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A mixed-methods study of the implementation of the Trigger Review Method in general medical practice

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Abstract

Introduction

There is now compelling evidence that a significant minority of patients suffer preventable iatrogenic harm during their interactions with health care, including in UK general practice. While our understanding of the extent of the problem and the contributing factors continues to increase, it remains incomplete. Further patient safety research is therefore urgently required, particularly to develop, test and successfully implement effective improvement strategies, methods and tools. Of the main approaches currently available for improving patient safety, the general practice Trigger Review Method (TRM) is of particular interest and the main focus of this study.

The TRM is, quite simply, a structured way to rapidly screen samples of random electronic patient records for undetected patient safety incidents (PSIs). It is essentially an adaptation of clinical record review, with the same underlying principles of learning from error and improving care. Development of the TRM commenced in 2007 in Scottish general practice, with subsequent testing in The Health Foundation-funded Safety and Improvement in Primary Care (SIPC) programme. In 2013, the TRM was included as one of the three core components of the Scottish Government's Patient Safety Programme for Primary Care (SPSP-PC). Scottish general practices were also financially incentivised through the Quality and Outcomes Framework (QOF) to routinely apply the TRM and report their findings.

However, despite the increasing and national interest in the TRM, many unanswered questions remained: what is its potential value, how acceptable and feasible is it and to what extent (if any) will, or should, it become part of routine general practice? The aims of this study were therefore to: (i) describe the patient safety perceptions of general practice clinicians and staff; (ii) determine the usefulness of the TRM; (iii) explain how the TRM worked; and (iv) identify the main factors that facilitated or hindered its implementation.

Methods

This study has a mixed-methods design. It was undertaken in the West of Scotland region in two NHS Health Boards: Greater Glasgow and Clyde (GGC) and Ayrshire and Arran (A&A). Convenience samples of 12 general practice teams and 25 GP Specialty Trainees (GPST) were recruited. Data were collected through: semi-structured interviews (n=62) with a range of general practice clinicians and staff; and cross-sectional trigger reviews of selected electronic patient records.

Normalisation Process Theory (NPT) underpinned all stages of the research. NPT is a socio-technical, middle-range theory about the 'work' people do collectively and as individuals to implement and sustain complex health care interventions such as the TRM. The majority of the qualitative data were analyzed thematically and a NPT framework was applied to the remaining data. Quantitative data were analysed using recognised statistical tests.

Results

A total of 47 primary care clinicians reviewed 1659 electronic patient records and detected 216 PSIs. A substantial minority of these were considered to have led to moderate or more substantial harm (29.2%), while the majority (54.8%) were rated as being preventable or potentially preventable. The most common type of PSI related to 'medication' (40.7%) and the most commonly implicated drug was Warfarin. The participants reported considering or undertaking specific improvement actions during and after approximately two thirds of trigger reviews. The most common action was 'feedback to colleagues'. More specific actions included: undertaking significant event analyses (SEAs) and clinical audits, designing or redesigning practice protocols and including their findings in their appraisal documentation.

The vast majority of participants identified four main factors as being particularly important for the successful implementation of the TRM, and by extension its potential normalisation. The first and most important factor was provision of adequate resources and protected time to conduct trigger reviews.

The second factor was whether senior leaders in the practice teams, the government and professional bodies practically demonstrated their support for the TRM through, for example, contextually integrating it into existing general practice processes. The third and fourth factors related to the characteristics of participants. Successful implementation required knowledgeable clinicians to remain engaged with the TRM, and to perceive it as useful, acceptable and feasible – which the vast majority of participants were, and did.

Discussion

This study is the first known attempt to investigate how the TRM is implemented and perceived from the perspective of general practice clinicians and staff. The main findings are that most participants experienced the method as acceptable, feasible and useful. It is clear that the TRM is uncovering important patient safety concerns and also driving improvements in related care systems and processes at the individual practice level. The implication is that this is making significant and demonstrable differences to patient care, while impacting positively on local safety culture. On the evidence presented, normalisation of the TRM in general practice can therefore be recommended.

