Understanding procedural violations and their implications for patient safety in community pharmacies

A thesis submitted to the University of Manchester for the degree of Doctor of Philosophy in the Faculty of Biology, Medicine and Health

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# Contents

List of tables ................................................................. 7

List of figures ........................................................................ 8

List of abbreviations .............................................................. 9

Abstract ................................................................................ 11

Declaration and copyright .......................................................... 12

Acknowledgements .................................................................. 13

Dedication ................................................................................. 14

About the author ........................................................................ 15

CHAPTER 1: Introduction .......................................................... 16

1.1 - Introduction to the research .............................................. 16

1.2 - Community pharmacies in the UK .................................... 17

1.2.1 - The pharmacy team .................................................. 17

1.2.2 - Overview of community pharmacy work ...................... 17

1.3 - Summary of this thesis .................................................... 21

1.4 - The structure of this thesis .............................................. 21

CHAPTER 2: Literature review .................................................... 23

2.1 - Introduction ................................................................. 23

2.2 - Patient Safety ............................................................... 23

2.3 - Why focus on community pharmacies? .......................... 25

2.4 - Existing patient safety research in community pharmacies 28

2.4.1 - Environmental influences on patient safety ................ 28

2.4.2 - Situational influences on patient safety ....................... 38

2.4.3 - Individual influences on patient safety ......................... 42

2.5 - Human error and violations ............................................. 44

2.5.1 - Errors ...................................................................... 44

2.5.2 - Why do errors happen? .............................................. 46

2.5.3 - The use of procedures in healthcare ............................ 49

2.6 - Exploring violations ....................................................... 51

2.6.1 - What are violations? .................................................. 51

2.6.2 - Why do violations happen? ........................................ 52

2.6.3 - How should violations be explored in healthcare? ......... 56

2.7 - Aims and objectives for the thesis ................................. 60
CHAPTER 8: Discussion

8.1 - Chapter outline .................................................................................................................. 191
8.2 - Key findings from each study ............................................................................................ 191
  8.2.1 - Study one: Exploring the prevailing safety culture in community pharmacies .......... 191
  8.2.2 - Study two (part one): How are procedures perceived in community pharmacies ...... 192
  8.2.3 - Study two (part two): Using Safety-I and Safety-II to understand how and why violations occur in community pharmacies ................................................................. 192
  8.2.4 - Study three: Using COM-B to explore the influences on and the frequencies of violations in community pharmacies ..................................................................................... 193
8.3 - What does this thesis tell us about violations in community pharmacies? ...................... 193
8.4 - How can violations in CP be understood? ......................................................................... 195
8.5 - Why do violations occur in community pharmacies? ....................................................... 200
8.6 - Are violations useful for understanding safety? ................................................................. 202
8.7 - Implications ....................................................................................................................... 205
  8.7.1 - Practical implications .................................................................................................... 205
  8.7.2 - Methodological implications ......................................................................................... 209
8.8 - Future research directions .................................................................................................. 210
8.9 - Reflexivity and reflection on the research ......................................................................... 211
8.10 - Final conclusions .............................................................................................................. 214
References ........................................................................................................................................215
Appendices .....................................................................................................................................230
Appendix 1 - PPI comments on the MaPSaF study .................................................................230
Appendix 2 - MaPSaF ..................................................................................................................233
Appendix 3 - MaPSaF patient information leaflet .................................................................244
Appendix 4 - Interview topic guide .........................................................................................247
Appendix 5 - Patient information leaflet for the interview study ........................................249
Appendix 6 - COM-B questionnaire .........................................................................................252
Appendix 7 - COM-B-Q questionnaire ......................................................................................268
Appendix 8 - Stakeholder feedback for the COM-B questionnaire .......................................270
Appendix 9 - COM-B invitation letter .......................................................................................275
Appendix 10 - COM-B information sheet ................................................................................276

Word count: 51,692
List of tables

Table 1 - Accuracy checking procedure as taught to MPharm students at the University of Manchester ................................................................. 20
Table 2 - Violation types (123, 125) ........................................................................................................ 52
Table 3 - The five levels of safety culture (51, 52) ........................................................................ 67
Table 4 - An overview of the Safety-I and Safety-II approaches (113) ............................................ 107
Table 5 - Definitions and examples of procedural violations in community pharmacies (123, 125) .... 112
Table 6 - Participants' demographic information .............................................................................. 144
Table 7 - Bivariate Pearson correlations between the IVs and the DV for each violation type ............ 148
Table 8 - Means and standard deviations for the optimising violation ........................................... 150
Table 9 - ANCOVA results for the optimising violation ................................................................. 153
Table 10 - The influence of habit and motivation on the optimising violation ............................... 155
Table 11 - Means and standard deviations for the situational violation ....................................... 155
Table 12 - ANCOVA results for the situational violation .......................................................... 159
Table 13 - The influence of habit and motivation on the situational violation ............................ 160
Table 14 - Means and standard deviations for the routine violation ............................................. 161
Table 15 - ANCOVA results for the routine violation .................................................................... 164
Table 16 - The influence of habit and motivation on the routine violation .................................... 165
Table 17 - Means and standard deviations for the exceptional violation ..................................... 166
Table 18 - ANCOVA results for the exceptional violation .......................................................... 169
Table 19 - The influence of habit and motivation on the exceptional violation ........................... 170
List of figures

Figure 1 - The dispensing process in community pharmacies (adapted from (8))................................. 19
Figure 2 - Cooper's reciprocal model of safety culture (45) ................................................................. 33
Figure 3 - The psychological varieties of unsafe acts (108) .................................................................. 45
Figure 4 - The Domino Theory (115) ....................................................................................................... 47
Figure 5 - The Swiss Cheese Model (108) ............................................................................................... 48
Figure 6 - Diagram illustrating TPB (139) ............................................................................................... 58
Figure 7 - The COM-B model (40) ........................................................................................................ 126
Figure 8 - The Behaviour Change Wheel (40) ....................................................................................... 129
List of abbreviations

A&E          Accident and Emergency  
ACT          Accuracy checking technician 
ANCOVA       Analysis of covariance  
APTUK        Association of Pharmacy Technicians UK  
BCW          The Behaviour Change Wheel  
CD           Controlled drug  
CIT          The Critical Incident Technique 
CPs          Community pharmacies 
DV           Dependent variable  
GM           Greater Manchester 
GP           General Practitioner 
GPhC         General Pharmaceutical Council 
IPA          Interpretative phenomenological analysis  
IV           Independent variable  
MaPSaF       Manchester Patient Safety Assessment Framework 
MUR          Medicines Usage Review 
NHS          The National Health Service 
NIHR         National Institute of Health Research 
NMS          New Medicines Service 
NPSA         National Patient Safety Agency 
OTC          Over the counter 
SOPs         Standard operating procedure 
TPB          The Theory of Planned Behaviour 
WY           West Yorkshire
## Researcher’s initials

<table>
<thead>
<tr>
<th>Initials</th>
<th>Name</th>
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<tbody>
<tr>
<td>CT</td>
<td>Christian Thomas</td>
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<tr>
<td>DA</td>
<td>Professor Darren Ashcroft</td>
</tr>
<tr>
<td>DLP</td>
<td>Dr Denham Phipps</td>
</tr>
<tr>
<td>DP</td>
<td>Professor Dianne Parker</td>
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The University of Manchester

Christian Emily Louise Thomas

Doctor of Philosophy

Understanding procedural violations and their implications for patient safety in community pharmacies

March 2017

Abstract

Background: Violations occur when individuals choose to bypass or deviate from procedures. Although violations are often not intended to cause harm, they are nevertheless breaches of the preferred way of working. Violations have been suggested to introduce risk into the environment by eroding the margin of safety. Therefore, violations are of potential concern to healthcare professionals that are responsible for patient safety. This thesis examines how and why violations occur in community pharmacies.

Method: The research adopted a mixed methods approach to explore violations in community pharmacies and three studies were undertaken. The first study was a qualitative study that explored the views of management and frontline staff with regards to the prevailing safety culture in community pharmacies. The aim was to understand the context in which violations occur and to explore the goals that staff manage in practice. The second interview study explored how procedures are perceived in practice and the types of violations that occur in this setting. The third study utilised a survey based on the COM-B model that further explored the influence of capability, opportunity and motivation on violating behaviours.

Results: Overall, findings demonstrated that numerous types of violations occur in community pharmacies. Mainly they occur either to ensure that timely patient care is provided or to ensure that productivity is maintained in practice. The safety culture study suggested that frontline staff and management have a different safety culture, with frontline staff reacting to risk in the moment and head office staff managing risk through the provision of multiple detailed procedures. The interviews suggested that procedures are useful for outlining what is expected of staff in practice; however they are not always possible to follow to the letter due to the complex working environment. The social norm within each pharmacy was suggested to influence violating behaviours, as was the professional judgement of the pharmacist. Violations were shown to be necessary for maintaining care at times, especially in exceptional circumstances. However, at times violations to maintain productivity did result in an increased risk to patient safety. The questionnaire study highlighted motivation, opportunity, length of experience, staff role and gender as influences on certain types of violations.

Conclusions: The mixed methods utilised as part of this thesis revealed the types of violations that occur in community pharmacies and the reasons why pharmacists and support staff choose to violate. The findings led to recommendations for policymakers to evaluate how procedures are implemented in practice, to provide additional support for staff in practice through improved workflow, to provide patient safety specific training in pharmacies, to improve communication between frontline and head office staff and to educate pharmacy students regarding the possibility that they will need to violate procedures at times to manage the complex reality of working within community pharmacies.
Declaration and copyright

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I would also like to thank my friends and colleagues at Manchester Pharmacy School for helping to keep me smiling and laughing throughout my PhD. My special thanks go to Sarah Bellis and Dr Vicky Silkstone for their friendship and unwavering support, to my good friends in office 1.132 who make me smile every day and to Dr Doug Steinke for his advice and support. I have felt extremely lucky to have been a part of such a supportive and inspiring department during my PhD.

I also need to thank all of my friends who have been there for every high and low of this journey. Special thanks go to my PhDivas Kate and Briony whose understanding and time have made all the difference. I’d like to say a huge thank you to my beautiful best friends Mari and Francesca, for everything that they do. And a thank you to Dave, Leanne and Katie for always making me smile.

I cannot put into words how grateful I am for the love and support of my family. Ollie, for keeping me grounded and especially for his help with my 8,000 plus questionnaires, I couldn’t have done this without you, thank you for keeping me sane! To my parents, my siblings, my grandparents and Ollie – thank you for believing in me even when I did not believe in myself, it has meant the world. Thank you.
Dedication

This thesis is dedicated to my Mum, Vanessa, my Dad, Adam and to my brother and sister, Alex and Anya. I couldn’t have done any of this without their love, light and laughter.
About the author

Christian, or Chrissy as she is more commonly known, was born and raised in North Wales, where she completed all of her education through the Welsh medium. From a young age Chrissy wanted to follow in her mother’s footsteps and study at the University of Manchester. In 2008, her dreams came true when she was accepted to study Psychology at the University of Manchester. She went on to complete an MRes in Psychology, also at the University of Manchester.

During her time in sixth form Chrissy applied for a job at Boots the Chemist, where she began working on the pharmacy counter (much to her dismay at the time, as she had been hoping for a role on the make-up counter!). However, Chrissy trained as a dispenser alongside her studies and has now worked at Boots for almost ten years. She continues to work as a dispenser for four hours a week alongside her studies. It was her background in Psychology and her practical experience of working in a pharmacy that led Chrissy to apply for this PhD project that sought to understand how and why procedures are not followed in practice.

Alongside the final year of her PhD, Chrissy was also appointed as a lecturer in Pharmacy Practice at The University of Manchester. She teaches classes on communication skills, selling over the counter medication and dispensing.

In her spare time, Chrissy loves nothing more than spending time with her husband Ollie and her family (especially her brother and sister who are 12 and 11) and she also runs a popular lifestyle blog called ‘Making it Mindful’, in which Chrissy shares her experiences of managing a busy life through mindfulness and a positive mind-set.
CHAPTER 1: Introduction

1.1 - Introduction to the research
Improving patient safety has become an international priority within healthcare (1). The past fifteen years has seen an increased focus on patient safety within the UK, with recent highly publicised cases of poor patient care such as those witnessed in Mid-Staffordshire. The ensuing ‘Francis Report’, costing £13 million to produce, suggested 290 recommendations to improve patient safety across the health service (2). The following Keogh report focused on the quality of care and treatment within the NHS, and found that the 14 trusts reviewed had significant scope for improvement and identified an urgent need to raise the standard of care provided (3).

As part of his report, Francis established that at times, frontline staff felt pressured to cut corners in order to manage production pressure from management. Francis warned that a careful balance between avoiding tolerance of unacceptable standards of performance and incentivising “short cuts” to manage productivity was needed. Francis stressed that the Department of Health must ensure that performance requirements are balanced by provision of qualifications to allow patient safety and well-being to remain the priority in practice as well the provision of resources and support which enable safety requirements to be met (2).

The actions that Francis describes here as “cutting corners” are often instances of what are known as procedural violations, which are the focus of this thesis. The Francis report suggests that cutting corners may occur in order to manage production demands in a secondary care setting. Extensive research has been conducted into the occurrence of procedural violations in various industries including aviation, construction, mining, rail, non-commercial driving as well as healthcare as reviewed by Alper (4). This review suggests that the occurrence of violations is influenced by individual characteristics, information, education and training, design to support worker needs, safety climate, competing goals, and problems with rules. The
main purpose of this research was to understand violations and their implications for patient safety in primary care, focusing on community pharmacies (CPs) in the UK.

1.2 - Community pharmacies in the UK

1.2.1 - The pharmacy team
Pharmacy teams in the UK are made up of at least one UK registered pharmacist who will have completed an accredited four year university pharmacy degree programme plus a year’s work-placed pre-registration training, culminating in a further academic examination before they are added to the Pharmaceutical register (5). 70% of pharmacists work in CPs as either owners of independent pharmacies, or more typically as employees of a private sector organisation (5). Pharmacy teams typically consist of one or more members of support staff. The support staff can include registered accuracy checking technicians (ACTs) and registered pharmacy technicians who have received extended clinical and practical training. Pharmacy technicians train for two years for a NVQ level 3 Diploma (5). Pharmacists, ACTs and pharmacy technicians are registered with the General Pharmaceutical Council (GPhC) and they must abide by the standards set by the GPhC (6). Pharmacy teams typically also consist of dispensers who are largely responsible for tasks such as dispensing medications, assembling stock, ordering and receiving stock. They receive training that usually takes between six and twelve months to complete. Healthcare advisors, who are responsible for selling pharmacy medication or “over the counter” (OTC) medications receive basic training regarding pharmacy medicines, and they do not typically work within the dispensary.

1.2.2 - Overview of community pharmacy work
There were 11,688 CPs in England as at 31 March 2016, compared to 11,674 as at 31 March 2015, an increase of 14 (0.1%). Of these pharmacies, 4,448 (38.1%) were independent pharmacies (7). There has been an increase in the number of CPs in England, which has risen by 15.3% since 2006/07. Most primary care prescription items are dispensed in CPs. From 2015-2016, 995.3 million prescription items were dispensed in CPs in the UK (91.5% of all
items dispensed in the community), a 1.7% increase compared to the previous year, and an increase of 50.4% since 2005 (7).

Every pharmacy contractor must provide seven essential services to patients that are commissioned by NHS England, and these include:

- Dispensing medicines;
- Dispensing appliances;
- Repeat dispensing;
- Maintaining clinical governance requirements;
- Public health (promotion of healthy lifestyles);
- Disposal of unwanted medicines;
- Signposting to alternative healthcare professionals when necessary.

As can be seen from Figure 1, there are up to fourteen separate stages involved in the dispensing of a prescription item (8). Support staff such as dispensers can conduct some stages such as the assembly of medication and the creation of a label for the medication, and ACTs and pharmacists can complete the final accuracy check.
As shown in Figure 1 each medication must be clinically checked and accuracy checked. A clinical check must be conducted by a pharmacist, and this involves identifying potential pharmaco-therapeutic problems by collating and evaluating all relevant information including patient characteristics, disease states, medication regimen and where possible, laboratory results (9). The accuracy check is a multi-step process that is illustrated in Table 1. It is worth noting that individuals may have their own personal procedure for accuracy checking, either developed during practice or taught during their training; however, the accuracy checking procedure that students are taught at the University of Manchester is provided for illustration purposes.
Table 1 - Accuracy checking procedure as taught to MPharm students at the University of Manchester

<table>
<thead>
<tr>
<th><strong>Medicine</strong> (check the following against the prescription)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug strength</td>
</tr>
<tr>
<td>Dosage form</td>
</tr>
<tr>
<td>Quantity: if the quantity has been calculated from information on the prescription double check the calculation as well as the actual physical amount supplied</td>
</tr>
<tr>
<td>Expiry Date: check the expiry date to ensure it is sufficient for the treatment period</td>
</tr>
<tr>
<td>Packaging/container: the most appropriate packaging/container should be used</td>
</tr>
<tr>
<td>Patient Information Leaflet: check that there is a relevant leaflet for each medicine.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Label</strong> (check the following against the prescription)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's name: ensure the name is spelt correctly</td>
</tr>
<tr>
<td>Drug name: check if the drug has a similar name to another medicine</td>
</tr>
<tr>
<td>Drug strength</td>
</tr>
<tr>
<td>Dosage form</td>
</tr>
<tr>
<td>Quantity: as above, if the quantity has been calculated from information on the prescription double check the calculation as well as the actual physical amount supplied</td>
</tr>
<tr>
<td>Directions: ensure they match the prescription and are unambiguous.</td>
</tr>
<tr>
<td>Appropriate additional labels/cautions/warnings for each medicine</td>
</tr>
</tbody>
</table>
As well as dispensing and supplying medication, CPs can also choose to provide advanced services to patients, for which they receive additional payment from NHS England (7). These include Medicines Usage Reviews (MUR) (10) and the New Medicine Service (NMS) (11). Pharmacies receive additional payment for conducting these services, and from 2015-16, 3.3 million MURs were provided in CPs and 821,893 NMS services were provided (7).

1.3 - Summary of this thesis
The overall aim of the studies reported in this thesis are to explore how and why procedural violations occur in CPs and their implications for patient safety in this setting. As briefly mentioned in this chapter, the workload is increasing in CPs and the following chapter will explore how patient safety is managed in this environment. The following chapter will set the agenda for the thesis by reviewing relevant literature related to patient safety in the CP setting.

1.4 - The structure of this thesis
This thesis is structured in chapters that reflect the development of research ideas and each stage of data collection.

Chapter 2 presents the background to the study. A literature review relating to patient safety in CPs and an exploration of errors and procedural violations is provided.

Chapter 3 presents the findings of the first qualitative study that explored the prevailing safety culture in CPs. The rationale for the study, the study design and analysis are detailed. The results are presented in relation to Cooper's reciprocal model of safety culture and discussed in relation to the literature presented in Chapter 2.

Chapter 4 presents the findings of the second qualitative study that explored how procedures are perceived in practice. Before the results are presented the supporting literature, the rationale and methods used for the interview are detailed. The results of this study are discussed in relation to the supporting literature.
Chapter 5 outlines further findings from the second qualitative study and provides the results on the types of violations that occur in CPs in relation to the Safety-I and Safety-II philosophies. This chapter begins with the background literature, aims and objectives, methods and analysis. The results are then presented and discussed in relation to the supporting literature.

Chapter 6 outlines the design and development of a quantitative study to further explore the influence of capability, opportunity and motivation on violating behaviours. The rationale, methods and analysis are detailed in this chapter in relation to the supporting literature.

Chapter 7 presents the results of the study described in Chapter 6. The characteristics of the respondents are provided alongside the results of the statistical analysis that explored the influence of capability, opportunity and motivation on violating behaviours, and the influence of habit. The findings are then discussed in relation to the supporting literature.

Chapter 8 draws the findings reported in Chapters 3, 4, 5 and 7 together to be discussed. Directions for future research and implications for practice are considered before the final conclusions of the research are drawn.
CHAPTER 2: Literature review

2.1 - Introduction
This chapter sets out the background to the research. The main purpose of this chapter is to discuss and review the current literature regarding procedural violations and then place these into the context of this study on the subject of procedural violations and their implications on patient safety in CPs.

2.2 - Patient Safety
Patient safety in the healthcare environment has received increasing attention over the past fifteen years, initially encouraged by documents such as ‘To err is human’ in the USA (12) and ‘An organisation with a memory’ in the UK (13). Patient safety has been defined as “the identification, assessment, analysis and management of patient-related risks and incidents in order to make patient care safer and to minimise harm to patients” (14). Ensuring patients are safe in the healthcare sector is a difficult task, as healthcare is inherently hazardous due to it bringing together unwell patients, complex systems, fallible professionals and advanced technologies (15). Furthermore, since the global financial crash of 2008, austerity has been a dominant factor in shaping healthcare delivery, leading to extra tensions in practice for healthcare staff (16).

As highlighted in the Francis Report (2) that reviewed the failures in patient care in the Mid-Staffordshire NHS Trust, and the Morecambe Bay investigation (17) that reviewed serious incidents in maternity services provided by the University Hospitals of Morecambe Bay Foundation Trust, at times things can go drastically wrong in healthcare. The Morecambe Bay report highlighted “failures at almost every level”, noted that clinical competence was substandard and that skills and knowledge were deficient. Working relationships were found to be extremely poor, particularly between different staff groups, there were failures of risk assessment, and care planning that had resulted in inappropriate and unsafe care.
Furthermore, the response to adverse incidents was grossly deficient, with repeated failures to investigate properly and to learn from previous failings (17). Both of these reports identified systemic and contextual factors as contributing to failings (15).

The patients treated within the healthcare system are also becoming increasingly complex, as outcomes of care improve and patients now survive illnesses that would once have proved fatal. This leads to healthcare staff having to manage a growing proportion of patients with multi-morbidities such as diabetes, respiratory diseases, depression, cardiac disease and renal disease (18). Each of these diseases requires specialist and tailored care, for example, the care of diabetic patients has been shown to rely on care that is delivered through the co-ordination of a multi-layered team of different professionals and that relies on the knowledge and resilience of specialist staff (19).

Based on the complex nature of the healthcare environment and the increasingly complex nature of patient conditions, healthcare could be considered a high-risk industry, alongside aviation and nuclear power where failures in the working environment can lead to serious harm (20, 21). The healthcare industry has been compared to the aviation industry for example, as they both involve professionals operating in a complicated and challenging environment whilst interacting and relying on advanced technologies (22). However, Dekker et al. (23) argue that industries such as aviation are in fact complicated as opposed to complex. The key distinction between complex industries such as healthcare and complicated industries such as aviation is that the complicated systems are “knowable”, in the sense that a set of rules can be drawn that fully captures their workings. Because of this, complicated systems are controllable, similar to machines (23). The variety of patient conditions and the varied interacting factors within a healthcare context can make creating a “one size fits all” approach to safety management difficult (18). As well as attempting to manage complex patient care, healthcare staff have multiple competing demands such as responding to problems that
requires allocating and managing a finite set of organisational resources including equipment; physical space, staff time and availability (19).

Given the complex nature of healthcare, it is understandable that at times, things unfortunately do go wrong. Vincent and Amalberti note that major progress has been made in assessing the nature and scale of harm in many countries (18). However, much of the research assessing and managing risks to patient safety have been conducted in secondary care settings (24-28). Yet, the role of primary care in the UK is substantial, with 85% of the contacts within the NHS taking place in primary care, and 300 million general practice (GP) appointments are made each year (29). Over a million interactions occur every day within primary care settings such as GPs, CPs and dental practices. The focus of this thesis will be CPs and the justification for focusing on this sector is provided in the following section.

2.3 - Why focus on community pharmacies?
One reason for choosing to focus on CP is the large amount of patient encounters that occur in this setting, as detailed in the previous chapter. Prescriptions dispensed in CPs in England alone have increased by 50.4% between 2005-2015 (7). In line with the notion that patients are living for longer whilst dealing with chronic conditions, the average number of prescription items issued per person rose from 13 items per person in 2003 to 19 per person in 2013 (30). These figures highlight the growing workload and pressure CP staff are facing. Furthermore, the earlier discharge rates of patients from hospitals will also have an effect on workload, with more than 70% of all prescriptions being issued outside of hospital (29).

Alongside the rising number of prescription items dispensed in this setting, pharmacists are expected to play a more integrated role in the healthcare system and to offer more than “just medicines” (31). Part of the reason for the pressure on pharmacy staff to provide extended services is based on the recent NHS reforms that resulted in economic, demographic and technological change in the UK (31). Pharmacies and pharmacists are playing an ever
increasing role in the holistic care of patients through the provision of services such as smoking cessation, weight management, sexual health, blood pressure and diabetes checks (16, 31). Pharmacists have also been identified by Pharmacy Voice, the Pharmaceutical Services Negotiating Committee and the Royal Pharmaceutical Society as a facilitator of personalised care for people with long term conditions, with the aim of encouraging the public to visit pharmacists as the first port of call for episodic healthcare advice and treatment (16).

In 2014, a level analysis spatial study was conducted to understand the accessibility of CP. The study used postcodes for all CPs in England and assigned each postcode to a population lookup table and lower super output area (32). The lower super output area was then matched to urbanity (urban, town, fringe or village, hamlet and isolated dwellings) and deprivation decile (using the Index of Multiple Deprivation score). The results found that 89.2% of the English population were estimated to live within a twenty-minute walk from a CP. For urban areas, this rose to 98.3% of the population, and for the areas of highest deprivation this rose again to 99.8% of this population. For town and fringe areas, 79.9% of the population were within a twenty-minute walk to a CP. This figure decreased to 18.9% for rural populations (32). Furthermore, in recent years policy drivers have attempted to improve access to medicines with the introduction of ‘100 hour pharmacies’, which must open 100 hours per week, for every week of the year (32). These results highlight some of the policies and strategies that have sought to capitalise on CPs potential to help meet the challenge of providing better healthcare outcomes as part of a wider integrated healthcare system (5).

One of the services introduced to some CPs was the minor ailments scheme, that aimed to help manage the burden on GPs in the UK and to provide the public with access to NHS treatment and/or advice via a pharmacist or pharmacy staff, or, where appropriate, to onward referral to other health professionals. The minor ailment scheme was originally proposed by the UK health departments as part of their long-term strategy to encourage patient self-care
and the utilisation of pharmacies as the first port of call for minor ailments where professional support was required (33). A 2015 report found that out of 25,956 minor ailment service consultations undertaken, 79% of the consultations had shifted workload from GPs, highlighting the important role CPs play in patient care (34). Another service is currently being piloted in CPs, known as the Pharmacy Urgent Care pilot, where patients who contact NHS 111 for their urgent repeat medications will be directed straight to CPs to potentially lessen the burden on out of hours GPs (35). These services highlight the ever expanding role of pharmacists, as pharmacies move away from a more traditional view of “just” dispensing medicines (31, 36).

In addition to the need for CP staff to play a greater role in patient care, the Department of Health proposed a reduction in pharmacy funding of 12% from December 2016 to March 2017 compared to previous funding levels. The funding for pharmacies during 2017-18 is set to be reduced by a further 7.4%. However, in response to these cuts, NHS England introduced the Pharmacy Integration Fund, a £42m fund to help transform how CP operates across the NHS for the benefit of patients over a two year period from October 2016. The aim of the fund is to drive the greater use of pharmacists and pharmacy technicians in new, integrated local care models (5). It is hoped that this fund will improve access for patients, relieve the pressure on GPs and Accident and Emergency (A&E) departments, ensure the best use of medicines, drive better value and improve patient outcomes (5). This further highlights the increased role that pharmacy staff are expected to play in the care of patients.

These changes are occurring in the context of an already complex system, in which medicines management relies on staff managing social and technical factors within their workplace (37, 38). Staff must also manage relationships with patients and multiple healthcare providers across community and hospital care (39). This is supported by the 2016 Pharmaceutical Services Negotiating Committee report titled “Community Pharmacy Forward View”. The
report also stresses the shift in practice towards involving patients in the decision-making regarding their care (16). The report explains that there has been a move towards personalisation and personal responsibility for patient care. It is thought that this is in line with the rise in consumerism in general across society, and patients are now more interested in their own care (16). This is especially true for patients managing long term health conditions, who rightly demand more control and autonomy regarding their care (16). Thus, patient demand and expectations regarding their care may also present an additional pressure to CP staff; however, this report is presented as a proposition as opposed to reporting on results of an empirical study.

2.4 - Existing patient safety research in community pharmacies

Much of the patient safety research conducted in CPs has focused on safety climate and errors in practice. The results of these studies will now be explored, followed by a more in-depth exploration of errors, violations and their implications for patient safety.

2.4.1 - Environmental influences on patient safety

2.4.1.1 - Safety culture

It is important to consider that the work of CP staff does not take place within a vacuum (40); rather, it takes place within a social context that is a complex fabric of various interactions and dependencies (41). In order to further understand the context in which pharmacy staff work, important research has been conducted into examining the safety culture or the safety climate a facet of safety culture within CPs.

Organisational culture is often defined as the “shared values (what is important) and beliefs (how things work) that interact with an organisation’s structures and control systems to produce behavioural norms (the way we do things around here)” (42, 43). Guldenmund (44, pg.251) reasons that safety culture specifically relates to the “aspects of the organisational culture which impacts on the attitudes and behaviours related to increasing or decreasing risk”. One of the most popular models of organisational culture is Schein’s three-layered
model that describes culture as the culmination of the visible artefacts in the environment, the espoused values and the underlying assumptions of the employees (43). Cooper argues that Schein’s model does not account for the dynamic nature of safety culture, and that the model seems to reflect a linear sequence of cause and effect where employees’ core assumptions dictate their beliefs, which then leads to behaviours (45). Reason (42) suggested that latent conditions such as design factors or staffing levels do not always immediately impact on safety and therefore these factors cannot always impact on beliefs and behaviours instantly.

The suggestion that culture may influence how errors are responded to in practice has been supported by quantitative and observational studies in CP. For example, a study that explored the safety climate in CPs in four European countries (UK, Denmark, the Netherlands and Portugal) using the Pharmacy Safety Climate Questionnaire (46), found that organisational learning, blame culture, working conditions and safety focus predicted the rating of pharmacy safety. Furthermore, in a study that involved 360 hours of observations and 38 interviews, pharmacist work stress and learning from quality related events was explored and the presence of a blame culture was found to impact on the extent of organisational learning (47). Thus, suggesting that a blame culture can lead to a lack of learning from errors. Phipps and Ashcroft (48) conducted a cluster analysis on the results of a quantitative study that explored safety climate and job characteristics in UK CPs. Their results suggested that CPs have some characteristics that are generic to all CPs, however they also identified that there are some characteristics that are specific to clusters of pharmacies. Their results suggest that there are four different types of pharmacy including “the disenfranchising pharmacy”; “the perilous pharmacy”; “the safety-focused pharmacy” and the “challenging pharmacy” (48). However, to date, qualitative methods have not been utilised to explore the presence of different sub-culture in CPs or the influence of culture on violations specifically in CP.
Safety culture has been explored previously in CP through qualitative methods using the Manchester Patient Safety Assessment Framework (MaPSaF) (49, 50). MaPSaF is based on Parker and Hudson’s model of safety culture (51) that was developed from Westrum’s typology of safety cultures (52). MaPSaF is a qualitative tool (51) which was specifically developed in order to help healthcare organisations to understand and improve their safety culture (49). MaPSaF was developed through an extensive literature review and interviews with opinion leaders from healthcare organisations including chief executives, practice managers and healthcare practitioners (53). The interview data helped to create descriptions of a primary care organisation in terms of each of the nine dimensions of patient safety, at five levels of safety culture maturity (51, 52, 54). The face validity and usefulness of MaPSaF was tested through holding 33 individual interviews with clinicians, risk managers, directors of nursing and pharmacists. A further 14 focus groups were conducted (with general practice staff, district nurses, specialist nurses and medicines management teams) where the comprehensiveness and clarity of the language used in MaPSaF were discussed and its potential usefulness in helping healthcare professionals think about safety culture was debated (53).

Multiple versions of MaPSaF exist including National Patient Safety Agency (NPSA) funded versions for acute, mental health and ambulance settings (55). The NPSA (56) considers MaPSaF useful for:
• Raising awareness of and stimulating discussion on patient safety;
• Promoting recognition that patient safety is a complex multidimensional concept;
• Profiling relative strengths and weaknesses in safety culture;
• Providing an indication of what a more mature patient safety culture would look like;
• Highlighting differences in perception across professional groups and teams; and
• Helping to evaluate any specific intervention to change the safety culture of the organisation.

A study conducted in secondary care utilised MaPSaF in an acute foundation trust with a cross-section of their staff that included pharmacists, doctors, consultants, nurses, assistants and ward clerks. MaPSaF was found to be helpful in identifying areas of weakness within their safety culture such as a lack of feedback from incident reporting that prevented organisation wide learning and the existence of a poor risk assessment culture, where risk assessments were seen as a ‘tick-box’ exercise (57).

MaPSaF has also been widely used in European primary care, it has been translated into many languages, and its use in many differing systems within primary care suggests that the heterogeneity of primary care in the UK should not be a barrier to the wider implementation of MaPSaF (29). Furthermore, the adoption of MaPSaF by the NPSA and the NHS Institute for Innovation and Improvement include MaPSaF as part of a wider framework for measuring and monitoring safety (29). Therefore, suggesting that MaPSaF is a useful tool to stimulate discussion around safety culture.

Ashcroft et al. (49) developed a version of MaPSaF for the CP setting, through the use of a focus group that consisted of four practicing community pharmacists who reviewed the original framework with the aim of developing a suitable version for CP. Written comments
from a further two pharmacists were also taken into account. Modifications to the original framework were made, such as changing some of the terminology to fit with CP and the removal of the ‘commitment to quality’ dimension, as it was felt that this was covered elsewhere in other dimensions. Subsequently, a further ten focus groups, consisting of 67 pharmacists and pharmacy support staff, reviewed the descriptions contained within the altered framework (49). Participants were asked if they agreed with the descriptions given and for any further suggestions on how to improve the framework. After each focus group, the suggestions were reviewed by the research team and if judged to be relevant, revisions to the framework were made (50).

Ashcroft et al. (49) confirmed that CP staff were able to understand the framework, including the five stages of safety culture outlined (49). Overall, their participants felt that the majority of CPs could be labelled as having a ‘pathological’ safety culture, where failure is often concealed and people refuse to acknowledge that problems exist – an example of a pathological culture being that,

‘A low priority is given to patient safety…and this pharmacy believes that risks are worth taking and that if an adverse event occurs insurance schemes are there to bail them out.’

(50, pg. 56)

Overall, the participants of Ashcroft et al.’s (49) study expressed a willingness to use the framework in practice, as long as protected time was given to staff to complete the initial assessment of the current safety culture in their pharmacy. Some participants did however raise concerns that finding a balance between completing the framework and carrying out their day to day work may be difficult (50). Overall, MaPSaF appears to be a useful tool for assessing safety culture in CP; however, the initial research is now over a decade old and as
discussed earlier in the chapter, the role of CP staff, as well as the types of services that they are providing has progressed considerably since then.

An alternative approach to understanding safety culture is Cooper’s reciprocal safety culture model (45) illustrated in Figure 2, based on Bandura’s model of reciprocal determinism from the Social Cognitive Theory (58). Cooper’s model takes into account the interactive relationship between personal, situational and behavioural factors whilst recognising the bi-directional influence of individuals and environments on each other (45, 58). Similar to Reason’s Swiss Cheese Model, the reciprocal model of safety culture notes that the influence of a person, situation or behaviour can take time to exert its influence (42, 45). In order to manage safety, it is proposed that individuals self-regulate their behaviour, by relying on cognitive supports to manage their environmental cues and the potential consequences of their behaviours (59). Based on this, it is suggested that safety culture is a product of multiple sub-goal interactions between people, jobs and the organisation (60).

![Cooper's reciprocal model of safety culture](image)

**Figure 2** - Cooper’s reciprocal model of safety culture (45)

If then, safety culture is the product of multiple goal-directed interactions, understanding the goals of an organisation’s employees may help to provide an insight into the prevailing safety culture of an organisation and provide an insight into why staff may choose to violate
procedures. Although safety culture may be espoused as a shared super-ordinate goal of an organisation, employees’ sub-goals are not necessarily the same. This is likely due to organisations being made up of many sub-cultures (such as teams or departments) that possess conflicting goals (42, 43, 61). In a qualitative study that involved observation and semi-structured interviews, McDonald et al. (62) explored the views of doctors and nurses in a hospital setting. Their results suggested a difference of opinion concerning how procedures should be followed, with doctors preferring to adhere to unwritten rules whereas nursing staff appeared to be much more stringent in their behaviours.

Reason (42) notes that balancing the goals of safety and production is often a delicate process and that the goals of management and frontline staff can sometimes differ. There has been some suggestion from a qualitative study that explored the benefits and tensions in delivering public health in CPs, that there was tension between trying to create spaces for health promotion stock whilst also maintaining space for commercial stock display, thus highlighting somewhat the tension between safety and commercial goals. However, as the study focused on one CP the findings should be interpreted with caution (63).

The safety culture within other healthcare settings, has been identified as a major source of medical errors following a review of healthcare management literature (64). This review highlighted the impact that management style could have on safety culture within healthcare settings, citing two main management philosophies of control-based or commitment based management. With control-based management, prescriptive and rigid practices are utilised to manage staff and there is often a hierarchical management system. Whereas with commitment based management, team work and co-operation are encouraged, and there is a much flatter organisational system (64). The review, conducted by Khatri et al. (64), found that a blame culture was more likely to occur in healthcare settings that utilised a control-based management style. As many community pharmacists have been identified to work within
private sector organisations (5), it is likely that most pharmacists work within a setting that has a hierarchical management system. This suggestion is supported by the finding that pharmacy chains have a more bureaucratic organisational culture (safety culture is a facet of organisational culture) and that this can lead to less autonomy for pharmacists in practice (65).

Vancouver (66) suggests that in order to determine whether behaviours (such as violations) are a function of striving for goals, researchers should focus on understanding the perceptions of the individuals primarily before assessing their behaviours directly. Powers (66, 67) noted that in order to understand these behaviours, researchers should also explore if sub-systems are trying to maintain perceptions and how these sub-systems interact. Two of the most important sub-systems within CP could be seen as the sub-systems of frontline staff and of managerial staff (such as area managers and head office staff). Currently, there is a lack of research in CPs as to how the perceptions of management and frontline staff differ with regards to safety culture and there is no understanding of how safety culture may lead to violations in this setting. Furthermore, research conducted outside of healthcare in three industrial sectors (manufacturing, chemical and food industries) found that management and frontline staff may differ in their perceptions of risk, as results highlighted consistent differences with regards to their perception of risk, with management found to consistently under-estimate workplace risks (68). Hence, understanding how safety is perceived and managed by both frontline staff and managerial staff may provide important insights into how safety is managed in CP and may begin to illuminate why CP staff make violations.

