descriptions within the thesis of setting, context and participants.

Confirmability was incorporated by taking a reflexive and reflective approach during and after the research, including the consideration of limitations, and rich descriptions of process and procedure.

Trustworthiness within the research is summarised by revisiting the descriptive table (Table 2.4) from Chapter 2, and expanding it to include the actions taken in this study, and the rationale behind each action (Table 5.1)

Table 5.1 Trustworthiness actions embedded in the current research (adapted from Shenton 2004)

Parameter	Planned action	Rationale
Credibility (whether the phenomena been accurately represented by the study)	<i>Choose appropriate research method - phenomenology</i>	The research method is consistent with similar studies exploring e.g. perception and understanding, as determined by evaluating research literature
	<i>Be familiar with cohort of study/"natural setting"</i>	The researcher works within organisation where the research took place and was known to participants; field work was undertaken prior to data collection to become familiar with practices, process and terminology
	<i>Robust sampling plan</i>	Research across multiple sites within organisation, and across different grades and levels of experience of staff, allowing for "multiple voices". Data saturation techniques applied.
	<i>Triangulation</i>	The selection of different methods – focus group and individual interview - allowed for cross verification of the data; Involvement of participants from different sites with different specialties gave multiple perspectives.
	<i>Integrity and honesty</i>	Researcher was independent of the clinical pharmacy service; iterative questioning used
	<i>Reflective commentary</i>	Field notes/reflective log completed by researcher (focus groups and interviews) and facilitator (focus groups) and formed part of analysis
	<i>Peer and supervisory support</i>	Peer/supervisor verification used to sense check themes emerging during focus groups and interviews; "member checks" obtained through adapted design of focus group
Transferability (whether the study could be "transferred" to other situations)	<i>Full description of the study context</i>	Description of study setting; numbers and grades of participants, inclusion or exclusion criteria; data collection methods; number of and duration of sessions; time period over which data collected: These were built into the study design and reported on
Dependability (whether the study could be repeated and get similar results)	<i>Use of overlapping methods</i>	Use of focus groups and individual interviews; textual reference to research design from planning to execution, including detail of operational issues and reflective commentary and appraisal
Confirmability (whether the study has been carried out as objectively as possible)	<i>Triangulation</i>	See above under triangulation
	<i>Reflective commentary</i>	See above under reflective commentary
	<i>Acknowledgment of bias of researcher and/or facilitators.</i>	Reflexivity summary descriptions throughout thesis
	<i>Audit trail</i>	Records and logs kept of data and processes for duration of research project; continuous input of supervision team to assure objectivity

In addition to trustworthiness, researcher skills are required in order that planned research is conducted according to design requirements. The researcher's previous experience in conducting internal quality audits, and additional knowledge and skills gained through self-directed as well as taught learning (Appendix IV) ensured that the qualitative methods used were applied effectively, extracting rich and meaningful data from the focus groups and interviews.

5.4.6 Reflexivity

Reflexivity describes less the actions taken to ensure the robustness of the research, and more the cognitive, philosophical and reflective stance of the researcher in understanding how bias arises, and the steps taken to minimise those biases influencing the results (Creswell 2014).

Known biases were identified: The researcher had long standing personal interest in drivers for ethical and professional development. In addition, the researcher had organisational responsibilities for quality management for clinical pharmacy, and was invested in finding a solution to a work-related problem and gap in knowledge. Actions taken to minimise the impact of personal bias have been described throughout the thesis, and included continual reflective practice, ongoing discussion with the research team and awareness of the areas where bias is most likely to occur.

Bias can be introduced during the preparation of research tools and instruments (Robson 2011; Bowling 2014). In this study tools included a topic guide for the focus groups and a semi-structured interview schedule for the interviews. The topics in the topic guide were reviewed within the research team for appropriateness in meeting the research objectives. The semi-structured interview schedule was reviewed to minimise use of biasing or leading questions by the research team. However, the conduct of the focus groups and interviews relied on researcher skills, and their ability to conduct the interviews without introducing bias, and this is recognised as a potential source of bias (Robson 2011).

In describing actions taken to minimise the impact of bias, and to enhance trustworthiness, the readership may draw their own conclusions on the effectiveness of the actions taken.

5.5 Future research

This study suggests that the concept of suboptimal pharmaceutical care can be used to describe events and episodes that pharmacists perceived as being less than the desired standard of care for patients. More research is needed to identify whether the terminology is applicable in other settings. In addition, the study identified that there were influences on the ability of pharmacists to provide optimal pharmaceutical care, and expansion beyond this small scale qualitative study may provide broader insight, identify other influences, and enable the development of interventions to support optimal pharmaceutical care delivery. This would be a Scotland or UK wide study, and is described below as Proposal 1.

Furthermore, the study identified that pharmacist independent prescribers may lack a mechanism to share the learning from prescribing errors and near misses that are made with their fellow independent prescribers. Research to date has been on determining accuracy (Latter et al 2012)) and error rate (Baqir et al 2015; Taylor and Davies 2019; Phillips et al 2019). Determining the nature and type of prescribing errors and near misses, and using the data to inform education and training of pharmacist independent prescribers would contribute to knowledge in this area. There has been no study to date comparing types of prescribing error between different sectors of pharmacist independent prescribers, meaning that no sector-specific learning is available. This would be a local study, and is described below as Proposal 2.

Finally, intervention research is proposed within the organisation to evaluate the implementation of recommendations made within this research, and this is described as Proposal 3.

Proposal 1: A large scale study of behavioural determinants relating to the provision of optimal and suboptimal pharmaceutical care is proposed. The current study used TDF to study determinants of behaviour using interpretivist philosophy and qualitative methodology, using focus groups and in-depth interviews to gather data. A large scale survey would require that a positivist philosophy and quantitative methodology be used to generate data. A cross-sectional survey of pharmacist across different sectors, hospital, general

practice and community could be carried out by means of an online questionnaire.

Sampling could be facilitated using existing networks of pharmacists across Scotland and the UK.

The aims of the research would be:

- To determine the key behaviours that inhibit the delivery of optimal pharmaceutical care
- To determine whether the same determinants influence delivery across the different sectors and settings
- To investigate pharmacists' views on whether capturing information on suboptimal pharmaceutical care enables quality improvement

The research would gather data on

- Participant demographics, including the sector they were currently working in
- Participant views on and experiences of suboptimal pharmaceutical care in self and in others
- Participant views on and experiences of provision of feedback and/or reporting on suboptimal pharmaceutical care

A quantitative questionnaire for online administration would be developed using the TDF, as has been described in literature (Taylor et al 2013, Taylor, Lawton and Conner 2013; Huijg et al 2014). Data would be gathered using a combination of closed questions, Likert scale fixed choice responses and open questions, as is usual for quantitative online surveys. Quantitative data from closed and fixed choice questions would be analysed using descriptive analysis. The inclusion of open questions would capture richer, qualitative data which would be used to expand and augment quantitative results. Qualitative data would be analysed using a framework approach (Ritchie et al 2006) developed from the literature, including this current study and literature pertaining to applications of TDF. Quantitative data from the online questionnaire would be presented using descriptive statistics.

Proposal 2: Evaluation of prescribing errors and near misses made by pharmacist independent prescribers. A small scale local cross-sectional mixed methods study across hospital, primary care and community pharmacy settings is proposed.

The aims of the research would be

- To evaluate prescribing errors and near misses made by pharmacist independent prescribers in different pharmacy settings
- To determine whether the types of pharmacist prescribing error/near miss differ across the different sectors of pharmacy practice
- To understand, using the accident causation theory (Reason 2000; Aronson 2009), the types of pharmacist prescribing error that occur (for example slips, lapses, mistakes or violations)

Data would be collected on

- Participant demographics, including the sector they are currently working in, and length of practice as a pharmacist independent prescriber
- Participants' perceptions and experiences of prescribing errors and near misses in their own and other's practice, and how they are acted on
- Participants' descriptive examples of prescribing errors and near misses

The qualitative phase would utilise focus groups in each sector, hospital, primary care and community pharmacy to explore perceptions and experiences of prescribing errors and near misses. The quantitative phase would use the results of the qualitative phase to inform the development of a questionnaire that would collect data on error types from across the different sectors of practice. The questionnaire would use Reasons' theory of accident causation (Reason 2000) as a model to determine the types of prescribing error that are experienced within pharmacist prescribing (for example slips, lapses, mistakes or violations). The questionnaire would include fixed choice and open questions. Qualitative data would be analysed using a framework approach. Data on types of errors and near misses would be analysed using Reason's theory of accident causation, using an expert panel (Reason 2000; Aronson 2009). Results would be presented using descriptive statistics and narrative description.

Proposal 3: Implementation research to address key barriers to delivery of optimal pharmaceutical care.

Within the current research study, behavioural change technique recommendations have been made to address barriers identified from the qualitative data generated. Behaviour change theories have been described as strengthening the effectiveness of intervention implementation, (Craig et al

2008). Moore et al (2015) have since outlined a framework to assist in implementation process evaluation using a model that incorporates fidelity (quality of intervention content), dose (how frequently the intervention is delivered) and reach (how many individuals the intervention reaches) (Moore et al 2015). The evaluation of effectiveness should be underpinned by appropriate theory (Moore et al 2015), for example diffusion of innovation (Rogers 2003), or Normalisation Process Theory (McEvoy et al 2014); the behaviour change wheel can also be used to evaluate implementation (Michie, Atkins and West 2014).

The proposed intervention research would be locally conducted, and would initially explore the optimum mode of delivery for each of the interventions identified using the APEASE criteria (Michie, Atkins and West 2014), described in Figure 4.15; this phase would use consensus methodologies, for example nominal group technique or the Delphi technique (Bowling 2014; Robson 2011). Next, the research would first determine and then apply the optimum underpinning theory to evaluate the implementation, and assess the effectiveness of the evaluation using qualitative methodology. The aims of the research would be:

- To determine the optimum mode of delivery for interventions, using consensus methodology
- To implement the interventions according to findings
- To determine the optimum underpinning theory to evaluate intervention
- To evaluate the implementation of interventions using the selected theory

Consensus methodology results would inform the intervention implementation. Implementation findings would then be described in accordance with the theoretical framework selected, using a qualitative approach to data presentation.

5.6 Impact and reach of the research

The impact and reach of research can be summarised under the four headings of knowledge, people, society and economy (Figure 5.1) (Economic and Social Research Council 2020).