However, while the usefulness of an intervention is an important factor in determining whether it is normalised or not, the study findings also clearly indicate – consistent with the international literature – that there are other factors that are at least equally important for normalisation. At the time of writing, there are no formal mandates or financial incentives for general practice clinicians or teams to perform regular trigger reviews. It therefore seems likely that normalisation of the TRM in Scottish general practice will be gradual and piecemeal, if it happens at all. Nevertheless, the lessons learnt from this study can be incorporated in the ongoing efforts to further improve the safety of care in general medical practice. In particular, researchers and policy makers should pro-actively identify and address the main factors that are known to facilitate or hinder the implementation of improvement initiatives; the existing knowledge and 'engagement' of clinicians should be recognised and harnessed; and the lessons learnt from PSIs should be more widely disseminated.

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Acknowledgements

Author's declaration

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

Dr Carl de Wet

Definitions

Term	Definition
Electronic medical record	Comprises the electronic patient record sections relating to: clinical encounter entries, repeat and acutely prescribed medication, correspondence with secondary care and other relevant organizations, clinical investigations (such as blood test results) and clinical codes for diseases and allergies.
Error	The result of choosing the wrong plan to achieve an aim, or not initiating or completing the right plan as intended (1). There are at least three different types of errors: *slips* (incorrectly executed plans), *lapses* (a plan or part of plan is not executed) and *mistakes* (choosing or executing the wrong plan). Not all errors will lead to harm, just as not all harms are caused by error. However, there is an association between error and harm (2). Errors are unintentional and should not be confused with violations, negligence or recklessness.
Harm	Impairment of structure or function of the body and/or any deleterious effect arising there from (3). A pragmatic interpretation is 'anything' that you would not want to happen to you or your relatives while receiving care. Although some incidents of harm are preventable, others are recognised complications of care. The severity of harm ranges from transient inconvenience and self-limiting symptoms, through prolonged admissions, disabling injuries, permanent functional impairment and even death.
Inappropriate medication prescribing	The prescription(s) that introduce a significant risk of an adverse drug related event when there is evidence for an equally or more effective alternative medication (4).
Near miss	An incident which did not reach the patient (3). It is also sometimes referred to as a 'close call' or 'free lesson'
Normalisation Process	A middle-range theory about the required work a complex health care intervention's intended users have to do to

Theory	implement, embed, integrate and normalise it as part of routine practice (5).
Patient safety	The reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum (3).
Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient (3). It has become the preferred term when discussing adverse events, near misses and significant events.
Positive deviance	The ability of some health care staff and teams to deliver exceptional performance by overcoming common problems through uncommon or different behaviours and using only existing resources within their communities (6).
Safety learning system (SLS)	A method of monitoring the occurrence of incidents and developing improvement strategies to address the cause of the incidents (7).
Significant event	Any event thought by anyone in the team to be significant in the care of patients or the conduct of the organization (8).
Violations	Deliberate deviation from an operating procedure, standard or rule (3). They are inconsistent with rules or recommended practice familiar to a health care worker. Violations are sometimes adaptive behaviour in response to complex, challenging or demanding situations. It has been argued that violations cannot be eliminated, but that they can be managed (9).
Work	Purposive social action that involves the investment of personal and group resources to achieve goals (5).

Abbreviations

Abbreviation	Description
Supervisors, study collaborators and administrative support	
CdW	Dr Carl de Wet
CB	Dr Chris Black
PB	Dr Paul Bowie
HB	Ms Hazel Bailey
JF	Dr Julie Ferguson
JM	Dr John McKay
COD	Prof Catherine (Kate) O'Donnell
SL	Dr Sarah Luty
Common study terms	
GP	General practice / general practitioner
GPST	GP specialist training / trainee
NPT	Normalisation Process Theory
PDSA	Plan-do-study-act
PLT	Protected learning time
PM	Practice manager
PN	Practice nurse
PSI	Patient safety incident
SS	Trigger Review Summary Sheet
SEA	Significant event analysis
TRM	Trigger Review Method
Normalisation Process Theory terms	
CO	Coherence
DI	Differentiation
IS	Individual specification
CS	Communal specification
IT	Internalization
CA	Collective action
IN	Initiation
EN	Enrolment