2.4.1.2 - Team working
Multiple interpersonal factors have been identified to potentially affect safety behaviours in CPs. One of the main perceived influences that were felt to impact on safety was the perceived conscientiousness of team members within the CP. As briefly mentioned in Chapter 1, pharmacy teams can consist of pharmacists and a mixture of pharmacy support staff including registered support staff, dispensers and healthcare advisors. Previous research that
interviewed seventeen pharmacists about work-related stress, identified that pharmacists sometimes felt their staff were not adequately trained and that they lacked confidence in their staff’s ability when delegating tasks (69). However, the opinion of support staff was not explored.

Some studies have sought to explore the views of both pharmacists and support staff, such as Ashcroft and Parker (49) who conducted focus groups with both staff groups and found that staff commitment and communication are also associated with safety in pharmacies. A 2009 study also used focus groups with support staff and pharmacists to understand how medication safety was managed in practice (70). Their results identified differences in morale and communication between staff in different types of pharmacies, with staff working for a large chain sometimes feeling demoralised as they were not treated as an individual by the company (70). This finding is supported by the results of the review of organisational culture conducted by Jacobs et al. (71) who suggested that, as for-profit organisations, CPs may prioritise business performance over ensuring the professional performance of pharmacists. The authors argued that this may be detrimental to the quality of care provided in practice (71). Jacobs et al. (65) also highlight that there is a lack of research studies that involve pharmacists and support staff. Given the involvement of both staff groups in the provision of care in CP, the exploration of safety behaviours including violations may benefit from including both pharmacists and support staff.

A further another reason to explore the opinions and behaviours of pharmacists and support staff is based on previous research within other areas of healthcare such as secondary care, where differences in attitudes towards procedures were identified. For example, doctors and surgeons in previous published studies championed the need for a degree of flexibility when working in healthcare as oppose to the notion of ‘cookbook’ care (62, 72, 73). Nursing staff were shown to prefer working stringently to procedures, and they appeared to disagree with
the flexible approach of doctors (74, 75). Ashcroft et al. (50) examined how pharmacists and support staff judged compliance with procedures, errors and violations. Results found that distinctions made between behaviour types were significantly more striking for support staff than those made by the pharmacists regardless of patient outcome. However, the results of this questionnaire should be interpreted with caution as the sample consisted of mainly locum pharmacists (60%). This questionnaire was useful for exploring how violations are judged, however, it did not unpick the reasons behind why violations occur in practice and furthermore, the researchers only sampled a limited number of support staff (52 support staff vs 223 pharmacists). Therefore, further research regarding the main influences on why violations occur in CP and how procedures are perceived in practice is needed.

As well as the relationship between staff members within the pharmacy team, the relationship of CP staff with the patient/customer has also been shown to influence patient safety. Pharmacists have been noted to feel under pressure to dispense efficiently by patients who were often unwilling to wait, even for short periods for their medication. This was thought to potentially increase the likelihood of an error (69), however given that the study was based on one-to-one interviews the increased risk was implied by participants as opposed to being objectively measured. On the other hand, a positive relationship between patients and pharmacists has been suggested to help patients, including patients with a lived experience of mental illness and addictions who noted that they felt able to ask for help from pharmacists about health problems which may in turn help to protect patient safety (76).

Relationships or communications with other healthcare professionals outside of the pharmacy, such as with the local GPs could impact on safety factors such as access to care and services provided by pharmacists. For example, the pharmacist-GP relationship was shown to potentially impede the implementation of the New Medicines Service (77). A lack of support from GPs was also identified as the main barrier to conducting MURs, with 62% of 216
respondents from primary care organisations rating this as a barrier or as a major barrier to implementation (10). However, a 2003 cross-sectional survey with pharmacists, dispensing GPs and non-dispensing GPs found that GPs and pharmacists have good relationships with each other, and that GPs agree that pharmacists’ possess expert drug knowledge (78). However, Phipps et al. (70), conducted ten focus groups, that involved sixty seven practitioners in order to explore risk management in CPs, and their results highlighted a tension within the pharmacist-prescriber relationship. On the one hand, pharmacists are keen to protect their dispensing from substandard prescribing, as pharmacists were also responsible for any medication that was given to the patient. On the other hand, pharmacists are dependent on prescribers for their business, and they seemed reluctant to disrupt their working relationship with the general prescriber (70). Thus, suggesting a tension between safety and profit in CPs.

2.4.2 - Situational influences on patient safety
Research shows that the working conditions within the pharmacy can also influence the safety behaviours of CP staff. In CP settings, the overall dispensing error rate identified has been seen to vary from between 3.0% to 0.04% (79-82) and the errors tended to be mainly content errors and labelling errors. The higher error rate was found in a study that utilised the Delphi technique and therefore the higher rate may be more reflective of the rate of errors in CPs, compared to the other studies that relied on self-reported errors (79). The errors identified in Ashcroft et al. (80) were shown to occur for a number of reasons such the member of staff misreading the prescription, confusing similar drug names, selecting a previously dispensed drug from a patient’s medical record and similar drug packaging. This was also supported in a literature review conducted by James et al. (8) who explored the incidence, type and causes of dispensing errors in pharmacies. Their results found that a high workload, interruptions, distractions and environmental factors such as inadequate lighting, increased the occurrence of dispensing errors (8). However, their review mainly included hospital based studies (68%) and
only 40% of the included literature was UK based. Nonetheless, this review helped to classify the types of errors found in pharmacies and suggested that factors such as the working environment led to errors. However, to date, the types of violations that occur in CP are unknown and the reasons why they occur is also unknown.

In a study that explored the safety systems for dispensing in CPs, Harvey et al. (47) identified organisational components that introduced risk to the dispensing process. The risk factors identified were related to relationships between people and other key components in dispensing. Risks included how different levels of staff communicated internally and externally, followed procedures, interacted with technical systems, worked with management, and engaged with the working environment. Likewise, the work design of CPs in the UK has been identified as an influence on medication safety (70). The physical design of the pharmacy has been identified as a key influence on the work of pharmacy employees (70, 83) and working conditions such as working within a restricted space or environment (47, 84) and the use and organisation of cupboards and shelves were identified as contributing factors to risk and errors. Interestingly, Harvey et al.’s (47) observational study identified subtle differences between the described formal procedures and adapted procedures in the routines of work practice (46). This finding suggests that organisational factors may contribute to violations of procedures in practice. However, such a direct link is yet to be empirically demonstrated in this setting. Furthermore, the participants in the Harvey et al. study (47) were not questioned as to why they were not following procedures during this study and there is a lack of research exploring the impact of organisational factors on violations in CP.

Workload within the pharmacy environment has been identified as a potential risk to safety (47, 85). In 2005, Ashcroft et al. (50) found that workload, or a lack of time could have a negative impact on whether incidents were reported in practice. Given the 50.4% increase in prescription items dispensed in CPs between 2005 and 2015, the impact of workload could be
a key influence on risk to patient safety in CPs. A 2012 literature review of the impact of workload on pharmacists’ work stress and job satisfaction found that increased workload contributed to increasing job-related stress and decreasing job satisfaction (86). A recent European study (87) found that most of the workload experienced by CPs is related to dispensing and half of pharmacists’ time was found to be spent interacting with customers and patients. However, the results of this study were based on one day of observations in four pharmacies and also the results may not be completely reflective of workload in UK CPs. Phipps et al. (88) found that work demand was the most consistently related job characteristic with risk taking behaviour, thus, highlighting the potential impact a high workload could have on patient safety. The results of this study may not completely reflect the work of CP staff in England, as the sample for this study were based in Northern Ireland and the sample had an over-representation of hospital pharmacists. Although it is not within the scope of this thesis to objectively measure workload, the suggestion that workload may influence CP staff to take risks could signify a role for workload in the occurrence of violations. However, the link between workload pressure and violations in CP has yet to be explored.

The role of stress within the workplace has also been identified as a potential contributor to risk in CPs. Boyle et al. (89) explored how work stress impacted on pharmacists’ ability to learn from quality related events using a survey method and found that work stress greatly influenced pharmacists’ perceptions of the working conditions within the pharmacy. An observational study that explored influences on dispensing safely, found that a high workload may lead to pharmacy staff dispensing under pressure, which was thought to potentially increase risk to patient safety (47). A 2009 qualitative study interviewed seventeen pharmacists in order to explore work stress in CPs and identified several influences on stress for pharmacists (69). These influences included staffing issues, interruptions, a lack of breaks, an open plan environment and the presence of demanding patients and customers (69). Lea et al.
used ethnography that involved shadowing ten pharmacists for one working day and one pharmacist for five working days to explore interruptions, multi-tasking and task-switching in CPs in England and found pharmacists’ working practices were permeated by interruptions, distractions and multi-tasking. These practices were suggested to impact on both patient safety and pharmacists’ perceptions of workload (90). The four studies presented here suggest that work stress can affect pharmacists’ working practices; however, no study has sought to explore the influence of the capability for both pharmacists and support staff to manage their workload. Concerning violations in CP, the capability of staff to manage their workload may have an impact on their decision to violate.

Aside from the physical workload experienced by CP staff, previous research has also identified the impact of mental workload on pharmacists (91). Research indicated that CPs experience sub-optimal mental workload (both mental underload and overload) on a daily basis, and that at these times pharmacists were susceptible to making dispensing errors. These findings were partly based on an experimental study that utilised a simulated accuracy checking task where participants were required to detect whether a dispensed item contained an error in different conditions including a high vs. low mental workload condition and a condition where participants were distracted vs. where participants were not distracted. Although the study was conducted in a simulated environment, the results suggest that distractions and interruptions influence pharmacists’ ability to detect errors and that a high mental workload resulted in higher levels of frustration. This study suggests that the capacity to deal with mental workload impacts on the ability to identify errors, however there is a lack of research that explores whether mental capability influences on the decision of CP staff to violate.
2.4.3 - Individual influences on patient safety

As well as environmental and situational influences on patient safety, there is some suggestion that individual differences may influence the safety behaviours of pharmacists in particular. A review of studies that examined factors influencing pharmacist performance found mixed evidence for the effect of personal characteristics such as age, gender, ethnicity and place of primary qualification (92). The review suggested that age may be related to dispensing errors as there was some evidence that older pharmacists may be more likely to make errors (83), or that their performance may worsen with age (93, 94). This review has focused mainly on errors as the main example of pharmacist performance. There is currently a lack of research exploring the influence of individual differences on violations in CPs.

On the other hand, some research studies suggest that older workers have more control and confidence in their work because of their increased experience (95). In a multi-level and longitudinal analysis of psychological distress in regulated occupations in Canada (the sample compared regulated professions such as pharmacists, lawyers and doctors with non-regulated professions such as managers and blue collared workers) psychological distress levels appear to significantly diminish over time (95). The authors of the study reason that this could be explained by the evolution of the age of their participants over the study. However, this study analysed all of the regulated professionals together as one group, and pharmacists were grouped together with other non-healthcare professionals such as lawyers, therefore the study does not provide any insights into the potential differences between these professional subgroups.

However, there is additional evidence that suggests an increased length of experience in CP results in less dispensing errors. A 2014 cross sectional study used the Safety Attitudes Questionnaire to explore the relationship between safety culture and reported dispensing errors (96) and found a significant negative association between reported dispensing errors and mean age i.e. older staff members made less dispensing errors (96). This Swedish study
should be interpreted with some caution in comparison to UK pharmacies, as in Sweden, pharmacies employ pharmacists who are trained for five years in university as well as “prescriptionists” who are similar to support staff here in the UK, but in Sweden they are required to study at university for three years and therefore they may not be suitable for comparison with UK pharmacy support staff as they are not required to attend university. A review of violations identified age as a potential influence on violations in multiple industries (4), but no research has currently explored the impact of experience on the likelihood of violating procedures in CP.

Gender has also been identified as a potential influence on safety behaviours. There is some evidence to support gender differences with regards to the behaviour of pharmacists. Results from the literature suggest that male pharmacists are more likely to be disciplined than female pharmacists are (97-100) and that pharmacists from an ethnic minority were more likely to be disciplined (99-102). However, there was not an effect for gender when comparing which gender was most likely to make dispensing errors (92). This appears to suggest that the difference exists when comparing purposeful deviations from procedures as opposed to accidental errors. A research study that explored driving behaviours found that young men were more likely to take risks when driving (103). However, no research has yet explored whether violations in CP are influenced by gender.

The impact of personality has also been explored in pharmacy, by Grasha (104) who identified that CPs who scored higher on a scale measuring impulsive personality were more likely to record making errors than those who scored lower. Also, pharmacists who had a cognitive style of attending to detail were less likely to make errors (104). Firth-Cozens et al. (105) suggest that individual characteristics including risk perception, sensation seeking, high self-esteem, psychological ill health and attitude towards safety were most likely to affect safety. This could suggest that personal motivation may play a role in how pharmacists decide to act.
in practice. It could be hypothesised that personal motivation may influence violating procedures, as these actions are intentional. To date, no research has sought to examine the motivation of pharmacists and pharmacy support staff to violate procedures. Understanding their motivation may help to improve understanding as to whether violations are carried out to help patients or whether they increase risk in practice.

The research presented so far has sought to highlight the many influencing factors that affect the ability of CP staff to maintain patient safety in practice. Although some studies have noted that violations do occur in practice (47, 70, 106) and have shown that violations are poorly judged by pharmacists and support staff, even when resulting in a good outcome for a patient (50), the majority of studies have explored the influencing factors on dispensing errors (91, 92, 96, 104, 107). The following section of this chapter will explore the differences between errors and violations and conclude with the overall aims and objectives for this thesis.

2.5 - Human error and violations

2.5.1 - Errors
The errors made by healthcare professionals have been labelled as a key threat to patient safety (12). Much of the research in CP settings focuses on errors. Errors can be defined as:

“A generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency.”

(108, p.9)

Often, errors are made because of an action becoming part of a routine and individuals can therefore be susceptible to absent-mindedness. The chance of making this kind of error is shown to increase in situations such as working on a particularly difficult task or during a particularly busy period of the day (108). Violations on the other hand, are conscious decisions
made by individuals to act in a certain way. Therefore, when researching violations it is crucial to understand the difference between behaviours that do not conform to procedures. A factor that must also be considered is the intention of the individual carrying out the behaviour. If the intention is not appropriate for the situation this can be classed as a mistake, whereas if the action or behaviour is not what was intended this is known as a slip (109). Figure 3 presents a summary of the psychological varieties of unsafe acts, classified by the individual’s intention, whilst also demonstrating the difference between errors and violations.

![Figure 3 - The psychological varieties of unsafe acts (108)](image_url)

Reason (108) states the importance of considering three main elements when considering errors: first, the nature of the task and the environment; second, the mechanisms governing performance; third, the nature of the individual. As shown in the previous section,
environmental factors, situational factors and individual factors were all suggested to impact on dispensing errors or to risk in general in CPs. Presently, little is known about the environmental, situational and individual influences on staff making violations in CPs. In an effort to understand more about why violations may happen, the literature on contributing factors for errors is reviewed primarily.

2.5.2 - Why do errors happen?
Some of the earliest attempts to understand why errors happen within organisations focused primarily on the role of the individual and the idea that some people may be more ‘accident prone’ than others (110). This approach was seen to dominate safety thinking and research for almost 50 years, often leading organisations to inadvertently neglect their safety responsibilities as accidents were solely blamed on individual employees (60). This approach is consistent with the idea of a blame culture discussed earlier in section 2.4.1.1. Reason (111) described this approach to maintaining safety as “the person approach”, which focuses on the staff at the “sharp end” of the healthcare industry, i.e. those coming into direct contact with patients. This approach emphasises the role of mental processes such as forgetfulness, inattention, poor motivation, carelessness, negligence or recklessness in the occurrence of errors. Approaches to discourage these types of behaviours from occurring have included poster campaigns, additional procedures, disciplinary action, the threat of litigation, retraining, naming, blaming and shaming (111). This approach believes “bad things happen to bad people” (112) and it is characteristic of the traditional approach to safety that focuses on how individuals are responsible for what goes wrong within an organisational system (113, 114). This traditional way of thinking about safety has been labelled as “Safety-I” and this is further explored in Chapter 5.

Following the idea that accidents are caused by accident prone individuals, came an approach that suggested that accidents were caused by either an unsafe condition, an unsafe act or both (115). Heinrich’s work was known as the ‘Domino theory’ and it provided the first sequential
theory of accident causation that showed the interaction between behaviour and working conditions (60). The domino theory is shown in Figure 4.

Heinrich’s (115) theory is useful for identifying the sequence of events in the accident causation chain, however the issue of ‘how’ and under what conditions accidents are seen to happen is not considered with this theory (60). This was later explained by Reason (116), who noted that more attention should be paid to the ‘latent’ factors within an organisation, which he likened to resident pathogens within the human body. Reason’s pathogen model made an important contribution to safety management as it identifies and distinguishes between the different types of errors that are made and how they may be introduced into an organisation (116). In an attempt to further explain how errors occur Reason (108) also compared the defences, barriers and safeguards in place within an organisation to Swiss cheese; the Swiss Cheese model is shown in Figure 5 which demonstrates the process of accident causation.
The model shown in Figure 5 highlights some of the contributing features involved in the occurrence of errors. A trajectory of accident opportunity is shown in Figure 5 and each of the planes has what can be explained as a ‘window of opportunity’ (these can also be thought of as one of the holes in the Swiss cheese) which is in a continuous state of flux due to the influence of hard to predict intrinsic and extrinsic factors. The window of opportunity can vary in size and location on each of the available planes, and they can occur at varying times and at different levels of the system. This model suggests that continued diligence is required to maintain safety, as working conditions are in a continuous state of flux (57, 117).

The second approach, defined by Reason as the “systems approach”, is reflective of the Safety-II approach, which accepts the likelihood that humans are likely to make errors as “a consequence rather than a cause” (111). This approach focuses on changing the “working conditions” as opposed to the “human condition” (111). Therefore, emphasis is placed on the development of system defences where barriers and safeguards are set up to try to prevent patient safety incidents from happening. Catchpole (118) and Hollnagel (113) reason that although at times things do go wrong, most of the time things go well in healthcare. The
reason that safety is maintained is based largely on the healthcare workers delivering the care as opposed to the presence of policies, processes or checklists. The following section examines how healthcare staff view procedures and how procedures maintain safety.

2.5.3 - The use of procedures in healthcare
One way in which safety is managed in many industries is through the use of procedures and guidelines. There is a persistent notion that not following procedures can lead to unsafe situations and procedures are often produced in response to a safety incident occurring, or new procedures or changes to existing ones occur, or stricter compliance is encouraged, as noted in the Safety-I approach which is explored in further detail in Chapter 5 (113). Although this is a common reaction, Dekker (117) highlights that it is often unsatisfactory; arguing that procedures could potentially be a more problematic than beneficial manner in which to control work behaviours.

Firstly, Dekker (117) believes that a mismatch between procedures and the behaviour actually carried out in practice does not always result in a safety incident occurring. Secondly, staff are often asked to abide by procedures but in a context of limited resources and multiple goals and pressures. Thirdly, some of the safest and most complex work only occurs despite the existence of procedures as seen in aircraft line maintenance. Finally, following procedures may not always have the personal safety of the worker in mind (117). This was seen in the 1949 US Mann Gulch disaster, in which the firefighters who perished were the ones who adhered to the procedure that stated they were to carry their tools everywhere (119). This also occurred during the Piper Alpha disaster, where the workers who survived were the ones who went against procedures (108).

From January 2005, the Royal Pharmaceutical Society of Great Britain (the regulatory body for pharmacy at the time) required that standard operating procedures (SOPs) covering the dispensing process needed to be in place in all CPs. These procedures include advice and
support for tasks such as the dispensing process, certain appliances and when dealing with repeat prescriptions. However, much of the research that has been conducted on the use of procedures and why they are violated has been conducted in secondary care. Some limited research has been conducted into how following procedures is viewed in pharmacy (50). However, no research has sought to explore how procedures in general are viewed in CP.

Furthermore, an important factor to consider when attempting to standardise practice in healthcare is that the guidelines or protocols apply to different healthcare professions. In a study that looked at the effect of protocols on different professions within the NHS (including staff from obstetrics, surgery and anaesthetics) twenty four focus groups were held to discuss the key features of protocols (120). The study highlighted how protocols and guidelines are viewed differently, with protocols being seen as a prescriptive measure and guidelines being considered as somewhat flexible. Protocols were seen as useful for defining best practice and in helping to explicitly define the expanding roles of nurses in particular. Furthermore, protocols were identified as a supportive tool when challenging the practice of a colleague. However, concerns were raised regarding the development of protocols as a measure to cover hospitals against litigation or to be given to trainees as oppose to standard training (120). Interestingly, improving patient care was rarely mentioned as a reason for the development of new protocols, with participants tending to believe a monetary gain i.e. to cover hospitals against litigation claims, was the motivation for new developments (120). To this date, little is known about how procedures are viewed and followed by different staff groups in CPs. Understanding how procedures are viewed by staff in practice may help to illuminate why procedures are violated. This section of the literature review has explored how and why errors occur and the following section will review the literature on violations.
2.6 - Exploring violations

2.6.1 - What are violations?
While much is now known about human error in healthcare settings including CPs, violations in this setting are less well understood. Violations are deliberate acts that are not often intended to cause harm but that breach established procedures. At times, some violations have led to harm such as the actions of Dr Harold Shipman, who intentionally caused the death of at least 215, possibly 260, of his patients (121) and those of a nurse, Beverley Allitt who intentionally caused the death of four children, attempted to murder another three children and inflicted grievous bodily harm on a further six children (122). However, Lawton (123) separates these actions from typical violations, labelling them instead as “sabotage” where there is an intent to cause harm. Violations, on the other hand, are actions that have been defined as:

“Deviations from those practices deemed necessary (by designers, managers and regulatory agencies) to maintain the safe operation of a potentially hazardous system.”

(20, p.539)

Similarly, to errors, attempts to classify different types of violation have been made. Reason et al.’s (123, 124) proposed a taxonomy of violations that are shown in Table 2.
Table 2 - Violation types (123, 125).

<table>
<thead>
<tr>
<th>Violation type</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Routine</td>
<td>These violations occur when a shortcut between two points presents itself and is taken on a regular basis.</td>
</tr>
<tr>
<td>Optimising</td>
<td>These violations are created by a motive to optimise the work situation and can include exploring the boundaries of a system that may be perceived to be too restrictive.</td>
</tr>
<tr>
<td>Situational</td>
<td>These violations are typically provoked by organisational failings and are typically seen as essential in order to get the job done.</td>
</tr>
<tr>
<td>Exceptional</td>
<td>These violations occur in a particular set of circumstances (abnormal or emergency situations) and because of this, they are rare.</td>
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</table>

Lawton (123) suggests that some violations may be committed where the act itself is not intended and in this case it may be known as an unintentional violation. Unintentional violations arise from a lack of understanding or inexperience on behalf of the worker. These violations are mostly unintentional and are motivated by the wish to save time. But as these violations are unintentional in nature, they may be considered an error as all other types of violations are knowingly carried out (108).

2.6.2 - Why do violations happen?
Amalberti et al. (126) state that an increased number of violations within a workplace can be a sign of high levels of safety. This is because in order for violations to occur, constraints and defences need to exist in the first place. For this reason, violations may be more common than errors in ultra-safe settings such as healthcare. Whereas errors may be explained in relation to the “cognitive processes of the individual”, violations on the other hand can be described with
regards to “a social context in which behaviour is governed by operating procedures, codes of practice rules and the like” (20, pg.539). This is thought to be due to different psychological origins being involved for errors and violations, which demand the use of different system pathways and remedial measures (20). For example, the primary error pathways may be attributed to “hardware defects and inadequate training” and the primary violations pathways are those which “closely reflect management attitudes with regard to safety” (20, pg.540). Therefore emphasising that it is important to consider that violations are not likely to be caused by a single factor, rather that many factors contribute to their occurrence (127).

A systematic review focusing on the empirical causes of safety violations in industry was conducted in 2009 and included data on settings such as healthcare, commercial driving, aviation, mining, railroad, and construction (4). Results show there are many potential causes of violations within industry. These included the characteristics of the individual making the violation (128), the education, training and information given to the individual; whether the design of the workplace supported the individual’s needs; the safety climate of the workplace; competing goals such as time pressure, conflicting demands and problems with rules. These influencing factors appear to align with the findings regarding the influencing factors on errors occurring in CPs, yet little is known about whether these factors such as individual motivation and work environment result in violations in CPs.

Alternative methods of understanding violations have focused on the “motivational antecedents of rule violations” (123) i.e. the attitudes and beliefs held by the individuals committing violating behaviours as this may provide an insight into how to manage violations in practice (123). Lawton (123) took this approach in her study focusing on the behaviours of railway staff. A 40-item questionnaire that contained rules concerning general safety on and around the track was utilised in order to assess perceived risk of behaviours and the frequency that these rules were broken. The participants noted feeling as if they were in a “Catch-22”
situation, where if all rules were followed production would be less efficient, but if rules were broken deliberately and an accident were to occur, the individual carrying out the violation would not be eligible to receive compensation (123). Although Lawton (123) provides an insight into the reasons why violations occur in the railway industry, it could be argued that some of the reasons she presents for violations occurring such as, the individual was inexperienced or the individual did not understand the rule suggest that some of the actions discussed were actually errors.

Research has been conducted in hospital settings to understand how procedures are violated in practice. In an attempt to identify why anaesthetists violate procedures Phipps et al. interviewed 23 consultant anaesthetists (129). Numerous factors were found to influence anaesthetists’ likelihood to follow guidelines and protocols. These included factors such as if the rule was a guideline it was then viewed as advisory rather than absolute, whereas protocols were viewed as more prescriptive and were less likely to be ignored. The credibility of the rule also influenced behaviour, with violations being more likely to occur if staff did not feel that the rule was based on concrete evidence, if the rule was set by management that had either not experienced working at the “sharp-end” of healthcare, or if the opinion of fellow anaesthetists had not been consulted when creating the rule. Furthermore, anaesthetists were found to make violations as long as they felt confident in their ability to justify their actions even though they were going against guidelines in doing so. Violations of this sort were more likely to occur when disciplinary action was not a common consequence of breaking the rules. One of the main incentives to abide by guidelines was the anaesthetists’ fear of criticism if they did not do so. Thus the findings of this study emphasise the suggestion that “quality in healthcare is judged by outcome only, with little reference to process” (129).

The results of Phipps et al. (129) are supported by further studies conducted in secondary care, that found who issued the guideline or protocol impacted on whether the procedures
were followed along with whether the department is working with limited resources (120). A separate study also found that procedures were less likely to be followed based on whether the protocol or guideline has been introduced to professional groups whose cultures actively encouraged taking risks (such as consultants), and protocols were often deemed inappropriate (129). The two studies mentioned here and the Phipps et al. (129) study described the opinion of hospital based staff; however little is known regarding how procedures are perceived in CPs.

Similar violating behaviours have been witnessed with GPs. The presence of a high workload can increase time pressure, resulting in the violation of clinical guidelines. Tisga and colleagues found GPs who were under increased time pressure asked patients less questions concerning their symptoms, conducted less thorough clinical examinations and were more likely to overlook less frequent illnesses (130). Furthermore, less advice regarding lifestyle, especially smoking habits was offered to patients, which in turn may compromise health. In this particular study, the diagnoses offered by the doctors were accurate in both the control and experimental condition, but the doctors in the time pressured condition felt less confident with their diagnosis (130). This research highlights how certain organisational factors such as time pressure may encourage violations, potentially resulting in medication and patient safety issues, such as a missed diagnosis.

One CP based study compared errors and violations whilst observing the sale of pharmacy (P) medicines (106). The sale of these medicines without a pharmacist present, goes against the guidelines that indicates how medicines should be supplied from CPs in their Code of Ethics (131). In addition, guidelines recommend that counter assistants obtain “sufficient information” before supplying P medicines, usually collected through use of the WWHAM technique (Who is it for; What are the symptoms; How long have the symptoms been present; Any other medication being taken; Medication tried already). However, WWHAM is not
always carried out due to constraints such as a lack of time or pressure from the customer to sell them the medication, therefore violating the recommend guidelines. Watson et al.’s (106) study is useful for identifying that violations occur in a CP setting, however the research is now over a decade old, it only focuses on the sale of over the counter medications and the researchers did not explore why participants chose to violate procedures. There remains a gap in the literature as to how and why procedures are violated in CP settings.

2.6.3 - How should violations be explored in healthcare?
Previous research has suggested that violations are more likely to be reported only when the outcome is not beneficial to the patient (132). This is unlike errors, where “near-misses” are also reported even though the error does not reach the patient. This lack of reporting all violations, regardless of whether the patient comes to harm or not, could be down to a healthcare professional,

“[Placing] high value on his or her time, convenience, self-image, status among peers, and other factors, and if be or she estimates the probability of being injured by disregarding an instruction as sufficiently low, then it is likely that the instruction will be ignored despite its clarity of presentation.”

(133, p.179)

Based on this, the researcher would not be able to gain a complete understanding of the violations occurring in CPs purely through studying the reporting systems. To do so, is likely to provide an account of only the violations that resulted in patient harm, as opposed to also including reports of the low risk violations that were made, that resulted in no harm to the patient. As previously mentioned, most studies that explore violations do not examine whether violations can improve system performance or safety (4). Catchpole (118) suggested
that understanding violations from the perspective of the healthcare professionals may be beneficial for understanding how behaviours are created in practice. To date, no research has explored the reasons why violations are made in CP settings.

However, research into the attitudes and beliefs of healthcare staff towards violations within secondary care has been conducted. The consideration of attitudes and beliefs have been noted as especially important when studying violations due to the influence social context has on behaviours (20, 134). One approach utilised to consider the attitudes and beliefs of individuals is the Theory of Planned Behaviour (TPB; 135, 136). This theory suggests an individual’s intention to engage in a particular behaviour relates to three factors:

1. The individual’s attitude to behaviour, which reflects the individual’s beliefs about the possible consequences of the behaviour.

2. The subjective norm, which relates to the individual’s perception of the level of social approval for the behaviour.

3. The perceived behavioural control, which reflects the individual’s beliefs regarding the level of control they have over the behaviour.

The TPB is illustrated in Figure 6. Studies that have applied the TPB to behaviours such as speeding or taking antibiotics after a caesarean section (137, 138) have found individuals’ beliefs about the expected outcome of a behaviour and the level of control individuals’ felt they had during a behaviour to be the most influential when deciding whether to execute a behaviour. The potential evaluation of a behaviour from others i.e. are others likely to judge the individual carrying out a particular behaviour, can have a varying influence on whether a
behaviour is likely to be carried out, mainly depending on the likelihood of others evaluating the individual’s behaviours (139). Within a healthcare setting, individual’s behaviours could be judged by multiple people such as other healthcare professionals, management and arguably most importantly, the patient.

![Figure 6 - Diagram illustrating TPB (139)](image)

In a study that applied TPB to anaesthetists’ use of practice guidelines, Phipps et al. (139) found the strongest influence on behaviour was the anaesthetist’s attitude towards the behaviour and the anaesthetist’s perceived control over their behaviour. Phipps et al. (139) measured both the subjective norm and the descriptive norm. The subjective norm is the perceived expectations of others with regards to behaviour, whereas the descriptive norm is what other members of staff were doing in the same situation. The study found the descriptive norm to be of influence, but this influence was not to the same extent as the anaesthetist’s own attitude towards the behaviour. Further evidence was found for the likelihood of a violation being committed based on the risk of potential outcome, with violations less likely to occur if the potential for the patient to suffer harm was high (140).
An interesting point raised by Phipps et al. (140) was that the violating behaviour was not only decided upon based on the individual’s perceived outcome, but also upon the anaesthetist’s beliefs regarding the worth of a particular behaviour. For example, anaesthetists who believed a pre-operative check-up to be in the patient’s best interests, were the anaesthetists most likely to carry out the check-up and therefore follow the guideline. These results did not seem to suggest that behaviours were carried out because the guideline was in place rather “because [the behaviour] should be [carried out], not because they could be [carried out]” (140, p.399).

Although TPB seems to have been a useful framework for understanding violations in the past, there have been some calls to retire the use of TPB (141). The theory has been criticised for a number of reasons, including its lack of predictive validity (142) and its lack of usefulness in helping practitioners to develop interventions (141). There is also a lack of experimental studies that utilise the TPB (141) – however, Armitage (143) argues that TPB should be considered as one theory within a broader framework of human behaviour. However, alternative theories such as the COM-B model proposed by Michie et al. (40) may be a more valid way to explore violations in CPs. Although no research has been conducted using COM-B to explore violations, the COM-B model explores the influence of motivation, opportunity and capability on behaviours and this may be a novel way of exploring why violations occur in CPs. The COM-B method is discussed in detail in chapter 7. Furthermore, in comparison to the TPB, the COM-B model also explores unconscious influences such as habit as part of the model, which may provide a new understanding of why routine violations occur for example. In a literature review that explored the role of habit and intention on behaviour, Ouellette and Wood (144) found that the most effective behaviour change strategies impede the performance of an established behaviour whilst facilitating the formation of a new behaviour. Therefore, understanding if habit is a key influence on violations may help with future behaviour change interventions if the violation poses a risk to patient safety. COM-B also
forms part of the Behaviour Change Wheel (BCW) and therefore using the COM-B method as opposed to the TPB method may be useful in helping practitioners to develop useful interventions.

2.7 - Aims and objectives for the thesis
The literature review has identified multiple gaps in the research regarding procedural violations and their implications for patient safety in CPs. The main aim of this thesis is to examine how and why violations occur in CPs. The objectives are:

- Explore the prevailing safety culture in CPs, in order to provide an insight into the context in which violations occur.

- Explore how staff from different levels of an organisation and from different pharmacy types manage their sub-goals of safety and productivity in practice through conducting focus groups with CP staff.

- To examine the perceptions of CP staff about following standard operating procedures and to explore how procedures are provided and managed in community pharmacy practice through one to one interviews.

- To examine the types of violations that occur in CP and to further examine the reasons why violations occur in CP using a questionnaire.

- To examine the influences of capability, opportunity and motivation on the frequency of specific violations using a questionnaire based on the COM-B model.

- To examine potential differences in capability, motivation and opportunity based on violation type and to examine the impact of demographic factors on violating behaviours (e.g. age, role, pharmacy type) using a questionnaire based on the COM-B model.
2.8 - Summary
This chapter began by considering patient safety within healthcare, followed by an exploration of the identified influences on risk in CPs, including environmental, situational and individual influences. An exploration of the influences on errors and violations was provided, the justification for the thesis and the aim and objectives of the overall project were provided. The next chapter presents the first study, which explores the prevailing safety culture within CPs.
CHAPTER 3: Exploring the Prevailing Safety Culture in Community Pharmacies

3.1 - Overview of chapter
The purpose of this chapter is to provide an insight into the prevailing safety culture in CP and to explore the influencing factors on behaviours in practice. The chapter begins with a brief background and the aims and objectives for the study are provided. The results of the qualitative study are then presented, followed by a discussion of the results.

3.2 - Background
As presented in the literature review, safety culture has been suggested to influence the safety behaviours of CP staff, such as the occurrence of errors (46, 47). Earlier qualitative work has explored the prevailing safety culture in CPs (49) however this research is now over a decade old. Furthermore, statistics show that the dispensing workload of CP staff has increased by 50.4% since this study was conducted in 2005. The aims and objectives of this study are presented in the following section.

3.3 - Aims and objectives
This study aimed to provide a rich contextual account of the prevailing safety culture in CP with the specific objectives of:

- Exploring the prevailing safety culture in CP, in order to provide an insight into the context in which violations occur.
- Exploring how different types of pharmacies manage their sub-goals of safety and productivity in practice.
- Exploring how staff from different levels of an organisation manage their sub-goals of safety and productivity in practice.
3.4 - Method
3.4.1 - Study design
This study utilised a qualitative design, and focus groups were conducted to collect data regarding the prevailing safety culture in CPs. During the focus groups, the Manchester Patient Safety Framework (MaPSaF) was utilised. The sampling frame for the study was CP branches in England and staff from head offices of pharmacy chains.

3.4.1.1 - Philosophical underpinnings
Qualitative research seeks to understand a phenomenon in a context specific setting, and therefore it was deemed an appropriate method to explore the occurrence of violations within the context of CP. This section outlines the researcher's epistemology for the qualitative study: critical realism. Traditionally, realism has been described as a philosophy that emphasises the use of objective evidence as the sole creation of truth (145). Pawson and Tilley (146) note that realism is a model of scientific explanation that ‘avoids the traditional epistemological poles of positivism and relativism’, with realism’s key feature being the stress placed on how things are explained by individuals. Unlike the traditional view of causation i.e. cause and effect, realism tends to assess human actions in terms of their location within different levels of social reality (146).

Three realist epistemologies are distinguished by Madill et al. (147): naïve realism, scientific realism and critical realism. Naïve realism corresponds to the philosophy that the world is ‘largely knowable and just as it appears to be’. Scientific realism believes that scientific methods can capture true representations of the world, although these representations are acknowledged as imperfect; whereas critical realism contends that the way individuals perceive facts depends partly on their beliefs and expectations (147). For this study, critical realism (148) was used as the researcher’s philosophical approach. This approach takes the view that, although we always perceive the world from a particular viewpoint, the world also impacts on us to constrain the points of view that are possible (149). Knowledge is always mediated by
pre-existing ideas and values, whether an individual acknowledges this or not. As the researcher has almost a decade of experience of working in CPs it was important to acknowledge from the outset that her pre-existing experience would influence her interpretation of the data. To try and ensure that bias was minimised as much as possible, the researcher made sure to challenge her perceptions, to seek out evidence that disproved or presented counter-information, and to ask colleagues for their insight into her work, particularly those with different experiences (150).

3.4.1.2 - The use of focus groups
Focus groups were used to explore the views of specific sub-groups of pharmacy organisations including branches and head office teams. The use of the focus group method was based on the opinion that focus groups are to,

“…listen and gather information… [They] are to better understand how people feel or think about an issue, product or service. Focus groups are used to gather opinions.”