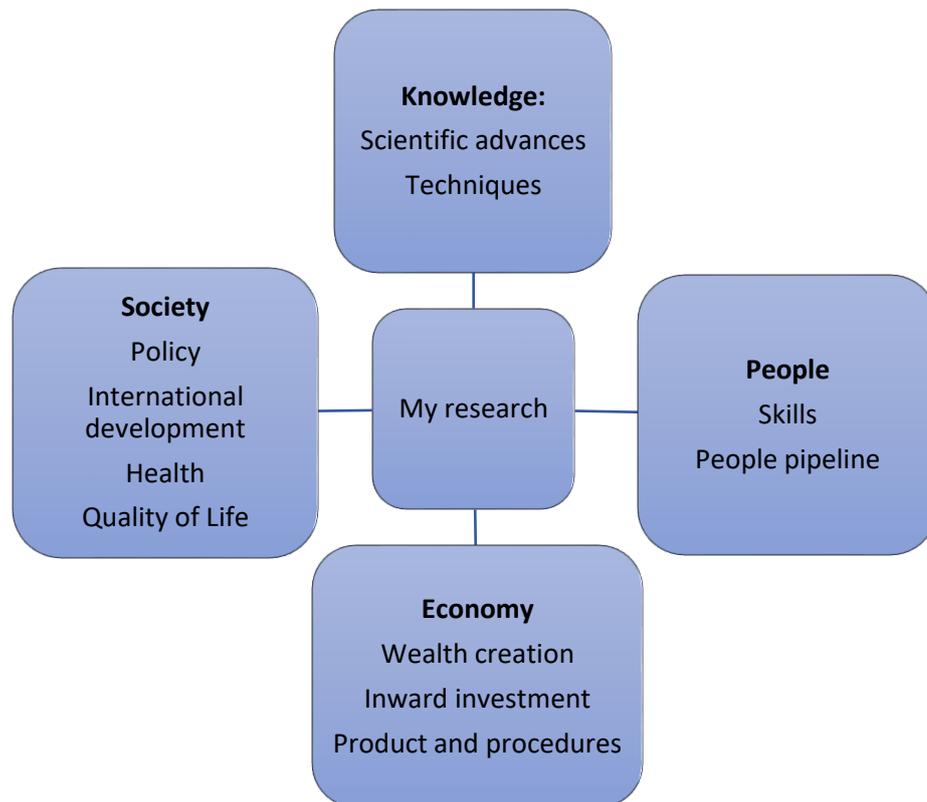


Figure 5.1 Impact and reach schematic for research

Each aspect of impact and reach was reflected on individually in relation to the current research; this was done both in advance (Appendix 5.1), when designing the research for impact and reach, and at the conclusion, to assess whether impact and reach had been achieved. Each aspect of impact and reach is considered here:

Knowledge

There were knowledge gains from this study. Firstly, the description of the novel concept of suboptimal pharmaceutical care adds knowledge to the field of pharmaceutical care research. Secondly, the research provided a unique assessment of clinical pharmacists' perception and experiences of suboptimal

pharmaceutical care in the researcher's local setting. Thirdly, the research developed and used a novel adaptation of focus group method that utilised a combination of written and verbal output.

In considering the impact of the research knowledge, transfer of knowledge must be considered. In the professional doctorate, the transfer of knowledge back to the organisation is important. For this research, this was achieved through sharing the results with the organisation's pharmacy senior management team, and with the clinical pharmacy teams (Appendix 5.1). Wider transfer of gained knowledge is achieved by sharing the findings of the research with other pharmacists and other research teams. For this research, knowledge sharing was achieved through presentations and publications, locally, nationally and internationally, and these are described under Research Outputs. Future plans for knowledge sharing include publication of findings, and further presentation locally and nationally.

People

There were many research skills and personal skills that the researcher developed over the course of the research study. These skills included the attainment of research skills through application of qualitative research skills in the current study, of study design and in the conduct of focus groups and of in-depth interviews. In addition, preparation of a thesis to describe conducted research requires the researcher to reflect on, and to describe alternate research methods, and thus broader knowledge is obtained. The researcher also gained knowledge of the use of software relating to research including NVivo[®], as data analysis software and Refworks, as a bibliography and reference database. Additional personal skills developed during the doctorate journey relate to time management and planning, writing skills, oral presentation skills, and poster and abstract design and development.

The reach of these research skills is primarily through transfer to the organisation's pharmacy service. Individuals who took part in the focus groups and one to one interviews were exposed to qualitative research methods, and took an interest in qualitative research methods used. Since the research took place, the researcher has supported other novice researchers in their research skills development.

Society

The society in the context of this research is the hospital clinical pharmacy community. Enhanced awareness of suboptimal pharmaceutical care will lead to shared learning, team work and ultimately patient safety. Locally this has already happened, with discussions on changes to how nonconformities are captured within clinical pharmacy services. Wider impact on the clinical pharmacy community has taken place through knowledge sharing at conferences, and will be developed with future research, and with publication and knowledge sharing.

Economy

Wealth creation and new company creation were not intended targets of this research. Changes to product and procedures, where product is the clinical pharmacy service were impacted with quality management principles becoming aligned with the clinical pharmacy service. In addition, there can be said to be inward investment of the existing and future workforce. The research had intention to bring efficiencies to current processes with shared learning, and the avoidance of duplication, and it is believed these were achieved.

5.7 Conclusions

This study aimed to answer the research question: *'How do hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care?'*

Participants in this study were hospital clinical pharmacists, delivering pharmaceutical care for a range of patients in secondary care. Using a theoretically informed approach, and qualitative methodologies of focus groups and interviews, the study has enabled the understanding of meanings, perceptions, experiences and behavioural determinants of suboptimal pharmaceutical care from the perspectives of hospital clinical pharmacist participants.

The study design, with the theoretical underpinning of the TDF, allowed an in-depth, rigorous and trustworthy exploration of the perceptions and experiences of hospital clinical pharmacists with optimal and suboptimal pharmaceutical care. The research has allowed the researcher insight into barriers that have to date prevented identification and reporting of suboptimal pharmaceutical care within the study setting. The key barriers described were time factors, lack of guidance or definition of what constitutes suboptimal pharmaceutical care, conflicting priorities, lack of knowledge (of trainees), and personal and professional barriers and enablers, including hierarchy, and professional embarrassment.

Further, use of the TDF to underpin the research enabled behaviour change techniques to be mapped to the key influencing domains, such as social/professional role and identity, environmental context and resources, knowledge, skills and emotion. The articulating behavioural change techniques include educational interventions, skills training, modelling, enablement, persuasion and coercion and environmental restructuring.

It is advised that, going forward, intervention development is underpinned by behaviour change theory to ensure the effectiveness of the intervention, and that effectiveness of implementation is adequately assessed.

The exploration of the concept of suboptimal pharmaceutical care has enabled hospital clinical pharmacists within the organisation to reflect on their current practice, and to consider areas for improvement. Aspects of the research findings will be applied within the quality management system for clinical

pharmacy to improve compliance with requirements of the quality management standard, including criteria on what and how to report in terms of suboptimal pharmaceutical care.

It is acknowledged that behaviour change, in itself, is not a strong intervention (Fan and Trbovich 2020; Hollnagel et al 2015), and that systems changes are more likely to produce lasting and effective results (McNab et al 2016; McNab et al 2020; Hollnagel et al 2015), and these will be addressed within the environmental restructuring components of recommendations. However, in the context of this phenomenological research study, the behaviours of the clinical pharmacists involved, and the potential barriers to them engaging with initiatives to enhance reporting on suboptimal pharmaceutical care was the interest and focus, and highlighted a number of interesting results. These results, articulated as recommendations, will be considered by the organisation in the future development of clinical pharmacy services.

Across the wider pharmacy profession, the research identified gaps in professional guidance for pharmacists. Current guidance for pharmacists on adverse event and error reporting remains focussed on dispensing errors, and should be widened to ensure adverse events from within clinical pharmacy services are captured, shared and learned from. Additionally, pharmacist independent prescribers are required to report prescribing errors, but methodology to achieve this requirement has not yet been described.

It is hoped that this research exploring suboptimal pharmaceutical care will allow for wider conversations amongst clinical pharmacists about the opportunities for improvement, and for quality assurance, that can arise from open and candid discourse on suboptimal pharmaceutical care.

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Appendix 1.1 Priority Coding Tool

<p>Phar: 1 Review Daily</p> <p>Phar: 2 Review Every 3rd day (range 2 - 4 days)</p> <p>Phar: 3 Review Weekly (range 5-9 days)</p> <p>Phar: 4 Review at 14 days or re-referral Phar: D Reviewed for Discharge</p>	<p>Patients may fulfill criteria in more than one of the prioritisation criteria - in this situation, allocate to the highest level of code.</p> <p>In the absence of specific examples relevant to each individual patient, allocate based on clinical judgement.</p>
<p>Phar 1 Criteria :</p> <p>High risk medicine / medicine requiring TDM</p> <p>e.g. SACTs, cytotoxics, digoxin, lithium, phenytoin, theophylline, vancomycin, warfarin, valproate in women of childbearing potential etc.</p> <p>NB Considered Phar 1 if some indication of toxic or subtherapeutic effect</p> <p>Severe chronic renal impairment (Est. CrCl ≤ 30ml/min)</p> <p>NB Considered Phar 1 if on medications requiring close adjustment.</p> <p>Acute kidney injury (urea ≥ 10, creat ≥ 30 from baseline)</p> <p>NB Considered Phar 1 if on potentially nephrotoxic medicines.</p> <p>Severe hepatic impairment (LFT's ≥ 3x upper limit of normal)</p> <p>Polypharmacy ≥ 10 regular medications</p> <p>NB Considered Phar 1 if complex regimen e.g. drug-drug or drug-disease interactions, non-compliance with evidence based guidelines.</p> <p>Nil by mouth/ swallowing difficulties</p> <p>NB Considered Phar 1 if essential medicine or medical condition must be treated.</p> <p>Short term use of antipsychotics/ benzodiazepines in delirium/ agitation</p> <p>NB Considered Phar 1 for patients with contra-indication/ cautions for use of antipsychotics e.g. Parkinsons, Lewy body dementia etc.</p> <p>Significant drug interaction</p> <p>NB Considered Phar 1 if indication of toxic/ subtherapeutic effect resulting from interaction</p> <p>Significant adverse drug reaction (ADR)</p> <p>NB Considered Phar 1 if noted ADR e.g. recent fall or prolonged QTc >500ms</p> <p>Unresolved medicines reconciliation or supply issue e.g. non-formulary and ULM use</p> <p>Patient with daily aseptic need e.g. on Total Parenteral Nutrition, antibiotic infusion</p> <p>Discharge issue resolution by next working day e.g. counselling, MCD, MAR</p>	<p>Phar 2 Criteria :</p> <p>High risk medicine / medicine requiring TDM</p> <p>e.g. SACTs, cytotoxics digoxin, lithium, phenytoin, theophylline, vancomycin, warfarin, etc.</p> <p>NB Considered Phar 2 if no indication of toxic or subtherapeutic effect.</p> <p>Severe chronic renal impairment (Est. CrCl ≤ 30ml/min)</p> <p>NB Considered Phar 2 if not on medications requiring dose adjustment.</p> <p>Acute kidney injury (urea ≥ 10, creat ≥ 30 from baseline)</p> <p>NB Considered Phar 2 if no potentially nephrotoxic medicines.</p> <p>Moderate hepatic impairment (LFT's > ULN but < 3X ULN)</p> <p>Polypharmacy ≥ 10 regular medications</p> <p>NB Considered Phar 2 if polypharmacy in absence of complex regimen and compliant with evidence based guidelines.</p> <p>Nil by mouth/ swallowing difficulties</p> <p>NB Considered Phar 2 if no essential medicine or medical condition to be treated.</p> <p>Short term use of antipsychotics/ benzodiazepines in delirium/ agitation</p> <p>NB Considered Phar 2 for patients with no obvious contra-indication to pharmacological management.</p> <p>Significant drug interaction</p> <p>NB Considered Phar 2 if no indication of toxic/ subtherapeutic effect resulting from interaction</p> <p>Significant adverse drug reaction</p> <p>NB Considered Phar 2 if no current indication of ADR e.g. history of falls or prolonged QTc monitor for any changes to medication</p> <p>Multiple new medications for new/ acute medical condition requiring monitoring/ education</p>
<p>Phar 3 Criteria :</p> <p>Phar 4 Criteria :</p> <p>Phar D Criteria:</p>	<p>Patient stable with no acute issues but requires weekly review</p> <p>Patient stable with no acute issues - review at 14 days or at re-referral</p> <p>Patient assessed as suitable for discharge with professionally checked Immediate Discharge Letter (IDL)</p>

Written approved for use by the clinical pharmacist operations group.



SCHOOL OF PHARMACY & LIFE SCIENCES

Robert Gordon University
Sir Ian Wood Building
Garthdee Road
Aberdeen
AB10 7GJ
United Kingdom
Tel: 01224 262500/2800
www.rgu.ac.uk

Ref: S67

2 February 2017

Dear Amanda

Re.: Exploring hospital clinical pharmacists' perceptions experiences and behavioural determinants relating to provision of optimal and suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework

The School Research Ethics Committee has assessed your application and the overall decision is that there are no ethical issues with your project.

I can now confirm that you are able to proceed with your research and any further ethics applications.

Should there be any amendments to this project during the research we would advise you to consult with the convener of the ethics committee as to whether a further ethical review would be required.