AC	Activation
LE	Legitimation
CP	Cognitive participation
IW	Interactional workability
SW	Skill-set workability
CI	Contextual integration
RI	Relational integration
RM	Reflexive monitoring
SY	Systematization
IA	Individual appraisal
CM	Communal appraisal
RE	Reconfiguration

Health care related terms

AA	NHS Ayrshire & Arran Health Board
ES	Enhanced Service
GGC	NHS Greater Glasgow & Clyde Health Board
HF	The Health Foundation
IHI	Institute for Healthcare Improvement
IT	Information technology
NES	NHS Education for Scotland
NHS	National Health Service
QI	Quality improvement
QOF	Quality and Outcomes Framework
RCGP	Royal College of General Practitioners
SIPC	Safety Improvement in Primary Care programme
SPSP	Scottish Patient Safety Programme
SPSP-PC	Scottish Patient Safety Programme in Primary care
UK	United Kingdom
USA	United States of America

Chapter 1. Introduction

The mantra '*first, do no harm*' has been a fundamental principle of health care for hundreds, if not thousands of years. It succinctly describes the duty of clinicians to fulfil the reasonable desire of any patient to receive care that is safe. However, around the turn of the century a series of landmark studies in the United states of America (USA) (10, 11), Australian secondary (12) and primary care settings (13) and the United Kingdom (UK) (14) provided irrefutable evidence that a significant minority of patients suffer preventable iatrogenic harm during their interactions with health care systems.

This finding has since been replicated by a large number of studies in these countries (15-22) and worldwide (23, 24). The importance of this research has been emphasized further by influential reports such as '*To Err is Human*' (25) '*Crossing the Quality Chasm*' (26) and '*An Organisation with a Memory*' (27) by leading institutions and government departments which sounded a clarion call to national governments and everyone else involved in health care to address the patient safety problem. The key messages from the reports are still relevant fifteen years later: health care should learn lessons from adverse events, take preventative action and that formal patient safety improvement initiatives are necessary.

The other key driver of the patient safety movement has been – and continues to be - the media. The in-depth and sustained reporting of selected examples of iatrogenic harm through multiple media sources increases the profile of certain patient safety incidents (PSIs) and raises public and patient awareness of this issue. Unfortunately there are many potential examples that could be provided. In the context of the UK National Health Service (NHS) the two most widely publicised examples are arguably the 'scandals' of the Bristol Royal Infirmary paediatric cardiac surgery service (28) and Mid Staffordshire NHS Foundation Trust (29). In both instances endemic and systemic failures in care resulted in preventable harm and death. At other times, the poignant story of one patient who suffered a catastrophic error has had the power to capture public and professional attention alike and galvanize improvement efforts. An example that reverberated through UK general practice was the preventable death of Mr.

David Gray from an inadvertent administration of a lethal dose of Diamorphine during what should have been a routine out-of-hours consultation (30).

The responses from national governments, health care organisations, regulatory bodies and health care professionals, managers and staff to the reported deficiencies in quality and safety of health care vary widely. Some acknowledge the problem but perceive it as relatively insignificant or as an intractable, intrinsic and unavoidable element of health care. On the other hand, some national governments and regulatory bodies and many health care organisations, units, teams and individuals acknowledge and prioritise the problem and are taking steps to ensure they deliver care of a consistently high standard. As the focus on patient safety began to grow in modern health care systems internationally, it became an increasingly acceptable area for research and has duly been prioritised in some institutions and at a national policy level. As a result our knowledge and understanding of patient safety continue to increase rapidly.

Literature review

Chapters two to four provide the background and rationale for this study. They also introduce and define key concepts through a narrative review of the international patient safety literature. The literature that is presented was initially identified through a systematic search of English language papers that was conducted in November 2011. The only limits were 'human' studies and 'English' language. The search terms and how they were combined are summarised in Box 1.1 on page 19 and the databases and periods of time that were included are listed in Box 1.2, page 20.