(150)

Compared to alternative methods of data collection, focus groups were thought to be beneficial for collecting rich and contextualised data, which was deemed important when trying to explore safety culture. One to one interviews would not necessarily have captured the rich context of how team members interact with each other, and as culture is the result of shared perceptions and beliefs within multiple sub-cultures (43), it was deemed appropriate to collect data in groups as opposed to individually. Furthermore, as much quantitative research has already been conducted in this setting with regards to safety climate (37, 46, 151), it was decided that a qualitative approach would help to produce a greater level of detail regarding culture that could not be achieved through the use of another safety climate survey.
Although a focus group may have raised issues regarding the confidence of team members to speak up in front of their managers, some research suggests that individuals are more likely to discuss sensitive information (including issues about quality and safety that may have put a patient at risk of harm), when they feel themselves to be in a safe, comfortable place with people who are like themselves (152). It was therefore hoped that participants would feel comfortable to discuss safety culture within their team. Furthermore, based on the importance of context when discussing safety culture (45), it was thought that having the whole team present may help to provide information on the context regarding the team that participants worked in. To try to ensure that participants were as comfortable as possible, the decision was made to hold focus groups at the participants’ place of work as opposed to holding focus groups at the university, so that participants were familiar with their surroundings. The decision to conduct focus groups with multiple pharmacies and with staff from different levels within the organisation was done to ‘identify trends and patterns in perceptions’ across participants on the whole, and to explore whether a prevailing safety culture could be identified for CP (150). The decision to utilise MaPSaF during the focus groups is discussed in the following section.

3.4.1.3 - The use of the Manchester Patient Safety Assessment Framework

As discussed earlier, MaPSaF has already been used to assess the prevailing safety culture in CPs (49) however, this was over a decade ago. The MaPSaF framework provides eight dimensions of safety culture for CP staff to consider within their team and/or organisation (49). These included:

- Commitment to patient safety
- Perceptions of the causes of incidents and their reporting
- Investigating incidents
• Learning following an incident

• Communication within the pharmacy

• Staff management

• Staff education and training about risk management

• Team working

For each of these eight dimensions, five brief descriptions are provided that each relate to a level of safety culture maturity. For example, participants that were assessing “team work” in their pharmacy would read the five descriptions of teamwork (each description varies and is related to a specific level of safety culture) and assess which description best matched teamwork within their team. Each of the five descriptions described behaviours and attitudes that related to a particular level of culture (as shown in Table 3). The description that participants choose provides an indication of the safety culture within their pharmacy or pharmacy organisation. As there are eight different dimensions of safety culture explored as part of MaPSaF, it is possible that teams and organisations will excel at some aspects and struggle with others. This is a key strength of MaPSaF, as teams and organisations are able to see the dimensions of safety culture that may need further attention in practice.
In order to ensure that the MaPSaF framework was an appropriate fit for the study, stakeholder engagement was sought.

### 3.4.1.4 Stakeholder involvement
Before the study commenced, a group of six practicing community pharmacists as part of the researcher’s stakeholder group reviewed the method and materials. Stakeholders were asked to comment on various components of the researcher’s study design and comments from the group can be found in Appendix 1.

The main recommendations concerning the MaPSaF framework that were taken from the stakeholder group were as follows:

- Ensuring that participants were made aware that the MaPSaF exercise was not a blaming exercise and that the purpose of MaPSaF was to encourage discussion amongst the team.

<table>
<thead>
<tr>
<th>Level of Safety Culture</th>
<th>Characterisation</th>
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<tbody>
<tr>
<td>1. Pathological</td>
<td>Why do we need to waste our time on risk management and safety issues?</td>
</tr>
<tr>
<td>2. Reactive</td>
<td>We take risk seriously and do something every time we have an incident.</td>
</tr>
<tr>
<td>3. Calculative</td>
<td>We have systems in place to manage all likely risks.</td>
</tr>
<tr>
<td>4. Proactive</td>
<td>We are always thinking about risks that might emerge.</td>
</tr>
<tr>
<td>5. Generative</td>
<td>Risk management is an integral part of everything we do.</td>
</tr>
</tbody>
</table>
• Ensure that teams were happy to have their manager (who was often the pharmacist, and therefore integral to the safety culture within branch) present during the focus group. The PPI group felt that some participants might feel uncomfortable to speak out about their opinion in front of their manager; therefore, a comments box was included on the rating sheets given to participants so that they could comment anonymously if they preferred.

• Participants were asked to rate the safety culture in their team and their organisation separately, as there is often a difference in practice between what employees are told to do in procedures, compared with what is actually done in practice.

• The MaPSaF framework was broken down into more manageable separate sheets for participants to assess, as the PPI group felt that this would be less daunting for participants to read than the original MaPSaF booklet.

The format of MaPSaF was updated following the stakeholder group. The framework was separated into eight separate sheets for the participants to consider one at a time, as the stakeholder group felt that this would be less daunting than handing participants all of the information at once in the MaPSaF booklet, as the booklet was felt to be text heavy. The version of MaPSaF and the rating sheet that were used in the study, following the comments from the stakeholder group are shown in Appendix 2.

3.4.2 - Participants

3.4.2.1 - Recruitment
Initially, pharmacy head offices (large chain (n=2); supermarket (n=1)) were approached to take part and they were asked to suggest pharmacy branches from their organisation to participate (large chain with over 200 branches (n=4); medium chain with between 26-200 branches (n=2); supermarket (n=2)). Independent pharmacies (n=2) were recruited via the NIHR Clinical Research Network. Head office teams were also invited to take part in separate
workshops to explore their managerial perspective regarding safety culture within their organisations. The participant information sheet for the MaPSaF study is shown in Appendix 3.

3.4.2.2 - Participant demographics
The head office focus groups (total participants n=36) consisted of the superintendent pharmacist (who is responsible for identifying and managing risks to all staff and patients) for each large chain, as well as members of the superintendent’s team (typically other pharmacists) and managers responsible for multiple pharmacy branches (a mixture of pharmacists and non-pharmacists). Within the branch focus groups (participants n=48) these participants consisted of, pharmacists (n=15), registered pharmacy technicians (n=7), dispensers (n=18), trainee dispensers (n=2), healthcare counter assistants (n=3) and trainee healthcare counter assistants (n=3). Each participant was offered reimbursement for travel costs and given £40 in shopping vouchers for their participation.

3.4.2.3 - Focus group procedure
Focus groups took place between May 2014 and April 2015 and each focus group lasted for two hours. During each focus group, all participants were asked to individually rate the culture within their team and the culture within their organisation as a whole. This was to ensure that any differences that may exist between sub-groups were captured (42, 45). Participants from independent pharmacies were asked to compare how they worked in practice compared to how they were instructed to work in their SOPs. Participants were provided with eight sheets of paper that each had related to a different dimension of safety culture (49). Each sheet had five descriptions on it, with each description relating to a level of safety culture as shown in Table 3. Participants had to read the five descriptions and choose which description best matched their team and which description best matched their organisation. The participants were required to go through this process for each of the eight dimensions of safety culture individually.
The results of the MaPSaF ratings were collated and provided to participants in a graph format that used a coloured system similar to a traffic light system, where red signified a pathological culture and green signified a generative culture. The results were then discussed as a group. Two facilitators were present, DLP, an Occupational Psychologist who acted as an informed (due to a history of conducting pharmacy based research) outsider, and CT a trained member of CP support staff and psychologist who acted as an insider with first-hand experience of working in the setting being explored, however, CT had not worked at any of the pharmacies sampled. Schein notes that utilising the perspective of an insider and an outsider when collecting data may help participants to feel confident in communicating their views regarding working in this setting whilst the outsider can probe any assumptions that do not match with what they have observed (43).

Participants were prompted to provide feedback regarding the results of the safety culture ratings and to note whether they agreed with the results that had been found. Participants were prompted by the facilitators to discuss areas for improvement; however, participants were also prompted to discuss areas where they had performed well. All focus groups were conducted on the pharmacy premises for the branches visited. The area management groups were conducted at head office for two groups and in a separate location for another area management group.

3.4.2.4 - Ethical approval
The University of Manchester Research Ethics Committee provided ethical approval for the study 26th of March 2014 (Ref: 14040).

3.4.3 - Data analysis

3.4.3.1 - What is template analysis and why was it chosen for the present study?
Template analysis involves developing a coding ‘template’ which summarises themes identified by the researcher as important within a data set, and attempts to organise them in a meaningful way (153). A ‘theme’ can be described as a feature of participants’ accounts that
describes a particular perception or experience judged to be relevant to the research question by the researcher. Coding, on the other hand, refers to the process of identifying where themes may occur in the data and attaching labels (i.e. codes) to those particular pieces of data. The use of hierarchical coding is recommended in template analysis to ensure that broad themes (154) i.e. attitudes towards safety can encompass more specific, narrower themes such as attitudes towards medication safety. Hierarchical coding allows the researcher to analyse the data at varying levels of detail and allows flexibility with regards to the number of levels allowed per theme. However, the extent to which the main i.e. top-level themes are elaborated in terms of number of sub-themes should reflect how rich they prove be in terms of offering insight into the topic being studied. It is important to note that having too many themes can be counter-productive and can result in a lack of clarity with regards to clarifying and interpreting the data (153).

Template analysis often begins with the act of developing a priori codes, where the researcher has already identified themes that are strongly expected to be relevant to the research question (154). However, the themes are flexible and if upon beginning to analyse the data it is found that the themes are not apparent or are not suitable for the data collected, they may be altered or disposed of all together. Once a priori themes have been decided on, the next step is to read the data and to mark any pieces of data that are relevant to the research question. If data relates to an a priori theme, a code is made where the data is identified as being relevant to the a priori theme. During the reading process, new themes are likely to emerge and are added to a ‘template’. The template can be modified after careful consideration of each transcript. Once all transcripts have been analysed and the data coded to the template, the template serves as the basis for the researcher’s interpretation of the data set and for the write-up of the data (154).
Template analysis was decided upon as an appropriate method as oppose to alternative approaches such as grounded theory (155), interpretative phenomenological analysis (IPA; 156) or the broad use of thematic analysis (157). The reasons for not utilising these approaches will now be explored.

Firstly, grounded theory (155) was not deemed suitable due to the approach being very prescriptive with clear directions on how the analysis should be conducted, whereas template analysis is more flexible and allowed the researcher to ‘tailor their approach to their own needs’ (153). Furthermore, two theories were already being utilised in the analysis (45, 49).

Secondly, interpretative phenomenological analysis (IPA) was deemed unsuitable (156). This was due to the tendency of IPA as a method to ‘individualise cases’ as oppose to integrating them, and also with the average sample size tending to consist of ten or less cases (153). IPA has been described as ‘in practice very similar’ to template analysis, with the main difference noted as being the use of *a priori* codes in template analysis (153). Template analysis in comparison, is less ‘time-consuming’ and typical samples sizes that utilise this data analysis method tend to range between 15-30 participants (153). Thirdly, thematic analysis when employed in a broad manner i.e. not committed to a particular theory or method as described by Braun and Clarke (157) can be extremely flexible. However, template analysis was thought to be a useful data analysis technique as it maintains the flexibility of thematic analysis, but provides some structure through the use of *a priori* themes and the use of an initial template (153).

**3.4.3.2 - How was template analysis utilised for the present study?**

All focus groups were audio-recorded and then professionally transcribed in full. Transcripts were then analysed using template analysis (154) and NVivo V.10 (QSR International) was used to support data analysis (158). CT checked the tapes by listening to each one whilst
reading the transcriptions simultaneously. Minor corrections were made such as adding or correcting words that had been missed during the original transcription.

For the analysis of the focus groups, a template of \textit{a priori} thematic codes was created based on MaPSaF (49) and Cooper’s reciprocal model of safety culture (45). The template was then independently applied to each transcript by authors CT, DP and DLP (DP is a professor of Psychology and was involved in the development of MaPSaF (49, 51) but she was not directly involved in facilitating the focus groups). The team then discussed the coding and agreed on modifications to the template in order to represent the ideas identified in the data. Once the next version of the template was agreed, it was refined through successive re-readings of the transcripts until no new themes emerged. The final template was then reviewed by DP, DLP and DA to ensure that it provided adequate coverage of the data and that the themes related to the research question. In order to ensure the quality of the analysis (153) methods such as independent coding and critical comparison among the research team were used.

3.5 - Results
To provide context of the working environment, each pharmacy was a dynamic setting where workload constantly fluctuated due to factors such as the day of the week, the location of the pharmacy in relation to a doctor’s surgery and the time of the day. This meant that no two days were the same in practice as workload and staffing levels were seen to vary. Hence, the reciprocal model was a useful framework for assessing the data, given its acknowledgement of the impact of context on the reciprocal relationships between personal, behavioural and situational factors at any one time.

Overall, the prevailing safety culture in CP appeared to differ depending on the staff sub-group. For example, frontline staff typically described a reactive safety culture where risk was managed in the moment; however, the safety culture ratings varied between each branch, including between branches from the same organisation. The head office staff described using
SOPs to manage safety behaviours in the branches, typical of a calculative culture. In each focus group, the ratings of staff highlighted a perceived difference in safety culture between their branch and their organisation. Thus, suggesting that pharmacy organisations consist of different sub-cultures.

To begin, the personal beliefs and attitudes of participants are provided, followed by their behaviours and their situational factors.

3.5.1 - Personal beliefs and attitudes
Overall, the commitment to patient safety was the highest rated dimension of safety culture across all focus groups, with head office and frontline teams priding themselves on their commitment to safety and the importance of bearing the patient in mind with everything they did. Participants often rated their commitment to patient safety as equalling a generative level of safety culture where “patient safety is integral to the work of the pharmacy and its staff and is embedded in all activities. Responsibility is seen as being part of “everyone’s role” (49). However, the superintendent pharmacist of a large chain noted that often, staff did not take personal responsibility for safety, with support staff sometimes seen to believe that the responsibility for safety lay in the hands of the pharmacist.

Although prioritising patient safety was deemed a key component of safe care, no explicit training was provided to staff on “patient safety” as such. Head office staff noted that patient safety was learnt “on the job” and that risk was managed through the provision of SOPs that staff were required to read and sign as a duty to abide by them in practice. Some participants from various levels within organisations including head office teams and frontline staff felt that newly qualified pharmacists did not have enough training on safety behaviours such as accuracy checking medication and managing teams effectively when they qualified. This may suggest a need for increased accuracy checking training for universities and pre-registration tutors to consider overall, however, pharmacy chains who had clearly noticed that pharmacists (and pharmacy support staff) did not have this experience lacked specific training on patient
safety. However, the head office of a large chain discussed how a new training programme was being developed to make safety everyone’s responsibility. Furthermore, the supermarket pharmacy was the only company sampled that provided a four week induction for new pharmacists in order to ensure that they were aware of the safety goals within the organisation.

“We’ve just [introduced] academy pharmacies, so that’s where [pharmacists] do the training, so we talked about best welcome, so pharmacists will come here for two days, but then they’ll have a period of four weeks in a pharmacy academy before they go out [to stores]. So they’ll have plenty of time to reflect and to get to know the culture of [the company] before they go out into the stores.”

(Head office 2, superintendent pharmacist)

“You’re meant to get time as part of your role [to complete you’re training] but it’s not possible for the management to allocate you the time, sometimes.”

(Site 10, dispenser, large chain, town)

“I think [it’s] really positive that pharmacy has set standards. I think what that does though is make [staff] up to standard and understand their job description and their job role, rather than be focused on patient safety necessarily. I think the patient safety aspect of their learning comes from on the job training and how that branch is managed, so what the focus is on in each individual branch especially.”

(Head office Site 1, area manager)
3.5.2 - Behaviours
Frontline staff were encouraged to engage in patient safety promoting behaviours by head office and area management staff, such as error and near miss reporting, attempting to learn from errors and to complete provided training. Managers and frontline staff mentioned the importance of creating a no blame culture within the pharmacy, where staff felt able to talk openly about their mistakes in practice. However, many participants across the different pharmacies mentioned that talking openly about their mistakes could result in shame and embarrassment for the individual involved.

“…every time someone makes a mistake I will try and ask them why… [But] it does take time…and there’s the embarrassment of talking to somebody [about their mistake.]”

(Site 4, pharmacist, independent)

“We do a lot of work and we’re always discussing things [like incidents] [but] it’s not always possible to document everything that we’ve had down.”

(Site 2, pharmacist, independent)

“I think [near miss reporting is] not used enough, you sort of forget it’s there, and when you’re busy it’s like it just gets overlooked…It’s remembering [to use it] sometimes.”

(Site 7, pharmacy technician, suburb)
Although staff were encouraged to complete these patient safety maintaining behaviours, frontline staff would commonly note that they simply did not have “time” to always complete these behaviours as they were busy reacting to the work in front of them. Part of the reason for this was because staff were attempting to balance productivity serving goals such as reaching service target levels set by area management and dispensing medications for patients as a means of remaining efficient and ultimately, profitable. Head office staff also noted this experience, with one area manager explaining that only the incidents that caused the most patient harm were investigated due to a lack of time to investigate all incidents reported. Staff from an independent pharmacy discussed the pressure they felt to have all of the prescriptions dispensed, during the focus group the management clarified that this was not expected of them, suggesting a potential lack of communication between management and frontline staff regarding goals in practice.

“I think sometimes you feel under more pressure because there [are] a lot of prescriptions waiting in the box or there seems to be an awful lot of [electronic prescription] downloads. Certainly, personally the more pressure you feel that you’re under perhaps the less particular you become about looking at those notes or glancing at something rather than studying what’s actually written.”

(Site 4, dispenser, independent, town)

“We never have enough hours in the day, to be honest with you, so just sometimes you feel as though, right, I’ll come to that, and [you just forget to do it] because you’ve got that much on in the day.”

(Site 9, pharmacist manager, supermarket, suburb)

One of the main issues of contention was the mixed messages received by staff concerning the purpose of incident reporting. On the one hand, the behaviour of reporting errors and
near misses was portrayed by head offices as crucial for learning from mistakes in order to help achieve the goal of maintaining patient safety. Yet, frontline staff in the pharmacy branches and the supermarket expressed that incident reporting had been used as a performance management tool at times. One superintendent noted that failing to move staff that were not performing well, was a risk to patient safety in it itself. However, it was the disconnect between what head offices said the tool was used for (i.e. learning) and the resulting behaviour that reporting errors may lead to (i.e. the potential loss of a contract), that led to frontline staff having a mixed attitude towards error reporting. One independent pharmacy noted that they openly used near-miss rates as a performance measure, and both management and support staff in this pharmacy felt that this practice helped encourage mindful dispensing.

“I’ve been around the block for many years as a pharmacist…I’ve known there’s been [managers] that have used it as evidence to basically [get] other people sacked…[management have] used it as evidence to discipline people… People have been sacked; dispensers [have] lost their jobs…”

(Site 6, second pharmacist, supermarket, suburb)

“[If someone’s] making more than half a per cent of errors then that puts someone into the red [laughter]. It’s just a grade of the way we’re looking at how one person performs against the next… I think [performance] has definitely improved since we’ve been measuring.”

(Site 4, pharmacist manager, independent, town)
“We’ve got all the [near miss and error reporting] data but we’re very careful how we use it to drive performance because actually we want to improve reporting and not to get very competitive regional managers… there are people who are like that would actually have the negative effect [on reporting].”

(Head office 3, large chain)

On the other hand, some branches discussed learning from specific errors that had occurred in their pharmacy that led to branch specific behaviours that the staff had developed in an effort to avoid the same error occurring again. Although these changes were made in an effort to maintain patient safety, these changes were not communicated to head office. This meant that there were differences in practice between what was stated in the SOPs and what the staff did in practice. This also meant that branches from the same organisation were working slightly differently, based on how things were done in that particular branch. One pharmacy team discussed how they had added extra steps to their controlled drug (CD) balance check following drugs going missing from the CD cupboard.

“We used to just do a weekly balance check and check the balance after the drug was given out. It’s now changed where the balance is written on the prescription…It’s checked at the point of dispensing. It’s checked at the point of being given out, and it’s also checked every single week and we all sign our initials… it’s worked perfectly since then.”

(Site 3, pharmacist, medium chain, suburb)

When asked whether this new practice had been taken up in other branches of the organisation, the team replied that it was “just them” that had incorporated the change, supporting the notion that individual branches may have slight differences in their work.

Another behaviour that was seen to serve both goals of safety and productivity was the act of communication. Communication was both top-down from head offices to frontline staff (this
mainly included information on meeting targets and at times, alerts with regards to patient safety issues) and within teams at frontline level. Communication appeared to be more bidirectional in the independents as opposed to the other pharmacy types. This was due to the independent pharmacies being less bureaucratic, and management being more readily available to contact.

“We’ve sort of learned that you have to just deal with things yourself and sometimes it’s better as a team and as a branch to just bite your tongue and get on with it rather than raising issues [with area management], where you will be frustrated because nothing’s been done about it.”

(Site 3, pharmacist manager, medium sized chain, town)

Communication at frontline level tended to be mainly regarding patient safety issues such as passing information on to colleagues regarding the status of a patient’s prescription. However, information was not always communicated due to staff prioritising managing current workload as opposed to proactively communicating regarding potential future issues. Furthermore, failure to communicate within branch could lead to issues within the whole team and was found to cause hostility as some staff were made to feel “out of the loop”. Hostility within the team was reported to cause an awkward working environment for staff that could make managing patient safety as a team difficult. The atmosphere of the working environment was another factor that was individual to each pharmacy, based on the team members working there.

“[Not leaving notes] makes it hard at evenings and weekends when we don’t have as much staff in, if there’s not been a note left and [a patient] comes at you and you think, I wasn’t here this [before] and I haven’t got a clue [what’s going on].”
3.5.3 - Situational
The working environment was perceived to have a large impact on the behaviours of pharmacy staff. The most common environmental issue noted was that there was not enough staff to manage workload. This perception was reported to create a barrier between management and frontline staff, with both staff types feeling disconnected from each other at times. Many participants from chains and the supermarket felt that management did not share the same perspective regarding safety, with head office staff being felt to prioritise productivity. Frontline staff did not always feel that head office understood what it was like to work in pharmacy practice and they were often frustrated when their requests for more staff were not granted. This led to frontline staff having to react and deal with issues in the pharmacy on their own as they arose, and staff appeared to create their own behaviours in order to manage their specific environment. This also led to behaviour such as pharmacists having to self-check their dispensing which was recognised by participants as introducing an element of risk to the dispensing process. Pharmacists were incredibly frustrated to be working in these conditions as they felt it added an unnecessary level of risk to safety.

“Our thoughts ([frontline staff] might think that [our company] doesn’t always understand how pharmacy works and I guess [in head office we] see things from a different perspective …we can see where we’re going and maybe the communication that the pharmacists get isn’t as clear as we think it is and maybe they get frustrated that things aren’t happening as we think that they’re happening.”

(Head office 2, superintendent pharmacist, supermarket)
“[Frontline staff] don’t see us, they don’t know who we are and they don’t know what we’ve done.”

(Head office 3, superintendent pharmacist, large chain)

“I end up dispensing, labelling, checking, assembling [the medication] all myself. Then, the phone will ring, and then there might be somebody in the shop shouting up to me to ask a question. There’s so much going on, that’s when mistakes happen, because you’re trying to do too much at once, it’s just trying to get through with the staff you’ve got.”

(Site 5, pharmacist manager, large chain, town)

Although frontline staff often discussed how more staff would ease the pressure that they felt under in practice, more staff were not always feasible in reality. There were multiple reasons for this, including a lack of applicants for advertised posts, a lack of suitably qualified staff to work in the pharmacy (this often resulted in trainees working in the dispensary who could be a source of distractions for the team) and a lack of business to justify the addition of new staff. However, management from all pharmacies discussed strategies used to try to facilitate a safe working environment for staff and patients. The head office staff from one of the chains noted how procedures were used to manage safety behaviours in practice. One area manager from a large chain expressed that they would encourage “100% compliance” within their branches. The head office staff from the supermarket provided an opportunity for pharmacists to reflect on their practice by providing ten hours of cover, however, staff would sometimes use the time to focus on catching up with dispensing which was met with some frustration by head office.
“Each of our pharmacies get 10 hours a week overlap time, there are two pharmacists there, which we ask them what they do in that time and sometimes they just, oh, we’re just catching up on dispensing, I say, no, no, no, that’s not what it’s for, it’s about thinking about the business, thinking how you can do things better. So driving sales as well, yeah, and visiting GPs or doing events, we’re also looking at here safety and compliance work.”

(Head office 2, superintendent, supermarket)

“We had a technician leave, and so there was no external recruitment so we weren’t going to get an experienced replacement; [we] had to recruit from within the store…we’ve got two great [new] colleagues, however they’re on their counter course. [So] it’s just me and those two colleagues, so as well as trying to train them…I’m also doing all the dispensing, [and] all the checking, by myself.”

(Site 6, pharmacist, supermarket, suburb)

Other management strategies for creating an environment where safety could be prioritised included staggering start times for staff. The frontline staff from the independent pharmacy that used staggered start times emphasised the positive impact working without distraction had on their ability to manage workload. The capability to utilise other areas within the pharmacy (e.g. creating an upstairs dispensary) also helped staff to concentrate and to work without distraction. However, it should be noted that the pharmacy team that described these organisational changes was an independent pharmacy, and therefore the management potentially possessed greater autonomy with regards to changing rotas in comparison to large multiples or supermarkets. Within chains, organisational factors that supported staff in
maintaining patient safety included ensuring that staff were working from a tidy workstation and the use of coloured baskets to allow staff to prioritise which medication to accuracy check first. Some participants noted that they had come into reorganise the branch in their own time when the store was shut, on the suggestion of their area manager.

“It’s a lot quieter upstairs. You’ve not got as many distractions. So you’ve not got people coming in looking for prescriptions and asking you… I don’t begrudge helping anybody. Don’t get me wrong. But you’ve not got that distraction. It’s quiet upstairs. It’s a lot quieter. [There are] definitely [less errors made].”

(Site 4, registered accuracy checking technician, independent)

3.6 - Discussion
The findings from this study suggest a reactive prevailing safety culture for frontline in CPs. Staff reported that managing workload was often prioritised as opposed to safety directly. The prevailing safety culture for the CP head office staff appeared to be calculative, where risk was managed through the use of SOPs, with the expectation that procedures would set the standard for staff to work to and that patient safety would be learnt on the job. Head office staff would regularly remind staff to work safely and to achieve targets in practice. However, frontline staff sometimes felt that the behaviour of head office staff, for example in not providing adequate staffing or enough time to complete training reflected a prioritisation of maintaining productivity over maintaining safety.

Overall, Cooper’s model of safety culture (45) provided a useful framework for exploring the prevailing safety culture in CP and the use of MaPSaF (49) during the focus groups was useful for aiding participants to assess and discuss their safety culture both in their teams, and within their organisation. Results suggested that although staff rated their commitment to patient
safety as an integral part of everything they did, unconscious beliefs and attitudes regarding productivity appeared to result in profit maintaining behaviours taking precedent in practice (43). This was frustrating for frontline staff especially, and mainly for staff working in chain and supermarket pharmacies as they felt powerless to change their environment and required to act in a way that did not always align with their belief that patient safety was integral to their work. The findings support the previous work on safety climate, where CP staff appeared to be impacted by the level of job demands and the resources available to meet said demands (46). This finding also supports the notion that the presence of beliefs and attitudes do not necessarily result in an associated behaviour as previously suggested by Schein (43).

The results support the reciprocal model of safety culture, as CP staff across levels of CP organisations appeared to alter their behaviours because of factors within their environment such as a perceived lack of time. In these periods of high time pressure, there appeared to be a preference for productivity maintaining behaviours. It could be argued that ensuring that the dispensing of medication was kept up to date, could count as a patient safety maintaining behaviour as it is important that patients receive their medications on time. However, our work suggests that the prioritisation of immediate environmental demands may be occurring to the detriment of proactive behaviours to manage safety such as planning for emerging risks and learning from previous errors.

Our study explored a range of different types of pharmacy, including multiple branches from the same large chain. The inclusion of multiple branches from within the same chain, allowed the observation of sub-cultures within an organisation. Findings support the notion that organisations are made up of smaller sub-cultures (42, 45), as results found differences between branches of the same company. Management were seen to encourage compliance with procedures at all times to ensure safety. However, our work suggests that one individual (namely the responsible pharmacist) can impose his or her values and rules within a branch,
and if these changes are successful, these rules are then accepted and passed down to new staff that are left to learn about patient safety “on the job” (43). This study raises the question of how procedures are perceived in practice. The results suggest a difference in opinion between head office staff and frontline staff with regards to risk management, and it also suggests that at times, procedures may not always be followed due to workload pressures, and due to “the way things are done” in particular pharmacies; however this finding needs further exploration.

3.7 - Chapter summary
This chapter has presented the results of the study that explored the prevailing safety culture in CPs. The aim of this study was to provide the reader with an insight into the prevailing safety culture in CPs and to provide an insight into the context in which violations occur. The findings highlight how staff have a positive attitude towards patient safety, however productivity promoting behaviours are often prioritised in practice by staff. This results in a reactive safety culture on the frontline of CP where risk is managed as and when it appears as time is not spent proactively anticipating risk. Head office staff however, appeared to rely on the use of procedures to manage risk. This study suggests that sub-cultures exist within pharmacy organisations where safety may be managed according to the social norm within a specific pharmacy branch. The results suggest that although procedures are provided in all pharmacies, procedures appear to be interpreted differently across organisations. Chapter 4 presents a qualitative interview study that further explored the use of procedures in CPs with the aim of understanding how procedures are perceived by staff in CPs.
CHAPTER 4: Exploring how procedures are perceived in practice

4.1 - Chapter Outline
The previous chapter provided detailed insights into the prevailing culture in CP. The findings highlighted that CP staff often manage multiple goals in practice, mainly the goals of maintaining patient safety and productivity. This chapter presents findings from the first part of the qualitative interview study conducted with CP staff that explored how procedures are perceived in practice. Firstly, the background and the aims and objectives of the study are provided. The methods used for the study are defined, followed by the results and a discussion.

4.2 - Background
Since 2005, pharmacies have been required to adopt SOPs for the storage, dispensing and supply of medicines and the provision of medicines advice to patients (159, 160). As discussed in the previous chapters all team members are expected to abide by SOPs and a CP team can encompass a range of staff members including pharmacists, registered and non-registered support staff, medicine counter assistants and delivery drivers as well as a range of trainees.

The previous chapter highlighted how head office staff have a calculative approach to risk management, where procedures are used to manage safety behaviours in practice. However, frontline CP staff seemed to have a reactive approach to risk management, where safety was dealt with in the moment. Previous research has shown that procedures for selling OTC medication in CP are not always followed (106), yet little is known about how procedures are perceived by dispensary staff in CPs. The aims and objectives of the first part of the interview study are outlined below.
4.3 - Aims and objectives
The aim of the first part of the interview was to explore the experience of CP staff in applying procedures to their everyday work.

More specifically the objectives were:

- To examine the perceptions of CP staff with regards to following SOPs.
- To explore how procedures are provided and managed in CP practice.

4.4 - Methods
The following sections detail the philosophical underpinnings, the design of the semi-structured interviews, the participants’ details and the data analysis.

4.4.1 - Interview design
Semi-structured interviews were chosen as an appropriate method to explore how pharmacists and support staff perceive procedures in practice. The interviews were also used to explore the types of violations that occur in practice and the reasons why they happen; however, this second aim will be discussed further in the following chapter.

Interviews were chosen as opposed to focus groups as the study asked participants to disclose potentially sensitive information that participants may have been reluctant or felt uncomfortable to share in a group (150). Furthermore, inviting pharmacy staff to a focus group to discuss violations could result in bringing together a group of individuals that hold differing opinions and given the potentially emotionally charged situations that may be discussed, it was thought that it may risk confrontation (150). One option would have been to hold a focus group that invited participants that were not known to each other (unlike the focus groups discussed in Chapter 3). However, confidentiality of sensitive information could not be guaranteed. Therefore, one-to-one interviews were chosen as the most appropriate method. Before the final interview schedule was decided upon, the schedule was piloted with a member of CP staff.
4.4.2 - Participant recruitment
Participants were identified on a purposive basis, using departmental contacts, professional networks and advertisements on Twitter. Once participants had expressed an interest in taking part, each of the participants was contacted to opt into the interview about the use of procedures in their work via email. This initial recruitment was followed up with snowball sampling, in which the preliminary participants were asked to recommend other members of the sampling frame for the researchers to invite (71, 161, 162).

4.4.3 - Sample inclusion and exclusion
As this study was exploring the use of procedures within the dispensary specifically, pharmacy staff that worked within the dispensary were sampled. The reason for this was as healthcare counter assistants do not have the training necessary to work in the dispensary and therefore, they do not encounter the full range of procedures utilised in CP. Therefore, healthcare counter assistants were excluded from the study. Furthermore, given the frequency with which procedures are updated in practice, participants were only included in the study if they currently worked in CP.

4.4.4 - Participant demographics
Twenty-four participants (pharmacists (n=13), ACTs (n=1), registered technician (n=1), non-registered accuracy checking assistants (n=3) and dispensing assistants (n=6)) agreed to participate. These participants represented staff from independent pharmacies (n=7), large pharmacy chains (n=9), medium sized pharmacy chains (n=2), small sized pharmacy chains (n=2), a supermarket (n=1) and locum/sessional staff (n=3; 2 pharmacists, 1 dispenser) who worked in a variety of pharmacy types. Participants worked in a range of locations including a city centre (n=2), a suburb (n=7), a town (n=10), a village (n=2) and some did not have a set location (n=3). Participants’ time since qualifying in their role ranged from six months to thirty years. Participants’ total time working in CP (either in their current role or in other roles) ranged from two and a half years to thirty five years.
### 4.4.5 - Interview procedure (Part 1)

The topic guide for the first part of the interview was developed based on the literature on procedural compliance in healthcare and based on the researcher's personal experience as a CP dispenser (the topic guide is shown in Appendix 4). Questions included:

- “How are you made aware of the procedures that you need to follow during your work?”
- “How useful are procedures for helping you to do your job?”
- “Do you feel able to follow the procedures at work?”
- “Are there certain times of the day, week, month or year that you feel procedures are typically deviated from or bypassed?”

Interviews were conducted between November 2014 and April 2015. Before the interview started, participants were fully informed of the aims of the interview through the participant information sheet (shown in Appendix 5) and each participant provided written consent to take part. Each interview was audio-recorded. Interviews were held in a private place with only the participant and the interviewer present. Each interview lasted 30-90 minutes. Participants were recruited until data saturation was reached and no new issues emerged during interviews. Participants were provided with a £20 shopping voucher for their time.

### 4.4.6 - Ethics

Research ethics approval was granted by the University Research Ethics Committee at the University of Manchester on the 29th of October, 2014 (Ref 14352).
4.4.7 - Analysis

4.4.7.1 - Template analysis
All interviews were digitally recorded and then professionally transcribed in full. CT checked the tapes by listening to each one whilst reading the transcriptions simultaneously. Minor corrections were made such as adding or correcting words that had been missed during the original transcription.

Transcripts were then analysed using template analysis (154) and NVivo V.10 (QSR International) was used to support data analysis (158). As discussed in the previous chapter, template analysis involves developing a coding ‘template’ which summarises themes identified by the researcher as important in a data set, and attempts to organise them in a meaningful way (153). For the analysis of the first part of the interviews, a template of *a priori* thematic codes was created based on previous literature regarding compliance and views of procedures [35]. The template was then independently applied to each transcript by authors CT and DLP (the latter not being involved in the interviews), who then discussed the coding and agreed on modifications to the template in order to represent the ideas identified in the data. Once the next version of the template was agreed upon, it was refined through successive re-readings of the transcripts until no new themes emerged. The final template was then reviewed by DLP and DA to ensure that it provided adequate coverage of the data and that the themes related to the research question.

In order to ensure the quality of the template analysis (153) the researchers used independent coding and critical comparison. In addition, respondent feedback was obtained from one pharmacist and one member of pharmacy support staff as an attempt to ensure that the results reflected the views of participants.
4.5 - Results
All participants appreciated the need for procedures in CP and agreed that the ultimate aim of procedures was to guarantee patient safety. Participants generally found SOPs useful for highlighting the ‘ideal’ way to work from a patient safety point of view. However, procedures were restrictive at times and could not be followed constantly for many reasons. Three main themes were identified; ‘the dissemination and creation of SOPs’; ‘complying with procedures’ and ‘procedural compliance versus using professional judgement’.

4.5.1 - The dissemination and creation of SOPs
One of the main themes with regards to the use of procedures as a whole in CP was how participants were made aware of the SOPs. Overall issues included the large amount of detailed procedures in CP. Participants felt complying with all procedures at all times was an unrealistic organisational aim given the complex setting and the high workload. The findings highlighted a difference between work-as-done and work-as-imagined due to the sometimes unrealistic expectations placed on CP staff, in terms of the large number of detailed procedures that resulted in difficulty for staff to learn and retain all of the procedures provided.

4.5.1.1 - Dissemination of SOPs
Most participants were provided with written SOPs that they were expected to read upon starting work in CP and this was often viewed as a prerequisite to start dispensing. Frequently participants mentioned an overload of procedures leading to difficulty in complying with expected practice. A pharmacist (P13) noted that procedures are ‘often left on a shelf and ignored’.

“I couldn’t dream of recalling every step of every policy and I don’t think the staff that work with me could either…some might say that undermines the value of having all the rules because there’s too many…but it’s important that things are laid out.”
“I think we often just read it, sign it and then you don’t look at it again until you get told to…you never look anything up…”

(P3, dispenser, large chain)

“[Staff are] presented with this massive folder [of procedures] and a lot of them are very repetitive… people will lose their attention span after five minutes…it defeats the point.”

(P16, locum pharmacist)

“I think the people who write the SOPs, they’ve never actually worked in [a branch] either.”

(P12, dispenser, large chain)

Disseminating pharmacy specific SOPs to locum/sessional staff was noted as unrealistic, therefore making SOPs available to refer to when needed was important.

“The agency I’m with have a lot of the [company] specific SOPs on their website…[So if] you’ve got a week in [a particular company], and they’ve got something particular that they do…you can read through before you go.”

(P19, locum dispenser)
“I think you’d be hard pressed to find a locum that could genuinely say, that if they walked into a pharmacy they’d never walked into before, they’re going to spend an hour scouring the SOPs [before they start any work]...you can’t work that way.”

(P16, locum pharmacist)

4.5.1.2 - The creation of SOPs
With regards to the creation of SOPs the level of input from CP employees varied. A supermarket pharmacist (P20) noted that branch pharmacists are heavily involved in procedure development and that amendments were available for branches if needed. Having front-line pharmacy staff comment on SOPs was useful for aligning work-as-imagined and work-as-done. Participants from an independent pharmacy spoke of the flexibility and control they had in creating and updating SOPs. Participants from a large pharmacy chain noted there was little flexibility and this could result in procedures that were not always appropriate.