We wish you success with your project.

Regards

A handwritten signature in black ink that reads "Susan Duthie".

Convener of the School Ethics Review Panel

Appendix 2.2 South East Scotland Research Ethics Approval (ethics not required)

South East Scotland Research Ethics Service

Amanda McLean	Date:3/3/17
MPhil MFRPSII MRPharmS	Your Ref:
GPhC Registered	Our Ref: NR/2003AB6
Specialist QA Pharmacist	Enquiries to: Helen Newbery
NHS Scotland Organisation	Direct Line: 0131 465 5679
Pharmacy Quality Risk and Governance Services	Email:

Dear Dr McLean,

Project Title:

Exploring hospital clinical pharmacists' perceptions, experiences and behavioural determinants relating to provision of optimal and suboptimal pharmaceutical care

You have sought advice from the South East Scotland Research Ethics Service on the above project. This has been considered by the Scientific Officer and you are advised that, based on the submitted documentation (email correspondence), it does not need NHS ethical review under the terms of the Governance Arrangements for Research Ethics Committees (A Harmonised Edition).

The advice is based on the following:

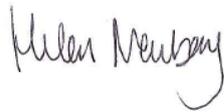
- *The potential participants are neither patients (identified from, or because of, their past or present use of NHS services) nor relatives or carers of patients (recruited for this reason)*
- *The project is a survey seeking the views of NHS staff on service delivery*
- *The project involves NHS staff and is an audit of current or past practice concerning a healthcare issue*

If the project is considered to be health-related research you will require a sponsor and ethical approval as outlined in The Research Governance Framework for Health and Community Care. You may wish to contact your employer or professional body to arrange this. You may also require NHS management permission (R&D approval). You should contact the relevant NHS R&D departments to organise this.

For projects that are not research and will be conducted within the NHS you should contact the relevant local clinical governance team who will inform you of the relevant governance procedures required before the project commences.

This letter should not be interpreted as giving a form of ethical approval or any endorsement of the project, but it may be provided to a journal or other body as evidence that NHS ethical approval is not required. However, if you, your sponsor/funder feel that the project requires ethical review by an NHS REC, please write setting out your reasons and we will be pleased to consider further. You should retain a copy of this letter with your project file as evidence that you have sought advice from the South East Scotland Research Ethics Service.

Yours sincerely,

A handwritten signature in cursive script that reads "Helen Newbery".

Helen Newbery
Scientific Officer
South East Scotland Research Ethics Service

Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

RESEARCH	SERVICE EVALUATION*	CLINICAL AUDIT	SURVEILLANCE	USUAL PRACTICE (In public health)
The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted solely to define or judge current care.	Designed and conducted to produce information to inform delivery of best care.	Designed to manage outbreak and help the public by identifying and understanding risks associated.	Designed to investigate outbreak or incident to help in disease control and prevention.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer: "What standard does this service achieve?"	Designed to answer: "Does this service reach a predetermined standard?"	Designed to answer: "What is the cause of this outbreak?"	Designed to answer: "What is the cause of this outbreak?" and treat.
Addresses clearly defined questions, aims and objectives.	Measures current service without reference to a standard.	Measures against a standard.	Systematic, statistical methods to allow timely public health action.	Systematic, statistical methods may be used.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	Involves an intervention in use only. The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.	May involve collecting personal data and samples with the intent to manage the incident.	Any choice of treatment is based on clinical best evidence or professional consensus.
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	May involve analysis of existing data or administration of interview or questionnaire to those exposed.	May involve administration of interview or questionnaire to those exposed.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research – uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.	No allocation to intervention: the health professional and patient have chosen intervention before audit.	Does not involve an intervention.	May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.
May involve randomisation.	No randomisation.	No randomisation.	No randomisation.	May involve randomisation but not for treatment.
Normally requires REC review. Refer to www.nres.npsa.nhs.uk/applications/apply/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.	Does not require REC review.

* Service development and quality improvement may fall into this category.

Appendix 2.3 NHS Scotland Organisation Pharmacy Quality Improvement Team Approval



CERTIFICATE NO. FS 31228

Amanda McLean
Ref: QIT83

Date: 16th March 2017

Dear Amanda

Project Title: Exploring hospital clinical pharmacists' perceptions, experiences and behavioural determinants relating to provision of optimal and suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework

I am pleased to inform you that the Pharmacy Quality Improvement Team has approved your project titled 'Exploring hospital clinical pharmacists' perceptions, experiences and behavioural determinants relating to provision of optimal and suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework'

Can I remind you that your project must conform to governance requirements as described in the audit and evaluation workbook. The Pharmacy ERD Administrator will contact you periodically for a report on your progress, to be logged in pharmacy records. At the end of the study please return the project completion form in the audit and evaluation workbook to the Pharmacy ERD Administrator and include plans for subsequent conference or publication submissions as detailed in the attached Pharmacy Project Guidance.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Moira Kinnear'.

Moira Kinnear

Head of Education, Research & Development

On behalf of Pharmacy QIT

Appendix 3.1 Participant information pack



Participant Information Pack

Hospital clinical pharmacists' perceptions on the provision of optimal and suboptimal pharmaceutical care

You are invited to take part in a research study. Thank you for taking the time to read the following information carefully. It is important that you understand why the research is being done and what it will involve. Please ask if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part.

The research study.

This study is being undertaken for my Doctorate in Professional Practice. This qualitative research will be in 2 phases. Phase I will seek to gain understanding and scope the meaning of optimal and suboptimal pharmaceutical care from the perspectives of clinical pharmacists. Phase II will further explore the experiences of clinical pharmacists in the provision of optimal and suboptimal pharmaceutical care in NHS Scotland Organisation. You are invited to participate in Phase I only or in Phase I and II.

Phase I will involve you taking part in a focus group at your site with 4 to 9 others, lasting up to 60 minutes. Each session will be audio recorded to enable analysis of the data. Phase II will consist of individual face to face in-depth interviews between you and me. Each interview will take 30-45 minutes and will be at a time and place most convenient for you. The interviews will be audio recorded and transcribed to enable analysis of the data.

Why take part?

You will help in the understanding of what barriers and enablers are at play when delivering individual pharmaceutical care. Participation in research can be recorded for portfolio development at foundation level: Personal Practice: Research and Evaluation competencies: *actively supports research and enquiry in the workplace* and in Management and Organisation competencies: *improves the quality of the services offered*. Advanced practitioners will be able to reflect on their own practice, and identify gaps in research, quality improvement or innovation. The results may contribute to the development of the clinical pharmacy service in NHS Scotland Organisation.

What next?

If you wish to take part on the study, please complete the Consent Form and Demographic Data Collection Form attached to the email and return to Amanda McLean by email or in internal mail by (date)

Researcher information:

The team supporting this research consists of Moira Kinnear, Head of ERDS, Caroline Souter, Principal Pharmacist ERDS, Professor Derek Stewart, Robert Gordon University and Dr Vibhu Paudyal, University of Birmingham.

I can be contacted with any queries relating to the research at a.p.mclean@rgu.ac.uk , amanda.mclean@nhslothian.scot.nhs.uk or on 0131 537 2325.

Amanda McLean. Quality Risk and Governance Pharmacist, NHS Scotland Organisation & Doctorate of Professional Practice Student, Robert Gordon University.

Appendix 3.2 Consent form for participants



Consent form for Participants

Project title: Exploring hospital clinical pharmacists' perceptions, experiences and behavioural determinants relating to the provision of optimal and suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework

1. I confirm that I have read the information pack dated March 17 for the above named study. I have had the opportunity to consider the information and ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without this having any adverse outcome.
3. I understand that, for Phase II, I can also withdraw after my participation if I change my mind within 14 days of the interview, by contacting the researcher to request this.
4. I understand that the data collected during the study will be used for research purposes including publication of anonymised findings and quotations. I grant permission to use these on the understanding that my confidentiality will be protected.
5. I agree to audio recording of my input. I understand that the audio recordings will be destroyed at the end of the study
6. I understand that any event where patient safety may have been compromised will be followed up following normal governance procedures for adverse event reporting.
7. I agree to take part in the study. I agree to take part in: (please tick one)

Phase I only

Phase I & II

Name of participant	Date	Signature

Consent recorded by:

(researcher) Date:

Appendix 3.3 Demographic data collection

Demographic Data Collection									
<p>Project title: Exploring hospital clinical pharmacists' perceptions, experiences and behavioural determinants relating to the provision of optimal and suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework</p>									
<p>Please answer the following questions and return with the consent form.</p>									
Are you:		<input type="checkbox"/> Female <input type="checkbox"/> Male							
Age (tick one)									
<input type="checkbox"/> Less than 25		<input type="checkbox"/> 25-35		<input type="checkbox"/> 35-45		<input type="checkbox"/> 45-55		<input type="checkbox"/> Over 55	
Years qualified (tick one)									
<input type="checkbox"/> Less than 5		<input type="checkbox"/> 5-15		<input type="checkbox"/> 15-25		<input type="checkbox"/> 25-35		<input type="checkbox"/> over 35	
Current level of work: (tick one)									
<input type="checkbox"/> Rotational Band 6		<input type="checkbox"/> Rotational Band 7		<input type="checkbox"/> Specialist Band 7		<input type="checkbox"/> Specialist Band 8		<input type="checkbox"/> Team Lead Band 8	
Are you prescribing?									
<input type="checkbox"/> Yes		<input type="checkbox"/> No							
Where are you currently working?									
<input type="checkbox"/> Royal Infirmary of Edinburgh		<input type="checkbox"/> Western General Hospital		<input type="checkbox"/> Royal Hospital for Sick Children		<input type="checkbox"/> Royal Edinburgh Hospital		<input type="checkbox"/> St John's Hospital Livingston	
Previous areas of work (tick as many as apply)									
<input type="checkbox"/> Other NHS Lothian hospital		<input type="checkbox"/> Hospital NHS other		<input type="checkbox"/> Community pharmacy		<input type="checkbox"/> Primary care		<input type="checkbox"/> Other (please add below)	
What day/time of the week suits you best for FOCUS GROUP DISCUSSION at your site? (tick as many as apply)									
<input type="checkbox"/> MONDAY		<input type="checkbox"/> TUESDAY		<input type="checkbox"/> WEDNESDAY		<input type="checkbox"/> THURSDAY		<input type="checkbox"/> FRIDAY	
<input type="checkbox"/> AM		<input type="checkbox"/> AM		<input type="checkbox"/> AM		<input type="checkbox"/> AM		<input type="checkbox"/> AM	
<input type="checkbox"/> PM		<input type="checkbox"/> PM		<input type="checkbox"/> PM		<input type="checkbox"/> PM		<input type="checkbox"/> PM	
<input type="checkbox"/> Twilight*		<input type="checkbox"/> Twilight		<input type="checkbox"/> Twilight		<input type="checkbox"/> Twilight		<input type="checkbox"/> Twilight	
*5.30-6.30pm									
Name of participant				Date		Signature			
<p>Data collection form processed by: _____ (researcher) _____ Date: _____</p>									

Appendix 3.4 Supplementary information pack for Focus group participants



Supplementary Information Pack for Focus Group Participants

Following some questions from potential recruits for my research, I am going to include some background information in this email.

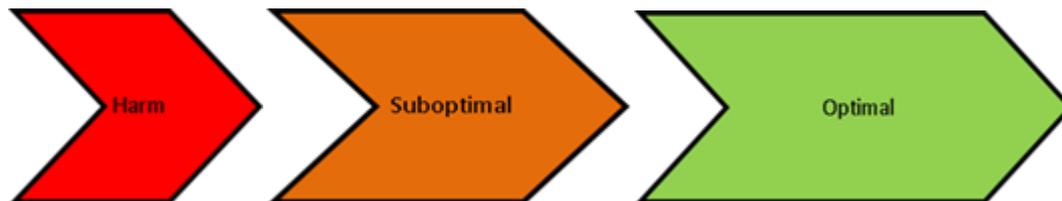
Question 1 What are the project objectives?