The initial search identified approximately 3500 articles. The abstracts of all studies identified during the search were screened for relevance. When abstracts were deemed relevant, full texts were obtained. A 'snowballing' technique was used to scan the references of the most relevant articles identified in the search to identify other potential useful papers and reports not identified by the formal search process.

Box 1.1. Literature search strategy: search terms

Patient safety	AND	General practice OR Family medicine OR Primary care	AND	Adverse event$ OR Adverse drug event$ OR Significant event$ OR Harm OR Error$ OR Patient safety incident$	AND	Trigger tool$

Box 1.2. Literature search strategy: databases

Medline (1996+)

Embase (1996+)

British Nursing Index (1994+)

Psychinfo (2002+)

Health Management improvement Consortium (HMIC)*

Maternity and Infant Care (MIDIRS)*

EBM reviews (all)*

*No date limits were selected for these databases

At the time of the initial literature search, there was considerably less evidence about patient safety in primary care settings compared with six years later, when this study formally concluded. In 2006 Charles Vincent wrote in the first edition of Patient Safety that '*primary care is more or less virgin territory in patient safety terms*' (31). Three years later, in 'Health Care Error and Patient Safety' the authors dedicated five lines in 288 pages specifically to the general practice setting (32).

Since then, there has been a substantial increase in the number of patient safety-related studies conducted in primary care, with several recent attempts to synthesize the rapidly expanding evidence through literature 'scans' and other review methods (22, 33-35). Given the sheer volume of the available literature the potential risks of selection bias and oversimplifying or omitting key patient safety principles or findings in this study therefore have to be acknowledged. These risks were at least partly addressed through three strategies.

The first strategy was to apply the procedure proposed by Whitlock et al, whereby the potential relevance of literature reviews (where available) are determined by considering whether they are 'on topic' and of sufficient quality to provide confidence in the conclusions (36). The second strategy was to search for 'pivotal' studies that had been conducted after the reviews and consider whether they provided significantly different or new insights (37). The third strategy was to continually update the selected literature for this study through: my practical experience of working in this discipline for the last ten years; the invaluable feedback and suggestions from colleagues, study participants and stakeholders during this time; and through regular electronic notifications of selected publications from the Patient Safety Network (38).

1.1. The Trigger Review Method

The focus of this thesis is the implementation of the Trigger Review Method (TRM) in general medical practice. This is discussed in detail in Chapter 2; however, a brief summary of its development, testing and implementation is outlined here, by means of an introduction.

The terms 'trigger review method' or 'trigger tool' are often used interchangeably and may be new or unfamiliar to some, but the underlying principle and approach of learning from error and improving care are not new. It is essentially an adaptation of clinical record review or 'case note audit' which should be familiar to most primary care clinicians. The TRM is, quite simply, a structured way to rapidly screen samples of random electronic patient records for *undetected* patient safety incidents (PSIs) (39).

1.1.1. Development and testing of the TRM

The TRM was adapted from the Institute for Healthcare Improvement's (IHI) Global Trigger Tool for secondary care in 2007 and subsequently further developed and validated in Scottish general practices. The aim at that time was to determine whether the TRM had value as a metric to quantify harm in general practice. In the pilot study trained clinicians reviewed a one year period in a random selection of 500 patient records. They detected an overall harm rate of 9.4%, although this included some incidents that had originated in secondary care settings and not all incidents were judged to have been preventable (40). However, the study provided evidence that the trigger tool approach was transferable to the general practice setting, and that it may potentially detect more and different types of harm than any other available method.