“Sometimes you can’t follow them exactly...[they’re] written for the whole of [the country] and each store...do things slightly differently even though they’re all supposed to be the same. They try but they can’t because customers want different things and surgeries do things differently...I think the company needs to recognise that they need to be a bit more flexible...”

(P9, pharmacist, large Chain)

4.5.2 - Complying with procedures
A variety of factors affected compliance with procedures in CP. Participants from all roles emphasised the impact that work demands, workload and the behavioural norm within the team had on their ability to comply with procedures. Organisational factors were often
attributed to result in a difference between work-as-imagined in the SOPs and the work-as-done by CP staff in practice.

4.5.2.1 - Work demands
As discussed in the previous chapter, one of the main work demands that impacted on the ability of CP staff to comply with procedures was work scheduling, which was frequently mentioned by all staff types. Particular pressure points included public holidays and the beginning and end of the week. During these times, participants found complying with procedures challenging with some participants describing how working in CP on a weekend could feel like a ‘different job entirely’, mainly due to the closure of general practices and other resources not being available out of hours. Under these circumstances, pharmacists often resorted to applying their professional judgement regarding patient safety.

“Easter weekend, the weekend before Christmas…the end of the week, Friday as well is usually very busy…sticking to the rules becomes less of a priority. [The job doesn’t] become less of a priority, it’s how you’re doing the jobs… [it] depends on how much experience you have…you can [figure] out what you need to carry on doing by the rule book and what you don’t.”

(P10, pharmacist, large chain)

Another crucial element that added to work demands was staffing levels. Participants in all roles expressed how following procedures was especially difficult with insufficient staff for their pharmacy.
“Staffing and [lack of] time are probably the biggest things that put extra pressure on what you’re doing, and maybe lead to [some things] not quite going as they should do.”

(P19, dispenser, large chain)

4.5.2.2 - Workload
Many participants spoke of regularly attempting to complete several tasks at once to manage workload, leading to occasional shortcuts. All participants mentioned the volume of tasks they had to complete under time pressure. Pharmacists also highlighted the need to achieve service targets set by head office or area management regarding professional services such as MURs [21] and the NMS [22].

“…The number of items goes up every year, the time [you have] to spend just doing those goes up and up and more and more services come out at the same time. [The challenge is] having time with the patient to do everything you can for them, so [following the] rules come into that and it’s really hard [to manage].”

(P15, pharmacist, large chain)

“The general thing [is] time…either you have too much work or…your colleagues isn’t there…there’s always steps in the SOPs which you cannot do, but still get the same result at the end…”

(P3, dispenser, large chain)

4.5.3 - Behavioural norms
Participants often spoke of the ‘the way we do things around here’, which did not always coincide with work-as-imagined in SOPs. Sessional pharmacists and support staff felt under
pressure to conform to local practice, even if this was not outlined in procedures. This resulted in differences between branches of the same company, despite an apparent purpose of SOPs being to standardise performance.

“You get mixed feelings…most of the time you just end up shutting up that side of you that’s saying… don’t do that, and [instead] you say if that’s what [the regular pharmacist does] then I’ll just do the same...you might be not 100 per cent sure of what’s going on...because of the demand around you [from the support staff]...you just get on with it.”

(P11, locum pharmacist)

“It would be nice to get a bit more back-up from pharmacists [regarding following the procedures]…the [procedures are] not just there for one person, they’re there for everyone and it’s safer if everybody follows the [procedures] properly."

(P22, accuracy checking dispenser, independent)

4.5.4 - Procedural compliance versus using professional judgement
There were varied opinions between participants about the relative merits of standardised practice and the use of professional judgement by CP staff. In our sample, the variation in opinion was particularly noticeable when comparing the views of the pharmacists with those of staff in other roles. The pharmacists appreciated that procedures were useful to an extent, but also felt that they reserved the right to bypass or deviate from procedures if they judged it necessary for the patient’s outcome.
“There are scenarios where the patient’s health is at risk if you follow them. So sometimes, you do have to make your own decision on what is best for the patient’s care, because that’s the most important thing to do as a pharmacist.”

(P4, pharmacist, large chain)

“If somebody’s on their way to dying and the doctor’s forgotten the Midazolam [is] CD schedule three, and forgot to put the quantity, where the figures all look clear and [the prescriber says] ‘okay, we’re on visits, we’ll be over in an hour to sign it’. Do I leave it an hour? The patient could be dead in an hour.”

(P6, pharmacist, independent)

However, some participants expressed concern that acting outside of procedures exposed them to the risk of disciplinary action or litigation. This result supports the findings from the previous chapter, which found that the prevailing safety culture for head office staff in CP is calculative.

“I think if something’s gone wrong then I’d definitely go back and have a look at the SOPs…[unless] you’re the actual pharmacy manager there and you work there full-time, you [don’t] have the time to take [SOPs] home [to read]…”

(P16, locum pharmacist)

“I suppose people follow the bits they agree with and they don’t follow the bits they don’t agree with. And being in a big company, there’s not really a lot you can do about the bits you don’t agree with. It’s not like they’re
going to change it, so you just have to take it upon yourself, which then leaves you open to being uninsured if you don’t follow them, so it’s a lose-lose situation really, but everybody kind of does it.”

(P9, pharmacist, large chain)

There were some procedures that were considered important enough that participants would adhere to them even in unfavourable circumstances.

“[Bypassing the procedure that states I should not work in the pharmacy alone means I can] actually do things properly. There are certain things that I would never be happy cutting corners with. I want to do a full CD balance every week. I’m not going to not do that. So if that means doing overtime for free then I’m going to do it…it’s protecting myself, it’s protecting my registration…”

(P14, pharmacist, large chain)

Interestingly, newly qualified pharmacists seemed to rely on SOPs as a guide to practice, however more experienced pharmacists noted that this was not a realistic approach to professional practice. This builds on the focus group data, that highlighted newly qualified pharmacists may lack business and people management skills.

“When you newly qualify…you’ve literally swallowed up the [Medicines, Ethics and Practice professional guide for pharmacists] and you’re so into the laws that when it comes to practise it’s quite shocking how much deviation takes place in a pharmacy …I was extremely cautious and very worried and I’d go home and I’d start thinking about everything that had happened [at work]. But, then eventually…you get used to it.”
“I think [making a professional decision] scares some pharmacists, some of them want it in black and white...pharmacy can’t be black and white. But that’s why we are professionals because we make those decisions. Anyone can follow a process, a dispenser can follow a process...the pharmacist has to make a professional decision.”

At times, pharmacists would face situations in which there was no set guidance and professional judgement was crucial.

“There’s a balance...I think the trouble with our profession is that we want a rule for everything and that’s not how a profession works...We shouldn’t anticipate that there's always going to be an SOP for everything.”

All participants alluded to “professionalism” – for pharmacists though, professionalism is about exercising professional judgement whereas for some support staff it was about following rules. For support staff, professional judgement played less of a part in their role – so following procedures was seen as a way to ensure patient safety.
“SOP’s are in place to make sure also the fact that we’re doing the right thing… If we don’t do as we’re told when we’re dispensing, then it’s a danger to the patient.”

(P22, non-registered accuracy checker, independent)

“I don’t want to be struck off…sticking within the rules, makes sure that the patient’s safe. Go out of the rules and the patient’s not safe, and neither’s your job.”

(P24, ACT, Independent)

“Being registered with the GPhC has a huge influence on the way that I feel, because I want to keep it…I value my job and I do value the rules…because I’m registered, I think it heightens my realisation that there are rules because I am responsible for myself and my own actions…”

(P24, ACT, Independent)

Notably, dispensers’ attitude towards procedures was seen to be more flexible at times. Some felt procedures were a ‘tick box exercise’ and did not necessarily shape their work to a large extent. Although dispensers are required to sign to say they have read and will abide by SOPs, in certain circumstances the instructions of the responsible pharmacist were followed as an alternative. Dispensers especially, did not always feel able to question the decision of the responsible pharmacist.

“[I do] what the pharmacist is telling me to do, because they’re responsible for what goes on, so it’s their call.”
4.6 - Discussion
Overall, the participants saw procedures in CP to be useful for setting expectations of practice and for improving knowledge, yet tensions were evident between the standardisation of practice and the scope of behaviour available to pharmacy staff in completing their tasks. The need to deviate from work-as-imagined when patient safety was at risk was an important part of being a professional for pharmacists. Dekker (117) describes tension between procedures and safety as a considerable practical problem. A successful outcome for patient safety is not guaranteed from following procedures, but instead created from a diversity of responses that allow staff to cope with their changing environment (23).

The findings expose elements of organisational resilience in CP. Participants relied on their ability to adjust; dealing with standardised systems on the one hand and with un-standardised situations on the other. This flexibility is fundamental to working in CP, as employees create changes to procedures and accommodate changes in order to meet patient needs (163). The formation of rule-related behavioural intentions in CP could be compared with the findings of Phipps and Parker (164) that found anaesthetists sometimes worked ‘in the moment’ when deciding how to act in a given situation. This process is most likely to occur in settings such as CP, as it involves a multidisciplinary team, time pressure; emergency situations; shifting goals and organisational norms and goals that may go against the employee’s interests (23, 165). Phipps and Parker note these are areas where procedural violations should be of most concern (166).

The interview findings show some variation in the views of participants about procedures. Some of this variation might be attributed to differences in role and responsibility between participants. For example, pharmacists tended to express similar attitudes to doctors and
surgeons in previous published studies which identified the need for a degree of flexibility was required when working in healthcare as oppose to the notion of ‘cookbook’ care (62, 72, 73). The pharmacists here appeared to invoke the notion of professional autonomy with regard to following procedures, echoing previous research exploring implementation of emergency hormonal contraception services in CPs (167). The attitudes of registered support staff were similar to nursing staff, as they approached patient safety by systematically following procedures (74, 75). In contrast, dispensers had a more flexible approach, as the ultimate responsibility for their actions was that of the responsible pharmacist at the time (168).

However, when following instructions that do not benefit the patient, support staff did not always feel able to voice their concerns (73, 169-171). Failing to communicate has been identified as a key threat to patient safety (12). Therefore, a culture in which all CP employees feel able to discuss adherence to or deviation from procedures needs to be encouraged. The previous study identified that staff will sometimes struggle to discuss making errors in CP. Given that accidental errors are considered difficult to discuss, and based on research that showed violations are poorly judged by fellow healthcare professionals (sometimes regardless of a positive patient outcome) (62); CP staff may struggle to discuss intentional deviations from procedures in practice.

Adherence to procedures may help manage risks to patient safety in some circumstances; however, an overreliance on procedures could be counterproductive. Efforts to align work-as-imagined with work-as-done, would be beneficial for creating SOPs that are more reflective of practice whilst providing an effective risk control. One method for achieving this is to maintain a dialogue between frontline staff and those responsible for creating SOPs regarding the correspondence between the SOPs and actual practice. As shown in the previous chapter, communication in CP is typically top-down. The results of this chapter highlight the potential benefit that a bottom-up approach to communication regarding practical issues may have for
ensuring procedures are fit for practice. This study has highlighted that there is a difference in work as imagined and work as done. The next chapter explores specific examples of violations in practice.

4.7 - Summary of the chapter
This study examined how procedures are perceived by staff in CPs and how this can impact on professional autonomy. The findings highlight the tension between standardising practice on the one hand and the need, at times, for greater flexibility for pharmacists to decide on the most appropriate course of action to manage risks to patient safety. Evidence of organisational resilience in CP practice was apparent and the findings should help to inform policy-makers and practitioners with regards to the factors most likely to influence the implementation of procedures in CP. The following chapter explores how procedures are violated in practice.
CHAPTER 5: Exploring violations in community pharmacies from a Safety-I and Safety-II perspective

5.1 - Chapter outline
This chapter presents the findings from the second part of the semi-structured interviews. In this chapter, findings relating to the specific examples of violations that occur in CP are presented along with the reasons behind why these violations occur in practice. The Safety-I and Safety-II philosophy is used to explore the motivations for making violations. To begin, the Safety-I and Safety-II philosophies are introduced, followed by additional information regarding the method used for the second half of the interview. The results are then provided and discussed in relation to the research outlined at the beginning of this chapter.

5.2 - Background
As introduced in Chapter 2, procedural violations are known to occur in a range of work settings, including healthcare (25, 172, 173). Although violations are usually not intended to cause harm, and indeed are sometimes made with explicitly good intentions, violations have been noted as a potential threat to patient safety. For example, Amalberti et al. (126) suggested that violations that are allowed to become routine work practice may lead to the “migration” of work towards or across nominal safety boundaries. Previous studies have suggested that violations are linked to the presence of latent factors in the environment, particularly concerning individual and collective beliefs about the applicability of rules to one’s work (25, 62, 172).

The notion that violations may be negative behaviours is consistent with the philosophy of ‘Safety-I’, where safety is based on the absence of incidents and accidents. This approach to safety has traditionally been the dominant view in healthcare, with procedures often being used as an attempt to protect against adverse events, with workers in the system being viewed as a liability or hazard. As Table 4 shows, the Safety-I approach to risk management may be
contrasted with the Safety-II approach, which places safety in the context of the variation in working conditions often found in complex work systems (174). The latter sees violations primarily as a matter of staff attempting to manage system complexity, thus demonstrating organisational resilience (23, 163, 175). In other words, it emphasises the need for staff to negotiate variability, diversity, limited resources, specialisation and ad-hoc teams in the course of their work, and it accounts for the limitations of procedures that do not account for these sources of complexity. Hence, it cannot be assumed that safety is always achieved by strict adherence to procedures as implied in the Safety-I approach.
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<th><strong>Table 4</strong> - An overview of the Safety-I and Safety-II approaches (113)</th>
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<td><strong>How is safety attained?</strong></td>
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<td>By preventing as many things from going wrong</td>
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<td><strong>How is healthcare viewed as a work-system?</strong></td>
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<td><strong>How is safety achieved in healthcare?</strong></td>
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<td><strong>How do staff react to risk?</strong></td>
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<tr>
<td><strong>How are staff typically viewed by management?</strong></td>
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<tr>
<td><strong>How do staff learn in practice?</strong></td>
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<td><strong>How are procedural violations judged?</strong></td>
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Whilst previous studies have focused typically on Safety-I and Safety-II as separate approaches (176, 177), it has been suggested that combining these philosophies may be required to manage safety (178). The current study seeks to explore the application of both Safety-I and Safety-II to violations in the CP setting. The aims and objectives of the second part of the interview study are detailed in the following section.

5.3 - Aims and Objectives
The aim of the second part of the interview was to further explore violations in CP. More specifically, the objectives were:

- To examine the types of violations that occur in CP.
- To examine the reasons why violations occur in CP.
- To understand how the use of Safety-I and Safety-II can be combined to support staff in providing safe care.

5.4 - Methods
The philosophical underpinnings for the qualitative study is provided in Chapter 3 and the justification for using an interview methodology, participant information and ethical approval details are provided in the previous chapter. This section aims to provide further detail and justification regarding the second part of the interview, which involved the use of the critical incident technique (CIT) (179).

5.4.1 - Interview procedure (Part 2)
The aim of the second part of the interview was to investigate specific examples of violations and to explore why they occur in practice. To investigate each procedural violation provided by participants, the CIT (179) was used. This technique was chosen due to its reputation as a well proven qualitative research approach that offers a practical step-by-step guide on how to
collect and analyse information about human activities and their meaning to the people involved (180). This technique is described as a,

“set of procedures for collecting direct observations of human behaviour in such a way as to facilitate their potential usefulness in solving practical problems and developing broad psychological principles.”

(179, pg.327)

Originally developed for understanding incidents within the armed forces, the CIT relies on informed observers (i.e. individuals who are familiar with the area being studied) commenting on events where the purpose or intent of the act is fairly clear to the observer, and where the consequences of the act leave little doubt regarding its effects (179). Although the technique is over sixty years old, the technique has proven responsive to changing research approaches, with researchers being able to extend its use beyond “scientific” behavioural analysis to more “holistic investigations of human experience” (180). Some of the identified benefits of utilising CIT noted by Hughes (180) include:

- Offers well-proven, clearly defined guidelines for data collection and analysis;
- Focuses on real-life human experiences;
- Enables the development of practical outcomes;
- Relatively flexible approach.

Participants had been forewarned that the interview would discuss violations and they were asked to prepare some examples to discuss in advance. This was to ensure that participants were not put under unnecessary pressure, and so that participants had time to reflect on their
practice and their reasons for violating. Each participant was asked about the nature of the violations, the circumstances leading to the violations, why they acted this way, what alternative courses of action were apparent and the perceived advantages and disadvantages to violating as noted in the CIT approach (179). Participants were then asked to indicate whether they could think of examples of violations that they did not feel happy to share with the researcher. Participants were also asked to indicate how honest they felt they’d been able to be during the interview.

5.4.2 - Analysis
As with the data from the first part of the interviews, template analysis was utilised for analysing the remaining data. Before template analysis could begin, the violations were classified into types, according to Reason et al.’s taxonomy of violations (124). The researcher and her supervisors independently categorised the violations provided as routine, optimising, situational or exceptional according to Reason et al.’s taxonomy of violations (124). They then discussed their categorisations until a consensus was obtained for each violation to understand the nature of violations that occur in CP.

Once the violations were categorised, template analysis (154) was performed on the data from the second part of the interviews. A priori themes based on previously identified literature relating to violations, safety management in practice and the Safety-I and Safety-II approaches (41, 113, 123, 124, 178) were used to create an initial template to be applied to each transcript (154). The transcripts were then read and compared to the template by the researcher and DLP, with themes in the template being updated accordingly if new themes were identified from the data. NVivo V.10 (QSR International) was used to support data analysis (181).
5.5 - Results

5.5.1 - Types of violations in community pharmacies
In total, 31 procedural violations were identified (15 by pharmacists; 16 by pharmacy support staff). Using Reason et al.’s (123, 124) taxonomy, fourteen were classified as routine; four as optimising, eight as situational and five as exceptional violations. Examples of the violations identified are shown in Table 5. Three main themes relating to why violations occur in CP were identified, namely, ‘maintaining social norms’, ‘efficiency’ and ‘patient need’.
Table 5 - Definitions and examples of procedural violations in community pharmacies (123, 125).

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<tr>
<th>Violation type</th>
<th>Definition</th>
<th>Examples</th>
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| Routine        | These violations occur when a shortcut between two points presents itself and is taken on a regular basis. | • Dispensing medication from unsigned prescriptions issued by a local general practice.  
• Not accurately measuring the water required to reconstitute antibiotic medication. |
| Optimising     | These violations are created by a motive to optimise the work situation and can include exploring the boundaries of a system that may be perceived to be too restrictive. | • Resupplying over-the-counter medication to the same patient that is recommended for short term use only when supplied over-the-counter.  
• Supplying controlled drugs to a patient on an alternative date to the date stated on the prescription. |
| Situational    | These violations are typically provoked by organisational failings and are typically seen as essential in order to get the job done. | • Not following all the steps in the procedure for accuracy checking medication due to high workload and a lack of staff. |
5.5.2 - Violations to maintain social norms

Many of the violations discussed were routine violations that participants deemed as unlikely to result in adverse consequences for either patients or staff, and they helped maintain ‘the way things were done’ within a particular pharmacy. These routine violations point to a difference between work as imagined in procedures, compared to the work as done in practice and that staff were violating as they perceived this to be a better way of working.

The social norm within the pharmacy impacted on violations. Participants often noted it was easier to continue acting in the same way as others rather than insisting on following procedures, or for some locum pharmacists, easier than reading all of the company specific standard operating procedures (SOPs). On the whole, participants did not question the social norm, tending to go along with the actions of their colleagues suggesting a lack of reflection in

| Exceptional | These violations occur in a particular set of circumstances (abnormal or emergency situations) and because of this they are rare. | • Pharmacist working alone after-hours, when procedures state two members of staff must be present at all times. • Supplying controlled drugs from prescriptions that do not fully meet legal requirements. • Dispensing controlled drugs that have passed their expiry date for a patient in urgent need of end of life care. |
practice. Reflecting on practice (either what went wrong or right) is crucial to improving safety management in both Safety-I and Safety-II yet participants often lacked time to do so.

“I think you see one person [going against a procedure] you think oh that’s alright.”

(P12, Dispenser, Large Chain)

“[I violate] if other colleagues do the same thing, and they’re just like, that’s fine; we always do it like this…”

(P3, Dispenser, Large Chain)

“I tend to just ask the dispensers…how they work, their daily routine, what goes on. It could be something as stupid as how do you bag up [medication]…just things like that…I would assume that they’re following the SOPs…there’s no way I could read a whole folder [of SOPs] in the space of five minutes.”

(P11, Locum Pharmacist)

Some violations eased working relationships with other healthcare providers. Participants sometimes felt uneasy about violating, especially when asked directly by GP staff to violate procedures. Yet not violating also had consequences; therefore staff acted to manage the situation and to maintain professional relationships. Although staff sometimes felt uncomfortable, they felt these violations did not necessarily increase risk to patient safety, in contrast to the Safety-I perspective in which deviating from procedures should be avoided.
“These are accepted practices… the problem is that by being awkward or maybe sticking to our [standard operating procedures] the doctors may lose faith in us and think that we [aren’t] doing our job properly and they might not trust [our] opinion in the future.”

(P6, Pharmacist, Independent)

In addition, participants violated to satisfy regular patients. One example was where procedures for selling OTC medicines were violated to avoid inconveniencing customers and to maintain their future business. This approach could potentially increase the risk to patient safety if patients are provided with medicines that are not suitable for them.

“If you’ve got [customers] just wanting to pay for things, and they’re waiting ages because you’re talking to somebody… it would be a lot quicker if I just sell what people are asking for, and if I don’t ask the questions.”

(P19, Locum Dispenser, Large Chain)

At times, participants were directly instructed by managers to violate. One pharmacist shared an optimising violation, where they were instructed by their area manager not to report an error involving a controlled drug that was supplied to a patient by mistake. The pharmacist in question felt unable to challenge their area manager. The optimising violations highlight that staff may rationalise deviating from procedures for a variety of reasons, as opposed to violating purely to manage safety, as suggested in the Safety-II approach. Optimising violations may support the need for procedures to outline suggested boundaries for clinical practice.
“They said, ‘I don’t think it’s something we need to do because we’ve done it in the past… [it] creates a lot of paperwork and nothing went wrong’…So, I deviated but I was kind of coerced into doing it… I was very uncomfortable but I felt I didn’t have a choice… they were the area manager, who else was I supposed to tell?”

(P10, Pharmacist, Large Chain)

5.5.3 - Violations for efficiency
Participants often worked within a conflicted environment in which they were urged to work efficiently without compromising patient care. Participants often found balancing this tension challenging. Frequently, participants felt efficiency was favoured, and procedures were routinely violated to manage productivity. These violations placed staff in a “grey area” where violations were considered both right (being efficient was supported by management) and wrong (potentially placing patients at risk). Staff rationalised that they would violate due to increased pressures such as a high workload or a perceived lack of time, whilst recognising that by violating, patient safety was potentially compromised. For example, one dispenser spoke of not accurately reconstituting antibiotics due to situational factors.

“Obviously now that I’ve thought about this [I wouldn’t do it again]…at the time it would seem we [needed] to keep things moving… there’s loads of people around; there’s loads of noise; kid’s not well; mum’s upset as well because the kid’s not well; all you can see is just stressed people, and by doing this quickly you can make [things] better.”

(P3, Dispenser, Large Chain)
One example of where efficiency impacted on thoroughness was when a pharmacist failed to check the clinical appropriateness of prescriptions before medications were supplied to patients. As a result, the accuracy checking technicians did not always identify potential drug-drug interactions between patients’ medications when completing an accuracy check, resulting in an increased risk to patient safety. Participants often justified these deviations, as a means to an end in ensuring patients received medication on time. This was an example of violations being potentially unsafe, consistent with the Safety-I approach.

“We often especially when we’re in a bad place [dispense], check and deliver without [getting a clinical check] on scripts and what the pharmacist will do at the end of the day is take a batch like that and then [clinically check] them retrospectively....”

(P2, Dispenser, Large Chain)

Another example of where violations increased risk was identified by a pharmacist who spoke of not always feeling able to conduct a full accuracy check of medication before supplying it to the patient, due to working in a highly pressurised situation.

“I was being interrupted by patients who would reach over and pick stuff [up]...it was awful and I remember [when checking]...I held up the box of [tablets to the patient] and I said, ‘have you had this before?’, and [they] said yes. It was [the wrong strength tablet].”

(P10, Pharmacist, Large Chain)
Some violations made for efficiency did potentially increase risk, yet appeared at times to still achieve the aim of things ‘going right’ as patients were not harmed. One participant described having signed a prescription after noticing the prescriber had not done so; without a prescriber’s signature, the prescription was invalid. The participant cited high pressure, low patient risk and the need to ensure payment for dispensing the item as reasons for violating.

“[The prescription] had already been counted, it had gone out, after it was checked, clinical checked, the patient had had it many times before…So, I squiggled on it and [filed it]. It was the end of the day, we were very short staffed…it was towards the end of the week as well, so [the prescription] wouldn’t have come back until the next week and then with the amount of prescriptions that we get in, these aren’t [followed up]…so it’s losing items.”

(P12, Dispenser, Large Chain)

These violations for efficiency may be judged as right and wrong simultaneously. Participants noted the impact specific circumstances had on how they rationalised violating, whereas others judging the situation may not rationalise these decisions. The suggested impact of situational factors supports the Safety-II view that healthcare is a complex setting, where staff must simultaneously manage multiple demands. The impact of situational factors was supported by the dispenser, who noted this behaviour would not happen when they were successfully managing workload. It appears that procedures in CP do not currently account for situational factors, typical of a Safety-I approach.

On the other hand, some violations to improve efficiency indicated that using procedures to protect against adverse events at all times, reflective of the Safety-I perspective, may not always be necessary or practical to follow. One pharmacist explained why they would violate
requirements for services provided within the pharmacy as they felt the requirements were unnecessarily detailed, and violating allowed the pharmacist to provide an efficient service.

“It’s credibility for the service…if you say, you’ve got to go to the doctor…[patients will] just forget about it straight away…[I] work in a rural community…it’s the kind of community where if a few people think it’s rubbish everyone will think it’s rubbish. You don’t want to ruin that for the sake of just following the rules black and white when there is going to be no harm or no risk to the patient.”

(P15, Pharmacist, Large Chain)

5.5.4 - Violations for patient need
Numerous violations were made to maintain patient safety. One violation described by many participants was loaning medication to patients to ensure they did not go without whilst waiting for a repeat prescription from the general practice. Loaning medication involves providing patients with a resupply of their medication in anticipation of receiving a future NHS prescription(39). This violation is an example of staff working flexibly and suggests this flexibility is needed for pharmacists to react appropriately in urgent situations. Furthermore, some participants felt loaning medication was more straightforward than issuing an ‘emergency supply’, which involved additional record keeping and a potential payment from the patient.

“[Loans happen] all the time…it almost feels like the surgeries won’t put the patients first, whereas we have to…[the surgery say the patient] should have [ordered their medication] sooner…[but] that’s not very helpful to anybody…I know that you’re busy but that means I’m going to have to give [the patient medication].”
Pharmacists in particular noted making exceptional violations to ensure patient safety. In contrast to the other violation types, exceptional violations mainly occurred outside of normal working hours, when the prescriber could not be contacted or when the risk of not supplying medication to a patient could result in a lack of care. Patients were often receiving end of life care or prescribed controlled drugs. Violating controlled drug procedures meant a higher risk of disciplinary or legal action for pharmacists; yet pharmacists justified their actions with the immediate patient need during these situations. These violations are evidence of the resilience of CP staff and their ability to adjust their performance to ensure patient safety as outlined in the Safety-II approach.

“If somebody’s on their death bed is it right to withdraw treatment on a [legal] technicality? There’s consequences of [following procedures] because we’ve not put the patient first, which is our first and foremost concern…The judgements that we make are serious judgement calls…that could jeopardise our careers and everything we’ve worked for”

(P6, Pharmacist, Independent Pharmacy)
5.6 - Discussion
This chapter has presented the first study to examine the use of both the Safety-I and Safety-II philosophies to violations in a healthcare setting and to highlight the reasons why staff choose to violate procedures in CP. The results highlighted that violations were made in CP for a variety of reasons (113, 182-185). The results support the Safety-II philosophy that some violations are made by staff to manage their complex working environment. In most cases, violations resulted in patients receiving their medication safely, in contrast to the Safety-I philosophy where any deviation from procedures may potentially be unsafe. The findings illustrate that some violations are healthcare staff attempting to deal with rapidly developing or unexpected situations as noted in the System-II perspective (178). The results highlight the limitations of an over-reliance on the Safety-I approach as situations may occur outside of predefined procedures, and pharmacists must exercise their professional judgement (186).

Overall, most violations can be said to ‘go right’ (187), such as routine violations to comply with the social norm. Consistent with the Safety-II perspective, employers should seek to understand factors that allow these behaviours to ‘go right’, as well as investigating what goes wrong as noted in the Safety-I perspective (178).

The results also highlight that sometimes violations increased risk to patient safety. Safety-II is typically described as staff making necessary performance adjustments to manage safety, not efficiency (113), however the results suggest situational violations sometimes occur to maintain productivity. Hollnagel (174) notes organisations often indirectly encourage staff to be efficient. In CP, organisations have been seen to encourage efficiency by emphasising performance targets (48, 188). According to Amalberti et al. (126), if individuals feel pressured to violate to increase performance it can result in individuals thinking that in some way, their behaviour is supported. If these violations are repeated over time, they may lead to a shift in safety margins (126).
Although violations were shown to sometimes increase risk, overall results suggest these violations cannot always be judged as right or wrong. Dekker (189) describes violations as contextual, contingent and a necessary part of clinical work supportive of the Safety-II philosophy. Ultimately, specific outcomes such as patient harm, will be judged as right or wrong and at these times the Safety-I approach of attempting to understand why things failed is necessary. However, when a patient is unharmed, yet a violation was made, staff work within a “grey area” (178). Combining the Safety-I and Safety-II approaches may aid staff in achieving a balance between safety and efficiency. This study highlights the benefits of reflecting on when violations went wrong, as the results have shown the role of situational factors in increasing risk. Staff in practice may benefit from proactively anticipating situations in which situational factors may cause additional pressure in the workplace.

Although this study is the first to explore the use of the Safety-I and Safety-II perspectives with regards to violations in primary care, it is not without limitations. Rich contextual insights are provided; however, the data relied on self-reported violations; yet participants may violate unknowingly, for example, if they are following the behavioural norm within the pharmacy. Furthermore, such intensive data collection can be conducted with a small sample only, and it is not possible to make generalisations (190). Research on a larger scale, such as a survey exploring the contributing factors and frequency of violations may add to these findings. The next chapter details the design of a quantitative study to explore the contributing factors and the frequency of violations on a wider scale.

5.7 - Chapter summary
This study applied Safety-I and Safety-II to violations and explored why procedural violations occur in CP. Participants reported adjusting their behaviour in response to their complex work-system to manage social relationships, work efficiently and for patient need. The findings suggests that relying on a Safety-I approach in healthcare settings, including CP, may
no longer be appropriate as procedures may be over-restrictive at times. A Safety-II approach could be combined to allow staff to adopt a tailored and appropriate approach to patient safety. However, flexibility may not be suitable when used only to promote productivity. The next chapter details the design of a questionnaire that was developed for the quantitative study.
CHAPTER 6: Designing a quantitative study to further explore what influences violations in community pharmacies

6.1 - Chapter outline
This chapter describes the process of designing a questionnaire for further exploring the influencing factors on violations in CPs. In this chapter, the COM-B theory is introduced; the questionnaire content, participant information and sampling are presented. This is followed by a description of the questionnaire administration strategy and the data analysis conducted. The results of the questionnaire are presented in a subsequent chapter.

6.2 - Background
Chapter 3 found that CP staff were expected to balance the conflicting goals of managing patient safety whilst maintaining productivity. The findings highlighted how the sub-cultures of an organisation impacted on employees’ attitudes to safety, and that at times, the opinion of management and frontline staff towards safety could differ. In particular, the social norm within the environment could impact on how procedures were followed, with management of a large chain indicating that staff often learnt about patient safety indirectly whilst “on the job”.

Following this, Chapters 4 and 5 presented the findings from qualitative interviews that explored how procedures were perceived in practice and how and why violations occur in CPs. As discussed in Chapter 4, the expected behaviour of pharmacy staff is mapped out in SOPs (186). However, the ability of staff to always behave as imagined in procedures was shown to vary based on workplace demands and professional judgement. Chapter 5 went into further detail regarding the types of violations in CP and why they occur. These qualitative findings highlighted that violations often occurred to serve a variety of goals including ensuring that patients receive the care that they need [2 3], or to ensure efficiency due to
pressures in the workplace such as limited staff and a high workload [3 4]. The violations discussed in Chapter 5 were classified based on Reason et al.’s (124) taxonomy of violations, and each violation was classified as either optimising, routine, situational or an exceptional violation. Reason et al. (124) suggested that there are different influencing factors with regards to each type of violation. The qualitative interviews provided detailed insights into the reasons behind specific violations occurring in CP, but given the qualitative nature of the work, it was limited to a relatively small number of participants. Building on these earlier findings, further work was required to understand the influencing factors on violations in CP on a broader scale.

Amongst the methods suggested in the literature, a survey was deemed an appropriate method to attempt to capture the views of CP staff on a larger scale. Surveys have been noted as an efficient method for collecting large quantities of data in a cost efficient way (191). To date, violating behaviours have only been examined using a questionnaire once before (50), in a study that examined the views of pharmacists and support staff regarding incident reporting of errors and violations dependent on the patient outcome. However, specific influences on the violating behaviours were not explored. In order to improve understanding of these behaviours in practice and to build on the information gathered in the qualitative interviews, the COM-B model was utilised to further explore violations in CPs. Justification for the use of this model is detailed in the next section.

6.2.1 - Justification of theory used to examine violating behaviours in CP practice
The use of a psychological theory to understand violations was deemed to be appropriate as violations are typically intentional as oppose to accidental, and their origins are in the attitudes and motivations of the individual (108). The safety culture study in Chapter 3 has already provided some insight into the shared beliefs held in CP relating to safety behaviours, however no research to date, has explored what influences violating behaviours in CP in this
way. For this study, the COM-B model (192) was chosen to explore violations in CP, shown in Figure 7.

The COM-B model was developed by Michie et al. (192), who originally developed the model based on motivation first of all, as it relates to the basic drivers and automatic processes of behaviour as well as the choice and intention of the individual. They then considered the ‘minimum number’ of additional factors that would need to be included to account for whether or not behaviour would occur. One of the main sources of inspiration that the authors drew upon was the US consensus meeting of behavioural theorists in 1991 (193). During this meeting, the theorists discussed five key theories of behaviour change (including the health belief model (194), the social cognitive theory (59), the theory of reasoned action (195), the theory of self-regulation and self-control (58) and the theory of subjective culture and interpersonal relations (196)). The theorists agreed on eight key variables that would enable the prediction and understanding of behaviour. The eight variables were:
1. Intention

2. Environmental constraints

3. Skills

4. Anticipated outcomes (or attitude)

5. Norms

6. Self-standards

7. Emotion

8. Self-efficacy

Following discussions, the theorists concluded that the first three variables were necessary and sufficient factors for producing behaviour. However, Michie et al. (40) also drew on information from the principle of the US criminal law which is now centuries old. In US law, to prove someone as guilty one has to prove that the individual had the means or capability, opportunity and motive to commit the crime (40). The authors felt that both separate sources provided a cohesive explanation of volitional behaviour. However, to ensure that non-volitional mechanisms of behaviour were also accounted for as part of motivation to act, the authors also added influences including habit to the model (40). Given these theoretical underpinnings, the use of COM-B was deemed to be a useful tool to explore the key influencing factors on violations in CP on a wider scale.

The COM-B model, as shown in Figure 7, assesses the capability, motivation and opportunity of individuals to behave in a particular way. Other commonly used models of behaviour such as the TPB (197), the Health Belief Model (194) and behavioural self-regulation (198) do not address the important roles of impulsivity, habit, self-control, associative learning, and emotional processing (40, 199). Glanz and Kelger (200) support the need for the inclusion of
these factors, with their suggestion that physical factors and psychological factors, habits and knowledge should be considered when exploring determinants of behaviour. They argue that a broad understanding of these key factors can help to identify the most influential factors for a population and that this approach can help researchers to focus on changing behaviours that are the most salient (200). Therefore, the COM-B model was deemed to be a robust method for further exploring violations in CP.

Another advantage of using the COM-B model is based on the model being at the core of the BCW, a guide for developing interventions shown in Figure 8. The BCW synthesises numerous intervention frameworks and also acknowledges that behaviours are part of an interacting, complex system. Thus, supporting the use of Cooper’s reciprocal model of safety culture utilised in Chapter 3 (45). Utilising the COM-B model at this stage, could provide a systematic way of determining which intervention could result in the required change in practice, through the use of the BCW. Although developing an intervention is outside the scope of this PhD, understanding the influence of capability, opportunity and motivation on the frequency of violations may provide a useful foundation for future research. This was felt to be an additional reason for using the COM-B model for further understanding violating behaviours.
Additionally, Reason et al.’s taxonomy of violations (124) was utilised in the questionnaire to further explore some of the violations discussed in the qualitative interviews. In the interest of further examining the proposed differences in violations types and to investigate any potential differences in the capability, opportunity and motivation of staff when making a routine versus a situational violation for example, a scenario for each type of violation, (each drawn from the findings of the earlier qualitative interviews) detailed in Chapter 5 was included in the questionnaire. The aims and objectives for the COM-B study are provided in the following section.
6.2.2 - Aims and Objectives
The overall aim of the survey was to gain a broader understanding of the influencing factors on violations in CP.

More specifically, the objectives were:

- To examine the influences of capability, opportunity and motivation on the frequency of specific violations;
- To examine potential differences in capability, motivation and opportunity based on violation type;
- To examine the impact of demographic factors on violating behaviours (e.g. age, role, pharmacy type).

6.3 - Methods

6.3.1 - Questionnaire design
The questionnaire shown in Appendix 6 was adapted from the COM-B self-evaluation questionnaire (COM-B-Qv1) shown in Appendix 7. Before beginning to explore a particular behaviour, Michie et al. (192) note the importance of defining the ‘problem’ in behavioural terms first of all. At this stage, defining the particular behaviour to be studied is crucial, rather than focusing on the overarching issue at hand. In the case of this questionnaire, the aim was to understand the influences of capability, motivation and opportunity on the frequency of particular types of violating behaviours.