The study is qualitative research from a phenomenological perspective (i.e from the viewpoint of hospital clinical pharmacists in NHS Scotland Organisation) with the objectives

- To explore perceptions and scope of the terms 'optimal' and 'suboptimal pharmaceutical care' in relation to practice.
- To explore their experiences of the provision of optimal and suboptimal pharmaceutical care within their practice.
- To explore the behavioural determinants relating to the provision of optimal and suboptimal pharmaceutical care using the Theoretical Domains Framework

Question 2 What is suboptimal pharmaceutical care?

This is the phenomena I am exploring with this study: The concept exists in healthcare – suboptimal healthcare delivery/suboptimal prescribing for example. I want to explore what it means within pharmaceutical care. I have depicted it by seeing pharmaceutical care as a continuum:



I am interested in exploring what factors have affect in this continuum, and how that helps us define what is suboptimal pharmaceutical care.

Examples of factors may be: lack of information/time/resource/access/training/planning..... I also want to look at what factors may impact e.g. different patient types? Different medicine types? Different clinical scenarios? I will explore these ideas in focus groups held at each site across NHS Scotland Organisation.

Question 3 Will my input be anonymous? YES – this is qualitative research and the results will be the anonymous input of the participants.

Appendix 3.5 Focus Group Rules

Focus group house rules The rules were presented and clarified during the introduction.

Be respectful no criticism of others' ideas or comments. You don't need to agree

Be courteous give everyone a chance to input, speak, and express themselves.

Be focussed keep to the topic, keep to time

Be considerate minimise impact of any interruptions

Be mindful of the meaning of consent; treat anything you hear or that is discussed as confidential – no sharing outside of the group

Appendix 3.6 Reflective field notes template

Reflective Field notes:

Location:	
Room set up (description/diagram)	
Date:	Time:
Investigator/Facilitator present	
Attendees	
(check consent in place for all)	

Audio recording – recorder used:	File reference and storage location
----------------------------------	-------------------------------------

Interruptions:
Participation? (Full/partial/variable/minimal?)
Interactions between participants (describe)
Key points described:
Debrief meeting between investigator/facilitator

Appendix 3.7 Operating procedure for Focus group discussions

Operating Procedure: The purpose of this procedure is to ensure consistency of approach and clarity of responsibilities.

In advance:

Liaise with facilitator(s).

Contact all pharmacist across NHS Scotland Organisation, outlining research and asking for notes of interest.

Where interest noted, send information pack with demographic data collection, preferred day/time, and consent forms.

Arrange dates for sessions. Book room at sites.

Once confirmed, send out advance notice of date and collect responses to ensure sufficient numbers.

On day:

Arrive in advance to set up room: 3 flip charts. Post-it notes. Pens. Flip chart pens. Water. Sweets/fruit.

Check participants have given consent, and get signatory of participation.

Introduce self and facilitator(s).

Introduce focus group topic and method of recording data; take questions before starting the discussion.

During:

Maintain focus and keep to time.

Note any observations about group working, distractions.

Give warning of time minus 5 minutes.

Sum up /clarify information provided on flipchart/post-it notes.

Immediately after:

Write reflective journal and encourage facilitator(s) to do same.

Afterwards:

Thank participants via email

Appendix 3.8 Focus group on the day checklist

Purpose: a checklist to follow on the day of the focus group, and a summary of the procedure for operating the digital recorder.

Refer to Focus Group Standard Operating Procedure

Collect together items for Focus Group:

Digital recorder, charger cable, manual

Flipchart with "suboptimal" overlay

Post its (green orange pink); pens, paperclips

Snacks for participants

Documentation: consent forms, reflective log/field notes forms, SOP, room booking information

Equipment check: Digital recorder – check battery > 2 bars.

Equipment operation: Digital recorder

1. Power on (slide switch)
2. Create new file by pressing NEW
3. Press REC to start recorder – verify by observing REC light illuminated
4. Press STOP to stop recorder
5. Download and save files using ODMS (connect recorder to PC via USB to open program)

Appendix 3.9 Standard introduction to focus groups discussions

'In the session, you will be asked about what suboptimal pharmaceutical care looks like in different situations. For this piece of research, the focus is on whether suboptimal pharmaceutical care is a description that can be understood, and that can be usefully applied. The definition of pharmaceutical care being used is: *Pharmaceutical Care is the pharmacist's contribution to the care of individuals in order to optimise medicines use and improve health outcomes.* (PCNE -Pharmaceutical Care Network Europe 2013)]

The session will be in two parts, the first looking at medicines reconciliation, and the second focussing on Kardex/medicines review.

Medicines reconciliation is the process by which the medicines that the patient is taking on admission or discharge are verified against documented records.

Kardex/Medicines review is the process by which the suitability of medicine and dose are assessed.'

Appendix 3.10 Information for Phase 2 interview participants

The following are themes extracted from Phase I focus groups where the topics were optimal and suboptimal pharmaceutical care with medicines reconciliation, and with Kardex/medicines review. This list is not exhaustive and represents discussions held within the focus groups. It is important to understand that these are given as examples, and that the interview will be looking to discuss your personal account of what suboptimal pharmaceutical care looks and feels like within your own experience.

Theoretical Domain mapped to

Environment context/resource

Being unable to follow up care issue due to other tasks

Not following up with Doctor due to lack of time

Not documenting actions on TRAK due to lack of time/lack of PC issues

Plan to see patient and then don't due to other pressures/constraints on time

Failing to check if complies with formulary because don't have time

Memory attention and decision-making:

Missing changes to prescription at transcription – saw what expected to see

Forgetting to follow up a care issue

Skills

Not actually seeing patient – didn't realise had nasogastric tube and this affected care issues

Intentions

Not following up in appropriate timescale –e.g. code 1 patient not seen for 48 hours

Social/professional role and identity

Not checking blood results because assumed someone else would

Knowledge

Lacking specialist knowledge for xx medicine and not acting on it, either by own learning or by contacting appropriate specialist

Beliefs about capabilities

Not passing onto colleagues ongoing issues at end of shift when not working next day

Appendix 3.11 Extracts from field notes for focus groups

Focus Group 1: Field notes from the researcher and facilitator indicated that participation was inclusive, with all participants contributing, and the discussion was wide ranging. There was a short delay whilst waiting for a participant who did not turn up. There were three interruptions (bleep). As this was the first session, researcher and facilitator discussed afterwards how to improve for next time, including using clearer instructions at outset to get discussion on the negative and positive influencing factors.

Focus Group 2: Field notes from the researcher and facilitator indicated that the discussion was wide ranging, with good participation, however the most junior member of staff needed to be prompted; was not reluctant but needed drawn in first. There were three interruptions (bleep, same person).

Focus Group 3: Field notes from researcher only, no facilitator at this session. Participation was dominated by two individuals and other participants needed to be prompted to input; sometimes they were talked over by dominant, more senior colleagues, and this was managed by researcher. There were no interruptions.

Focus Group 4: Field notes from the researcher and facilitator indicated that participation was inclusive with all participants contributing; although less input from the most junior member of staff, who needed to be prompted. There was one interruption (bleep).

Focus Group 5: Field notes from the researcher and facilitator indicated that participation was inclusive although with less input from the most junior member of staff, and there were two interruptions (bleep) and one participant arrived late. It was felt this group had a more negative outlook.

Appendix 3.12 Transcripts of post-it notes and illustrative quotes

Written statements were transcribed, and are presented. Where necessary, the example of suboptimal pharmaceutical care is expanded to give contextual understanding [in square brackets]. The use of colour in the tables reflects the different colours of post-it notes for: example of suboptimal pharmaceutical care (green), negative influencing factor or barrier (orange) and positive influencing factor or enabler (pink). Illustrative quotes extracted from the audio files are included. Tables are presented for medicines reconciliation and Kardex/medicines review separately for each focus group, as per study design.

Medicines Reconciliation

Focus group 1: Written statement/illustrative quotes transcript: medicines reconciliation.

Example of suboptimal pharmaceutical care		Illustrative quote
Lack of shared ownership/responsibility [for medicines reconciliation]		<i>'Technically the pharmacist's role should be a verification process, but it's not.'</i>
Not seeing as a dynamic process [i.e. process that needs to be updated during patient stay]		
Using inappropriate sources – GP print; old IDL, incomplete or wrong ECS;		<i>'There's not a policy that says which sources, it just says two sources'</i>
Medicines reconciliation not carried out at all		
Inability to complete medicines reconciliation – patient absent, distractions, beeped/called away from ward		
No clear area to document medicines reconciliation		<i>'I mean, where do you keep a med rec?- there's just no consensus'</i>
Negative influencing factor/barrier	Positive influencing factor /enabler	
Loose paper being lost	Agreed location and format	
Incomplete medicines reconciliation – <ul style="list-style-type: none"> • Specialist area focus only • not using 2 sources • incomplete documentation 		<i>'maybe they don't feel as confident when it's general medical things or maybe they are happy doing their specialist area but can't be bothered with anything out with that'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Lack of motivation/time Only focussing on area of specialty rather than all medicines	Maintaining generalist knowledge. Using ECS as primary source Motivation as see benefit	

Focus group 2: Written statement/illustrative quotes transcript: medicines reconciliation.

Example of suboptimal pharmaceutical care		Illustrative quote
Too many resources to access – ECS, renal vital data, GP letter, patient [increases time taken to do medicines reconciliation thoroughly]		'sometimes when there are too many sources of information it can be difficult to get to the point where it all matches up'
Negative influencing factor/barrier	Positive influencing factor/enabler	
Out of date ECS Lack of time Patient volume	Clinical technician referral tool/input	
Location of documentation [not easy to find]		
Health care professionals and patients not recognising medicines as medicines – e.g. patch, pill, inhaler, ointment		'the patient forgot to mention one that wasn't listed, -and it was specialist prescribed SACT!' (systemic anti cancer therapy)
Over reliance on one source [best practice suggests two sources of information]		
Over emphasis on medicines reconciliation [impeding other aspects of pharmaceutical care]		'sometimes I think med rec has become such a focus; pharmaceutical care equals med rec, whereas to me it's only part of it' 'I must have all this documented before he goes to the next ward otherwise that pharmacist will think I'm terrible'
Lack of available resources e.g. ECS [up to date ECS not always available]		
Time issues – more patients less intensely or less patients done well		'I always think it's better to see less patients and try and finish what you're doing with each patient'
Patient unable to provide information [on their medicines]		
Revisiting an incomplete episode duplicating effort [due to poor documentation]		
Traceability of documentation – who has completed/seen/added [for purpose of follow up]		'TRAK is set up different on different sites so we don't always know where stuff is'
Asking closed questions of patient [to obtain information required for thorough medicines reconciliation]		'a patient may give their whole life story but not give you relevant information'
Negative influencing factor/barrier	Positive influencing factor/enabler	'I think it's just the way we're trained – pharmacists may focus on medicines too much' 'I need to think about how I'm going to speak to this patient, how I introduce myself so they know who you are and what you're there for'
Patient expectation Overemphasis on medicines and not seeing other factors e.g. medical history Time consuming task	Health literacy Holistic approach Training in open questioning skills	

Focus group 3: Written statement/illustrative quotes transcript: medicines reconciliation.