Once the behaviours are identified, Michie et al. (192) suggest that the location of the behaviour should be specified as well as specifying the individual, group or population that carry out these behaviours. In the case of this study, the violations specified during the qualitative interviews, occurred in CPs and involved pharmacists and support staff. The safety culture study detailed in Chapter 3 provided an insight into the context in which violating
behaviours occur. Due to the regulations stated by the GPhC, operational activities within the pharmacy such as the sale or supply of pharmacy medicines and the supply of prescription-only medication to patients can only take place under the supervision of the responsible pharmacist (9). However, support staff are almost always involved in the dispensing process (sometimes pharmacists will dispense and self-check medication however, this approach is typically not encouraged in practice) therefore, all types of support staff who work mainly in the dispensary were sampled to gain a rich representation of violating behaviours in CP practice.

The next step for examining particular behaviours using the COM-B model is to select target behaviour(s). To do so, it is important to consider the context in which the behaviour occurs and the influence of environmental factors, as Michie et al. note that behaviours do not ‘occur in a vacuum’ (192). To select target behaviours, it is suggested that a ‘long list’ of all behaviours that might be relevant to the ‘problem’ that needs solving should be generated. The violations provided in the qualitative interviews discussed in Chapter 5 were used as the ‘long list’. The use of CIT (179) during the interviews, provided a detailed account of the context each violation occurred in.

The next step was to decide which violations to focus on in the questionnaire. Michie et al. (192) note that indications from the literature may help to decide which behaviours to choose. As mentioned in section 6.2.1, one of the aims of the questionnaire was to further explore the validity of Reason et al.’s taxonomy of violations (124), it was decided that one violation of each type would be included in the questionnaire (one optimising, one situational, one routine and one exceptional). Michie et al. (192) also suggest considering the impact in practice if the behaviour were to be changed and the likelihood of the behaviour being changed in practice (192). In order to do this, CP stakeholders were asked for their input in an effort to utilise local knowledge, as recommended by Michie et al. (192).
6.3.2 - Stakeholder involvement in the development of the questionnaire

Pharmacy staff were invited to rate which violations had the biggest impact on patient safety and how easy they felt it would be to change the violating behaviour in practice. Respondents were recruited via social media sites including Twitter and Facebook. Pharmacy staff were invited to complete an online survey. The survey was hosted on ‘SelectSurvey’ a site recommended by the University of Manchester for hosting questionnaires.

In total, 29 members of CP staff provided feedback (store based pharmacists (n=6); relief pharmacists (n=3); locum pharmacists (n=10); registered accuracy checking technician (n=1); registered pharmacy technician (n=1); accuracy checking dispenser (n=1) and dispensers (n=7). Respondents worked in a range of pharmacy types (large pharmacy chain (n=23); medium sized chain (n=2); small chain (n=1) and an independent pharmacy (n=1)). On average the pharmacists who participated had been qualified in their role for 5.58 years (SD = 5.59) and had worked in CP for an average of 7.53 years (SD = 5.24). With regards to support staff, they had been qualified in their role for 4.30 years (SD = 3.13) and had worked in CP for 6.85 years on average (SD = 4.35). The results from the stakeholder questionnaire are provided in Appendix 8. The results of these questionnaires helped to determine which violations should be included in the final questionnaire, which is discussed in the following section. The COM-B questionnaire is detailed in the following section. A justification of which violations were included in the questionnaire and the hypotheses with regards to the outcome of the questionnaire is also provided in the following section.

6.3.3 - COM-B questionnaire content

6.3.3.1 - Demographic information

Respondents were asked to provide demographic information including their gender, age, role, the year that they qualified in their current role, the year that the respondent started working in CP, the type of pharmacy they worked for and the geographical location of the pharmacy.
Although there are a number of ways to collect demographic information, previous training, age and experience have all been shown to impact on the rate of violations (4). A review of violations in industries including healthcare, mining, commercial driving, aviation, railroad and construction found no difference in violation frequency with regards to gender (4), however some studies have found this effect (103). Research suggests that staff working in independent pharmacies may have more autonomy than their peers in chain pharmacies (201); therefore type of pharmacy was included in the demographics section (65, 186).

6.3.3.2 - Violation scenarios
The scenarios that were included in the questionnaire were based on the feedback from the stakeholder engagement exercise as detailed in section 6.3.2 and on Reason et al.’s taxonomy of violations (124). The use of the COM-B model (192) helped to provide detailed information regarding an individual’s reasoning for making a violation. In an effort to explore the reasoning behind why violations made for patient benefit and those made for efficiency as explored in Chapter 5, a mixture of violations were chosen. The violations that were chosen were as follows:

**Optimising violation** – regularly selling over the counter medications to the same patient that should be taken only on a short term basis.

*Hypothesis* – it was hypothesised that respondents would be most influenced by motivation to act i.e. whether making the regular sale was easier than refusing the customer. As optimising violations typically serve multiple goals, respondents may be influenced by financial pressures (this factor is part of the opportunity measure) or they may be acting out of habit as the medication is sold regularly to the same person.

**Situational violation** – not following every step in the accuracy checking procedure when checking medication (support staff who are not responsible for the final check were asked to consider their self-check).
Hypothesis – it was hypothesised that opportunity would be a significant predictor for this behaviour, i.e. situational factors such as time pressure would lead to staff cutting corners to remain efficient. It was also hypothesised that capability may be a significant influence i.e. the ability of staff to deal with the mental workload.

Routine violation – Supplying medication from an unsigned prescription at a GP’s request (support staff were asked to consider their role in dispensing the medication).

Hypothesis – it was hypothesised that routine violations would be significantly influenced by the individual’s motivation to act i.e. it makes the staff member’s life easier and violating also ensures that negative consequences for the patient are avoided. Habit may also be a significant predictor given the routine nature of the behaviour.

Exceptional violation – Supplying out of date medication to patients (support staff were asked to consider their role in dispensing the medication).

Hypothesis – It was hypothesised that staff would be influenced by their motivation to avoid negative consequences of not supplying the medication, even though it was out of date.

The situational and optimising violations included in the questionnaire were rated by both pharmacists and support staff in the stakeholder exercise as two of the most risky violations with regards to patient safety. Therefore, these violations were included in the questionnaire, as understanding more about the main influences on these behaviours may have implications for patient safety in practice. The routine violation was rated as relatively low risk and relatively unlikely to change, typical of a routine violation (123). Finally, the exceptional violation, although the pharmacist who made this violation did so to support a patient receiving end of life care, the behaviour was still rated as risky by the pharmacists in the PPI exercise, typical of an exceptional violation (123).
6.3.3.3 - COM-B questions and ratings

The suggested questionnaire format for the COM-B questionnaire provided by Michie et al. (192) is included in Appendix 7. The suggested questionnaire format was reviewed thoroughly, as it had not yet been validated in this format. Therefore, in an effort to ensure that the questionnaire was appropriate for CP staff to complete, stakeholder input was sought once again.

Four practicing community pharmacists and two CP dispensers were asked to provide their feedback regarding the questionnaire format. Initially, respondents were provided with the chosen violations and asked to complete the suggested COM-B-Q questionnaire provided by Michie et al. (192) in relation to each violation. However, feedback suggested that the generic COM-B-Q questionnaire was unclear and not tailored enough for this setting.

Therefore, efforts were made to tailor each element of the capability, opportunity and motivation questions to a CP setting. Based on feedback from respondents, they felt the questions relating to motivation were best asked first for each violation, followed by opportunity questions and finally followed by the capability questions. Respondents reasoned that they often had to thoroughly consider making a violation in practice, and that motivation was felt to be the most important factor when violating. Failure to include the motivation items at the start of the questionnaire may have led to respondents questioning the face validity of the questionnaire.

Once each statement had been tailored to a CP setting (e.g. amending the suggested “have more money” item noted by Michie (192) to “how much this helps the pharmacy to meet financial targets”) these statements were then re-checked with the respondents. The statements were also reviewed iteratively between the researcher and her supervision team.

In contrast to the COM-B-Q questionnaire suggested by Michie et al. (192) where respondents are asked to tick or circle the factors that influence their behaviours, it was
decided that in order to gain a greater understanding of the influence of each factor, that Likert scales would be utilised (202). Respondents were asked to rate on a scale of one to seven the extent to which they agreed that each statement influenced the likelihood of making each violation as shown in Appendix 6. The use of a Likert scale has been recommended for building in a ‘degree of sensitivity and differentiation of response’ (203, pg. 386). The questionnaire utilised a 7-point Likert scale as opposed to a 5-point Likert scale. The use of a 5-point scale has not been recommended by Cohen et al. (203) as they found that most respondents will not answer in the extremes of a scale e.g. extremely bad or extremely good. When using a 5-point scale, the choice in-between the two extremes is limited, therefore the use of a 7-point scale means a higher degree of detail can be achieved from the responses. 7-point scales have also been noted as showing a higher degree of reliability as it is easier to discriminate between the values and between respondents who may be undecided when compared to the results of a 5-point scale (204).

6.3.3.4 - Comment section
An open-ended comment section was included at the end of the questionnaire. Respondents were asked to provide comments regarding factors within their work place that they felt influenced how they follow procedures. Respondents were also invited to provide any general comments regarding completing the questionnaire. This section was included to provide respondents with the opportunity to comment on any factors that may not have been included in the COM-B model.

6.3.4 - Sample inclusion and exclusion criteria
Pharmacists and support staff (ACTs, dispensers, trainee dispensers) working in CPs in the North of England were invited to participate in this study. Only staff that were currently working in practice were invited to take part as it was important that respondents had a good understanding of current practice in CP. Healthcare counter assistants were not invited to participate, due to their job role typically not requiring them to be involved in dispensing
processes therefore they may not have been able to comment on all the violations included in the questionnaire.

6.3.5 - Sample size
The sample size was decided upon using Tabachnick & Fidell’s method of \( N = (104 + t) \) where \( t = \) number of predictor/independent variables (205). Therefore, to test the effect of 7 independent variables (capability, motivation, opportunity, role, length of experience, pharmacy type and gender) on the dependent variable of how often the participant carries out a violation, the minimum required sample size was 111 participants. It was expected that there will be non-responders within this sampling frame (previous surveys conducted in this setting have had response rates of between 25-45% (206)). Therefore, a large number of CP staff were sampled to ensure a sufficient number of responses were collected from a range of CP types in differing areas with the aim of ensuring that enough responses from different staff types were received in order to compare their responses.

6.3.6 - Sampling procedure
Initially, questionnaires were sent to pharmacy premises across Greater Manchester (GM) and West Yorkshire (WY), in an effort to obtain a relatively diverse range of pharmacy types and locations. It was not possible to address questionnaires to individuals directly as the GPhC would not provide personal details of registered pharmacists or technicians. However, due to the potentially sensitive nature of violations it was thought that addressing questionnaires personally to staff members would not have been appropriate as staff may have feared that they were being targeted. Furthermore, as we were hoping to recruit more than one respondent per pharmacy, writing to an addressee directly would not have been appropriate either.

Addresses of pharmacy premises in WY were provided by Community Pharmacy West Yorkshire. A list of all CP addresses in GM was obtained via the NHS choices website. Questionnaires were sent to a total of 1117 pharmacies. Following a poor response rate, the
sampling frame was increased to include CPs across the North of England; the details of these additional pharmacies were obtained through NHS Choices and through the Cumbria Local Pharmaceutical Committee. Questionnaires were initially sent to an additional 1871 pharmacies across the North of England, bringing the total number of pharmacies contacted to 2988 pharmacies.

In an effort to learn from the recruitment issues faced during the qualitative interviews with regards to recruiting registered ACTs and registered pharmacy technicians, the Association of Pharmacy Technicians UK (APTUK) were contacted to enquire if they would be happy to support distribution of the questionnaire to their members. APTUK are the professional leadership body for registered pharmacy technicians and therefore they have access to a large number of technicians. However, as it is not compulsory for registered pharmacy technicians to join the APTUK, their members do not include all of the technicians in the UK. They currently have around 1000 members; with just over 200 of these members working in CP (the others practice in other settings such as hospital settings). APTUK agreed to email the questionnaire to their members, and it was requested by their president that an electronic version of the questionnaire was made available. It was not be possible for them to share the personal details of their members (i.e. their address) in order for a postal questionnaire to be sent directly to them due to data protection concerns.

6.3.7 - Survey administration
Both postal questionnaires and electronic questionnaires were used in part for this study. With the growing use of technology, online surveys are becoming increasingly popular (207). Electronic questionnaires reduce costs, they allow a fast delivery and response, they allow access to large populations and, in the case of web-based applications, they allow direct data capture and the data can be easily imported for analysis (208). Disadvantages of electronic questionnaires include the time-consuming initial development, coding, and testing, as well the possible introduction of sampling bias due to computer illiteracy or non-availability (207).
Postal questionnaires are more costly and are a slower method of data collection (208). However, posting surveys is still a viable mode of survey administration and in some cases they were found to be more effective in improving response rate than the electronic format (209). Furthermore, postal surveys allow the researcher to calculate a response rate. The use of electronic questionnaires can make it difficult to determine who has accessed the questionnaire and furthermore, electronic questionnaires typically have a lower response rate than postal questionnaires (208). Hence, postal questionnaires were chosen as the main administration method for the questionnaires. This is with exception to the APTUK members who were emailed a link to an electronic questionnaire.

Each pharmacy received a survey pack, which consisted of two copies of the questionnaire (one for a pharmacist, one for a member of support staff), an invitation letter (Appendix 9) and two participant information sheets (Appendix 10). Respondents were also given two freepost envelopes to return the questionnaires. The use of an invitation letter and providing freepost return envelopes have been noted as methods that increase response rate (206, 210).

6.3.7.1 - Initial mail out
The first mail out to 1117 pharmacies in GM and WY was sent on the 22nd of August 2016. The president of APTUK sent members a link to the online survey on the 24th of August 2016. Following a lower than expected response rate (62 (2.78%) postal questionnaires returned out of 2,234 and 8 (3.6%) out of 220 electronic questionnaires) by the end of October 2016, the decision was made to expand the sample. Although widening the sample will not decrease the number of non-responders (211), it was deemed necessary to increase the sample in an effort to obtain the minimum number of responses needed for statistical power (212).

Therefore, as detailed previously in section 6.3.6, the decision was made to send questionnaires to additional pharmacies across the North of England. A further 1871 survey
packs were sent to pharmacies the week commencing the 31st of October, meaning that on the whole 5976 individual questionnaires were sent out, with a total of 2,988 pharmacies being sent the questionnaires initially.

6.3.7.2 - Reminder
Postal reminders consisting of the survey pack sent in the initial mail out, were sent on the 3rd of October to pharmacies in GM and WY. Reminder packs were sent to the additional pharmacies across the North of England the week commencing 23rd of November. APTUK members were also sent a reminder email along with the link to the online questionnaire on the 7th of October 2016. After the second reminder was sent no further attempt to contact non-responders was made due to time constraints.

6.3.8 - Ethical approval
The study was granted ethical approval from the University of Manchester Research and Ethics Committee (Ref 16303).

6.3.9 - Data analysis
6.3.9.1 - Data screening
A total of 288 questionnaires were received. Of these 12 (4%) were removed from the sample as they contained missing responses. Before analysis, the data were screened using the widely used recommendations of Tabachnick and Fidell (205) which include three main steps:

1) Check the accuracy of data entry

2) Dealing with missing data

3) Assess whether the data meets necessary assumptions for normality, linearity and homoscedasticity and multicollinearity.

Data was analysed using IBM SPSS v22. The significance level set for the analyses was $p = 0.05$. Mean and standard deviation values were rounded to two decimal places and percentages
were rounded to one decimal point. Upper and lower bound confidence intervals were set to 95%.

6.3.9.2 - Quantitative analysis
This section will discuss the statistical analyses conducted on the data. The results are structured by violation type.

A 2 x 2 x 4 between-subjects analysis of covariance (ANCOVA) was performed on the dependent variable (DV) (the frequency of violations). The independent variables (IV) (gender (male vs female), role (pharmacist vs support staff) and pharmacy type (independent vs small chain vs medium chain vs large multiple vs supermarket)) were factorially combined. The covariates were total length of experience, capability, motivation and opportunity total scores. Tabachnick and Fidell note that from a regression perspective, covariates can be considered high priority IVs, where the remaining IVs are evaluated after the relationship between the CV and DV is removed (212). As the aim of this research was to examine the influences of capability, opportunity and motivation on the frequency of violations they were entered as “high priority” CVs. Length of experience was added as a high priority CV based on the earlier qualitative study identifying that length of experience may result in pharmacists especially, feeling more comfortable to violate. Furthermore, for the purposes of this analysis the covariates used as part of the ANCOVA will be interpreted as predictors of the DV (212). Statistical justification for the use of the CVs is provided in the following chapter, section 7.2.3.2.

An ANCOVA was utilised due to the main effects and interactions of the IVs being assessed after the DV scores are adjusted for differences associated with one or more covariates which are measured before the DV is correlated with each of them. ANCOVA was deemed appropriate as it increased the sensitivity of the test of main effects and any interactions by reducing the error term and therefore using this test allows for a more precise look at the IV-DV relationship after the removal of the effect of the covariates. Tabachnick and Fiddell (212)
note that using an ANCOVA helps to increase the power of an $F$ test for a main effect or interaction, as it removes predictable variance associated with the covariates from the error term.

The results of the analysis are detailed in the following chapter.

6.3.9.3 - Qualitative analysis
All written comments received were typed up by the researcher and entered into NVivo (181).

The data were then thematically analysed using the template analysis method (154; see also Section 4.4.7.1). *A priori* thematic codes included workload, patient need and compliance (186). Additional themes were then added to the original template upon reading the comments (154).

6.4 - Chapter summary
This chapter has described how the questionnaire was designed and a rationale was provided for the decisions that were made. The quantitative and qualitative analyses have been described. The following chapter will detail the results of the questionnaire.
CHAPTER 7: Exploring the influencing factors on violations using the COM-B model

7.1 - Introduction
This chapter presents the quantitative and qualitative results of the COM-B questionnaire detailed in Chapter 6. The chapter begins by detailing the respondent characteristics, followed by the findings from the quantitative and qualitative analysis. A summary of the key findings is provided and discussed.

7.2 - Results
7.2.1 - Response rate
A total of 288 responses were obtained. The final response rate was (2.66%). Of these 12 (4.2%) were not eligible to be considered for the study (questionnaires returned completely blank, n=4; questionnaires returned with more than one page left blank, (n=8). Participants often left the questions regarding the exceptional violation blank (n=4). One explanation may be that due to the exceptional nature of this violation, some participants did not feel able to comment on the scenario as they had never experienced it. One respondent explained:

“I have never been in a situation during my 16 years qualified when I have been requested to, or have supplied out of date medication.”

(Pharmacist manager, independent, village)

7.2.2 - Respondent demographics
This section provides the results for the demographic data of respondents. The descriptive statistics for the age and gender of the respondents are provided in Table 6. The GPhC Register of Pharmacists and Pharmacy Technicians (213, 214) highlighted that 90.2% of all registered pharmacy technicians in 2011 were female, whereas only 59.4% of pharmacists sampled in 2011 were female. Data analysis shows that 89.1% of support staff sampled for
this questionnaire were females, and 57.6% of the pharmacists in the sample were female. Thus, the sample collected closely matches the general population of pharmacy staff with regards to gender.

**Table 6 - Participants' demographic information**

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>83</td>
<td>30.1</td>
</tr>
<tr>
<td>Female</td>
<td>193</td>
<td>69.9</td>
</tr>
<tr>
<td>Staff role</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacy owner</td>
<td>17</td>
<td>6.2</td>
</tr>
<tr>
<td>Pharmacy manager (pharmacist)</td>
<td>110</td>
<td>39.9</td>
</tr>
<tr>
<td>Regular employee pharmacist (non-manager)</td>
<td>13</td>
<td>4.7</td>
</tr>
<tr>
<td>Locum pharmacist</td>
<td>20</td>
<td>7.2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Range (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>275</td>
<td>38.16</td>
<td>12.11</td>
</tr>
<tr>
<td>Time qualified in role (years)</td>
<td>275</td>
<td>12.68</td>
<td>10.59</td>
</tr>
<tr>
<td>Total time spent working in CP (years)</td>
<td>274</td>
<td>15.39</td>
<td>11.19</td>
</tr>
<tr>
<td>Role</td>
<td>N</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----</td>
<td>------</td>
<td>-----</td>
</tr>
<tr>
<td>Relief pharmacist</td>
<td>3</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>Second pharmacist</td>
<td>3</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>Registered Accuracy Checking Technician</td>
<td>16</td>
<td>5.8</td>
<td></td>
</tr>
<tr>
<td>Registered Pharmacy Technician</td>
<td>23</td>
<td>8.3</td>
<td></td>
</tr>
<tr>
<td>Dispenser</td>
<td>58</td>
<td>21.0</td>
<td></td>
</tr>
<tr>
<td>Trainee Dispenser</td>
<td>5</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>Other (all were pre-reg pharmacists)</td>
<td>8</td>
<td>2.9</td>
<td></td>
</tr>
<tr>
<td>Pharmacy type</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Independent (less than 6 stores)</td>
<td>78</td>
<td>28.3</td>
<td></td>
</tr>
<tr>
<td>Small chain (6-25 stores)</td>
<td>37</td>
<td>13.4</td>
<td></td>
</tr>
<tr>
<td>Medium chain (26-200 stores)</td>
<td>48</td>
<td>17.4</td>
<td></td>
</tr>
<tr>
<td>Large chain (over 200 stores)</td>
<td>82</td>
<td>29.7</td>
<td></td>
</tr>
<tr>
<td>Supermarket</td>
<td>31</td>
<td>11.2</td>
<td></td>
</tr>
<tr>
<td>Pharmacy location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>City centre</td>
<td>15</td>
<td>5.4</td>
<td></td>
</tr>
</tbody>
</table>
### Table

<table>
<thead>
<tr>
<th>Area</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>Range (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large town</td>
<td>42</td>
<td>15.2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small town</td>
<td>87</td>
<td>31.5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suburb (outskirts of a city)</td>
<td>59</td>
<td>21.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Village</td>
<td>72</td>
<td>26.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural area</td>
<td>1</td>
<td>0.4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 7.2.3 - Statistical analyses

**7.2.3.1 - Internal consistency of the questionnaire**

In order to judge whether capability (C), opportunity (O) and motivation (M) impact on the frequency of violations in practice, it was important to assess whether the items included in the questionnaire were reliable. To determine the internal consistency of the scales, Cronbach's alpha values were determined for each of the C, O and M items. The C measure consisted of 7 items and was found to be highly reliable ($\alpha = 0.90$). Both the O measure, which consisted of 5 items ($\alpha = 0.79$) and the M measure, which consisted of 5 items ($\alpha = 0.76$) were shown to have satisfactory internal reliability as $\alpha > 0.7$ (215).

In an effort to further ascertain whether items within each measure were related, the homogeneity of the questionnaire items was evaluated by conducting inter-item correlations. Items that correlate highly ($r>0.9$) and items that have a weak correlation ($r<0.3$) should be considered for deletion (216).

Inter-item correlations were conducted for the 17 C, O and M items (these 17 items were repeated for each of the four violation scenarios). Correlations were acceptable for most
items; however some items within each measure were outside the suggested limits for inter-item correlations. The items that correlated highly ($r>0.9$) were from the capability measure:

- “My ability to deal with work pressures” and “My ability to cope with the mental demands of the workload” ($r = 0.90$)
- “My ability to cope with the physical demands of the workload” and “My ability to cope with the mental demands of the workload” ($r = 0.92$)

The items that were weakly correlated from the opportunity measure were:

- “How much time I have” and “whether there are additional reminders to remind me not to act in this way” ($r = 0.27$)

The items that were weakly correlated from the motivation measure were:

- “Whether I routinely act in this way without thinking” and “whether I need to act in this way e.g. there will be negative consequences for the patient if I don’t” ($r = 0.27$)
- “Whether acting in this way makes my life easier” and “whether I need to act in this way e.g. there will be negative consequences for the patient if I don’t” ($r = 0.29$)

Given that the inter-item correlations were marginally outside of the ($r>0.9$ and $r<0.3$) the decision was made to keep all items in the questionnaire. This decision was made so that the COM-B model as a whole could be utilised when analysing the results. As detailed previously, the decision was made to analyse the impact of habit on the violating behaviour both as part of the motivation measure and that it would also be assessed independently in an effort to further explore motivational influences.

7.2.3 - Quantitative results
This section presents the findings from the quantitative analysis conducted. Firstly, the hypothesis that experience would be positively associated with length of time in current role
was confirmed as results showed that total length of experience was positively correlated with the respondent’s length of time in their current role \((r = 0.87, p<.001)\) and with their age \((r = 0.78, p<.001)\). Length of experience in their current role and age were also positively correlated \((r = 0.70, p<.001)\). Therefore, only the total length of experience variable was used as the covariate in subsequent analysis, in order to capture the respondent’s whole time spent in pharmacy.

**7.2.3.2 - Examining the inter-relationships between variables**

Bivariate Pearson correlations were conducted to explore the strength of the relationship between the CVs and the DV. The results of the relationship between the CVs and the frequency of each violation type are provided in Table 7.

<table>
<thead>
<tr>
<th>Covariates</th>
<th>Optimising violation</th>
<th>Situational violation</th>
<th>Routine violation</th>
<th>Exceptional violation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capability total</td>
<td>0.01*</td>
<td>0.32**</td>
<td>0.21**</td>
<td>0.14*</td>
</tr>
<tr>
<td>Opportunity total</td>
<td>0.36**</td>
<td>0.46**</td>
<td>0.30**</td>
<td>0.17**</td>
</tr>
<tr>
<td>Motivation total</td>
<td>0.42**</td>
<td>0.34**</td>
<td>0.42**</td>
<td>0.18**</td>
</tr>
<tr>
<td>Total length of experience</td>
<td>-0.01</td>
<td>-0.09</td>
<td>0.18**</td>
<td>0.07</td>
</tr>
</tbody>
</table>

* indicates \(p<0.05\) ** indicates \(p<0.01\)

The results of the bivariate Pearson correlations highlight that capability \((r_{(276)} = 0.01, p<0.001)\); opportunity \((r_{(276)} = 0.36, p<0.001)\) and motivation \((r_{(276)} = 0.42, p<0.001)\) were all positively correlated with the frequency of the optimising violation. Length of experience was not significantly correlated with the frequency of the optimising violation \((r_{(276)} = -0.01, p = 0.81)\).
For the situational violation, the bivariate Pearson correlations indicated that capability ($r_{(276)} = 0.32, p<0.001$); opportunity ($r_{(276)} = 0.46, p<0.001$); and motivation ($r_{(276)} = 0.34, p<0.001$) were positively related to the frequency of the situational violation. Length of experience was not significantly correlated with the situational violation ($r_{(276)} = -0.09, p = 0.12$).

With regards to the routine violation, the bivariate Pearson correlations show that capability ($r_{(276)} = 0.21, p<0.001$); opportunity ($r_{(276)} = 0.30, p<0.001$); motivation ($r_{(276)} = 0.42, p<0.001$) and length of experience ($r_{(276)} = 0.18, p = 0.02$) were positively related to the frequency of the routine violation.

The bivariate Pearson correlations for the exceptional violation showed that capability ($r_{(276)} = 0.14, p = 0.02$); opportunity ($r_{(276)} = 0.17, p = 0.005$) and motivation ($r_{(276)} = 0.18, p = 0.003$) were positively correlated with the frequency of the exceptional violation. Length of experience was not significantly correlated with the frequency of exceptional violations ($r_{(276)} = 0.07, p = 0.23$).

The Pearson bivariate correlations highlight the relationship between the CVs and the DV. Although length of experience was only a significantly related variable for the routine violation, the decision was made to include the length of experience variable as an ‘IV’ of high importance based on previous qualitative findings that highlighted this as a potential influence on the frequency of violations.

### 7.2.3.3 - Optimising violation: selling an over the counter medication that is licensed for short term use to the same customer on a regular basis

Descriptive statistics for the optimising violation are shown in Table 8. The mean scores (and standard deviations) for pharmacists and support staff are shown separately to illustrate any potential staff differences. The mean scores for the capability, opportunity and motivation measures are included, as well as the individual item means and standard deviations.
<table>
<thead>
<tr>
<th></th>
<th>Pharmacist (n=165)</th>
<th>Support staff (n=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Whether I know what the consequences of acting in this way are</td>
<td>4.45</td>
<td>1.80</td>
</tr>
<tr>
<td>for the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I know what the consequences of acting in this way are</td>
<td>3.97</td>
<td>1.86</td>
</tr>
<tr>
<td>for me</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I understand the procedure that tells me not to act in</td>
<td>4.15</td>
<td>1.92</td>
</tr>
<tr>
<td>this way</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I am able to think through what I am doing</td>
<td>4.53</td>
<td>1.94</td>
</tr>
<tr>
<td>My ability to deal with work pressures</td>
<td>3.92</td>
<td>1.88</td>
</tr>
<tr>
<td>My ability to cope with physical demands of the workload</td>
<td>3.70</td>
<td>1.94</td>
</tr>
<tr>
<td>My ability to cope with the mental demands of the workload</td>
<td>3.92</td>
<td>1.94</td>
</tr>
<tr>
<td>Capability Total</td>
<td>28.64</td>
<td>10.32</td>
</tr>
<tr>
<td>Range of scores (0-49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much time I have</td>
<td>2.96</td>
<td>1.70</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>-----------------------------------------------------------------</td>
<td>--------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>How much this helps the pharmacy to meet financial targets</td>
<td>2.10</td>
<td>1.52</td>
</tr>
<tr>
<td>Whether the people I work with do this too</td>
<td>2.41</td>
<td>1.67</td>
</tr>
<tr>
<td>Whether there are additional reminders to remind me not to act in this way</td>
<td>2.84</td>
<td>1.68</td>
</tr>
<tr>
<td>Whether my colleagues support me in making this decision</td>
<td>3.20</td>
<td>1.78</td>
</tr>
<tr>
<td>Opportunity Total Range of scores (0-35)</td>
<td>13.51</td>
<td>6.27</td>
</tr>
<tr>
<td>Whether I want to act in this way e.g. I judge this to be a better way of working</td>
<td>3.19</td>
<td>1.66</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences for the patient if I don’t</td>
<td>4.17</td>
<td>1.70</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences</td>
<td>3.17</td>
<td>1.78</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>for me if I don’t</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I routinely act in this way without thinking</td>
<td>2.40</td>
<td>1.46</td>
</tr>
<tr>
<td>Whether acting in this way makes my life easier</td>
<td>2.92</td>
<td>1.75</td>
</tr>
<tr>
<td>Motivation Total</td>
<td>15.85</td>
<td>6.12</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>3.13</td>
<td>1.24</td>
</tr>
<tr>
<td>Range of scores (0-7)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A 2 x 2 x 4 between-subjects ANCOVA was conducted to determine a statistically significant difference between gender (male vs female), role (pharmacist vs support staff) and pharmacy type (independent vs small chain vs medium chain vs large multiple vs supermarket) on the frequency of the optimising violation, controlling for capability, opportunity, motivation and total length of experience. The results of the ANCOVA for the optimising violation are shown in Table 9. As shown below, motivation, opportunity, gender and role were found to be a significant influence on the frequency of violations. After adjustments by covariates, frequency of the optimising violations varied significantly with motivation ($F_{(1, 251)} = 25.54$,

---

1 The means provided are based on the respondents’ answer to the question relating to how often they make this particular violation as part of their work (1 = never, 2 = hardly ever, 3 = infrequently, 4 = occasionally, 5 = often, 6 = most of the time, 7 = always).
Motivation was found to be a significant predictor of the frequency of optimising violations; further analysis was conducted to explore the influence of habit as a potential influence on the
frequency of the optimising violation. A sequential regression was conducted where the IVs (habit rating, motivation total minus habit item score) were sequentially added to the model to assess the relationship with the DV (frequency of the optimising violation). Habit was entered primarily, with the additional factors being added during the second step. Results show habit independently influences optimising violations. However, the remaining motivation items also significantly predict the occurrence of optimising violations. The results for the influence of habit are shown in Table 10.

The final model showed that the IVs (habit and motivation minus habit) accounted for 17% of the variance in the frequency of the optimising violation. The optimising violation was more likely to occur based on the individual’s motivation without habit; however, habit was also a significant predictor.

The regression coefficients were 0.32 for habit (95% CI = 0.01 – 0.24) and 0.40 for motivation minus habit (95% CI = 0.05 – 0.12). Standardised regression coefficients indicated that motivation without habit was the strongest predictor for the optimising violation. Taken alone in the final model, motivation without habit accounted for 16.0% of the variance in the frequency of the optimising violation and habit accounted for 10.2%. Table 10 shows the regression coefficients for the optimising violation with regards to the influence of habit.
Table 10 - The influence of habit and motivation on the optimising violation

<table>
<thead>
<tr>
<th>Step</th>
<th>R² change</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.11</td>
<td>Habit</td>
<td>0.32</td>
<td>5.67**</td>
</tr>
<tr>
<td>2</td>
<td>0.07</td>
<td>Habit</td>
<td>0.14</td>
<td>2.17*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Motivation total minus habit</td>
<td>0.32</td>
<td>4.83**</td>
</tr>
</tbody>
</table>

* indicates p<0.05 ** indicates p<0.01

7.2.3.4 - Situational violation: Not completing a full accuracy check of a medication against a prescription

Respondents were asked to consider not being able to complete a full accuracy check of a medication against a prescription as a situational violation. Descriptive statistics for the situational violation are shown in Table 11.

Table 11 - Means and standard deviations for the situational violation

<table>
<thead>
<tr>
<th></th>
<th>Pharmacist (n=165)</th>
<th>Support staff (n=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Whether I know what the consequences of acting in this way are for the patient</td>
<td>3.66</td>
<td>2.47</td>
</tr>
<tr>
<td>Whether I know what the consequences of acting in this way are for me</td>
<td>3.70</td>
<td>2.47</td>
</tr>
<tr>
<td>Whether I understand the procedure</td>
<td>3.55</td>
<td>2.37</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td><strong>Mean</strong></td>
<td><strong>SD</strong></td>
<td><strong>Mean</strong></td>
</tr>
<tr>
<td>that tells me not to act in this way</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I am able to think through what I am doing</td>
<td>3.73</td>
<td>2.23</td>
</tr>
<tr>
<td>My ability to deal with work pressures</td>
<td>3.54</td>
<td>2.12</td>
</tr>
<tr>
<td>My ability to cope with physical demands of the workload</td>
<td>3.39</td>
<td>2.09</td>
</tr>
<tr>
<td>My ability to cope with the mental demands of the workload</td>
<td>3.57</td>
<td>2.12</td>
</tr>
<tr>
<td><strong>Capability Total</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range of scores (0-49)</td>
<td>25.13</td>
<td>13.25</td>
</tr>
<tr>
<td>How much time I have</td>
<td>2.93</td>
<td>1.99</td>
</tr>
<tr>
<td>How much this helps the pharmacy to meet financial targets</td>
<td>1.77</td>
<td>1.40</td>
</tr>
<tr>
<td>Whether the people I work with do this too</td>
<td>1.89</td>
<td>1.41</td>
</tr>
<tr>
<td>Whether there are additional reminders to remind me not to act in this way</td>
<td>2.45</td>
<td>1.76</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>-----------------------------------------------------------------</td>
<td>---------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Whether my colleagues support me in making this decision</td>
<td>2.27</td>
<td>1.68</td>
</tr>
<tr>
<td></td>
<td>3.04</td>
<td>2.10</td>
</tr>
<tr>
<td><strong>Opportunity Total</strong></td>
<td>11.30</td>
<td>6.35</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td>13.22</td>
<td>7.53</td>
</tr>
<tr>
<td>Whether I want to act in this way e.g. I judge this to be a better way of working</td>
<td>1.84</td>
<td>1.47</td>
</tr>
<tr>
<td></td>
<td>2.18</td>
<td>1.85</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences for the patient if I don’t</td>
<td>3.59</td>
<td>2.50</td>
</tr>
<tr>
<td></td>
<td>3.61</td>
<td>2.52</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences for me if I don’t</td>
<td>3.49</td>
<td>2.46</td>
</tr>
<tr>
<td></td>
<td>3.45</td>
<td>2.42</td>
</tr>
<tr>
<td>Whether I routinely act in this way without thinking</td>
<td>2.60</td>
<td>1.78</td>
</tr>
<tr>
<td></td>
<td>2.68</td>
<td>1.85</td>
</tr>
<tr>
<td>Whether acting in this way makes my life easier</td>
<td>2.24</td>
<td>1.64</td>
</tr>
<tr>
<td></td>
<td>2.28</td>
<td>1.61</td>
</tr>
<tr>
<td><strong>Motivation Total</strong></td>
<td>13.76</td>
<td>7.69</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td>14.20</td>
<td>8.15</td>
</tr>
</tbody>
</table>
A 2 x 2 x 4 between-subjects ANCOVA was conducted to determine a statistically significant difference between gender (male vs female), role (pharmacist vs support staff) and pharmacy type (independent vs small chain vs medium chain vs large multiple vs supermarket) on the frequency of the situational violation, controlling for capability, opportunity, motivation and total length of experience. The results of the ANCOVA for the situational violation are presented in Table 12. After adjustments by the covariate, the situational violation varied significantly with opportunity ($F_{(1, 250)} = 25.36, p<.001$).
### Table 12 - ANCOVA results for the situational violation

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>DF</th>
<th>Type III sum of squares</th>
<th>Mean Square</th>
<th>$F$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of experience</td>
<td>1</td>
<td>0.03</td>
<td>0.03</td>
<td>0.02</td>
</tr>
<tr>
<td>Motivation total</td>
<td>1</td>
<td>3.65</td>
<td>3.65</td>
<td>2.23</td>
</tr>
<tr>
<td>Opportunity total</td>
<td>1</td>
<td>41.46</td>
<td>41.46</td>
<td>25.36**</td>
</tr>
<tr>
<td>Capability total</td>
<td>1</td>
<td>0.94</td>
<td>0.94</td>
<td>0.58</td>
</tr>
<tr>
<td>Gender</td>
<td>1</td>
<td>0.48</td>
<td>0.48</td>
<td>0.29</td>
</tr>
<tr>
<td>Pharmacy type</td>
<td>4</td>
<td>2.24</td>
<td>0.56</td>
<td>0.34</td>
</tr>
<tr>
<td>Role</td>
<td>1</td>
<td>0.01</td>
<td>0.01</td>
<td>0.00</td>
</tr>
<tr>
<td>Gender x Pharmacy type</td>
<td>4</td>
<td>4.64</td>
<td>1.56</td>
<td>0.71</td>
</tr>
<tr>
<td>Gender x Role</td>
<td>1</td>
<td>1.76</td>
<td>1.76</td>
<td>1.08</td>
</tr>
<tr>
<td>Pharmacy type x Role</td>
<td>4</td>
<td>2.22</td>
<td>0.56</td>
<td>0.34</td>
</tr>
<tr>
<td>Gender x Pharmacy type x Role</td>
<td>4</td>
<td>7.07</td>
<td>1.77</td>
<td>1.08</td>
</tr>
</tbody>
</table>

* indicates $p<0.05$  ** indicates $p<0.01$

As with the optimising violation, analysis was conducted to investigate the potential influence of habit on the situational violation. A sequential regression analysis was conducted to investigate the influence of habit firstly, followed by the motivation total minus the habit item score. The final regression model found $R = 0.43$, $R^2 = 0.18$, Adjusted $R^2 = 0.18$. The model
was a significant predictor for the frequency of situational violations. The regression coefficients are provided in Table 13. The results show that habit alone is a significant predictor for situational violations. The model showed that the IVs (habit and motivation minus habit) accounted for 18% of the variance in the frequency of the situational violation. The situational violation was more likely to occur based on the individual's habit as motivation without habit was not a significant predictor.