Example of suboptimal pharmaceutical care		Illustrative quote
Lack of understanding of medicines reconciliation and why doing it within multidisciplinary team		
Pharmacy staffing – priorities [competing priorities on time]		<p><i>'so, you don't actually finish the process, not through lack of following the process, or lack of skill, but because of other priorities pulling you away'</i></p> <p><i>'I may have covered it for me, but it still feels suboptimal for the patient'</i></p>
Timeliness [completing within appropriate timescale]		
Patient factors – capacity/cognition [and impact on ability to carry out medicines reconciliation]		<i>'sometimes – it's not an ideal scenario – but for that patient, that is the best (pharmaceutical) care that's going to be available'</i>
IT access on wards limited		<p><i>'you can't record in real time due to lack of access'</i></p> <p><i>'I can't sit there and do that like for every patient and hog the computer'</i></p>
Not following process [for carrying out and documenting medicines reconciliation]		
Lack of access to relevant information [relating to patient's medicines]		<i>'good TRAK training would help; everything I find on TRAK that has been useful has been shown to me by someone else, not through pharmacy training and not through TRAK training'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Structure of IT system makes information retrieval difficult		
Prescribing split into specialties with no transfer of information; (primary/secondary/specialist) complex care for vulnerable p patients [relates to lack of single system to access information relating patient's medicines]		<i>'you may feel you've done med rec, may or may not have spoken to the patient, but you can still end up finding that something is missed'</i>

Focus group 4: Written statement/illustrative quotes transcript: medicines reconciliation.

Example of suboptimal pharmaceutical care written statement)		Illustrative quote
Availability of sources for med rec e.g. ECS not available/not up to date [impacts on ability to perform medicines reconciliation]		
Reassignment of staff/priorities whilst carrying out task [referencing that task is not always possible due to service pressures]		
Patient cognition/language barrier/willingness to engage; patients' expectation		<i>'sometimes a frustrated patient just wants to vent'</i>
Distractions on ward		<i>'you can be half way through a task and then another priority comes up and you're called away, and not handed over'</i>
Patient not present e.g. away for scan/x-ray		
Kardex/ECS/Med rec don't match [requiring time to establish accurate list of current medicines]		<i>'the patient was clearly on an inhaler, it was right by them, but it wasn't recorded anywhere'</i>
Communication/handover between staff e.g. Dr to Dr, pharmacist to Dr. pharmacist to pharmacist/pharmacy staff		<i>'The nurse said -I don't know why you're reviewing that kardex, that patient isn't going home yet'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Differences across different sites yet all sites access TRAK. Lack of understanding of pharmacy/pharmacy staff role by doctors and nurses – e.g. sometimes seen as policing role	Robust system in place with same terminology Clear documentation on what has been done/still to do	
Medicines reconciliation issues not followed up		<i>'some doctors do a great job and others just don't seem to think it's important and then, you know, you'll have to put in more effort and time'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Staff time constraint Complexity of patient; poor documentation – unable to identify and understand issues like stopped/withheld	Culture and attitude Training (pharmacist and doctor); clear processes (standardisation) One national single computer system through NHS Staff engagement with med rec	<i>'nursing staff are maybe not as involved with it, maybe see it as a doctor and pharmacist thing to sort out'</i>

Focus group 5: Written statement/illustrative quotes transcript: medicines reconciliation.

Example of suboptimal pharmaceutical care written statement)		Illustrative quote
Not seen by specialists (boarders)) [refers to patients outwith the speciality and the additional burden this brings]		
Incomplete (e.g. hospital only supply not on ECS-emergency care summary) [medicine reconciliation not being fully completed, using all sources, and documented appropriately]		<i>'the focus can be on what they get from the GP rather than everything'</i> <i>'the process might have happened but it's not clear that it has'</i>
Decision process not clearly documented (stop/continue/withhold)		<i>'sometimes med rec is seen in isolation as a task rather than as part of an ongoing process'</i>
Review of doses as appropriate for patient – age/weight, renal function		
Non-stock medicines – omitted doses or incorrect alternatives		<i>'patients may come back in with different things that we don't have and that can cause continuity issues that we can get caught up in'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Unlicensed medicines need ordering specially Access to medicines/supply process	Staff training/awareness session; Technician support e.g. with non-stock medicines	<i>'it doesn't take a pharmacist to say something is non-stock and needs to be ordered'</i>
Omission of OTC medicines on list		
Incorrect formulation/unmeasurable doses prescribed; targeted training for nurses		
Not completed		
Not being documented adequately		<i>'there is a lack of access to PC's on the ward, and now you need longer on the computer to find everything'</i>
Negative influencing factor /barrier	Positive influencing factor/enabler	
Access to computer Electronic case notes difficult to navigate	Writing notes straight onto TRAK; standardised medicine reconciliation form	<i>'Yesterday I saw a 2 day admission and there were 150 pages!'</i>

Focus group 1: Written statement/illustrative quotes transcript: Kardex/medicines review

Example of suboptimal pharmaceutical care		Illustrative quote
Not following up in appropriate timescale [according to local priority coding process]		<i>'suboptimal is not reviewing the patient in the timescale that you think is right'</i>
Locating appropriate resources to answer questions – ed Dr, nurse, pod keys, drug cupboard keys, order books		<i>'I can spend a lot of time trying to find the doctor, trying to find the notes, trying to find the kardex, the nurse, the keys, trying to get into the pods, the cupboard, finding the order book'</i>
No medicine reconciliation done on admission (example where patient not referred for review until 3 weeks later)		<i>'as a pharmacist I find it very difficult not to get bogged down in the first kardex'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	<i>'maybe sometimes I am trying to go into too much depth; I've got too much knowledge and not enough time'</i>
Too many new patients to see to achieve proper medicines reconciliation Trying to do 'swoop' of kardexes to identify high risks but getting stuck (e.g. due to too much knowledge/unable to prioritise)	Culture and management support Pharmacy technician support	<i>'band 6's are much better trained now, but it's almost like they don't know what to do with their knowledge, and I don't think there's a lot of advice out there on that'</i> <i>'I was told – you saw this patient and you missed this – and it might have been for a million different reasons and I found that very difficult' (taken as criticism)</i>
Not checking blood results where appropriate[for medicines the patient is on]		
Not checking route of administration is appropriate		
Not actually seeing patient to assess risk factors e.g. NG tube, weight (high or low), IV cannula. [where review carried out remotely]		
Overreliance on notes and not speaking to staff or patient[to ascertain or confirm details of medicines patient is taking]		

Focus group 2: Written statement/illustrative quotes transcript: Kardex/medicines review

Example of suboptimal pharmaceutical care		Illustrative quote
Review of Kardex without patient having medicines reconciliation completed [contrary to best practice]		
Not prioritising high risk patients [for Kardex review practice according to priority coding process]		<p><i>'I'd ask nurses or doctors whether any patients are on high risk medicines, or I would have to check myself, before deciding who to kardex review'</i></p> <p><i>'suboptimal would be if you didn't flag those patients for follow up'</i></p>
Conflicting priorities		<p><i>'depends on whether you think it is suboptimal. Say you've got half an hour to whip round, what is better use of your time – to med rec 2 patients or to nip round 16 kardexes and make sure there are no overdoses, drug interactions, anything that is going to cause harm'</i></p> <p><i>'due to patient turnover in xx, it's maybe more risk reduction: look at kardex, everything's fine, move on'</i></p>
Signature in pharmacy box – what does it mean? [lack of clarity and variation in practice as not defined]		<i>'I might not be inclined to sign off a kardex in a situation where I have 20 minutes to see 20 patients...like as a communication tool – I haven't signed off because I haven't been able to do all the checks I want to do. But this is just something I have set up for myself'</i>
Pharmacy/clinical team's expectations		<i>'expectations are different in each area and staffing is different in each area; some areas have clinical technicians and some have none'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Making assumptions Mixed messages within one team	Rotation packs for team Clear criteria for pharmacy as a whole Team specific induction to make expectations clear	<p><i>'when I started in xx I kind of just had to go, had to decide what were the priorities'</i></p> <p><i>'there is an assumption made that you will know what to do, maybe of your skill set and competence'</i></p>
Multidisciplinary team's expectations		<i>'I want to know what is expected of ME!'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Ongoing need for team specific criteria		

Focus group 3: Written statement/illustrative quotes transcript: Kardex/medicines review

Example of suboptimal pharmaceutical care		Illustrative quote
Familiarity with patient care/case [can be barrier or enabler]		<i>'so, you know the patient really well, and you look at a kardex and you see what you expect to see, and you miss the glaringly obvious transcription error '</i>
Only see what expect to see [confirmation bias, and related to familiarity]		
Access to Kardex [to carry out review]		
Lack of technician resource [to identify at risk patients]		
Negative influencing factor/barrier	Positive influencing factor/enabler	
	Skills mix Use of technician referral tool	
Missing changes to medicines since admission due to infrequent visits to ward/not checking back		<i>'you base the coding on what the patient is on at the start, but a few days later they could have been started on a high-risk medicine'</i>
Lack of specialist knowledge and training [to be able to provide adequate medicine review in a specialist role]		<i>'there's not adequate time to train yourself before you need to use that knowledge, you kind of wait until something has happened and go, I need to learn about that'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	
Online only access to journals limits reading	Regular MI updates and training Critical appraisal skills Protected learning time and resource Journal club	<i>'to prepare for a journal club we would need time and there isn't any, and we don't necessarily have the appraisal skills either'</i> <i>'we may be better at voicing our thoughts and our knowledge with the multidisciplinary team but we maybe don't have the level of expert knowledge we'd like'</i>
Ability to pass on issues to other pharmacists in team [handover of ongoing and unresolved pharmaceutical care issues]		<i>'sometimes a doctor will call to get an answer, and you really don't know what the other person has already said or what to do next'</i>
Multiple roles of pharmacists, may be off site. [as a barrier to conducting adequate and timely medicine review]		<i>'sometimes you are communicating without being able to know whether the action has been done or not'</i>
Time management [as a barrier to conducting medicine review]		

Focus group 4: Written statement/illustrative quotes transcript: Kardex/medicines review

Example of suboptimal pharmaceutical care		Illustrative quote
Issues with medicine availability and access		<i>'sorting out unlicensed medicines and non-formulary- that all takes time'</i>
Decision making		<i>'sometimes you're waiting for a decision to be made, you've flagged up issues but they haven't been acted on and there's no one around'</i>
Access to computers (especially when paperlite)		<i>'I can't get access to a computer and I think, I'll do it later, and maybe don't, or I think I'll do it tomorrow, or half complete and then not go back'</i>
Timely review – staff availability, competing priorities		<i>'suddenly that patient that should have been seen, won't get seen'</i>
Negative influencing factor/barrier	Positive influencing factor/enabler	<i>'the frustration is I know where I should be focussing my time but I still don't have enough time'</i>
Lack of documentation to support review Lack of pharmacist resource; lack of doctors to follow up Incomplete TRAK notes, time added unknown	More staff would help, variety of grades and clinical technicians	<i>'it's so time-consuming putting things on TRAK compared to how we used to do it'</i>
Experience of pharmacists to know what should be followed up-competence/experience/training.		<i>'there are issues you'd be able to sort out yourself if you were a prescriber'</i>

Focus group 5: Written statement/illustrative quotes transcript: Kardex/medicines review

Example of suboptimal pharmaceutical care		Illustrative quote
Capacity		<p><i>'we have quite a tight schedule so we only really see discharges'</i></p> <p><i>'I may plan to see a patient but then don't'</i></p> <p><i>'I aim to see every kardex every day and then kind of prioritise with my own internal system'</i></p> <p><i>'we often just work to demand, and there's still another whole workload, with no slack built in'</i></p> <p><i>'I spend a lot of time going between the doctor and the nurse-nurses contact me first and I'm the conduit'</i></p>
Negative influencing factor	Positive influencing factor	
Get drawn into technical issues	<p>Review of skill mix, use of pharmacy technicians/upskilling</p> <p>Defined role within multidisciplinary team</p> <p>Clinical pharmacy service aims clarified</p> <p>Team working – learning from each other and supporting each other</p>	
Formulary adherence		<p><i>'don't have time to check, like say non-formulary prescribing, there's just not time, you have to just make sure it's safe'</i></p>
Medicines stewardship		
Priority review vs comprehensive		<p><i>'sometimes I don't have enough time to access the information I need to be able to prescribe'</i></p> <p><i>'there's a huge emphasis on discharge, rather than carrying out pharmaceutical care'</i></p>
Standalone computer prescribing system		
Time pressures		
Communication		