The regression coefficients were 0.42 for habit (95% CI = 0.10 – 0.41) and 0.39 for motivation minus habit (95% CI = -0.02 – 0.08). Standardised regression coefficients indicated that habit was the strongest predictor for the situational violation. Taken alone in the final model, habit accounted for 17.6% of the variance for the frequency of the situational violation whereas motivation without habit accounted for 15.2%. Table 13 shows the regression coefficients for the situational violation with regards to the influence of habit.

Table 13 - The influence of habit and motivation on the situational violation

<table>
<thead>
<tr>
<th>Step</th>
<th>R’ change</th>
<th>Predictor</th>
<th>Beta</th>
<th>t</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.18</td>
<td>Habit</td>
<td>0.42</td>
<td>7.67**</td>
</tr>
<tr>
<td>2</td>
<td>0.01</td>
<td>Habit</td>
<td>0.32</td>
<td>3.27**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Motivation total minus habit</td>
<td>0.12</td>
<td>1.28</td>
</tr>
</tbody>
</table>

* indicates $p<0.05$ ** indicates $p<0.01$

7.2.3.5 - Routine violation: supplying or dispensing medication from an unsigned prescription
For the routine violation participants were asked to consider supplying or dispensing from an unsigned prescription. Descriptive statistics for the routine violation are shown in Table 14.
### Table 14 - Means and standard deviations for the routine violation

<table>
<thead>
<tr>
<th></th>
<th>Pharmacist (n=165)</th>
<th>Support staff (n=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whether I know what the consequences of acting in this way are for the patient</td>
<td>5.19 1.88</td>
<td>4.88 1.97</td>
</tr>
<tr>
<td>Whether I know what the consequences of acting in this way are for me</td>
<td>4.41 1.98</td>
<td>4.46 2.16</td>
</tr>
<tr>
<td>Whether I understand the procedure that tells me not to act in this way</td>
<td>3.65 1.96</td>
<td>4.53 2.00</td>
</tr>
<tr>
<td>Whether I am able to think through what I am doing</td>
<td>4.22 1.98</td>
<td>4.23 2.00</td>
</tr>
<tr>
<td>My ability to deal with work pressures</td>
<td>3.61 2.01</td>
<td>3.73 2.19</td>
</tr>
<tr>
<td>My ability to cope with physical demands of the workload</td>
<td>3.29 2.00</td>
<td>3.62 2.12</td>
</tr>
<tr>
<td>My ability to cope with the mental demands of the workload</td>
<td>3.42 2.04</td>
<td>3.68 2.11</td>
</tr>
<tr>
<td>Capability Total</td>
<td>27.79 10.58</td>
<td>29.13 11.95</td>
</tr>
<tr>
<td>Range of scores (0-49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much time I have</td>
<td>3.07 1.83</td>
<td>2.58 1.87</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>---------------------------------------------------------------</td>
<td>-------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>How much this helps the pharmacy to meet financial targets</td>
<td>1.84</td>
<td>1.34</td>
</tr>
<tr>
<td>Whether the people I work with do this too</td>
<td>2.62</td>
<td>1.79</td>
</tr>
<tr>
<td>Whether there are additional reminders to remind me not to act in this way</td>
<td>2.51</td>
<td>1.59</td>
</tr>
<tr>
<td>Whether my colleagues support me in making this decision</td>
<td>3.22</td>
<td>1.85</td>
</tr>
<tr>
<td>Opportunity Total</td>
<td>13.25</td>
<td>6.36</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I want to act in this way e.g. I judge this to be a better way of working</td>
<td>3.76</td>
<td>1.97</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences for the patient if I don’t</td>
<td>5.45</td>
<td>1.55</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences</td>
<td>3.57</td>
<td>1.81</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>for me if I don’t</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I routinely act in this way without thinking</td>
<td>2.35</td>
<td>1.53</td>
</tr>
<tr>
<td>Whether acting in this way makes my life easier</td>
<td>3.14</td>
<td>1.88</td>
</tr>
<tr>
<td>Motivation Total</td>
<td>18.27</td>
<td>6.01</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>3.18</td>
<td>1.23</td>
</tr>
<tr>
<td>Range of scores (0-7)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A 2 x 2 x 4 between-subjects ANCOVA was conducted to determine a statistically significant difference between gender (male vs female), role (pharmacist vs support staff) and pharmacy type (independent vs small chain vs medium chain vs large multiple vs supermarket) on the frequency of the routine violation, controlling for capability, opportunity, motivation and total length of experience. The results of the ANCOVA are presented in Table 15. Results show that length of experience, motivation and role are significant influences on the frequency of the routine violation. After adjusting for the covariate of length of experience, the routine violation varied significantly with length of experience ($F_{(1, 251)} = 10.38, p = .001$), motivation ($F_{(1, 251)} = 14.12, p = 14.12$) and role ($F_{(1, 251)} = 4.50, p = .033$).
A regression analysis was conducted to explore the role of habit for the routine violation. For the final regression model, $R = 0.46$, $R^2 = 0.21$, Adjusted $R^2 = 0.21$. The model was a significant predictor of the frequency of the routine violation ($F(2,273) = 36.81, p<.001$). The coefficients
are shown Table 16 and results suggest that routine violations do not occur due to habit. However, the remaining motivation items were still significant.

The regression coefficients from the final model were 0.12 for habit (95% CI = -0.19 – 0.00) and 0.45 for motivation without habit (95% CI = 0.08 – 0.13). Standardised regression coefficients indicated that motivation without habit was the only significant predictor for the routine violation; motivation without habit accounted for 20.3% of the variance and habit alone accounted for 1.4% of variance for the frequency of the routine violation. The regression coefficients for the impact of habit on the routine violation are shown in Table 16.

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$ change</th>
<th>Predictor</th>
<th>Beta</th>
<th>$t$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.01</td>
<td>Habit</td>
<td>0.12</td>
<td>1.95</td>
</tr>
<tr>
<td>2</td>
<td>0.20</td>
<td>Habit</td>
<td>-0.12</td>
<td>-1.94</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Motivation total minus habit</td>
<td>0.50</td>
<td>8.30**</td>
</tr>
</tbody>
</table>

* indicates $p<0.05$ ** indicates $p<0.01$

7.2.3.6 - Exceptional violation: supplying or dispensing out of date medication

Descriptive statistics based on staff type are provided with regards to frequency of the exceptional violation are shown in Table 17. Results show that on the whole, the frequency of the exceptional violation is low across staff types, which is to be expected given the exceptional nature of the violation.
Table 17 - Means and standard deviations for the exceptional violation

<table>
<thead>
<tr>
<th></th>
<th>Pharmacist (n=165)</th>
<th>Support staff (n=111)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>Whether I know what the</td>
<td>3.56</td>
<td>2.59</td>
</tr>
<tr>
<td>consequences of acting in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>this way are for the patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I know what the</td>
<td>3.13</td>
<td>2.41</td>
</tr>
<tr>
<td>consequences of acting in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>this way are for me</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I understand the</td>
<td>2.83</td>
<td>2.25</td>
</tr>
<tr>
<td>procedure that tells me not</td>
<td></td>
<td></td>
</tr>
<tr>
<td>to act in this way</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I am able to think</td>
<td>3.16</td>
<td>2.40</td>
</tr>
<tr>
<td>through what I am doing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My ability to deal with</td>
<td>2.38</td>
<td>1.91</td>
</tr>
<tr>
<td>work pressures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My ability to cope with</td>
<td>2.25</td>
<td>1.81</td>
</tr>
<tr>
<td>physical demands of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>workload</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My ability to cope with the</td>
<td>2.43</td>
<td>1.93</td>
</tr>
<tr>
<td>mental demands of the</td>
<td></td>
<td></td>
</tr>
<tr>
<td>workload</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Capability Total</td>
<td>19.74</td>
<td>12.69</td>
</tr>
<tr>
<td>Range of scores (0-49)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How much time I have</td>
<td>1.64</td>
<td>1.29</td>
</tr>
<tr>
<td>Question</td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>How much this helps the pharmacy to meet financial targets</td>
<td>1.36</td>
<td>0.99</td>
</tr>
<tr>
<td>Whether the people I work with do this too</td>
<td>1.60</td>
<td>1.32</td>
</tr>
<tr>
<td>Whether there are additional reminders to remind me not to act in this way</td>
<td>1.65</td>
<td>1.31</td>
</tr>
<tr>
<td>Whether my colleagues support me in making this decision</td>
<td>1.97</td>
<td>1.67</td>
</tr>
<tr>
<td>Opportunity Total</td>
<td>8.23</td>
<td>5.47</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I want to act in this way e.g. I judge this to be a better way of working</td>
<td>1.95</td>
<td>1.75</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences for the patient if I don’t</td>
<td>2.99</td>
<td>2.37</td>
</tr>
<tr>
<td>Whether I need to act in this way e.g. there will be negative consequences</td>
<td>2.31</td>
<td>1.92</td>
</tr>
<tr>
<td></td>
<td>Pharmacist (n=165)</td>
<td>Support staff (n=111)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>--------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>for me if I don’t</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether I routinely act in this way</td>
<td>1.62</td>
<td>1.30</td>
</tr>
<tr>
<td>without thinking</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whether acting in this way makes my</td>
<td>1.61</td>
<td>1.23</td>
</tr>
<tr>
<td>life easier</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Motivation Total</td>
<td>10.48</td>
<td>7.00</td>
</tr>
<tr>
<td>Range of scores (0-35)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>1.21</td>
<td>0.70</td>
</tr>
<tr>
<td>Range of scores (0-7)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A 2 x 2 x 4 between-subjects ANCOVA was conducted to determine a statistically significant difference between gender (male vs female), role (pharmacist vs support staff) and pharmacy type (independent vs small chain vs medium chain vs large multiple vs supermarket) on the frequency of the exceptional violation, controlling for capability, opportunity, motivation and total length of experience. The ANCOVA results for the exceptional violation are presented in Table 18. No significant predictors were found for the exceptional violation.
Table 18 - ANCOVA results for the exceptional violation

<table>
<thead>
<tr>
<th>Independent variables</th>
<th>DF</th>
<th>Type III sum of squares</th>
<th>Mean Square</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Length of experience</td>
<td>1</td>
<td>0.61</td>
<td>0.61</td>
<td>1.75</td>
</tr>
<tr>
<td>Motivation total</td>
<td>1</td>
<td>0.45</td>
<td>0.45</td>
<td>1.30</td>
</tr>
<tr>
<td>Opportunity total</td>
<td>1</td>
<td>0.44</td>
<td>0.44</td>
<td>1.26</td>
</tr>
<tr>
<td>Capability total</td>
<td>1</td>
<td>0.09</td>
<td>0.03</td>
<td>0.27</td>
</tr>
<tr>
<td>Gender</td>
<td>1</td>
<td>0.03</td>
<td>0.03</td>
<td>0.08</td>
</tr>
<tr>
<td>Pharmacy type</td>
<td>4</td>
<td>0.94</td>
<td>0.24</td>
<td>0.67</td>
</tr>
<tr>
<td>Role</td>
<td>1</td>
<td>0.06</td>
<td>0.06</td>
<td>0.16</td>
</tr>
<tr>
<td>Gender x Pharmacy type</td>
<td>4</td>
<td>0.36</td>
<td>0.09</td>
<td>0.26</td>
</tr>
<tr>
<td>Gender x Role</td>
<td>1</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Pharmacy type x Role</td>
<td>4</td>
<td>0.43</td>
<td>0.11</td>
<td>0.31</td>
</tr>
<tr>
<td>Gender x Pharmacy type x Role</td>
<td>4</td>
<td>0.34</td>
<td>0.23</td>
<td>0.67</td>
</tr>
</tbody>
</table>

* indicates \( p < 0.05 \) ** indicates \( p < 0.01 \)

A sequential regression was also conducted to explore the role of habit on the exceptional violation. The final regression model found, \( R = 0.24 \), \( R^2 = 0.06 \), Adjusted \( R^2 = 0.05 \). The model was a significant predictor of exceptional violations \( (F_{(1,273)} = 7.96, \ p < .001) \). The regression coefficients are shown in Table 19.
The model showed that the IVs (habit and motivation) accounted for 5% of the variance for the frequency of the exceptional violation. The multiple regression results indicate that habit was positively related to the frequency of the exceptional violation.

The regression coefficients from the final model were 0.24 for habit (95% CI = 0.04 - 0.17) and 0.15 for motivation without habit (95% CI = -0.02 - 0.02). Standardised regression coefficients indicated that habit was the only significant predictor for the exceptional violation; habit accounted for 5.8% of variance for the frequency of the exceptional violation, whereas the motivation without habit accounted for 2.3% of the variance. The regression coefficients for impact of habit on the exceptional violation are shown in Table 19.

<table>
<thead>
<tr>
<th>Step</th>
<th>$R^2$ change</th>
<th>Predictor</th>
<th>Beta</th>
<th>$t$</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.06</td>
<td>Habit</td>
<td>0.24</td>
<td>4.00**</td>
</tr>
<tr>
<td>2</td>
<td>0.00</td>
<td>Habit</td>
<td>0.24</td>
<td>3.05**</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Motivation total minus habit</td>
<td>-0.00</td>
<td>-0.03</td>
</tr>
</tbody>
</table>

* indicates $p<0.05$ ** indicates $p<0.01$

**Table 19** - The influence of habit and motivation on the exceptional violation

2.4 - Qualitative analyses
This section presents findings collected as part of the comment box provided at the end of the questionnaire. In total 94 qualitative responses were provided (34.1% of the respondents provided comments). The data was analysed using template analysis (153) and six themes were identified. These themes (compliance, pressure, patient need, workload, staffing and additional violations) closely match the themes identified from the previous qualitative interviews, detailed in Chapter 5.
7.2.4.1 - Compliance

Compliance was the most frequently mentioned theme by respondents. Many participants spoke of their aim to comply with procedures as much as possible.

“I aim to follow procedures and SOPs to the best of my ability.”

(Relief pharmacist, large chain, suburb)

“I always follow SOPs none of my colleagues influence my decisions.”

(Dispenser, medium chain, village)

“It’s very rare to deviate from procedures within pharmacy.”

(Pharmacist manager, medium chain, small town)

“[It] shouldn’t matter how busy we all are correct procedures should be followed at all times.”

(ACT, small chain, small town)
Interestingly, although participants would comment that they always follow the procedures during their work in the comment box, they would also rate how often they would go against procedures as part of the questionnaire. This suggests that ‘cognitive dissonance’ may be present, where the respondents’ behaviour may be at odds with their attitude (217). These comments suggest that respondents may have found the notion that they do not follow procedures to be uncomfortable and in an effort to decrease that discomfort perhaps caused by completing the questionnaire, they stated that procedures are always followed in the comments box. However, some participants did note that procedures cannot always be complied with due to the complex nature of pharmacy practice.

“Procedures cannot always be followed to the letter, and it is important that staff show creative thinking and good initiative when problems arise.”

(Pharmacist manager, large chain, large town)

“Knowledge of procedures and how easy the procedures are to follow [influence my behaviour]. [It’s about] whether or not you can fully justify your actions and [if] they cause no harm to the patient. Also, [violating needs] full consideration of the law and what the consequence of breaking it would be. [I also consider] of the support from the company I work from and whether they would support my actions.”

(Pharmacist manager, supermarket, suburb)

7.2.4.2 - Pressure
Pressure was one of the main reasons cited by participants for making violations. This supports the notion that violations are made to maintain efficiency and that violations such as the situational violation occur due to workplace pressure.
“The pressure of day to day life within community pharmacy is ever changing. The complexities of each individual patient mean no two days are the same and different situations arise because of them so you are always challenged.”

(Dispenser, medium chain, village pharmacy)

“You do your best to perform all tasks correctly but time and workload pressures in community pharmacy are now at an all-time high. There are just too many duties that need doing so corners get cut or things are missed.

Staffing levels are always kept to a minimum so that holidays/sickness is not covered.”

(Pharmacy manager, large chain, village)

One element of this theme was the impact of pressure from patients to go against procedures. This was a theme that was also discussed in the qualitative interviews.

“Selling [a] repeated supply of short-course medication: we all know that [the patient] will go somewhere else anyway if we don’t sell, but [we] will have to go through the earache of them getting angry. Plus if some [patients] come on a quiet day and there’s only ladies working I actually feel not safe to refuse a sale of co-codamol as customers reactions can be threatening and really no-one cares about banning customers in large multiples (so [we receive] no help from head office)”

(Dispenser, large chain, suburb)
“Patient behaviour [and] attitude [adds] additional pressure”

(Locum pharmacist, independent, village)

“Patient pressure/demands [influence how I follow procedures].”

(Pharmacy manager, large chain, suburb)

7.2.4.3 - Patient need
Respondents appeared to separate pressure received from patients from patient need. Patient need was deemed a matter of safety, whereas deviating in response to patient pressure appeared to stem from a pressure to provide a timely service. Patient need appeared to be one of the most socially accepted reasons for deviating from a procedure.
“I feel as long as the decision is explainable with emphasis on patient care and safety, the license of the pharmacist to make decision outside of set procedure is important and in most cases effective – very much depends on the ethics and professional practice of the pharmacist.”

(ACT, small chain, large town)

“I believe procedures are often over-ridden by the needs of patients and experience of the staff.”

(Pharmacy owner, independent, village)

“Patient benefit is the primary focus to all decisions I make. They are the main concern in my thinking. [The] procedure is there to have safe operation of a pharmacy and [for legal reasons], but patient needs have to be considered first”

(Pharmacist manager, large chain, large town)

“I always try my best to follow procedures set in place. However depending on patient circumstances some procedures may be changed to ensure the patient best interests are at the heart of my decision.”

(Regular employee pharmacist, small chain, small town)

7.2.4.4 - Workload
A high workload was noted by many staff as a burden on their performance. Managing a high workload led to violations that were made to increase efficiency. As suggested in the interviews and in the results of the COM-B questionnaire, this pressure could lead to
violations that increased risk to patient safety such as staff not feeling able to conduct a full accuracy check of medication. Successful management of workload appeared precarious, where ‘small’ events such as following up an error on a prescription led to a build up of workload that was difficult to manage going forward.

“Completing a final accuracy check on all my work would be amazing if I never had endless amounts of work to do, if I was to do this on every prescription then my work load would be massive.”

(Dispenser, large chain, suburb)

“Unsigned prescriptions and errors on prescriptions need amending but getting into contact with the prescriber about these issues can take a long time, which has a knock on effect of the workflow of everything in the pharmacy, particularly in a small shop.”

(Pharmacist manager, large chain, large town)

“Workload is the biggest pressure, which influences how much I adhere to procedures. At times I have to balance work demands and accuracy. I never compromise on patient safety though”

(Pharmacist manager, large chain, small town)

7.2.4.5 - Staffing
Part of the reason that participants felt that they could not manage their workload successfully at all times was due to the perceived lack of staff in CP. Participants highlighted periods such as when regular staff were ill or if staff were on holiday as particularly difficult to manage.
“Under resourcing, predominantly regarding support staff, is a major influence on deviation from SOPs. Supermarkets do not respect pharmacy as a profession. They operate on a lowest-cost possible basis. This not only undermines service quality and patient safety, but, also endangers the physical and mental health of the pharmacy team trying to do their best.”

(Pharmacist manager, supermarket, city centre)

“[I] cannot follow SOPs if [there is] not enough staff e.g. staff for only 4 hrs a day or no staff after 7 pm therefore have to self-check so going outside SOP procedures so all liability is on the responsible pharmacist even if the pharmacy does not have enough staff contracted to work…That’s why locum(s) routinely do not work at shop(s) where [there is] no staff. Workload or staff hours not [being] maintained [could] lead to loss of job [for the pharmacist]”

(Pharmacist manager, large chain, suburb)

“Main influence [on how I follow procedures] is too few staff.”

(Pharmacist manager, large chain, large town)

7.2.4.6 - Additional violations
As part of the comments, many respondents provided additional examples of violations in CP that had not been discussed as part of the questionnaire or as part of the qualitative interviews. Pharmacists conducting a self-check was raised as a potentially dangerous violation that should be further researched by a few respondents.
“Supermarket policy would like all pharmacists to stay signed on as a responsible pharmacist whilst on a break. Technically the pharmacist cannot leave; the pharmacy must close if pharmacist leaves the store. Second example, pharmacists do technically have full authority of who has access to the pharmacy, but I have seen in many supermarket pharmacies, unauthorised staff entering the pharmacy.”

(Pharmacist manager, supermarket, suburb)

“While working with locums I have come across, many times in many independent pharmacies they re-use return medicine which I don’t think is the right thing to do.”

(Registered pharmacy technician, supermarket, suburb)

“When counter assistant/dispensers ring in sick on the day, there are situations like self-dispense and self-checking.”

(Pharmacist manager, medium chain, small town)

Furthermore, respondents also provided further details on the conditions that would lead them to violate, or not in some situations.
“I always dispense an unsigned prescription if it is a regularly used/prescribed item for a patient UNLESS it is a CD which I never dispense. I do this with full knowledge despite workplace pressures etc., it is a cognitive decision.”

(Pharmacist manager, independent, small town)

“I can’t think of a scenario where I’d dispense a script without a full accuracy check – on occasion a script for the rest of an owing might be missing but I would still accuracy check against the owing slip.”

(Locum pharmacist, small chain, suburb)

“I would never dispense a script for a controlled drug that wasn’t signed unless it was an exceptional circumstance and I had at least received verbal conformation from the prescriber that it was ok to supply.”

(Locum pharmacist, small chain, suburb)

As part of this, theme some respondents provided feedback on the violations included in the questionnaire. Many expressed surprise at the nature of the scenarios included in the questionnaire. Respondents were especially shocked at the inclusion of the exceptional violation (where out of date medication was knowingly and purposefully given to a patient), as they noted that they had never acted in this way. Although this caused some disbelief from respondents, these responses help to support the notion that the classification of this violation as an exceptional violation was correct (124), as it suggests that this violation truly did occur
under exceptional circumstances and that it is extremely rare. Some respondents noted that they had only ever supplied out of date medication in error.

“I haven’t completed the questions asked as I don’t agree with them. Especially where it says about dispensing out of date stock to people on end of life care. It’s just unheard of! Anyone who does that needs to have a serious word with themselves.”

(Dispenser, medium chain, small town)

“With regards to question 4 – dispensing out of date medication would never be a part of our procedure regardless of the scenario. An end of life situation would most likely make me even more cautious of the expiry dates”

(Pharmacist manager (Pharmacist), large chain)

7.3 - Summary of findings

7.3.1 - Findings relating to the optimising violation

- Pharmacists were significantly more likely to make an optimising violation than support staff.

- Motivation was a significant influence on optimising violations.

- Habit alone was a significant predictor for optimising violations. The total of the remaining motivation items minus the habit score were also found to be a significant predictor.

- Opportunity was a significant predictor for the optimising violation.
• Respondents from supermarket pharmacies were more likely to make the optimising violation.

7.3.2 - Findings relating to the situational violation
• Opportunity was found to be significant influence on the situational violation.

• Habit was a significant influence on the situational violation.

7.3.3 - Findings relating to the routine violation
• Pharmacists were significantly more likely to make a routine violation.

• Length of experience was a significant predictor, with participants who had more experience shown to be more likely to violate.

• Motivation was a significant influence on the routine violation.

• Habit was not a significant predictor for the routine violation. However, the total of the remaining items minus the habit item score were found to be a significant influence on routine violations.

7.3.4 - Findings relating to the exceptional violation
• The exceptional violation was rated as the least frequent violation.

• The only significant influence on the exceptional violation was found to be habit.

7.4 - Discussion
Overall, the results identify the significant influence of motivation and opportunity on the frequency of CP staff making violations in practice. Habit was also shown to be a significant influence for some violations. Capability was not seen to significantly predict the frequency of any of the violation although capability scores were consistently rated as a higher influence across the all four violations. One of the reasons for capability not being a significant factor may be due to the requirement that participants had a minimum level of training in order to complete the questionnaire; 74.5% (n = 205) of the sample were registered professionals with
a high level of training. Interestingly, capability was consistently rated as the highest influencing factor by staff, suggesting that the ability to think through decisions is important to staff, however capability was not found to be a significant influence on any of the violations.

The main demographic variables to influence the frequency of violations were seen to be job role and length of experience. Supermarket pharmacies were the only pharmacy type to be significantly related to the frequency of the optimising violation. Pharmacy type to influence violation frequency for any situation. The influence of job role was to be expected as pharmacists are responsible for the decisions made within the pharmacy and based on their qualifications, they possess more autonomy compared to support staff. The significant influence of length of experience was expected to influence routine violations, as previously noted in Chapter 4, newly qualified pharmacists sometimes felt uncomfortable with bypassing or deviating from procedures at times (186).

The findings highlighted that different violation types were influenced by different factors in practice. Each violation type will be discussed in turn:

7.4.1 - Optimising violation
It was hypothesised that motivation would be a key influence on the optimising violation, as optimising violations involve an individual having the motive to optimise their situation whilst exploring the boundaries of the system in which they work (123, 124). The results support previous literature that states optimising violations occur to serve a variety of goals – this study found pharmacy staff were meeting the goals of making sure the patient was not inconvenienced and to save time. As predicted the results for this violation showed that motivation is a key predictor, with both habit and the motivation items without habit also being found to be significant influences.
Analysis of the motivation item means illustrated that the need to act in this way to avoid negative consequences for the patient was rated as the highest motivation for the optimising violation. This result is interesting due to the potential risk involved in repeatedly selling the OTC medication to patients. Therefore, it is hypothesised that staff may have been selling the medication to avoid inconveniencing patients and due to their habit of previously selling these medications to the same patient. However, analysis of the mean scores should be interpreted with caution.

The significant result of the opportunity measure supports the notion that participants may be violating due to environmental pressures. The social norm within the pharmacy has previously been identified as a potential influence on violations during the qualitative interviews (1). The social norm has also been identified as a key influence on the safety culture within teams and organisations (43, 45). This finding was to be expected from support staff as the final decision of whether to sell OTC medication is the pharmacist’s decision. However, pharmacists may also be influenced by their colleagues as support staff are typically more directly involved in selling OTC medicines than pharmacists. Support staff may have more information regarding the regular customers, therefore pharmacists may wish to confirm with the support staff regarding the regularity of patient purchases with regards to the OTC medication.

As opportunity was a significant influence on the situational violation, how much time CP staff had appeared to influence their decision to make this violation. These results support the qualitative results discussed in Chapter 5, where trying to manage demands on the OTC counter alongside customer satisfaction led to violations in practice. Pharmacists may have been more motivated to act in this way, as they ultimately had the knowledge to assess the danger of selling these medications long term. Furthermore, if an adverse event did come from the customer taking too much OTC medication, then the responsibility of this decision would lie with the responsible pharmacist.
7.4.2 - Situational violation

For the situational violation, participants were asked to consider not being able to complete a full accuracy check of medication against a prescription. This situation was chosen as an example of a violation that would typically have been provoked by organisational failings (as opposed to a conscious decision to purposefully not accuracy check medication, this is more likely to be considered sabotage as opposed to a violation (123), due to the obvious negative connotations that it could pose to patient safety). It was hypothesised that opportunity would be a significant predictor for this behaviour, i.e. situational factors such as time pressure would lead to staff cutting corners to remain efficient. It was also hypothesised that capability may be a significant influence i.e. the ability of staff to deal with the mental workload. The first hypothesis was proven to be correct as opportunity was a significant influence on the frequency of the situational violation. However, the second hypothesis regarding capability was not supported.

Opportunity was a significant influence on situational violations. Thus, suggesting that factors such as time, the presence of additional reminders and whether colleagues supported an individual’s decision to violate would influence the likelihood of making the situational violation. Habit was also found to be a significant influence on not completing a full accuracy check. This finding has obvious negative connotations for patient safety, if staff are regularly and somewhat unconsciously, not completing a full accuracy check. If the goal of the staff member is to work efficiently (i.e. to quickly check medications) this may create a tension with patient safety, where incorrect medications are handed out to patients as noted in Chapter 5. Based on the results of the qualitative interviews, one reason that staff may prioritise checking quickly over checking completely, may be because staffing levels within the pharmacy are often linked to the amount of items that the pharmacy is able to check. Therefore, by accuracy checking as many items as quickly as possible, this may mean that in the long run, the pharmacy is rewarded with more staff. Furthermore, this result appears to support the finding
in Chapter 3, where both frontline and head office staff identified a lack of accuracy checking training as a risk to patient safety.

Policy makers may benefit from considering the social norm within the pharmacy, including how support staff are trained with regards to accuracy checking (43). Previous research into the training provided for registered pharmacy technicians noted that the training provided tends to focus on historical methods of dispensing such as extemporaneous dispensing for example, as opposed to training staff on patient safety and professionalism directly (218). Implementation intentions (219) may be useful for tailoring and promoting specific safe habits with regards to accuracy checking in CPs. Furthermore, specific reminders relating to safe accuracy checking behaviours may be useful to remind staff of the procedure that they are recommended to follow. The balance between safety and productivity is a well-established problem (42) and as shown in Chapter 3, policymakers in CP note the difficult task of managing staffing levels and budgets. However, the results identified as part of this study, such as pharmacy staff do not always complete a full accuracy check due to situational factors including time pressure, may suggest that further consideration should be given to staffing levels in CP.

7.4.3 - Routine violation
Participants were asked to consider supplying medication to a patient from a prescription that had not been signed by the prescriber for the routine violation. This behaviour was deemed to be a routine violation as it was mentioned numerous times by participants in the qualitative interviews as a low risk violation that was often necessary to ensure that patients received their medication on time. It was also thought to be easier to act in this way to ensure that the patient was safe and satisfied at the time, and to get the prescription signed at a later date. It was hypothesised that routine violations would be significantly influenced by the individual’s
motivation to act i.e. it makes the staff member’s life easier and violating also ensures that negative consequences for the patient are avoided. Habit was also predicted as a potentially significant predictor given the routine nature of the behaviour.

The first hypothesis was supported, as motivation was found to be the key influence on the frequency of the routine violation. These results support the findings from the earlier chapter on the use of procedures, that outlined the importance of using professional judgement when deciding whether or not to violate (186). This suggestion is further supported by the finding that habit was not a significant predictor for the routine violation, which may have been predicted the routine nature of the scenario. However, the remaining motivation items minus habit were a significant predictor. These results add weight to the suggestion that although routine violations may occur more than others, they are not carried out unconsciously, the pharmacy staff appear to be using professional judgement to decide whether or not to make the routine violation in each situation based on patient need at the time rather than unconsciously dispensing the medication due to habit.

It was also hypothesised that length of experience would be a significant predictor as earlier qualitative work suggested that newly qualified pharmacists may be more hesitant to go against procedures, even when doing so for patient benefit (186). This hypothesis was confirmed, with participants more likely to make the routine violation if they had more experience in practice. Furthermore, role was also seen to significantly influence the frequency of the routine violation, with pharmacists being shown to make this violation more often. The reason for this is likely to be due to pharmacists possessing the autonomy to decide whether or not to supply the medication to patients.

As this violation is suggested to occur as a result of patient need, pharmacists were shown to be following at least two of The Seven Principles (1. You must make patients your first concern; 2. You must use your professional judgements in the interests of patients and the
public) outlined by the Royal Pharmaceutical Society (9). In this scenario, to not violate may have been considered unprofessional. Based on the significant role of length of experience, policymakers and pharmacy educators may wish to consider providing additional training for newly qualified pharmacists with regards to having to go against procedures at times in order to maintain patient safety. Feeling unable to go against procedures for fear of personal consequences, may be leading to situations where patient care is unnecessarily compromised.

7.4.4 - Exceptional violation
Finally, respondents were asked to consider an exceptional violation where an out of date medication was supplied to a patient knowingly. This situation was chosen as an exceptional violation due to the abnormal set of circumstances and the perception that this type of behaviour in pharmacies is rare (123). It was hypothesised that participants would choose to make this violation for patient need (i.e. that motivation would have been a significant predictor).

The results did not support the hypothesis. Perhaps the most surprising result of them all was that habit was found to be a significant predictor for the exceptional violation. As the violation was chosen as an exceptional example it was not predicted that habit would be a significant predictor. One potential explanation, based on the qualitative results from the questionnaire is that some participants may have misunderstood the question and were considering the behaviour as an error and not a purposeful violation. This may have been due to the wording of the question which read “supplying out of date medication would depend on...” One option to avoid potential misunderstanding would have been to phrase the question as “Purposefully supplying out of date medication would depend on...” The qualitative results support the suggestion that the violation was potentially judged as an error, for example,
“[I’ve] never knowingly [dispensed an out of date medication]. [I’ve] hardly ever unknowingly dispensed out of date medication.”

(Pharmacist, large chain, large town)

Therefore, further research may be required to understand the key influences on exceptional violations in CP.

7.4.5 - The use of the theory in explaining violations in community pharmacies

This study is the first to utilise a questionnaire based on COM-B to explore violations. Overall, the COM-B model appears to provide a relatively coherent model for understanding violations in CP. The utilisation of the COM-B model in a questionnaire format, allowed the researcher to access a fairly large amount of CP staff that would not have been possible through qualitative methods. The COM-B model appeared to capture some of the influencing factors for behaviours in CP, yet a proportion of variance was not explained. However, respondents did note the influence that pressure received from patients had on their decisions. Future versions of the questionnaire to be used in a healthcare setting may benefit from including this factor, in order to obtain a more complete view of the influencing factors on behaviour in healthcare.

The extent to which the COM-B model predicts behavioural frequency appears to vary across the four violations. Based on Cohen’s guidelines for effect size (where 0.2 = small effect; 0.5 = medium effect and 0.8 = large effect) analysis of the partial eta squared scores suggested that the COM-B was a relatively robust model for predicting violations. For the optimising violation, motivation explained 90% of the variance; opportunity explained 30%; gender
explained 50% and role explained 40% of the dependent variable. For the situational violation, opportunity explained 90% of variance for the dependent variable. For the routine violation, role explained 20% of the variance; length of experience explained 40% of the variance and motivation explained 50% of the variance. The average of these scores is 50% which is a moderate effect size.

The results of the questionnaire appear to support Reason et al.’s taxonomy of violations (124). As suggested in their model, violations occur for a range of reasons and they appear to be influenced by intrinsic and extrinsic factors. The results of the questionnaire suggest that CP staff are inclined to violate based on whether they think it is the right thing to do, or at times, based on situational factors within their environment that lead them to violate procedures. These results support the notion that the influence of individuals and the environment are reciprocal (42, 45). The results of the questionnaire also suggest that the exceptional violations occur very rarely. However, the results of the exceptional violation may need to be interpreted with caution as it seems that the question may have led respondent’s to consider supplying out of date medication in error as opposed to through a purposeful violation.

7.4.6 - General discussion
The results from both the quantitative and qualitative results collected in the questionnaire provide a clear message that when given the chance, pharmacy staff will make the right decision for patients through the use of professional judgement. However, when pharmacy staff are placed under pressure to work efficiently and to work within a culture where the social norm allows potentially unsafe behaviours to continue, risk to patient safety is introduced. Taken together, the results suggest the importance of ensuring that a good safety culture is maintained in CP, where safety is the priority as opposed to efficiency.
In one sense, pharmacists appear to be choosing whether they ‘will or won’t’ make this violation (192). However, for the situational violation, opportunity was found to be the biggest influence on the violation frequency. In this situation, staff could be deemed as having to choose whether they ‘can or they can’t’ follow a procedure (192). Based on the qualitative data and the preceding qualitative interviews, it was clear that CP staff wanted to work safely and accurately. Motivation to work safely was not the issue at hand. The results of this questionnaire supported the hypothesis that motivation is a key influence on violations in CP. However, increased pressures within the working environment were suggested to lead to staff cutting corners to maintain efficiency at times.

7.5 – Chapter Summary
This chapter presented the analysis of the COM-B questionnaire. Both quantitative and qualitative results were provided regarding the main influences on procedural violations in CP. The following chapter brings together the results of the three studies and discusses the findings of this thesis as a whole.
CHAPTER 8: Discussion

8.1 - Chapter outline
This thesis has presented the findings of a mixed methods programme of research that sought to understand procedural violations and their implications for patient safety in CPs. Three studies were undertaken, and the results of each study have been discussed individually in the preceding chapters. In this chapter, the findings from these studies are triangulated in order to provide an overall understanding of procedural violations in CPs and their implications for patient safety.

This chapter presents a summary of the findings in relation to the overall aims and objectives of this thesis. It then discusses what the results tell us about violations in CPs, what the research tells us about violations in general, the reasons why violations occur in CPs and how violations can help us to understand safety. The chapter concludes with the practical and theoretical implications as well as directions for future research. The final conclusions for the thesis as a whole are also presented.

8.2 - Key findings from each study
8.2.1 - Study one: Exploring the prevailing safety culture in community pharmacies
- The prevailing safety culture within CPs appeared to differ between frontline and head office staff.

- Frontline staff appeared to have a reactive safety culture where risk was managed as and when it appeared in practice.

- Head office staff appeared to have a calculative safety culture where risk was managed through the use of detailed SOPs.

- All CP staff had to manage the sometimes competing goals of productivity and safety.
• Patient safety training was not directly provided to staff; rather, patient safety was learnt “on the job”.

8.2.2 - Study two (part one): How are procedures perceived in community pharmacies

• The work-as-imagined in SOPs appeared to be different to work-as-done in practice.

• Pharmacists expressed the need to bypass or deviate from procedures to ensure that tailored patient care was provided.

• Registered support staff preferred working to the procedures as they felt this was the safest way to work and important for protecting their registration.

• Dispensers appeared to work more flexibly depending on the social norm within the pharmacy and based on how the responsible pharmacist at the time preferred them to work.

8.2.3 - Study two (part two): Using Safety-I and Safety-II to understand how and why violations occur in community pharmacies

• Broadly, violations appeared to occur based on whether staff were trying to fulfil the goal of productivity or working safely.

• Violations that were made to increase productivity appeared to increase the risk to patient safety.

• Safety-I and Safety-II were useful frameworks for exploring violations. A mixture of both philosophies (i.e. looking at why things have “gone right” as well as wrong in practice) were a useful way to consider violations in CP.

• Reason et al.’s taxonomy of violations was a useful framework for classifying the types of violations that occur in CP.
8.2.4 - Study three: Using COM-B to explore the influences on and the frequencies of violations in community pharmacies

- Motivation, opportunity, staff role, length of experience, gender and habit were shown to be significant influences on some violations in CPs.

- Routine and optimising violations appeared to occur most frequently; however, on the whole violations appeared to occur relatively infrequently.

- Qualitative results provided a deeper insight into the influences on violations as well as providing additional examples of violations that occur in CPs that had not been uncovered during the earlier studies.

8.3 - What does this thesis tell us about violations in community pharmacies?

Taken as a whole, the results of this thesis provide rich insights into how and why violations occur in CPs. The results of the research conducted support the notion that violations occur due to environmental, situational and individual influences (20, 123, 127, 139).

All three studies support the suggestion that environmental influences such as the safety culture (46), workload (47), stress or frustrations (89), technology within the workplace (220) and the social norm within the pharmacy (25) contribute to how safety is managed in CPs. Although factors such as workload, staffing or stress were not explicitly measured as part of this PhD, participants regularly mentioned them as contributing factors when deciding to violate. For example, in Chapter 5 participants expressed that they would violate procedures when they were “in a bad place” to help manage workload and that behaving in this way caused them to feel frustrated as they were aware of the potential risk of violating in this way. Furthermore, the significant impact of opportunity on the occurrence of optimising and situational violations further highlights the link between environmental influences and the occurrence of violations.
Habit was identified as a significant influence on the occurrence of some violations. Previous literature has shown habit to be influential on healthcare staffing following procedures. Potthoff et al. (221) in a study of primary care GPs and practice nurses found that healthcare professionals who scored higher on planning (action or coping plan) for providing advice, prescribing or examining a patient were more likely to report performing such care and this relationship operated indirectly through habit. Webster et al. (222) suggested that habits learnt during early training may be a potential influence on violations. As the studies presented support the suggestion that the social norm within an environment has an influence on violations (25), this may support the notion that violating habits could be developed during training.

The role of interpersonal factors such as team working and differences in attitudes towards safety (50, 69), communication (49), relationships with head office (65), the SOPs used in practice (70) and the relationships with patients (69) and other healthcare providers (70) were all shown to influence safety behaviours in CPs. Staff role was suggested to influence the occurrence of violations, with a significant difference between roles being suggested in Chapter 4 and significantly proven in Chapter 7. Pharmacists appeared to use their professional judgement (or their motivation) to decide whether or not to violate. Chapter 3 and 4 especially, highlighted how the relationship of frontline pharmacy staff with head offices can result in violations as head offices provide procedures to manage risk that frontline staff do not always feel are practical to follow in reality. A lack of communication both within the pharmacy and between healthcare professionals was shown to result in violations as pharmacists would make routine violations to ensure that patients received medication when ordering processes had not gone to plan. The role of patient demand on violations was supported in Chapter 3, as participants explained that situational violations would occur to try and provide an efficient service to waiting patients. Although this influence was not directly
explored as part of the COM-B study, patient demand was noted as a key influence by respondents in the qualitative studies.

The results of the studies conducted for this thesis provide evidence for violations also being influenced by individual differences, including length of experience (92) and gender (97, 101). The results in Chapters 4, 5 and 7 suggest that experience has an impact on frequency of violations. More experienced staff appeared to feel more comfortable making violations that were required for patient need (95). The results of the COM-B study found that men were significantly more likely to make an optimising violation. Although this finding was not prominent within the qualitative results, the finding does support previous literature that suggests that men may be more likely to take to take risks (103) and this may partly explain why a greater proportion of men than women are likely to be disciplined in pharmacy (97, 99-101).

8.4 - How can violations in CP be understood?

The results of this thesis can be explained from multiple perspectives. Firstly, Reason et al.’s taxonomy of violations (124) was a useful framework for understanding the types of violations that occurred in CPs as shown in Chapter 3. The results of Chapters 5 and 7 seemed to support the taxonomy’s proposed reasons for the occurrence of violations such as the influence of situational factors and whether the individual perceived violating to be a better way of working. Lawton’s (123) suggestion of the occurrence of unintentional violations was not supported during this research however, as the violations were mainly self-reported participants may have had difficulty discussing violations that they did not know they were making. Future research that incorporates ethnography conducted by a trained observer may provide evidence as to whether these types of violations occur in CP, however it should be noted that Reason would not consider these unintentional violations as true violations, rather they would be considered as an error as the act was unintentional (108).
Cooper’s reciprocal model of safety culture (45) was also utilised to help understand the prevailing safety culture in CPs. The reciprocal model appeared to be useful for explaining why violations occur in CPs. All three studies highlighted the reciprocal relationship between individual and situational factors on CP employees’ decision to violate. The first study explored in Chapter 3, provided detailed evidence of the context in which CP employees are working. This study mainly highlighted how the social norm within a CP organisation can impact on the aims and behaviours of a particular team (42, 45). This study also provided an insight into the many latent factors that can arise in CP, and highlighted that these factors do not always have an instant impact on patient safety (108). The results of Chapters 5 and 7 suggest the key role personal motivation has on the occurrence of violations. Therefore, it is suggested that Cooper’s reciprocal model of safety culture is a useful framework for appreciating the reciprocal nature of individual and situational influences on violations as well as safety culture.

The suggestion that violations may be based on reciprocal influences is supported by Catchpole (118) who supported the use of the naturalistic decision making paradigm (223) for understanding violations, due to the links that the theory made between system and person whilst acknowledging the systemic trade-offs between safety and efficiency that occur in practice. The naturalistic decision making paradigm (223) supports the results of this thesis as it suggests that the decision to violate is usually made in uncertainty and under time pressure and that violations are based on expertise, pattern matching or recognition of a given situation, and are thus “nonlinear, non-analytical and not necessarily logical, rational or based on risk/benefit considerations” (118, pg.3). The naturalistic decision making paradigm has been utilised for exploring violations in secondary care (166), and this may be a useful avenue to explore for violations that occur in primary care settings.
Another theory regarding violations specifically is that of Amalberti et al. (126), who suggested that violations that are allowed to become routine work practice may lead to the “migration” of work towards an “illegal-normal space” where staff work in a way that is forbidden based on the work-as-imagined in the procedures, however extreme pressure/conditions results in staff having to adapt to maintain efficiency. They also noted that if staff feel pressured to violate in order to increase performance it can result in staff thinking that in some way, their behaviour is supported by management. Working in this way can result in “close-calls” where a patient does not come to harm however, the risk is drastically increased. The findings presented in this thesis support the notion that CP staff may work within an “illegal-normal” space when faced with extreme pressure caused by a busy time of year or by environmental factors such as a lack of staff. Amalberti et al. (126) argued that if the violations that occur during the illegal-normal phase are repeated over time, they may lead to a shift in safety margins with the violations that were once reserved for times of high pressure becoming the “new normal” (126). The risk then, is that when staff face another period of high pressure that the “new normal” behaviours will be further violated and staff will be working in an “illegal-illegal” area.

Although violations have been suggested to increase the risk to patient safety, most of the violations discussed in this thesis did not result in patient harm. This may have been due to participants not feeling able to share examples of violations that resulted in direct patient harm. Participants were asked as part of the interviews to note if they could think of examples of times where they had violated that they felt unwilling or unable to discuss with the researcher. Six out of twenty four (25%) of participants indicated that there were examples that they did not feel able to discuss with the researcher. However, it is not possible to ascertain what these violations involved and whether they resulted in patient harm. Two violations that were openly discussed that had led to patients receiving the incorrect
medication, included prescriptions not being clinically checked before the medication was handed to a patient and medication not being fully accuracy checked against a prescription before being given to a patient. The participants explained how the instance of a patient coming potentially to harm having being given the wrong drug, caused a reactive safety response (i.e. the provision of more staff in the first example, and the closure of the pharmacy for an hour and the provision of a second pharmacist in the second example to help manage work demands).

These examples taken from Chapter 5 could suggest that the reference model of migration and transgression of practices proposed by Amalberti (224) may operate in a cyclical fashion where staff return to the “legal” position of following SOPs for some time after violations result in a medication error or patient harm, only to return to the “illegal-normal” way of working during the next period of high workload and pressure to remain efficient, until working in this way becomes illegal-illegal once more following a violation of the “new normal”. Further support for the suggestion that the migration model may be cyclical may come from considering the traditional Safety-I approach to risk management, where additional SOPs or changes to SOPs are made only after an incident has occurred (113).

One approach to “breaking the cycle” may be to encourage organisational resilience in practice (225). Organisational resilience relates to the ability of staff and systems to adjust their functioning whilst maintaining safety, in the presence of continuous stress and an ever-changing environment (226). Hollnagel notes foresight, coping and recovery as the three key elements of resilience (185, 227). A key characteristic of organisational resilience is the ability of staff to adjust prior to, during or following changes within the working environment (228). Resilient organisations do not wait for errors or ‘close calls’ to occur before making corrections as shown in Amalberti’s migration model (224). Organisational resilience is often contrary to traditional safety practices where a large proportion of time is spent investigating
past mistakes and where safety is achieved by restricting behaviour through the use of SOPs (79, 229-231).

Woods (232) warns that if staff continually adjust their behaviour to deal with current demands and continue to prioritise efficiency over safety, this can increase “brittleness” or vulnerability in other areas of the system. An example of this was shown in Chapter 3, where communication between team members was not prioritised over maintaining efficiency and at times, failure to communicate was felt to lead to lapses in providing patient care (232, 233). Woods suggests that if a work system cannot continue to respond to demands and meet some of its goals to some degree, then the system will experience a sudden failure or collapse as shown in the two violations discussed above, where the violation led to patients receiving the incorrect medication (37).

The literature review provided in Chapter 2 highlighted the emphasis placed on incident reporting in CP (50, 89, 234, 235). The reactive nature of CP may benefit from a more mindful approach to patient safety. The role of mindfulness in resilient organisations has gained increasing support in the literature (185, 236, 237). The act of being mindful and constantly monitoring safety, as oppose to reacting in haste to safety issues may enable CP staff to deal with unexpected situations before they develop into a greater risk to patient safety. Jeffcot et al. (185) suggest that paying attention to failure yet not anticipating it in the future, suggests an interactive stage of resilience, also known as ‘partial resilience’. The results of this thesis support the notion that CP on the whole is partially resilient, as for the most part staff appear to be able to cope with demands without patients being harmed. The results suggest that violations play a part in CP staff being able to deal with their work demands in the present moment. However, working in this way cannot be permanently maintained or recommended as situational violations appeared to increase the risk to patient safety, even if patients did not actually come to harm each time.
One approach to using resilience to maintain and promote safety could be to foster a more proactive culture in CP. Staff may benefit from also learning from what allows patient care to be provided successfully (232, 238). However, progress in patient safety cannot be made by encouraging more of the same behaviours (176, 187), and given that incident reporting has been noted as ineffective for reporting bypassing or deviating from procedures in the past (234), a paper based tool may not be appropriate for exploring flexibility in practice. Furthermore, research suggests that reporting systems may not be appropriate for violations (126). Learning has been described as a ‘social process’ (176), thus open discussions between teams may be beneficial. Sujan (239) suggests staff learning from “hassle situations” in the dispensary by assessing what behaviours allowed things to “go right” in a stressful situation. Chapter 5 suggested that routine and situational violations can help to “keep the job going”; CP staff may benefit from discussing these scenarios as a team to understand which actions in particular were beneficial for maintaining productivity whilst allowing for patient safety to also be maintained.

8.5 - Why do violations occur in community pharmacies?
The findings presented in this thesis provide rich insights into the reasons why violations occur in CPs. The results of all three studies suggest a role for the working environment in the occurrence of violations in CPs. The results of Chapters 3 and 4 supported previous literature that identified the social or behavioural norm as an influence on violations in healthcare (172). Chapter 5 supported the notion that latent conditions such as a lack of staff may be resulting in violations in CP (106). Participants in Chapter 4 discussed how they were expected to follow a large amount of detailed procedures that could result in staff feeling overloaded.

Vincent and Amalberti (18) suggest that the vast number of procedures used to manage safety in healthcare drains resources, presents staff with an “unconscionable” burden and results in a paradoxical threat to patient safety. Thus, one reason that violations may occur in CPs is
because of the sheer amount of procedures that they are expected to abide by which makes it difficult for staff to follow them all during their work, therefore resulting in violations. Vincent and Amalberti (18) suggest that efforts should be made to separate essential safety critical behaviours from trivial procedures to allow staff to focus on providing safe care.

Another reason for violations occurring in CPs was shown to be the motivation of the individual making the violation as shown in the results of Chapter 4, 5 and 7. The results support previous research that found the intention of the individual as a key determinant of violating behaviour (123, 240). Interestingly, the results of Phipps et al. (25) suggested that safe behaviours did not occur purely based on a guideline being in place, but rather because the healthcare staff sampled believed that the behaviour should be carried out, not because the behaviour could be carried out. One benefit to utilising COM-B as opposed to the TPB was that the COM-B model allowed for the measurement of habit (40), which was found to be a significant influence on optimising and situational violations. This finding may have important implications for how CP staff are trained in practice.

The results of Chapter 7 especially appear to support the notion that pharmacy staff are deciding whether they will or will not follow procedures (e.g. when deciding whether or not to make a routine violation) or whether they can or they can’t follow procedures in practice (e.g. with the situational violation). These results could suggest that when given the opportunity to make the correct decision for patient safety, pharmacy staff will violate for patient need based on their strong commitment to patient safety, as highlighted in Chapters 3 and 4. However, when faced with a time pressured and under-resourced environment pharmacy staff appeared to make violations out of necessity to keep the job going and to manage workflow.

Although this thesis provides a rich and deep insight into the reasons why violations occur, any notion of causation should be treated with trepidation as causal relationships are assumed rather than confirmed on the basis of the present findings. The results of the qualitative
research cannot be generalised due to the limited sample, and likewise given the cross-sectional survey design of the COM-B questionnaire the researcher could not measure the extent to which the change in the IV led to a change in the DV. However, the results do provide evidence of an association of the significant IVs with the frequency of violations. The results could be considered as an introduction to the exploration of why violations occur in CP and a longitudinal study or an experimental study may be useful for exploring the extent to which the IVs led to a direct change in the frequency of violations. Direct measurement of environmental factors such as workload, safety culture and motivation of staff along with the measurement of the frequency of violations may provide a greater understanding of the cause of violations in practice.

8.6 - Are violations useful for understanding safety?
Although violations have often been defined as well intentioned behaviours that are not made specifically to cause harm (4, 123), they have been previously labelled as a “key threat to patient safety” (12). The view that any deviation from procedures is negative is aligned with the traditional view of safety as highlighted in the Safety-I perspective. Vincent and Amalberti (18) suggest a revised vision of patient safety where instead of focusing on the reduction of harm and error, the focus should instead be on maximising the overall balance of benefit and harm to the patient given that departures from the standards of care are not the exception, but rather the reality of day to day life in healthcare settings.

As discussed in Chapter 5, the results of this research suggest that violations are used by CP staff to manage their complex environment. Dekker (23) believes that within complex environments ‘best practice’ and ‘compliance’ are misleading concepts and potentially meaningless as the one “best method” of care does not exist as the system is continually reshaping itself. In these complex environments universal rules that apply to all staff and all situations (such as SOPs used for nationwide pharmacy chains) may be impractical, and rather
safety in that moment and that situation relies on the knowledge of practitioners and their knowledge of their given situation.

As discussed earlier in this chapter, certain violations appear to lead to an increased risk in CPs. This appears to happen when individuals prioritise productivity as opposed to safety. Although some violations were shown to sometimes increase risk, overall results suggest these violations cannot always be judged as right or wrong based on the complex environment in which they occurred. As discussed in Chapter 5, Hollnagel (178) believes that what is “good enough” in a pressurised situation, may not be good enough in a situation where the individual has plenty of time. Phipps and Parker (166) suggest violations in healthcare may be better understood as a form of situated action rather than rule-breaking therefore non-compliance may not always be judged as wrong. Ultimately, specific outcomes such as patient harm are likely to be judged as wrong, however judging violations based on the violating action alone without due consideration of the context in which the violation was made will likely result in an unfavourable opinion of violations in general and of the individual who has violated as the causal role attributed to violations is often inflated with hindsight (241). Exploring the context in which a violation was made, the individual’s motivation for violating in that situation as well as the violating behaviour, may help to provide team members and management with insights into areas of the work system that may be brittle (232). Staff in practice may then benefit from proactively anticipating similar situations in which the same situational factors may arise again.

Although violations may lead to patient safety issues in some situations, many violations do essentially “go right” and the flexibility and knowledge application of professionals is crucial for ensuring patients receive the necessary care (23, 113). The question arises, then, whether the use of professional judgement is enough to ensure that violations always go right. The results of this thesis suggest that professional judgement is pivotal for ensuring that correct patient care is provided and although no evidence was found during the three studies that the
use of professional judgement when violating led to any increased risk to patients, it is possible that this may occur as an example of an unintentional violation (123). Unintentional violations may occur when pharmacists have the patient’s best intention at the heart of their decision to knowingly go against procedures, however, given the complex environment in which they work and the complex patients that they care for, it is unlikely that pharmacists will ever be able to “know” the full details of a situation and therefore violations may result in unintended consequences (18, 189). One suggestion for ensuring that pharmacists know as much as possible about their environment when deciding whether or not to violate, may be to ensure that briefings and debriefings occur each day so that any vital information can be shared with the pharmacist and amongst the team (18).

One way to consider violations could be to compare procedures to a GPS navigation system in the sense that procedures provide healthcare professionals with a map of how to arrive at a safe destination based on the knowledge available at the time of creation. In this analogy, the driver (healthcare professional) will undoubtedly encounter roadblocks (a lack of resources for example), traffic jams (a time pressured environment), areas of the map that have yet to be updated (exceptional or novel circumstances) or a GPS system failure (technology problems). In this situation the driver must decide how best to “go off the beaten track” in order to still arrive safely at their destination based on their local knowledge and their driving skills. Threats to safety may still arise from the other drivers on the roads that are out of the driver’s control. Similarly in healthcare, professionals must decide how best to deal with the situation in front of them based on their knowledge and skill within an inherently risky environment. The aim of the journey (safe care) has not changed but the way in which it is achieved may not always go as planned. When preparing for another car journey a driver may prepare by ensuring they have up to date knowledge of the roads before setting off on their journey by proactively checking traffic reports (healthcare staff could use briefing to achieve this) and choosing an
alternative route in advance if situational factors such as a bad weather forecast may result in an unsafe journey (re-arranging work flow and prioritising safety over the fastest or most efficient way of working) or by making sure that their GPS system had the latest update downloaded (ensuring that technology is kept in good-working order). The purpose of this analogy is to help provide an alternative means for explaining violations and to emphasise that the most crucial thing is that everyone arrives safely even if the journey does not follow the original map.

A different perspective on violations may be required as healthcare becomes an increasingly complex setting with ever advancing medicines, technologies and the increasing pressure placed on CP staff to deliver a wide and varied range of services for patients. The expectation that healthcare staff will abide with procedures at all times is becoming increasingly unrealistic. A paradigm shift may be on the horizon with regards to safety management in healthcare. The dominant paradigm in patient safety currently is to focus on controlling behaviour through the use of procedures and on focusing on past harm. The results of this thesis support the notion that following the procedures is not always best for patient safety (70, 186). This shift in perspective may involve a mixture of Safety-I and Safety-II approaches where errors and violations are learnt from when they go wrong but, it is also appreciated that flexibility is completely necessary for ensuring that the outcome of care is as beneficial as possible (41).

8.7 - Implications

8.7.1 - Practical implications
The findings of this thesis have implications for policymakers, practitioners and for the training of pharmacy staff. Given that violations have been shown to be influenced by both environmental and individual factors, the implications are a mixture of system and person-centred approaches. Five implications are suggested as a result of this thesis, and they are included below:
1. Evaluate how procedures are implemented in practice

The results of Chapter 4 highlighted how staff were overloaded with SOPs in CPs and staff felt that following them all was an impossible task. One suggestion may be to evaluate how procedures are implemented in practice. Based on the results from the one-to-one interviews, one implication for policymakers and organisations may be to combine the Safety-I and Safety-II approaches by introducing procedures that support organisational resilience. Flexible procedures could offer different options and decision criteria for staff as opposed to a single ‘safe’ way of working (40). Staff sometimes did not feel comfortable with going against procedures for fear of litigation or a lack of support from head office. Reminders on SOPs such as “pharmacists are reminded to make patient safety their first priority in all situations” could help to encourage staff to work flexibly when appropriate. Observational methods may be required however, based on the potential cognitive dissonance highlighted in Chapter 7, that could result in staff not feeling comfortable to self-report violations.

2. Provide additional support to pharmacy teams

Across this thesis as a whole, the impact of a high workload and a lack of resources was often reported by staff to have an impact on how procedures are followed in CP. Factors such as pressure from management regarding achieving targets or setting procedures that are difficult to follow when working out of hours can create an environment where following procedures and achieving required outputs is sometimes felt to be unachievable. It is appreciated that given the fraught landscape of pharmacy funding at the time of writing these recommendations that the option of more staff is not always a viable option. However, frontline staff may benefit from better work planning by working proactively to anticipate times where additional staff are crucial for maintaining safety such as when regular team members are away on holiday. Results of this thesis suggest the large impact environmental demands have within the pharmacy including the impact of patient demand, interruptions and
training. One implication for pharmacies that do not already operate in this way, may be to consider re-arranging the rotas of staff to ensure that staff experience a period of time during the day to be able to concentrate on crucial tasks without interruptions.

3. **Provide patient safety specific training in pharmacies**

The focus groups described in Chapter 3 highlighted that patient safety is “learnt on the job” and the results of the thesis as a whole suggest that the social norm within the pharmacy has an impact on violations. One method to try and encourage a positive safety culture could be to provide staff with patient safety specific training to emphasise the importance of patient safety promoting behaviours such as discussing errors and near misses within the team. There is currently ongoing work within the research group involving a CP collaborative, where pharmacy stakeholders are working together to improve patient safety through the development of safety cases for example.

The results from Chapter 3 highlight how pharmacy staff lack patient safety specific training. This may be an area for pharmacy head office to provide detailed training regarding accuracy checking to staff, so that they begin their work having been trained with the goal-directed behaviour of dispensing accurate medication (162, 218). Perhaps most importantly in relation to the findings shown in Chapter 7, Potthoff also found that healthcare professionals who scored higher on coping were more likely to report executing guideline recommended clinical behaviours even when faced with barriers (221). This result could be particularly important in relation to the results from the questionnaire regarding the situational violation of not completing a full accuracy check of medication, given the situational nature of the violation and given the significance of opportunity on the frequency of this violation. Therefore, providing pharmacy staff with coping strategies, perhaps in the form of training regarding implementation intentions (219) may help staff to work safely during periods of high pressure.
The results of Chapter 3 also suggest implications for pharmacy educators, as newly qualified pharmacists were found to be lacking in business and people management skills. As CP is a retail business, additional training in this area may help newly qualified pharmacists feel more prepared for practice and help to foster a positive working environment for branch teams. Furthermore, only one of the companies that took part provided their pharmacists with an extended induction. Policymakers may wish to consider the benefits of providing newly qualified pharmacists with the opportunity to align with their company’s safety philosophy, as teamwork, open communication, a shared vision and ownership have been identified as important for improving safety culture in pharmacies (242-245).

4. Improve communication between management and frontline staff

One implication for CP staff could be to utilise MaPSaF as a discussion tool in practice to help improve communication between head office and frontline staff. Chapter 3 utilised MaPSaF during the focus groups and one of the issues that was raised was that communication is typically top-down in CPs. The results of this research suggest that the procedures that are provided to staff do not typically reflect how staff work in practice. Pharmacy organisations may benefit from using participatory work design when considering SOPs to provide to their employees. The supermarket head office staff noted that they would regularly invite some of their pharmacists to comment on their procedures, and they found this practice to be extremely useful.

5. Educate pharmacy students regarding the realities of practice

The results of the qualitative interviews highlighted that newly qualified pharmacists often feel uncomfortable when going against procedures, even when doing so for patient benefit. Cresswell et al. (246) noted that pharmacy students had limited opportunities for linking education, practice and policy. One implication for educators may be to provide pharmacy students with real-life examples of procedural violations, taken from the interviews presented

208
in Chapters 4 and 5 in order to inform pharmacy students that they will encounter situations that require them to go against procedures to help with the transition to practice (247). During her PhD the researcher has already used some of the findings from her PhD to inform the curriculum at Manchester Pharmacy School and she provided a workshop to 2nd year MPharm students. The workshop provided real-life examples of violations to students and asked them to consider what they would do if presented with the same scenario in practice. 94% of 144 students agreed real-life examples helped prepare for practice, 85% agreed this was a useful exercise and 86% agreed exercise helped with professional development.

8.7.2 - Methodological implications
This thesis has presented a mixed methods investigation into procedural violations and their implications for patient safety in CPs. The use of focus groups, one-to-one interviews and a questionnaire allowed the researcher to triangulate her findings across three different studies. Each study provided a complementary and insightful perspective with regards to how and why violations occur in CPs. One of the main strengths to the methodology chosen for this thesis has been the sampling of both pharmacists and support staff throughout the project. The research was also strengthened by the recruitment of head office staff for the focus group study and from stakeholder engagement throughout the project. Previous research identified that safety literature tends to focus primarily on the views on pharmacists, however it was felt to be important to include as much of the pharmacy team as possible (65). Furthermore, Chapter 5 highlighted that the critical incident technique was an appropriate methodology for exploring violations as well as errors (28), as the use of this method allowed for a detailed account of how and why violations occur in CPs.

Overall, it is the opinion of the researcher that the stakeholder engagement has been a key strength to the research conducted as part of this PhD project. Substantial changes were made to the MaPSaF discussion tool and to the COM-B questionnaire based on their feedback. To the researcher’s knowledge, this thesis is the first instance of the COM-B questionnaire being
used to explore violations in healthcare. The significant results suggest that this was a useful theory for exploring the influencing factors on violations in CP. One methodological implication for researchers that may wish to utilise the COM-B questionnaire to further explore violations would be to include the impact of patient demand on pharmacy employee’s decision to violate procedures.

8.8 - Future research directions
This section will explore future research directions that could be explored based on the findings presented in this thesis. Firstly, the focus group study suggested that the prevailing safety culture within CPs is reactive for frontline staff and calculative for head office staff. MaPSaF was shown to be a useful discussion tool for exploring safety culture, and a future research study could explore how MaPSaF could aid positive safety culture change over time. A review of organisational culture research noted that there was a lack of longitudinal studies exploring culture (65). Therefore, a longitudinal study to explore how culture could be improved within CP could be novel and may provide valuable insights into positively changing culture.

The results of the survey study have shown that the COM-B model is a useful tool for understanding the influencing factors on violations in CPs. Future work may wish to further explore the influence of patient demand on violations as this was mentioned as an influence on violations, but its influence was not explored on a larger scale. This may be an interesting avenue to explore in the future. Furthermore, the questionnaire may be useful to explore violations in other areas such as other primary care settings including general practice.

Apart from providing detailed insights into prevailing safety culture in CPs, this research was limited to frontline staff within the dispensary team. Previous research observed that healthcare counter staff sometimes make violations when selling OTC medication (248), yet the opinions of counter staff with regards to their reasoning for making violations was not
explored as part of this research. As the social norm was found to be an influence on how procedures are followed in practice, exploring the opinions of the whole team could be a beneficial next step.

As habit was found to be a significant predictor for the optimising and situational violations, future research into the use of implementation intentions may be useful for helping pharmacy staff to prioritise patient promoting behaviours in practice. It should be noted that habit was also a significant predictor of exceptional violations, however given the exceptional nature of these violations it may be more beneficial to focus on situational and optimising violation in the first instance as they appear to occur more frequently. The results of Potthoff et al. (221) may have interesting connotations with regards to these potentially unsafe violations. Potthoff et al. note that their results are consistent with the literature on implementation intentions (i.e. specific ‘if-then’ plans) (219). Their paper suggests that healthcare professionals who form an action plan through a process of conscious deliberation create a mental link between a cue in the clinical context and a goal-directed behaviour. Once the cue is encountered in the environment, the healthcare professional may be more likely to perform the planned behaviour as an automatic response to that cue. Therefore, implementation intentions may be useful for encouraging safer practice in CP.

So far, a similar study exploring violations in hospital pharmacy is yet to be conducted. It would be interesting to interview hospital pharmacy staff regarding the types of violations that occur in this setting as well as the reasons why they happen. One potential difference between hospital and community may be workload, as hospital pharmacies have automated dispensing systems for example and work in larger multi-disciplinary teams; it would be interesting to explore any differences in violations and their implications for patient care.

8.9 - Reflexivity and reflection on the research
Reflexivity has been described by King (249, pg.20) as the
“recognition that the involvement of the researcher as an active participant in the research process shapes the nature of the process and the knowledge produced through it.”

As the researcher has an educational background in Psychology (BSc and MRes) and almost ten years of practical experience of working in CP as a dispenser, it is important to recognise and acknowledge that the research presented here will undoubtedly have been influenced by the beliefs, values and experiences of the researcher (250). Given the researcher’s experience of working in practice, it was important for the researcher to reflect on what she thought to be true based on her experience throughout the research process. According to Schein (43), it is possible that the researcher had underlying, taken for granted assumptions that determined her thoughts, perceptions and feelings.

With regards to study design, the researcher engaged stakeholders to provide feedback on the design of her studies to ensure that the materials and research processes would work in practice. This was felt to be important as the researcher has worked for the same large chain during her pharmacy career; therefore it was important to harness the views of individuals who had experiences from different pharmacy companies or pharmacy types to ensure that the research was relevant for staff from different pharmacies.

With regards to data collection, six months prior to carrying out the qualitative interviews, the researcher trained as a ChildLine counsellor and although this was not directly related to the researcher’s PhD the experience had a definite influence on how the one to one interviews were conducted. The training for becoming a call handler for ChildLine involved over 30 hours of intensive training. The experience as a whole provided the researcher with a certain amount of resilience in dealing with difficult and at times, distressing topics of conversation.
This was thought to be useful training as the topic of violations in practice can be a sensitive subject.

The researcher was trained on the importance of reflecting what the caller was feeling throughout a call by using phrases such as “it sounds like this has been happening for you – is that right?”, this was useful in the research interviews as it ensured that the researcher had correctly understood what the participant was trying to say, and it also gave the participant the opportunity to clarify or expand on their point. Furthermore, the researcher received training on showing empathy as opposed to sympathy (i.e. trying to see things from the perspective of the individual rather than showing pity or sorrow for the individual based on the researcher’s perceptions of what had happened). This was especially useful for the research topic of violations, as at times participants would discuss situations that could have put the patient at risk. As a dispenser herself, the researcher was aware of the risk that these actions could have in practice, however it was important to empathise with the participant and to not pass judgement on the participant. The ability to do this, led to the researcher building a rapport with her participant’s and oftentimes, participants would discuss the most “risky” violations at the end of the interview. This could suggest that the participant was attempting to gauge whether they could trust the researcher with this information. Finally, the training also allowed the researcher to become comfortable with silence in conversations and with relation to the interviews, this allowed the participant the chance to consider their thoughts before speaking and often the participant would further expand on their previous point.

In an effort to challenge her perceptions when analysing data, the researcher made sure to attempt to find contradictory results to the main themes, to try and provide a full picture of the data. Also, self-reflection was an important process throughout the research and the purposeful challenging of things that the researcher had perceived to be true. In an effort to ensure that a true reflection of the data was presented throughout this research, the researcher
made sure to have regular discussions regarding the results with her supervisors (Prof Darren Ashcroft, a pharmacist who has worked in both hospital and community pharmacies and Dr Denham Phipps, an Occupational Psychologist). These discussions were incredibly useful as the researcher was often encouraged to expand on her reasons for her interpretations of the data. Overall the researcher found that her practical knowledge of working in CP as a dispenser provided her with a useful insight into the challenges facing CP staff in practice.

8.10 - Final conclusions
This thesis has explored procedural violations in CPs. As a part of this research, the types of violations that occur in this setting along with the reasons for these violations have been presented. The results of this research highlight that CP staff are motivated to work safely and they will often bypass or deviate from procedures to ensure that patient safety is maintained. The results have also demonstrated that at times, staff will feel compelled to violate procedures in an effort to manage work demands, which can increase the risk to patient safety. This in-depth exploration of violations in CPs has implications for both pharmacy policymakers and educators, and recommendations have been made with regards to supporting pharmacy staff in their desire to behave in a way that promotes safer patient care in practice.
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Appendices

Appendix 1 - PPI comments on the MaPSaF study

MaPSaF presentation

- Pharmacists felt that there needed to be a standout statement regarding the aim of MaPSaF at the start of the presentation.

- In addition, it is worth explaining what a ‘framework’ is.

- Consensus that the presentation should be reframed in order to show pharmacy staff what they are expected to do with MaPSaF, and what does this mean for them.

- No harm to give theory behind the framework, but needs to be written in lay language and only a little bit of theory is needed.

- Noted that it is worth explaining what primary care means.

- Explain that for example when speaking about error reporting, that we encourage them to report everything that goes wrong, not just the errors that reach the patients.

- Stress why MaPSaF is important and how it will help the pharmacy.

- Be clear that it is not about blame culture, and that it is rather about moving away from blame culture – this was felt to be a good selling point of the framework.

- It was thought that the presentation should ideally last around ten minutes.

MaPSaF framework

- Pharmacists thought breaking down the framework into separate sheets for each category was very helpful and not as daunting as being presented with the whole framework at once.
• Noted that if the framework was broken down, that the sheets needed to be consistent with the framework e.g. consistent use of letters or numbering.

• Use of colour coding was thought to be useful, however the use of a neutral colour as opposed to the use of, for example, a traffic light system that may lead participants in their answers. Pharmacists thought using a scale of green might be useful.

**Rating**

• Pharmacists thought that the rating scale was easy to use; however, all agreed that the use of electronic clickers would be more useful and interesting for staff to use. They all felt that they would be particularly useful in ensuring anonymity.

• However, it was noted that clear instructions would be needed on how to use them and solutions to common mistakes such as if someone were to change their mind concerning their rating.

• Pharmacists also thought it might be useful to be able to code who was making the ratings e.g. could be interesting to monitor the rating of the pharmacist/manager, and also to see if job role/years of experience had an effect on ratings.

• All of the pharmacists thought that it was important for the participants to rate both the organisation and the team. It was felt that this would help avoid confusion.

• The instance of rating both team and organisation in independents was also discussed, where it may be difficult or impossible to separate team and organisation. It was thought that staff in this situation should still rate them both, and use the same rating e.g. pathological for both team and organisation. This would be to avoid discrepancies when analysing data.

• The group also thought it would be interesting to measure opinions regarding the influence of locums. (This may need a separate study!)

**General**
• With regards to the discussion that will be held by participants regarding their safety culture,
the pharmacists thought that in order to hear everyone’s opinions that it may be useful to have
everyone write their opinion on a post-it note anonymously. Another option might be to ask
participants to put their opinions in a brown bag and to discuss results as a group. (This would
be useful in making sure that all opinions are heard, as quiet or unexperienced staff may find it
difficult to comment)

• It was noted that staff may reflect on the session, and offering them the opportunity to email
us with their thoughts after the session would be useful (it was noted that being reflective is
desirable!).

• View was divided with regards to should the pharmacist/manager be present when asking the
staff to comment on the culture.

• The importance of gathering staff demographics was stressed.

• The words on the framework may need some explaining e.g. use the word pathological, but
explain what is meant by that.

• It was clear that all pharmacists felt strongly about stressing to participants that this is not a
performance management tool.

• Could be useful to help stores with GPHC inspections.
Appendix 2 - MaPSaF

A. Commitment to patient safety

1. A low priority is given to patient safety. The few risk management systems that are in place are there because they have to be and nothing is actually improved. This pharmacy believes that risks are worth taking and that if an adverse event occurs insurance schemes are there to bail them out.

2. Patient safety only becomes a priority once an incident occurs and the rest of the time only lip service is paid to the issue apart from meeting legal requirements. There is little evidence of any implementation of a risk management strategy. Patient safety is only considered by the manager/owner in relation to specific incidents. Any measures that are taken are aimed at self-protection and not patient protection.

3. Patient safety has a high priority and there are a number of procedures in place to protect it. However these systems are not widely circulated to staff or reviewed. The methods also tend to lack flexibility to respond to unforeseen events and fail to capture the complexity of the issues involved. Responsibility for managing risk is given to a single individual who does not communicate it to the wider pharmacy staff.

4. Patient safety is promoted throughout the pharmacy and staff are actively involved in all safety issues and processes. Patients, the public and other community pharmacies are also involved in reviewing risk. Measures taken to reduce risk are aimed at patient protection and not self-protection. Risks to patients are identified and action taken to manage them. There are clear accountability lines and while one individual takes the lead for patient safety in the pharmacy, it is a key role of all staff.

5. Patient safety is integral to the work of the pharmacy and its staff and is embedded in all activities. Responsibility is seen as being part of everyone’s
role. Staff are constantly assessing risks and looking for potential improvements. Patient safety is a high profile issue throughout the pharmacy.
B. Perceptions of the causes of incidents and their reporting

1. Incidents are seen as ‘bad luck’ and outside the control of pharmacy staff. Ad hoc reporting systems are in place but the pharmacy is largely in ‘blissful ignorance’ unless serious adverse events occur or they are visited by a pharmacy inspector. Incidents and complaints are ‘swept under the carpet’ if possible. There is a blame culture with individuals subjected to disciplinary action.

2. Staff in the pharmacy are seen as the cause and the solution is retraining and punitive action. There is a reporting system, although staff are not encouraged to report incidents. Minimum information on the incidents are collected but not analysed. There is a blame culture, so staff are reluctant to report incidents. When incidents occur there is no attempt to support any of those involved, including the patient and their relatives.

3. There is a recognition that systems contribute to incidents and not just individuals. The pharmacy says that it has a no blame culture but it is not perceived in that way by staff. An anonymous reporting system is in place with a lot of emphasis on form completion. Attempts are made to encourage staff to report incidents and near misses, but they do not feel comfortable doing so.