Appendix 4.1 Template for field notes – interviews

Field notes and observations for Phase 2 Interviews	
Interviewee Name:	Interviewee reference:
Date:	Time:
Room booking details:	
Consent confirmed: Y/N	
Digital recorder used:	File reference for audio recording
Participant engagement: e.g. full/distracted	Duration of interview
Reflective notes observations and commentary:	
Key themes from interviews:	

Appendix 4.2 Semi-structured interview schedule designed around Theoretical Domains Framework (TDF)

	Domain	Sample questions
1	Knowledge	What would you describe as suboptimal pharmaceutical care? Do you know how to identify report or act on suboptimal pharmaceutical care in context of your own practice? What does it mean to you?
2	Skills	What skills, attributes or information do you think you need to be able to identify or report suboptimal pharmaceutical care? Have you been trained in any of these skills?
3	Social/professional roles and identity	Who do you think would be best at identifying suboptimal pharmaceutical care? Who should report, and who should develop actions to take?
4	Belief about capabilities	How would your ability to identify suboptimal pharmaceutical care be affected by external factors? e.g. time, access to patient data. How confident are you that you can overcome the barriers?
5	Optimism	With regard to identifying, reporting or acting on suboptimal pharmaceutical care, are you optimistic about the task?
6	Belief about consequences	Will there be any disadvantage to you if identifying, reporting or acting on suboptimal pharmaceutical care? (treat as 3 questions)
7	Reinforcement	Do you think there will be recognition from within Pharmacy or within the multidisciplinary team if you identify report or act on suboptimal pharmaceutical care? Would that be positive? Negative?
8	Intentions	Have you intended to report or escalate an episode where suboptimal pharmaceutical care has been a concern, in yourself or in another? How strong was the intention? Were there barriers? What would you expect outcome to be?
9	Goals	When thinking about identifying reporting or acting on suboptimal pharmaceutical care, how often is something else higher on your agenda?
10	Memory, attention and decision-making	How often do you forget to complete a task, or lack the focus that is needed to complete a task?
11	Environment context and resource	Would resources or a different work environment make a difference to your likelihood to identify report or act on suboptimal pharmaceutical care? Time? Computer access? Other team members availability?
12	Social influences	Who would benefit from pharmacists identifying reporting or acting on suboptimal pharmaceutical care? Who would influence or affect the reporting?
13	Emotion	Are there instances when your reflection on an example of suboptimal pharmaceutical care has caused anxiety? Or where optimal pharmaceutical care has led to feeling of satisfaction?
14	Behavioural regulation	How do you reflect personally on your delivery of pharmaceutical care? How do you track your personal progress in the delivery of pharmaceutical care to patients?

Appendix 4.3 The Big 5 Inventory personality test

The Big Five Inventory (BFI – dimensions of personality)

Here are a number of characteristics that may or may not apply to you.

Please write a **number** next to each statement to indicate the extent to which you agree or disagree with that statement.

Disagree strongly	Disagree a little	Neither agree nor disagree	Agree a little	Agree Strongly
1	2	3	4	5

I see myself as someone who...

	Score		Score
Is talkative		Tends to be last	
Tends to find fault with others		Is emotionally stable, not easily upset	
Does a thorough job		Is inventive	
Is depressed, blue		Has an assertive personality	
Is original, comes up with new ideas		Can be cold and aloof	
Is reserved		Perseveres until the task is finished	
Is helpful and unselfish with others		Can be moody	
Can be somewhat careless		Values artistic, aesthetic experiences	
Is relaxed, handles stress well		Is sometimes shy, inhibited	
Is curious about many different things		Is considerate and kind to others	
Is full of energy		Does things efficiently	
Starts quarrels with others		Remains calm in tense situations	
Is a reliable worker		Prefers work that is routine	
Can be tense		Is outgoing, sociable	
Is ingenious, a deep thinker		Is sometimes rude to others	
Generates a lot of enthusiasm		Makes plans and follows through with them	
Has a forgiving nature		Gets nervous easily	
Tends to be disorganized		Like to reflect, play with ideas	
Worries a lot		Has few artistic interests	
Has an active imagination		Likes to cooperate with others	
Tends to be quiet		Is easily distracted	
Is generally trusting		Is sophisticated in art, music or literature	

Amanda McLean. Quality Risk and Governance Pharmacist, NHS Scotland Organisation & Doctorate of Professional Practice Student, Robert Gordon University.

Appendix 4.4 Standard Operating Procedure for Interviews

Standard Operating Procedure

Phase II interviews with hospital clinical pharmacists in NHS Scotland Organisation, to explore their experiences of 'optimal' and 'suboptimal' pharmaceutical care.

The purpose of this procedure is to ensure the interviews function effectively, to ensure consistency of approach and clarity of responsibilities.

In advance:

Contact pharmacists from Focus Groups, outlining research and asking for recruits.

Where interest noted, assess preferred day/time.

Arrange dates for sessions. Book room at sites.

Once confirmed, send out advance notice of date/time

On day:

Arrive in advance to set up room : 2 chairs, table with digital recorder.

Check participants have given consent, and get signatory of participation.

Introduce self, ask participant to complete Big 5 inventory personality test (3-4 minutes)

Introduce interview topic and method of recording data; take questions before starting the discussion.

During:

Maintain focus and keep to time. Aim for unstructured interview but refer to Interview Guide for prompts and probes if necessary.

Make notes, including emerging themes relating to TDF

Give warning of time minus 5 minutes.

Close the interview. Thank participant.

Immediately after:

Write reflective journal

Afterwards:

Thank participants via email.

Appendix 4.5 Standardised one to one interview introduction

Reminder of Project title: Experiences and behaviours of hospital clinical pharmacists relating to the identification, reporting and responding to suboptimal pharmaceutical care (SOPC).*

The purpose of this interview is to expand on discussions from focus group where suboptimal pharmaceutical care was discussed. You will now have an opportunity to expand those discussions individually. I will be looking for themes which will be matched to the theoretical domains framework which is a psycho-social tool for analysing qualitative data such as that that comes from focus groups and interviews. It has been chosen because the domains can be matched to intervention types.

As this is a research interview, it will be audio recorded. As an interviewer, I may appear more formal than you thought and may ask probing or seemingly intrusive questions. The data will be anonymous and cannot be traced to an individual. You were sent some information on themes that were assimilated following the focus groups (share Appendix 3.10)

During the interview you will be asked to think about suboptimal pharmaceutical care particularly in your own experience and practice. When you signed the consent form you were asked that you understood that any event disclosed where patient safety may have been compromised would be followed up following normal governance procedures for adverse event reporting. Your consent form is here, (show to participant), and you are asked to confirm that it is your signature on it

We will be discussing how you can identify and/or act on and/or report suboptimal pharmaceutical care, and also about your feelings related to this. As an ice breaker you are now asked to complete a personality profile called the Big 5 inventory. This looks at the following as dimensions of personality: extroversion, agreeableness, conscientiousness, neuroticism and openness. (Hand the test sheet over for completion)

Appendix 4.6 Big Five Inventory scale scoring

The Big Five Inventory (BFI – dimensions of personality) : Scale scoring

Disagree strongly	Disagree a little	Neither agree nor disagree	Agree a little	Agree Strongly
1	2	3	4	5

I see myself as someone who...

E = extroversion; A=Agreeableness C=conscientiousness N=neuroticism O=openness			
Is talkative	E	Tends to be lazy	C(R)
Tends to find fault with others	A(R)	Is emotionally stable, not easily upset	N (R)
Does a thorough job	C	Is inventive	O
Is depressed, blue	N	Has an assertive personality	E
Is original, comes up with new ideas	O	Can be cold and aloof	A(R)
Is reserved	E (R)	Perseveres until the task is finished	C
Is helpful and unselfish with others	A	Can be moody	N
Can be somewhat careless	C (R)	Values artistic, aesthetic experiences	O
Is relaxed, handles stress well	N (R)	Is sometimes shy, inhibited	E(R)
Is curious about many different things	O	Is considerate and kind to almost everyone	A
Is full of energy	E	Does things efficiently	C
Starts quarrels with others	A(R)	Remains calm in tense situations	N (R)
Is a reliable worker	C	Prefers work that is routine	O (R)
Can be tense	N	Is outgoing, sociable	E
Is ingenious, a deep thinker	O	Is sometimes rude to others	A(R)
Generates a lot of enthusiasm	E	Makes plans and follows through with them	C
Has a forgiving nature	A	Gets nervous easily	N
Tends to be disorganized	C (R)	Like to reflect, play with ideas	O
Worries a lot	N	Has few artistic interests	O(R)
Has an active imagination		Likes to cooperate with others	A
Tends to be quiet	E(R)	Is easily distracted	C (R)
Is generally trusting	A	Is sophisticated in art, music or literature	O

Amanda McLean. Quality Risk and Governance Pharmacist, NHS Scotland Organisation & Doctorate of Professional Practice Student, Robert Gordon University.

Appendix 4.7 Report template for personality scores for participants

BIG FIVE INVENTORY OF PERSONALITY TRAITS

The five traits are said to be EXTROVERSION, AGREEABLENESS, CONSCIENTIOUSNESS, NEUROTICISM AND OPENNESS,

	average	max	min	Your score
Extroversion	29.3	38	21	
Agreeableness	37.7	43	31	
Conscientiousness	33.4	43	24	
Neuroticism	23	33	13	
Openness	34.2	45	24	

Extroversion has two familiar ends of the spectrum: extroversion and introversion. It concerns where an individual draws their energy and how they interact with others. In general, extroverts draw energy or “recharge” from interacting with others, while introverts get tired from interacting with others and replenish their energy from solitude.

People high in extroversion tend to seek out opportunities for social interaction, where they are often the “life of the party.” They are comfortable with others, gregarious, and prone to action rather than contemplation. People low in extroversion are more likely to be people “of few words,” people who are quiet, introspective, reserved, and thoughtful.

Agreeableness concerns how well people get along with others. While extroversion concerns sources of energy and the pursuit of interactions with others, agreeableness concerns your orientation to others. It is a construct that rests on how you generally interact with others.

People high in agreeableness tend to be well-liked, respected, and sensitive to the needs of others. They likely have few enemies, are sympathetic, and affectionate to their friends and loved ones, as well as sympathetic to the plights of strangers. People on the low end of the agreeableness spectrum are less likely to be trusted and liked by others. They tend to be callous, blunt, rude, ill-tempered, antagonistic, and sarcastic. Although not all people who are low in agreeableness are cruel or abrasive, they are not likely to leave others with a warm fuzzy feeling.

Conscientiousness is a trait that can be described as the tendency to control impulses and act in socially acceptable ways, behaviours that facilitate goal-directed behaviour. Conscientious people excel in their ability to delay gratification, work within the rules, and plan and organize effectively.

Someone who is high in conscientiousness is likely to be successful in school and in their career, to excel in leadership positions and to doggedly pursue their goals with determination and forethought. A person who is low in conscientiousness is much more likely to procrastinate, to be flighty, impetuous, and impulsive.

Neuroticism is not a factor of meanness or incompetence, but one of confidence and being comfortable in one’s own skin. It encompasses one’s emotional stability and general temper

Those high in neuroticism are generally given to anxiety, sadness, worry, and low self-esteem. They may be temperamental or easily angered, and they tend to be self-conscious and unsure of themselves. Individuals who score on the low end of neuroticism are more likely to feel confident, sure of themselves, and adventurous. They may also be brave and unencumbered by worry or self-doubt.

Openness to experience has been described as the depth and complexity of an individual’s mental life and experiences. It is also sometimes called intellect or imagination. Openness to experience concerns an individual’s willingness to try to new things, to be vulnerable, and the ability to think outside the box.

An individual who is high in openness to experience is likely someone who has a love of learning, enjoys the arts, engages in a creative career or hobby, and likes meeting new people. An individual who is low in openness to experience probably prefers routine over variety, sticks to what they know, and prefers less abstract arts and entertainment

Appendix 4.8 Extracts from field notes for interviews

Interviewee	Reflective field note (extract)
1	<ul style="list-style-type: none"> • Fixing not solving • Poor self-reporting/responsibility/ownership • Age and experience as factor • Prioritisation • Highlighting gaps.
2	<ul style="list-style-type: none"> • Self-blame • Competing priorities • Failing to follow up • Hierarchy • Fixing • Embarrassment and self esteem
3	<ul style="list-style-type: none"> • Time pressures • Fixing • Failing to share learning • Only feeding back serious issues • Hierarchy
4	<ul style="list-style-type: none"> • Time pressures • Lack of feedback from MDT • Fixing not feedback • Informal peer review • Embarrassment as barrier
5	<ul style="list-style-type: none"> • Feedback -giving and receiving • Fixing not solving • Attitude and culture • Reluctance (professional embarrassment) • Dissatisfaction
6	<ul style="list-style-type: none"> • Fixing • Time as barrier • Feedback • Difference in opinion/variation across profession • Barriers to sharing learning • Hierarchy as barrier
7	<ul style="list-style-type: none"> • Junior staff support via informal peer review • Blame culture • Professional embarrassment • Attitude and culture • PC access
8	<ul style="list-style-type: none"> • Making assumptions • Failure to feedback to colleague • Own poor experience of feedback • Informal peer review/sharing
9	<ul style="list-style-type: none"> • Developing experience • Time pressures and prioritisation • Informal peer review • Hierarchy barrier
10	<ul style="list-style-type: none"> • Time pressure • Dissatisfaction • Lack of timely access to PC • Self-esteem • Informal mechanisms

Appendix 4.9 Examples of suboptimal pharmaceutical care from interview transcripts

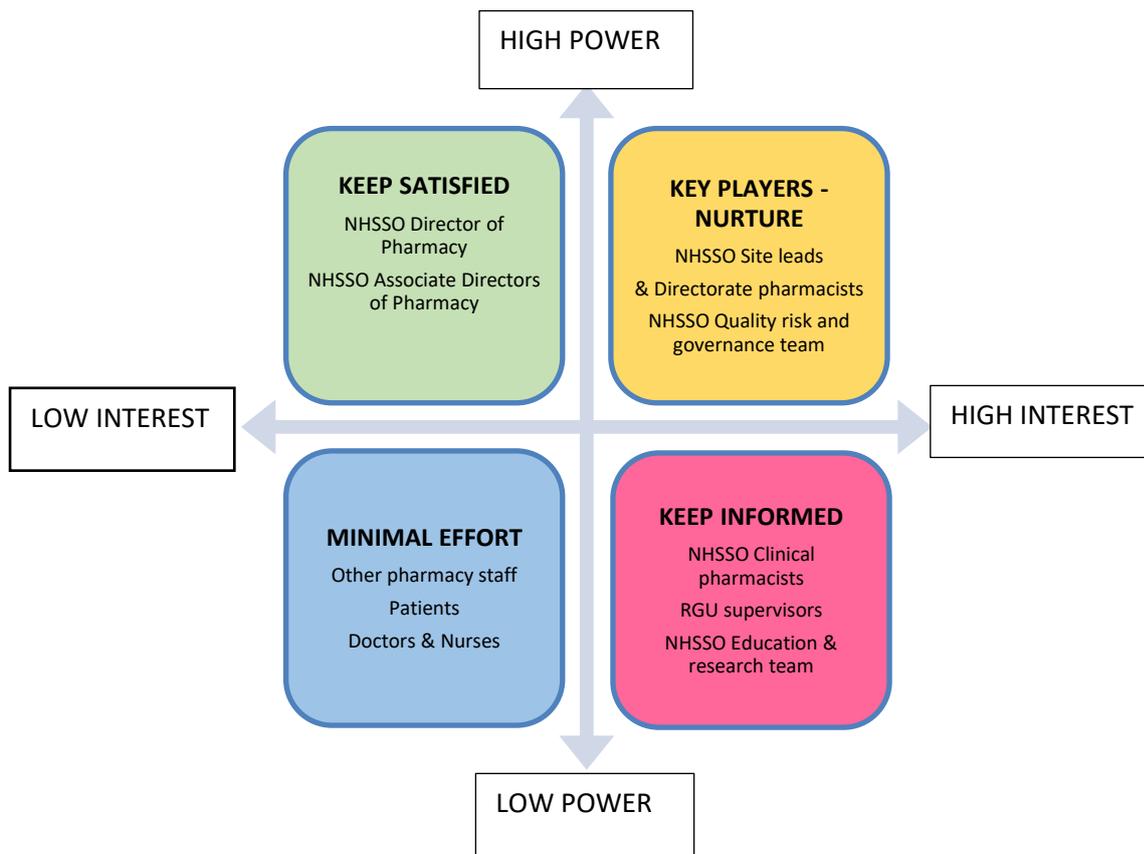
Error by: (Self or other)	Identified by	Example	Type of error (according to Reason's* accident causation model)
SELF	OTHER Pharm	Error missed when chart rewritten – drug prescribed twice a day instead of daily; chart had been seen but overlooked	SLIP
SELF	OTHER Dr	Wrong advice given about reduction in opioid dose	MISTAKE
SELF	SELF Near miss	Mixing two patients vancomycin results and getting dose calculations wrong	SLIP Near miss
SELF	OTHER Dr	Error missed when chart rewritten – chart not seen	LATENT
OTHER	OTHER Pharm	Interaction missed, not known about by trainee pharmacist	MISTAKE
SELF	OTHER Dr	Error on discharge prescription missed at clinical check	LAPSE
SELF	SELF	Failed to get round all patients had planned to see in a session, unknown consequence but included high risk patients	LATENT
OTHER	OTHER Pharm	Failed to detect omission on prescription – did not have knowledge of protocol.	MISTAKE
SELF	SELF	Missed satisfactorily reviewing patient due to lack of time (fixed by completing next day)	LATENT
SELF	SELF	Not communicating discharge to community pharmacy (fixed by completing next day)	LAPSE

SELF	OTHER Nurse	Prescribed insulin at wrong frequency when transcribing (pharmacist independent prescriber)	SLIP Reportable error
SELF	SELF	Did not flag a patient for warfarin counselling resulting in it needing to be done in a rush	LAPSE
SELF	OTHER Pharm	10 fold error in prescription for patients own meds (pharmacist independent prescriber)during medicines reconciliation. 2 doses administered	SLIP (violation if approved process not followed) Reportable error
SELF	SELF	Not documenting on discharge letter that has been clinically checked, creating additional work	LAPSE
SELF	OTHER	Colleague pointed out a missed interaction between medicines that both contribute to QT prolongation	MISTAKE Reportable error

*(Reason 2000)

Appendix 5.1 Creating local impact for the research

As this was professional practice research, taking place within the researcher's base in NHS Scotland Organisation (NHSSO) pharmacy department, prior approval was sought from the senior management team. During planning of the study, a power/interest impact diagram was constructed to ensure all stakeholders were identified, and to understand the relationship between them and the research:



Different methods were used to seek approval and to raise awareness of the proposed research in advance. Oral and written presentations were made to senior management teams asking for support in the research project, particularly in terms of allowing and enabling staff to be released to take part in the research study. There was support for the project from all Site Leads and the Director and Associate Directors of Pharmacy, and this was recorded in meeting minutes.

Support from clinical pharmacists was gained by presenting the research proposal as a short oral presentation at an open-invite R & D session, and by presenting to the clinical pharmacy operations group.

Stakeholder approval for research project.

Key players or stakeholder	Method
NHSSO Director of Pharmacy (Keep satisfied)	Oral presentation of outline proposal and request for NES funding approval
RGU Supervisors (Keep informed)	Research approval, through university procedures; annual update
NHSSO Associate Directors of Pharmacy (Keep satisfied)	Pharmacy Operations Group – presentation at meeting
NHSSO Site Leads (Nurture)	Pharmacy Operations Group – presentation at meeting
NHSSO Pharmacy Education Research and Development Team (Keep informed)	Pharmacy Operations Group – presentation at meeting Presented proposal at NHS Scotland Organisation R&D Session Lead also at presentation of outline proposal and request for NES funding approval
NHSSO Clinical pharmacists (Keep informed & Nurture)	Presented proposal at NHS Scotland Organisation R&D Session, and at the clinical pharmacy operations group (Lead clinical pharmacists also attend Pharmacy Operations Group)
NHSSO Quality risk and governance team (Keep informed)	Ongoing communication Lead also at presentation of outline proposal and request for NES funding approval

NHSSO = NHS Scotland Organisation where research took place.

As the study progressed, steps were taken to keep stakeholders informed. An annual monitoring progress report (as required by Robert Gordon University)

was used for communication both to university supervisors (academic) and to the NHS Scotland Organisation Education Research and Development team (workplace).

Interim findings were presented at a further NHS Scotland Organisation open-invite R & D session, and oral and poster presentations (as described in the research outputs section of this thesis) were made available on the NHS Scotland Organisation pharmacy Education Research and Development intranet site and included in newsletters. The reach of these sessions was to all pharmacy staff and included clinical pharmacists.

In addition to these formal means, there were interim informal meetings with academic and workplace supervisors, the education and research team, lead directorate pharmacists and the quality risk and governance team. In addition to being beneficial for impact building, the informal meetings formed an integral part of the research project, on reflexivity, and on continued governance. Specific parts of this process of reflexivity and reflection are referenced in the thesis, but the ongoing interaction with others who are stakeholders, to ensure the project remained focussed, was an important component of the research planning and conduct.

Appendix I Output from research Poster 1

Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework



Amanda McLean (NHS Lothian & RGU); Derek Stewart (RGU); Vibhu Paudyal (University of Birmingham); Moira Kinnear, Elaine Rankine & Caroline Souter, (NHS Lothian)
 ✉ a.p.mclean@rgu.ac.uk

Background/Introduction

Pharmaceutical care describes the delivery of clinical pharmacy services & has been defined by the Scottish Government in "Prescription for Excellence" as: "a model for pharmacy practice which requires pharmacists to work in partnership with patients and other health and social care professionals to obtain optimal outcomes with medicines and eliminate adverse events where possible"

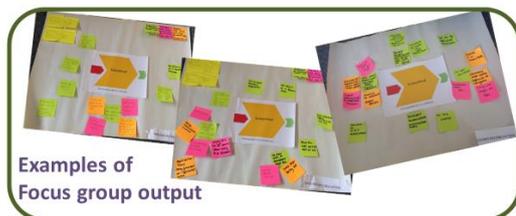
Whilst there have been many studies on the quality of other pharmacy services there have been fewer that have focussed on pharmaceutical care delivery. This research aims to look at how hospital clinical pharmacists perceive suboptimal pharmaceutical care, where it can be described as a continuum:



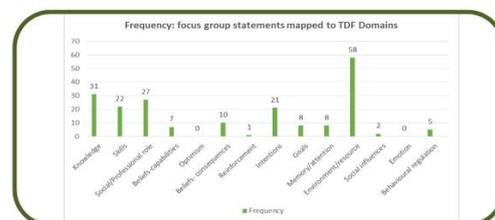
Methods

This study is qualitative, looking at the "lived experience" of pharmacists who are delivering pharmaceutical care to patients. In the first phase, five focus groups were held with a total of 20 hospital clinical pharmacists from NHS Lothian. The focus group method was adapted, with participants asked to records statements onto post-it notes that best described suboptimal pharmaceutical care in the areas of medicine reconciliation and medicines review. Each session was audio recorded to get additional verbal quotes.