4. It is accepted that incidents occur due to individual and system faults. Reporting incidents is encouraged and they are seen as learning opportunities. Accessible, ‘staff friendly’ reporting methods are used, allowing trends to be readily examined. Staff feel comfortable reporting near misses. Staff and patients are supported from the moment that an incident is reported.

5. Failures are noted, although staff are aware of their own accountability in relation to errors. It is second nature for staff to report incidents as they have
confidence in the investigation process and understand the value of such reporting. Integrated systems enable incidents and complaints to be analysed together. Staff and patients are actively supported from the time of the incident.
C. Investigating incidents

1. Incidents are superficially investigated with the aim of ‘closing the book’ and ‘hiding any skeletons in the cupboard’. Information gathering from the investigation is stored but little action is taken apart from disciplinary action (‘public executions’) and attempts to handle the pharmacy inspector.

2. Investigations aim to limit the damage for the pharmacy and assign blame to individual(s). The investigation focus on a specific event and the actions of an individual. Quick fix solutions are proposed that deal with the specific incident but may not be carried out once the ‘heat is off’.

3. The investigation focuses on the individuals and systems surrounding the incident. There is a detailed procedure for the investigation process, which involves the completion of multiple forms. The investigation is conducted for its own sake rather than examining root causes. There is some desire to review procedures and/or change the way in which procedures are communicated to staff.

4. The pharmacy is open to inquiry and welcomes any outside involvement in investigations. The staff involved in an incident are also involved in its investigation, which examines the root causes. The aim of the investigation is to learn from incidents and communicate the findings widely. Information from the investigations is used to analyse trends, identify ‘hot spots’ and examine training implications.

5. The pharmacy conducts internal investigations that include the staff involved in incidents. Investigations are seen as learning opportunities and focus upon improvement rather than judgement. The investigation process itself is thoroughly reviewed by all staff. Fewer incidents are occurring as a result of learning from the past. It is a learning pharmacy.
D. Learning following an incident

1. This is not a learning organisation, as no attempts are made to learn from incidents unless imposed by the pharmacy inspectors. The aim of the pharmacy after an incident is to ‘paper over the cracks’ and protect itself. The pharmacy considers that it has been successful when the inspectors do not become aware of an incident. No changes are made after an incident apart from those directed at the individuals concerned.

2. Little if any learning occurs and what does take place only relates to the amount of irritation that the manager/owner has experienced. All learning is specific to the particular incident. Any changes made after an incident are not maintained, as they are knee jerk reactions to individual errors and are devised and imposed by the manager/owner. Consequently similar incidents tend to reoccur.

3. Some systems are in place to enable learning to take place but the lessons learnt are not communicated throughout the pharmacy. This learning results in some enforced local changes that relate directly to the specific incident. The manager/owner decides on the changes that need to be introduced and this lack of staff involvement leads to changes not being integrated into working patterns.

4. The pharmacy has a learning tradition and systems exist to share learning, such as reflection and audit. Members of staff are actively involved in deciding what changes are needed and there is a real commitment to change throughout the pharmacy. Hence changes are maintained. The pharmacy looks for learning opportunities and is keen to learn from others’ experiences. The learning that follows incidents is used in forward planning. It is an open, self-confident pharmacy.

5. The pharmacy learns and shares information about incidents with staff and other pharmacies. It is committed to sharing this learning both within the pharmacy and with other community pharmacies. Incidents are openly
discussed where all staff feel able to contribute. Incidents are seen as a learning opportunity, they are inevitable but learning can occur to reduce their likelihood of occurrence. Learning within the pharmacy is evaluated. Improvements in practice occur without a trigger of an incident, as the culture is one of constant improvement.
E. Communication

1. Communication is poor. What communication there is comes directly from the manager/owner, with no mechanism for staff to speak to their manager/owner themselves about risk. Incidents are not talked about. The pharmacy is essentially closed, not open to new ideas. What communication there is, is negative, with a focus upon blame.

2. Communication about risk from staff to the manager/owner is possible but only after something has gone wrong. Communication is ad hoc and restricted to those involved in a specific incident. Communication is very directive, with the manager/owner issuing instructions. This is a ‘telling-off’ pharmacy.

3. There is a communication strategy though it is not directly linked to the management of risk within the pharmacy. Procedures and ways of dealing with risk and incidents are in place, and lots of records are kept. This leads to information overload in which little is actually done with the information recorded by staff and received by managers. A method to communicate risk issues is in place, but no one checks whether it is working.

4. The method of communication and record keeping are both fully audited. There is communication between pharmacies which helps to identify and reduce risk. All levels of staff are involved. Information about safety issues is shared; there are regular risk management discussions where members of staff are encouraged to set the agenda.

5. All staff are involved in communication about safety issues. The manager/owner realises that they can learn a lot from their staff. They expect everyone to know about and learn from each other’s experiences as it happens. Novel ideas are encouraged. Mechanisms for communication are well established within the pharmacy. This is a ‘praising’ pharmacy.
F. Staff management and safety issues

1. Members of staff are seen just as bodies to fill posts. There is no structured staff development program and the recruitment of staff is ad hoc. Staff feel unsupported, and there is a clear hierarchy of roles. The management of staff takes on a punitive role following an incident; the language is negative and poor health and attendance records are seen as disciplinary matters.

2. Job descriptions and staffing levels change only in response to problems, so there are good selection and retention policies in areas that have been vulnerable in the past. The recruitment of staff has been developed in response to incidents that have already been experienced.

3. Recruitment and retention procedures for staff are in place, which are separate from risk management procedures. References are always checked for new staff. Procedures on appraisal, incident investigation and staff development are there but are not rigidly applied and so do not always achieve what they were designed for. These procedures are seen as a tool for the manager/owner to control staff.

4. There is some commitment to matching individuals to posts. There are also visible, flexible support systems, tailored to the needs of the individual. There is a review of staffing levels in light of changes in risk management policy; and changes are made when necessary. There are attempts to understand why incidents occur and to ‘nip problems in the bud’. There is genuine concern about staff health and good systems of appraisal, monitoring and review.

5. The pharmacy is committed to its staff, and everyone has confidence in the management structure. The management of staff is not a separate entity but an integral part of the pharmacy. Reflection and review about safety issues (risk) occur continuously and automatically, rather than periodically.
G. Staff education and training about risk management

1. Training has low priority. It is seen by the manager/owner as irritating, time consuming and costly. There are consequently no checks made on the quality or relevance of any risk management training given. Staff are seen as already trained to do their job, so why would they need more training?

2. Training occurs where there have been specific problems and relates almost entirely to high-risk areas where obvious gaps are filled. Information about risk management is given to new staff in an introductory pack. It is the responsibility of the individual to read and act upon this. Education and training focus on maximising income and covering the pharmacy’s back.

3. The training program reflects the pharmacy’s needs and is supported only if it benefits the pharmacy. Basic personal development plans are in place so everyone has their own file. However, these are not very effective as they are not properly returned or given priority. Training about safety issues is seen as the way to prevent mistakes.

4. There is an attempt to identify the training needs of the pharmacy and the training needs of individuals about safety issues, and to match them up. Such training is well planned, well resourced and continually updated. Education is seen as integral to individual professional and personal development and is linked directly to other safety systems, like incident reporting.

5. The approach to risk management training and education is flexible and seen as a way of supporting staff in fulfilling their potential. Individuals are motivated to negotiate their own training program. Education about safety issues is integral to the pharmacy culture. Learning is a daily occurrence.
H. Team working

1. Individuals mainly work in isolation but where there is a team they are ineffective in terms of risk management. There are tensions between the team members and a hierarchy within the pharmacy. They are more like a group of people brought together under the direction of a leader.

2. There is a team but they have been told to work together, and only pay lip service to team working. People only work as a team following an adverse event. There is a clear hierarchy within the pharmacy. The team does work together, but individuals are not actually committed to the team.

3. A team is put together to respond to new initiatives but there is no way of measuring how effective they are. Working as a team is seen by lower grades of staff as paying lip service to the idea of empowerment. There is little sharing of ideas or information about safety issues across the team.

4. There is a flexible team structure with people taking up the role most appropriate for them at the time. Teams are collaborative and adaptable and actively contribute to the risk management agenda within the pharmacy. There is evaluation of how effective the team is and changes are made when necessary. Teams may involve people who do not routinely work in the pharmacy.

5. Membership to the team is flexible, with different people making contributions when appropriate. The team is about shared understanding and vision about safety issues, rather than groups of people. This way of working is just the accepted way in the pharmacy. Everyone is equally valued and feels free to contribute. ‘Everybody is part of the risk management team.’
Appendix 3 - MaPSaF patient information leaflet

Using quality improvement methods in community pharmacies

Participant Information Sheet

You are being invited to take part in a research study at the University of Manchester; the aim of the research is to assess the use of quality improvement methods in community pharmacy. This research will be undertaken as part of a PhD degree. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

Who will conduct the research?
The research will be conducted by Miss Christian Thomas, Dr Denham Phipps, Professor Darren Ashcroft and Professor Dianne Parker, who are based at the Manchester Pharmacy School, University of Manchester.

Title of Research: Using quality improvement methods in community pharmacies.

What is the aim of the research?
This study aims to assess the use of the quality improvement method MaPSAF (Manchester Patient Safety Assessment Framework) for use in community pharmacies.

Why have I been chosen?
You have been chosen because of your role as a member of staff within a community pharmacy. Everybody in your pharmacy team will be invited to take part. We are hoping to work with a range of community pharmacies, including large and small pharmacy chains and independent pharmacies.

What would I be asked to do if I took part?
We have four activities that we would like you to take part in:
- The first activity is a workshop, in which you and your colleagues will be introduced to MaPSAF and take part in a facilitated discussion about quality issues in your pharmacy. You and your colleagues will be asked to think of ways in which quality can be improved in your pharmacy;
- The second activity is a self-directed development exercise, in which you and your colleagues carry out the actions that were agreed during the first workshop to address the quality issues in your pharmacy. This will be carried out over a six month period, as and when you have time to work on it. During this time, we will visit you on a monthly basis to observe you working on your development actions and discuss your progress;
- To remind you and your colleagues of the principles of a MaPSAF a further discussion group will be conducted 3 months after the initial MaPSAF workshop.
- Lastly, follow up focus groups will be held after 6, 9 and 12 months in order to assess how you and your colleagues have found applying MaPSAF in your pharmacy.

Both MaPSAF workshops and the three focus groups will be audio recorded. Notes will be taken by the researcher during the monthly visits for the six months duration. Our notes are about your pharmacy’s progress in implementing MapSAF only; we are not evaluating the overall performance of the pharmacy or of individual staff members.
What happens to the data collected?
All data collected will be anonymised, and consent forms will be stored separately and in a locked filing cabinet at the university and on password protected university computers.

How is confidentiality maintained?
Data collected via audio recording and note taking will be anonymised and any identifiable information will be removed. Direct quotes may be used when reporting the results of the study; however these will also be anonymised. Consent forms will be kept in a locked file accessible only to the study team.
Any discussions that take place during the study are confidential. However, if you were to tell us something new that could put someone at risk of harm, or reveal unsafe practice, we may have to report this information to a clinical supervisor. If so, we would discuss this with you and tell you what we intend to do.

What happens if I do not want to take part or if I change my mind?
You do not have to take part in the study. If you decide to take part and then later change your mind, either before you start the study or during it, you can withdraw without giving a reason and if you wish your data will be destroyed. However, once data has been written up and anonymised, it will not be possible to identify or delete specific participant data. This study is being conducted independently of your employer, and so your decision whether or not to take part will not have an effect on your employment status.

Will I be paid for participating in the research?
We will reimburse out-of-pocket expenses incurred as a result of taking part in our study e.g. travel to work on a day that you would not normally be working. You will be paid at a rate of £20 an hour in gift vouchers for your participation in workshops and focus groups that take place outside of your normal working hours.

What is the duration of the research?
The two MaPSAF workshops are expected to last up to 2 hours each. The focus groups held after 6, 9 and 12 months are also expected to last up to 2 hours each. The monthly visits will consist of the researcher visiting the pharmacy for up to one day a month for 6 months.

Where will the research be conducted?
Each part of the study will be conducted in your pharmacy.

Will the outcomes of the research be published?
Once the study is complete we aim to publish our findings in a peer-reviewed academic journal. No participant will be identified in any publication.

Who has reviewed the study?
This project has been reviewed by the University of Manchester Research Ethics Committee.

Contact for further information
If you wish to find out more about this study please contact Miss Christian Thomas (christian.thomas@manchester.ac.uk / 0161 2758363) or Dr Denham Phipps (denham.phipps@manchester.ac.uk).

What if something goes wrong?

245
If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to ‘The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester M13 9PL’, by emailing: Research.Complaints@manchester.ac.uk, or by telephoning 0161 275 7583 or 275 8093.
Appendix 4 - Interview topic guide

1. Please describe what your role is in community pharmacy.

2. What kind of policies and procedures do you have to follow in community pharmacy?

3. How are you made aware of the policies and procedures that you need to follow in your work?

4. How useful are policies and procedures for helping you to do your job?

5. How do you feel policies and procedures benefit you in your work?

6. Do you feel able to follow the policies and procedures?

7. What is your opinion of the policies and procedures that you are expected to follow during your work?

8. I’m wondering if there are tasks that you feel you must prioritise during your working day (What are they?).

9. Do you find that there are certain times of day, week or year where policies and procedures are typically deviated from or bypassed?

Participants will then be asked if they have been able to think of specific instances where they have deviated from a policy or procedure in the past and these examples will each be expanded on using the questions below (repeat structure for multiple incidents):

a) The general circumstances leading up to the particular behaviour;
b) Exactly what they did to deviate from the procedure;

c) When did this happen?

d) Why was this behaviour committed at this time?

e) What alternatives were available at that point?

f) Would they do anything differently?

g) Were there any benefits or problems associated with deviating from that particular rule?

Participants will then be asked if they have any other general comments that they wish to add relating to the subject of deviating from policies or procedures in community pharmacy. Finally, participants will be asked to complete a small questionnaire consisting of 2 questions in order to understand if there is any information that they may not have felt comfortable to share with the researcher.
Appendix 5 - Patient information leaflet for the interview study

Participant Information Sheet

How are policies and procedures bypassed or deviated from in community pharmacy?

Introduction

You are being invited to take part in a research study. This research will be undertaken as part of a PhD. Before you decide it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and to discuss it with others if you wish. The information provided below will hopefully give you a good understanding of what the research is about and how you might be able to help. However if there are any other questions or clarifications, please do not hesitate to contact me on the telephone number or email address given below. Please take time to decide whether or not you wish to take part.

What is the study about?

There is a perception that rules are not always followed in community pharmacy, however there is evidence that deviating from the rules does not always result in negative consequences. The aim of this study is to explore how the rules that govern how you undertake your work, such as standard operating procedures are used in community pharmacy and the reasons that pharmacy staff may not be able to follow the rules at all times. This research is funded by the National Institute of Health Research, there are no commercial interests.

Why have I been chosen?

You have been chosen because of your role as a member of staff within a community pharmacy in the UK. You have some sort of experience of working within a community pharmacy and you might also be expected to have had experience of being unable or unwilling to follow the rules at times.

Will I be paid for participating in the research?

You will be paid £20 in gift vouchers for taking part in this research. Reimbursement of travel expenses will also be provided.

What would I be asked to do if I took part?
You will be asked to attend a one-to-one interview at a time and place convenient to you. It will be an informal chat about the use of rules in community pharmacy and how factors such as lack of time or staff may have led to you deviating from the rules. The interview is not to judge the quality of your work, but to give you an opportunity to talk through some of the rules you may have deviated from in the past.

Before the interview, you will be asked to consider the role that you do and to make a note of any rules that you may have deviated from. This experience will be the basis of the interview and you will also be asked some general questions about how rules are used in community pharmacy. We are particularly interested in the nature of the rule that was deviated from, the situation in which this happened and your reasons for doing so. The whole process will take approximately 30-60 minutes. The interview will be tape recorded with your permission, if you object the researcher will take notes instead. The tape recorder can be turned off at any point during the interview.

Do I have to take part?

No, participation in this study is entirely voluntary. You are free to withdraw from the study at any point, without giving a reason. This study is being conducted independently of your employer. Your participation in the research will not be disclosed to anyone.

Confidentiality

Any discussions that take place during the study are confidential. However, if you were to tell us something that had led to patient harm, we would discuss this with you and encourage you to report it through your company's established incident reporting systems. If you were to reveal unsafe practice such as working under the influence of drink or drugs or dishonest practice such as theft we may need to report to the GPhC after discussing this with you first. All data collected will be anonymised, and stored on password protected university computers. Consent forms will be stored separately in a locked filing cabinet at the university. Data collected via tape recording and note taking will be anonymised and any identifiable information will be removed. Direct quotes may be used when reporting the results of the study; however these will also be anonymised.

What will happen to the results of the study?

Once the study is complete we aim to publish our findings in a peer-reviewed academic journal and the results will be used as part of a PhD thesis. The data may also be used to inform future work. No participant will be identified in any publication.

Who has reviewed the study?
This project has been reviewed by the University of Manchester Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

**Contact for further information**

If you wish to find out more about this study or have any questions please contact Miss Christian Thomas by emailing christian.thomas@manchester.ac.uk or by telephoning 0161 2758363 or contact Dr Denham Phipps by emailing Denham.phipps@manchester.ac.uk.

**What if something goes wrong?**

If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact the Research Governance and Integrity Team by either writing to ‘The Research Governance and Integrity Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester M13 9PL’, by emailing: Research.Complaints@manchester.ac.uk, or by telephoning 0161 275 7583 or 275 8093.
Appendix 6 - COM-B questionnaire

Understanding influences on how procedures are followed in community pharmacies

A questionnaire for community pharmacists and pharmacy support staff

IMPORTANT – PLEASE READ

This is a survey of community pharmacy staff. We are interested in your views about what factors within the workplace influence how you follow procedures in practice. The findings will be important to both community pharmacy staff and policy makers in helping to provide support for staff in practice.

We are asking over 4000 community pharmacy employees in England to complete this questionnaire. It will take only 15 to 20 minutes to complete.

Everything you say in this questionnaire will remain strictly confidential.

There is an ID number on the questionnaire – this is simply there so that we know who has replied and do not send out reminders unnecessarily – it will not be used to link individuals or organisations to responses which will be stored anonymously.

After your responses have been entered onto a computer database, the questionnaire will be securely stored in accordance with data protection regulations and destroyed after five years.

It will not be shared with any third party and no single pharmacy or pharmacy chain will be identified in any report arising from this research study. The results of the questionnaire may help to inform future research studies.

Please return this questionnaire to:

Ms Christian Thomas

Room 1.132, The University of Manchester, Manchester Pharmacy School, Stopford Building, 1st floor, Oxford road, Manchester M13 9PT.

Supported by
CONSENT INFORMATION

Returning this questionnaire to the researcher tells us that you are happy to take part in this study. In order to re-affirm that you are happy to take part please tick below

I consent to taking part in this study (please tick)

BACKGROUN INFORMATION

1. What is your age? (you must be 16 years old or over to take part in this study)

2. What is your gender? (please tick ONE box only)

   Male
   Female

3. Your job title. Which of the following best describes your main role? (please tick ONE box only)

   - Pharmacy owner
   - Pharmacy manager (pharmacist)
   - Regular employee pharmacist (non-manager)
   - Locum pharmacist
   - Relief pharmacist
   - Second pharmacist
   - Registered Accuracy Checking Technician
   - Registered Pharmacy Technician
   - Accuracy Checking Dispenser
   - Dispenser
   - Trainee Dispenser
   - Other, please state

4. What year did you qualify for your current role?
5. What year did you start working in community pharmacy? (Include time you may have spent in other roles such as a trainee or in other roles)

6. **Type of pharmacy.** Which of the following categories describes the pharmacy you mainly work for? (*please tick ONE box only*)

- Independent (less than 6 stores)
- Small chain (6-25 stores)
- Medium chain (26-200 stores)
- Large Multiple (over 200 stores)
- Supermarket

7. **Geographical location.** What type of area do you work typically in? (*please tick ONE box only*)

- City Centre
- Large town
- Small town
- Suburb (outskirts of a city)
- Village
- Rural area
This questionnaire is not to judge the way you work, it is to understand what factors might influence you to behave in this way. We appreciate that some of the statements might look strange, but it is just because we need to include anything that might possibly apply for some people.

**SCENARIO ONE**

Past research has shown us that at times community pharmacy staff will sometimes sell over the counter medication that is licensed for short term use to the same customer on a regular basis.

**Selling an over the counter medication that is licensed for short term use to the same customer on a regular basis depends on…**

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SCENARIO TWO

Past research has shown us that at times, community pharmacy staff will not conduct a full accuracy check of medication against a prescription. For example, staff might not always check every detail of the medication such as whether the formulation of the medication matches the one prescribed on the prescription. (If the final accuracy check is not a part of your role, please think about what might influence you to double check / self-check your work before the medication is given a final accuracy check by a suitably trained member of staff.)

Not completing a full accuracy check of a medication against a prescription would depend on...

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SCENARIO THREE

Past research has shown us that at times, community pharmacy staff will supply medication from an unsigned prescription. Pharmacy support staff should consider what factors would influence their decision to *dispense* medication from an unsigned prescription.

**Supplying or dispensing medication from an unsigned prescription would depend on…**

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SCENARIO FOUR

Past research has shown us that at times, community pharmacy staff will supply out of date medication in situations such as a patient receiving end of life care or if the medication was only two weeks out of date. Pharmacy support staff should consider what factors would influence their decision to knowingly dispense out of date medication.

**Supplying or dispensing out of date medication, would depend on…**

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Do you have any other comments about factors within your workplace that influence how you follow procedures? Please also include any general comments you may have about completing this questionnaire.

Thank you very much for completing this questionnaire.

Please return this questionnaire to:

Ms Christian Thomas

Room 1.132, The University of Manchester, Manchester Pharmacy School, Stopford Building, 1st floor, Oxford road, Manchester M13 9PT.

In the unlikely event that completing this questionnaire raises any concerns, you may wish to contact Pharmacist Support or Listening Friends (a confidential helpline for people seeking to talk about their issues and concerns) on 0808 168 5133.
Appendix 7 - COM-B-Q questionnaire

This questionnaire is taken directly from the book by Michie et al (192) to illustrate the suggested format for using COM-B through a questionnaire.

**COM-B-Qv1**

When it comes to you personally [doing or not doing x; e.g. stopping smoking], what do you think it would take for you to do it? (Circle any of the items on the list that you think apply; you can circle as many or as few as you think appropriate. Some of the items may looks strange, but that is just because we need to include anything that might possible apply for some people.)

In each case please would you say why you think it might be important for you.

I would have to…

**Capability**

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<td>2.</td>
<td>Know more about how to do it</td>
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<td>3.</td>
<td>Have better physical skills</td>
<td>e.g. learn how to operate machinery more effectively in one’s job</td>
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<tr>
<td>5.</td>
<td>Have physical strength</td>
<td>e.g. build up muscles for demanding physical work</td>
</tr>
<tr>
<td>6.</td>
<td>Have more mental strength</td>
<td>e.g. develop stronger resilience against cravings</td>
</tr>
<tr>
<td>7.</td>
<td>Overcome physical limitations</td>
<td>e.g. get around problems of stature or disability</td>
</tr>
<tr>
<td>8.</td>
<td>Overcome mental obstacles</td>
<td>e.g. reduce unwanted urges or feelings</td>
</tr>
<tr>
<td>9.</td>
<td>Have more physical stamina</td>
<td>e.g. develop greater capacity to maintain physical effort</td>
</tr>
<tr>
<td>10.</td>
<td>Have more mental stamina</td>
<td>e.g. develop greater capacity to maintain mental effort</td>
</tr>
</tbody>
</table>

**Opportunity**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>Have more time to do it</td>
<td>e.g. create dedicated time during the day</td>
</tr>
<tr>
<td>12.</td>
<td>Have more money</td>
<td>e.g. be given or earn funds to support the behaviour</td>
</tr>
<tr>
<td>13.</td>
<td>Have the necessary materials</td>
<td>e.g. acquire better tools for the job</td>
</tr>
<tr>
<td>14.</td>
<td>Have it more easily accessible</td>
<td>e.g. provide easier access to facilities</td>
</tr>
<tr>
<td>15.</td>
<td>Have more people around them doing it</td>
<td>e.g. be part of a ‘crowd’ who are doing it</td>
</tr>
<tr>
<td>16.</td>
<td>Have more triggers to prompt them</td>
<td>e.g. have more reminders at strategic times</td>
</tr>
<tr>
<td>17.</td>
<td>Have more support from others</td>
<td>e.g. have one’s family or friends behind one</td>
</tr>
</tbody>
</table>
**Motivation**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>18.</td>
<td>Feel that they want to do it enough</td>
<td>e.g. feel more of a sense of pleasure or satisfaction from doing it</td>
</tr>
<tr>
<td>19.</td>
<td>Feel that they need to do it enough</td>
<td>e.g. care more about the negative consequences of not doing it</td>
</tr>
<tr>
<td>20.</td>
<td>Believe that it would be a good thing to do</td>
<td>e.g. have a stronger sense that one should do it</td>
</tr>
<tr>
<td>21.</td>
<td>Develop better plans for doing it</td>
<td>Have clearer and better plans for achieving it</td>
</tr>
<tr>
<td>22.</td>
<td>Develop a habit of doing it</td>
<td>e.g. get into a pattern of doing it without having to think</td>
</tr>
<tr>
<td>23.</td>
<td>Something else (please specify)</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix 8 - Stakeholder feedback for the COM-B questionnaire

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Risk to patient safety 0-5</th>
<th>Likelihood of changing the behaviour 0-5</th>
<th>Total 0-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working in the pharmacy alone out of hours to catch up on work.</td>
<td>2.25</td>
<td>3.08</td>
<td>5.33</td>
</tr>
<tr>
<td>Not following every step in the accuracy checking procedure when checking medication.</td>
<td>4.58</td>
<td>3</td>
<td>7.58</td>
</tr>
<tr>
<td>Keeping personal belongings such as your bag or purse/wallet in the dispensary outside of a locker.</td>
<td>1.92</td>
<td>2.67</td>
<td>4.59</td>
</tr>
<tr>
<td>Loaning medication to a regular patient i.e. providing medication without possessing a prescription and without providing an emergency supply</td>
<td>3.42</td>
<td>3.25</td>
<td>6.67</td>
</tr>
<tr>
<td>Supplying medication in a packaging that is not child-resistant.</td>
<td>3.83</td>
<td>3.33</td>
<td>7.16</td>
</tr>
<tr>
<td>Choosing stock to dispense using the label you have created rather than using the original prescription.</td>
<td>4.36</td>
<td>3.45</td>
<td>7.81</td>
</tr>
<tr>
<td>Not accurately measuring the required amount of water to reconstitute antibiotic medication.</td>
<td>3.36</td>
<td>2.91</td>
<td>6.27</td>
</tr>
<tr>
<td>Not providing patients with detailed safety advice on over the counter medications due to time restrictions.</td>
<td>4</td>
<td>2.45</td>
<td>6.45</td>
</tr>
<tr>
<td>Amending the directions for medications at a patient's request e.g. labelling a medication as take 1 ON instead of 1 OM (as prescribed) due to the patient preferring to take this medicine at night.</td>
<td>3.45</td>
<td>3.27</td>
<td>6.72</td>
</tr>
<tr>
<td>Allowing a non-pharmacist member of the dispensary team to sign to receive a delivery of controlled drugs.</td>
<td>2.55</td>
<td>3.36</td>
<td>5.91</td>
</tr>
<tr>
<td>Handing out medication from a post-dated prescription earlier than instructed.</td>
<td>4.18</td>
<td>4.09</td>
<td>8.27</td>
</tr>
<tr>
<td>Selling over the counter medication outside of product license e.g. selling Ametop gel for use when getting a tattoo.</td>
<td>3.18</td>
<td>2.45</td>
<td>5.63</td>
</tr>
<tr>
<td>Allowing hot drinks and food to be consumed in the dispensary.</td>
<td>1.73</td>
<td>1.45</td>
<td>3.18</td>
</tr>
<tr>
<td></td>
<td>Score 1</td>
<td>Score 2</td>
<td>Score 3</td>
</tr>
<tr>
<td>------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>Supplying an original pack of 28 tablets to patients that have been prescribed 30 tablets to save time.</td>
<td>2.36</td>
<td>2.45</td>
<td>4.81</td>
</tr>
<tr>
<td>Supplying medication from an unsigned prescription at the request of the GP surgery.</td>
<td>2.45</td>
<td>2.27</td>
<td>4.72</td>
</tr>
<tr>
<td>Supplying controlled drugs on a date different to the date noted on the instalment prescription. You have checked with the prescriber and the date on the prescription is incorrect due to a clerical issue. You do not yet possess the amended prescription.</td>
<td>2.82</td>
<td>3.09</td>
<td>5.91</td>
</tr>
<tr>
<td>Deciding not to report a handout error involving a controlled drug because the patient wasn't harmed and you don't have time to complete the paperwork involved.</td>
<td>3.91</td>
<td>3.27</td>
<td>7.18</td>
</tr>
<tr>
<td>Regularly selling over the counter medicines to the same patient that should be taken only on a short term basis.</td>
<td>4.36</td>
<td>2.37</td>
<td>6.73</td>
</tr>
<tr>
<td>Noticing when counting prescriptions at the end of the day that a prescription has not been signed by the prescriber, and deciding to sign it yourself and put it through to be sent back to the NHSBSA.</td>
<td>3.82</td>
<td>4.09</td>
<td>7.91</td>
</tr>
<tr>
<td>Supplying unchecked medication to a patient as the script cannot be located when the patient comes to collect, but you recall seeing the script and are confident that the medication you hand out matches the prescription.</td>
<td>4.27</td>
<td>3.64</td>
<td>7.91</td>
</tr>
<tr>
<td>Supplying a controlled drug that is three weeks out of date for a patient receiving end of life care.</td>
<td>4.09</td>
<td>3.82</td>
<td>7.91</td>
</tr>
<tr>
<td>Supplying controlled drugs to a patient on end of life care from a prescription that does not meet legal requirements e.g. only figure supplied instead of the required words and figures.</td>
<td>2</td>
<td>2.55</td>
<td>4.55</td>
</tr>
<tr>
<td>Supplying a second daily dose of methadone after the patient smashed their original dose on the floor. You do not yet have a valid prescription covering the second dose supplied.</td>
<td>3.36</td>
<td>3.82</td>
<td>7.18</td>
</tr>
</tbody>
</table>

Pharmacists’ stakeholder engagement feedback
<table>
<thead>
<tr>
<th>Scenario</th>
<th>Risk to patient safety 0-5</th>
<th>Likelihood of changing the behaviour 0-5</th>
<th>Total 0-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not following every step in the accuracy checking procedure when checking medication. (If you are not responsible for the final accuracy check, please answer based on yourself check)</td>
<td>4.56</td>
<td>3.89</td>
<td>8.45</td>
</tr>
<tr>
<td>Keeping personal belongings such as your bag or purse/wallet in the dispensary outside of a locker.</td>
<td>2.22</td>
<td>2.89</td>
<td>5.11</td>
</tr>
<tr>
<td>Supplying medication in a packaging that is not child-resistant.</td>
<td>3.44</td>
<td>3.33</td>
<td>6.77</td>
</tr>
<tr>
<td>Choosing stock to dispense using the label you have created rather than using the original prescription.</td>
<td>3.33</td>
<td>2.78</td>
<td>6.11</td>
</tr>
<tr>
<td>Not accurately measuring the required amount of water to reconstitute antibiotic medication.</td>
<td>3.56</td>
<td>2.89</td>
<td>6.45</td>
</tr>
<tr>
<td>Not providing patients with detailed safety advice on over the counter medications due to time restrictions.</td>
<td>3.44</td>
<td>3.11</td>
<td>6.55</td>
</tr>
<tr>
<td>Amending the directions for medications at a patient's request e.g. labelling a medication as take 1 ON instead of 1 OM (as prescribed) due to the patient preferring to take this medicine at night.</td>
<td>3.89</td>
<td>3.56</td>
<td>7.45</td>
</tr>
<tr>
<td>Activity</td>
<td>Score 1</td>
<td>Score 2</td>
<td>Score 3</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>---------</td>
<td>---------</td>
<td>---------</td>
</tr>
<tr>
<td>Signing to receive a delivery of controlled drugs as a non-pharmacist member of staff.</td>
<td>2.44</td>
<td>3.33</td>
<td>5.77</td>
</tr>
<tr>
<td>Handing out medication from a post-dated prescription earlier than instructed.</td>
<td>3.44</td>
<td>3.33</td>
<td>7.77</td>
</tr>
<tr>
<td>Selling over the counter medication outside of product license e.g. selling Ametop gel for use when getting a tattoo</td>
<td>3.22</td>
<td>2.89</td>
<td>6.11</td>
</tr>
<tr>
<td>Allowing hot drinks and food to be consumed in the dispensary.</td>
<td>2.33</td>
<td>2.67</td>
<td>5</td>
</tr>
<tr>
<td>Deciding not to report a handout error involving a controlled drug because the patient wasn't harmed and you don't have time to complete the paperwork involved.</td>
<td>3.56</td>
<td>3.33</td>
<td>6.89</td>
</tr>
<tr>
<td>Regularly selling over the counter medicines to the same patient that should be taken only on a short term basis.</td>
<td>3.89</td>
<td>3.44</td>
<td>7.33</td>
</tr>
<tr>
<td>Noticing when counting prescriptions at the end of the day that a prescription has not been signed by the prescriber, and deciding to sign it yourself and put it through to be sent back to the NHSBSA.</td>
<td>3.56</td>
<td>3.56</td>
<td>7.12</td>
</tr>
<tr>
<td>Not providing a patient with an owing slip when their medication is not in</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Stock.</td>
<td>Not regularly date checking medication due to high workload and a lack of time.</td>
<td>3.67</td>
<td>3</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Support staff stakeholder engagement</td>
<td>Allowing POM medication to leave the pharmacy without a pharmacist present.</td>
<td>2.89</td>
<td>3</td>
</tr>
</tbody>
</table>
Dear Pharmacy Staff,

You are invited to participate in a research study that is seeking to understand influences on **how procedures are followed in community pharmacies**. This work is not to judge the way you work, but to further understand how procedures are used in community pharmacies.

If you choose to participate you will be asked to complete a questionnaire which will take no more than 15-20 minutes to complete. **Your participation in this research will be kept completely confidential and will not be linked to you personally or to the pharmacy you work at.** There is an ID number on the questionnaire but this is simply there so that we know who has replied and do not send out reminders unnecessarily – it will not be used to link individuals or organisations to responses which will be stored anonymously. Your answers will be used to help inform future studies. For further details please see the attached participant information leaflet.

This research is **not** being conducted by the GPhC or by your employer; it is sponsored by the National Institute of Health Research. There are two copies of the questionnaire included, **one for a pharmacist and one for a member of dispensary support staff to complete if possible.** Any member of the dispensary team is invited to take part. If more than two members of staff wish to take part, please contact me on the email address stated below, and additional copies can be sent out to you. Unfortunately, this survey is not open to healthcare counter assistants as we are investigating dispensary specific procedures at present.

If you are interested in taking part in the study or have any questions regarding taking part please email christian.thomas@manchester.ac.uk or denham.phipps@manchester.ac.uk for more information. If you agree to take part, we ask that you complete the questionnaire booklet and send it back to us in the freepost envelopes provided.

Kind regards and many thanks,

Ms Christian Thomas

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Appendix 9 - COM-B invitation letter
Appendix 10 - COM-B information sheet

Understanding influences on how procedures are followed in community pharmacies

Participant Information Sheet

You are being invited to take part in a research study that is exploring influences on how procedures are followed in community pharmacies. The study is part of a PhD project at The University of Manchester. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

Who will conduct the research?

The research is being conducted by Ms Christian Thomas and her supervisors, Professor Darren Ashcroft and Dr Denham Phipps. They are based at Manchester Pharmacy School at The University of Manchester.

What is the purpose of the research?

Research has shown that community pharmacy employees sometimes bypass or deviate from procedures. This can be for many reasons, such as patient need or high workload. The purpose of this study is to examine what influences community pharmacy employees’ to bypass or deviate from procedures.

The study is funded by the National Institute of Health Research. It is not connected with the General Pharmaceutical Council or with your employers.

Why have I been chosen?

You have been invited to take part as you currently work in community pharmacy in the North of England.

What would I be asked to do if I took part?

If you decide to take part you will be asked to complete a questionnaire. As part of the questionnaire you will be asked to consider four examples of where procedures have not been followed. These examples have been provided by staff working in community pharmacy during a previous research study. You will be asked to rate how different factors might influence you to not follow these procedures at work. You will also be asked how often you bypass or deviate from this procedure in your work. All data provided will be kept strictly confidential.

How will the data be used?

Once the study is complete, the data will be analysed to identify which factors cause pharmacy staff to bypass or deviate from procedures. It is hoped that the results of this study will help us to develop resources to help staff to provide safe patient care. The data will be stored for use in informing future studies.

How is confidentiality maintained?
All data collected will be stored in locked filing cabinets and on password protected university computers. Each questionnaire will include an ID number – this is simply so that we know who has replied and do not send out reminders unnecessarily – it will not be used to link individuals or organisations to responses. The anonymised data will be used to inform future research projects.

What happens if I do not want to take part or if I change my mind?

There is no obligation for you to take part in this study. However, if you do decide to return the questionnaire you cannot then withdraw it from the study as we will not be able to identify your data once it has been entered into our database. In the unlikely event that completing this questionnaire raises any concerns, you may wish to contact Pharmacist Support or Listening Friends (a confidential helpline for people seeking to talk about their issues and concerns) on 0808 168 5133.

Will I be paid for participating in the research?

You will not be paid for participating in this research. There are no direct benefits to taking part, but your participation may help in gaining more understanding about how procedures are followed in pharmacy.

What is the duration of the research?

The questionnaire will take around 15-20 minutes to complete.

Will the outcomes of the research be published?

Once the study is complete, we aim to publish our findings in a peer-reviewed academic journal and the results will also be used as part of a PhD thesis. As all data collected is anonymous, participants will not be identifiable in any way.

Who has reviewed the research project?

This project has been reviewed by the University of Manchester Research Ethics Committee to protect your safety, rights, wellbeing and dignity.

What if I want to make a complaint?

If you have a minor complaint then you need to contact the researcher(s) in the first instance. Denham Phipps, by email: denham.phipps@manchester.ac.uk or by telephoning 0161 275 2351. If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part then please contact the researcher, Ms Christian Thomas, by emailing Christian.thomas@manchester.ac.uk or by telephoning 0161 375 8363.

This project has been approved by the University of Manchester's Research Ethics Committee [Ref 16303]