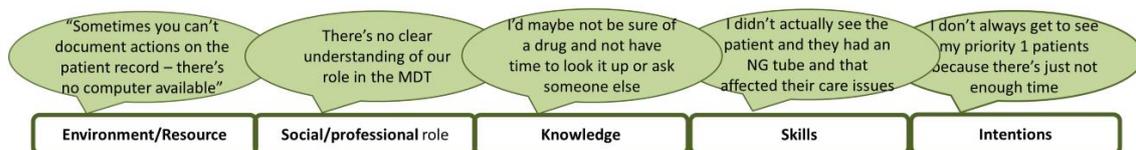
Results



Examples of Focus group output



Quotes from focus group participants: top 5 domains



Conclusion: Suboptimal pharmaceutical care can be identified by hospital clinical pharmacists in relation to the services they are providing. The theoretical domains framework can be used to map the examples, and can help to identify behavioural determinants

Next Steps: One to one interviews with hospital clinical pharmacists in NHS Lothian looking at their experiences of providing and/or encountering suboptimal pharmaceutical care. The interviews will be mapped to the theoretical domains framework and thematic analysis used to identify behavioural determinants

References

- References
- [1] Kitzinger, J. Introducing focus groups. *BMJ* 1995; 311; 299-302
- [2] Cane, J., O'Connor, D. and Michie, S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci.* 2012; 7; 27-35

Appendix II Output from research – Poster 2

Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework (TDF)



Amanda McLean (NHS Lothian & RGU); Derek Stewart (RGU); Vibhu Paudyal (University of Birmingham); Moira Kinnear, Elaine Rankine & Caroline Souter, (NHS Lothian)
 ✉ a.p.mclean@rgu.ac.uk

Background/Introduction

Pharmaceutical care describes the delivery of clinical pharmacy services & has been defined by the Scottish Government in "Prescription for Excellence" as: "a model for pharmacy practice which requires pharmacists to work in partnership with patients and other health and social care professionals to obtain optimal outcomes with medicines and eliminate adverse events where possible"

Whilst there have been many studies on the quality of other pharmacy services there have been fewer that have focussed on pharmaceutical care delivery. The aim of this research is to explore how hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care. The study recruits were asked to consider pharmaceutical care as a continuum, as shown in the schematic below.



Methods

This study is qualitative, looking at the "lived experience" of pharmacists who are delivering pharmaceutical care to patients.

Phase 1 involved 5 focus groups with a total of 20 hospital clinical pharmacists from NHS Lothian, recruited purposively. The focus group method was adapted, with participants asked to record statements on post-it notes to describe suboptimal pharmaceutical care. Audio recording was used to back up the statements with verbal quotes. A focus group guide was developed and a facilitator was present. The output was mapped to TDF, and independently verified by the research team.

Phase 2 consisted of one to one interviews with 10 volunteers recruited from the focus group cohort, to explore their experiences of providing, or experiencing the output of, suboptimal pharmaceutical care. The interview guide was based on the Theoretical Domains Framework (TDF) and was piloted and validated by the research team. Interviews were audio recorded, transcribed, mapped to the TDF and verified by the research team.

Use of the TDF in qualitative research: The framework was developed by social scientists from 33 different theories of behavioural change. The aim was to simplify the process by which behavioural change theory could be applied, and make it accessible to a wider range of disciplines across healthcare, as a means of understanding the behavioural changes that can act as barriers or facilitators when planning or implementing changes in practice. The use of theory in the understanding of and in the planning of behaviour change has been shown to improve the intervention effectiveness.

The 14 domains are: Knowledge; Skills; Social/professional role and identity; Beliefs about capabilities; Optimism; Beliefs about consequences; Reinforcement; Intentions; Goals; Memory attention and decision processes; Environmental context and resources; Social influences; Emotion; Behavioural regulation

Results - Focus Groups: Top 5 domains and exemplar quotes

"what does suboptimal pharmaceutical care look like?"

20 Pharmacists in 5 focus groups discussed what they considered to be suboptimal in relation to topics of medicines reconciliation and medicines review. When mapped to the TDF, all domains were represented apart from reinforcement, emotion and optimism. The domains most frequently mapped are shown here, with exemplar quotes.

Environmental context and resources (37 statements identified)	Knowledge (21 statements identified)	Social professional role and identity (17 statements identified)	Memory attention and decision making (10 statements identified)	Skills (10 statements identified)
"Sometimes you can't document actions on the patient record – there's no computer available"	"I'd maybe not be sure of a drug and not have time to look it up or ask someone else"	"There's no clear understanding of our role in the MDT"	"I didn't actually see the patient and they had an NG tube and that affected their care issues"	"I don't always get to see my priority 1 patients because there's just not enough time"

Results – Interviews: Top 5 domains and exemplar quotes

"what are your experiences of providing or experiencing suboptimal pharmaceutical care?"

10 pharmacists were interviewed and gave accounts of their experiences of providing or experiencing suboptimal pharmaceutical care. When mapped to the TDF, all domains were represented. The domains most frequently mapped are shown here, with exemplar quotes.

Social professional role and identity (75 statements identified)	Behavioural regulation (45 statements identified)	Skills (44 statements identified)	Emotion (43 statements identified)	Environmental context and resources (33 statements identified)
"I think within pharmacy we're maybe not as good at sharing our negative experiences"	"Certainly after that I was incredibly careful when I was checking"	"I suppose self reporting is very difficult – that you have to blame yourself"	"I felt awful" "I felt terrible" "I felt guilty" "I felt mortified" "It just makes you feel sick"	"What's suboptimal? I mean a lot of it is about time pressures"

Conclusion

The focus groups identified an understanding of the concept of suboptimal pharmaceutical care amongst hospital clinical pharmacists. In one to one interviews they were able to give examples where they felt suboptimal pharmaceutical care had been provided. By identifying frequently mapped domains, some initial barriers, for example social professional role and identity and skills were identified, as well as facilitators, like behavioural regulation and emotion, when considering identifying and reporting on suboptimal pharmaceutical care.

Implications for practice and research

The theoretical domains framework can be used to identify behavioural determinants. Further research will explore what behaviour changes could be utilised to address barriers or to promote facilitators, in order to encourage the shared learning opportunities that reporting on suboptimal pharmaceutical care can provide for the hospital clinical pharmacy team. Future research will look to see whether these findings are replicated across the wider community of hospital clinical pharmacists.

References

- References
- [1] Kitzinger, J. Introducing focus groups. *BMJ* 1995; 311; 299-302
- [2] Cane, J., O'Connor, D. and Michie, S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci.* 2012; 7; 27-35

Appendix III Output from research Poster 3

Perceptions and experiences of hospital clinical pharmacists relating to suboptimal pharmaceutical care: qualitative studies using the Theoretical Domains Framework (TDF)



Amanda McLean (NHS Lothian & Robert Gordon University); Derek Stewart (University of Qatar); Vibhu Paudyal (University of Birmingham); Scott Cunningham (Robert Gordon University); Moira Kinnear, Elaine Rankine & Caroline Souter, (NHS Lothian)
 ✉ a.p.mclean@rgu.ac.uk

Background/Introduction

Pharmaceutical care describes the delivery of clinical pharmacy services & has been defined by the Scottish Government in "Prescription for Excellence" as: "a model for pharmacy practice which requires pharmacists to work in partnership with patients and other health and social care professionals to obtain optimal outcomes with medicines and eliminate adverse events where possible"
 Whilst there have been many studies on the quality of other pharmacy services there have been fewer that have focussed on pharmaceutical care delivery. The aim of this research is to explore how hospital clinical pharmacists perceive and experience suboptimal pharmaceutical care.

Methods

This study is qualitative, looking at the experience of hospital clinical pharmacists delivering pharmaceutical care to patients. Phase 1 involved 5 focus groups with 20 participants and the output from these informed the input to the 10 semi structured one to one interviews for Phase 2, with participants from Phase 1. Phase 2 data was mapped to TDF for thematic analysis, and example of suboptimal pharmaceutical care were mapped to Reason's error taxonomy. Themes from TDF were mapped to COM-B (capacity, opportunity, motivation-behaviour)- a behaviour change model, to identify which type of interventions work against the identified behaviours.

Findings

28 examples of suboptimal pharmaceutical care were extracted from 10 interviews and mapped to Reason's error taxonomy; these included examples from different types of error:

SLIP: *Error missed when chart rewritten – drug prescribed twice a day instead of daily; chart had been seen but overlooked*

MISTAKE: *Interaction missed, not known about by trainee pharmacist*

LATENT: *Failed to get round all patients had planned to see in a session, unknown consequence but included high risk patients*

LAPSE: *Error on discharge prescription missed at clinical check*

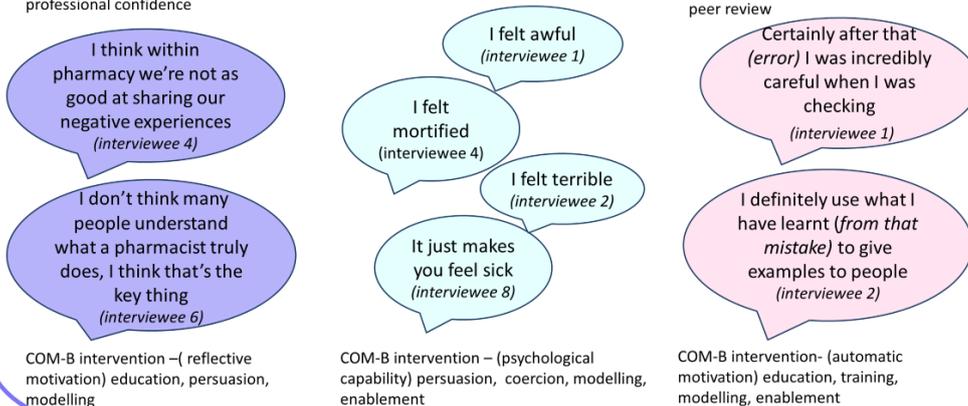
VIOLATION: *10 fold error in prescription for patients own meds by PIP during medicines reconciliation; process not followed.*

Interview transcripts were mapped to TDF to allow behaviours to be identified, which were then mapped to COM-B to identify interventions

TDF Domain: Social and professional role and identity: behaviours at work; professional confidence

TDF Domain: Emotion: personal influences like anxiety or stress

TDF Domain: Behavioural regulation: changing actions by self monitoring or peer review



Conclusion

In one to one interviews hospital clinical pharmacists were able to give examples where they felt suboptimal pharmaceutical care had been provided. By identifying frequently mapped domains, for example social and professional role and identity, behavioural regulation and emotion, some initial behavioural determinants were identified that can be utilised in planning interventions, and in supporting pharmacists when delivering pharmaceutical care. Use of TDF and COM-B increase confidence in the results and give theoretical underpinning.

Implications for practice and research

Further research will explore what behaviour change interventions could be used to address barriers or to promote facilitators, in order to encourage the shared learning opportunities that reporting on suboptimal pharmaceutical care can provide for the hospital clinical pharmacy team. Future research will look to see whether these findings are replicated across the wider community of hospital clinical pharmacists.

References

- [1] Atkins, L et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems *Implement Sci* 2017; vol 12, 77
- [2] Cane, J., O'Connor, D. and Michie, S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci.* 2012; 7; 27-35
- [3] Reason, J Human error: models and management; *BMJ* 2000 320;768

Appendix IV Formal training and learning

Formal training undertaken during professional doctorate:

Doctor of Professional Practice Modules 2014-2016; Robert Gordon University

1. Skills for research
2. Applied research methods
3. Creating impact in professional practice
4. Research process and critical evaluation

Questionnaire design – May 2015; Wellcome Trust Clinical Research Facility
Edinburgh

NVivo training. June 2016 University of Edinburgh Summer School for Scottish
Graduate School of Social Science

The art of qualitative interviewing. November 2016; Social Research
Association. Edinburgh

Health Sciences Research and Pharmacy Practice May 2017; Reading, UK. (as
delegate, to observe and learn about research presentation as posters and oral
presentation)

Tougher Minds for research students. September 2019; The Burn, Edzell, c/o
Robert Gordon University, Aberdeen.

Be a better writer (academic writing workshop) October 2019; Robert Gordon
University, Aberdeen.