The TRM was subsequently tested as part of The Health Foundation-funded Safety and Improvement in Primary Care (SIPC) programme in around 70 general practices in seven territorial Health Boards in Scotland over a two year period, commencing in May 2010. The SIPC programme evaluation suggested that the TRM had important educational and improvement value by enabling previously undetected threats to patients to be uncovered in clinical records, thereby providing the general practice team with a new perspective and opportunity to make patient care safer (41). However, it also found that some reviewers were uncomfortable with the term 'harm' or (rightly) pointed out that it unnecessarily restrained their findings. For example, by focusing on harm, potential opportunities for improvement suggested by errors, 'near misses' or 'acts of omission' were not recorded.

As a result, the TRM was modified so that its main aim became the detection of PSIs. In addition, the aim of the TRM was expanded. The detection of PSIs was no longer the only outcome of interest. Rather, detecting and recording PSIs should explicitly be considered by clinician reviewers and their practice teams as opportunities to identify potential learning needs and act as 'prompts' to implement the necessary corrective changes and improvements to care processes when judged appropriate.

1.1.2. Implementation of the TRM

In 2013, at the same time this study was nearing the end of its second year, two developments occurred that dramatically influenced the implementation, adoption and potential value of the TRM. The first of these was that the TRM was included as one of the three core components of the Scottish Government's Patient Safety Programme for Primary Care (SPSP-PC) that launched in March 2013 (42). The other was that all Scottish general practices were financially incentivised through the Quality and Outcomes Framework (QOF) to routinely apply the TRM and report their findings (43). As a result, the TRM was implemented across most general practices in Scotland, even though the findings of this study in relation to its acceptability, feasibility and potential usefulness had not yet been confirmed or shared.

Despite the increasing and national interest in the TRM, many unanswered questions therefore remained: what is its potential value, how acceptable and feasible is it and to what extent (if any) will, or should, it become part of routine general practice? It is also important to acknowledge the assumption underlying much of the aforementioned initiatives, e.g. that all clinicians possess the requisite knowledge, skills and attitudes necessary to routinely apply safety improvement interventions, including the TRM. And that in doing this they are able to apply the technique correctly, produce robust data, evaluate their findings and then plan and implement meaningful and sustainable improvements. A further assumption is that healthcare and educational authorities are able to up-skill the GP workforce in the use of the TRM on the

scale necessary to support the proposed implementation of this approach on a national basis.

The main aims of this study are to test these assumptions and thereby provide evidence with which to answer these questions. The study aims are formally stated and discussed in Chapter 4, page 105, but are summarised for now in Box 1.3, page 25.

1.1.3. Complex Healthcare Interventions

The vast majority of quality improvement interventions in health care are described as 'complex', and the TRM is no exception. Complex health care interventions are defined as '*deliberately initiated attempts to introduce new or modify existing patterns of collective action in health care*' (44). The words 'deliberate initiation' are important and imply that the intervention is: institutionally sanctioned; formally or informally defined; consciously planned; and intended to lead to a change in outcomes (44). Complex interventions are characterised by emergent activities, multi-layered hierarchies and adaptive capacity which occurs within complex environments and are affected by internal and external feedback (45).

Complex health care interventions consist of three interlinked components: (i) 'actors', e.g. the people implementing and using the intervention; (ii) 'objects', e.g. the intervention and the materials it relates to; and (iii) 'contexts' in which they are implemented (46). All three of these components will be considered in detail. In particular: Chapter 6 will describe the 'contexts' within which the TRM was implemented; Chapter 7 will provide information about the 'actors' who implemented and interacted with the TRM; and Chapters 8 and 9 will examine the 'object' component further by considering how the TRM works and the barriers and facilitators to its implementation.

Box 1.3. Summary of the main study aims

- To describe the perceptions and understanding of general practice clinicians and staff of patient safety (Chapter 6)
- To determine the usefulness of the TRM by describing the outcomes from its implementation (Chapter 7)
- To explain how the TRM works (Chapter 8)
- To identify and describe the main factors that facilitated or hindered the implementation of the TRM in general practice (Chapter 9)

The effectiveness of complex health care interventions such as the TRM are determined not only by their utility, but also by the unique and dynamic 'contexts' within which they are implemented, and the characteristics and knowledge of the 'actors' who are responsible for using them. So, while the TRM proposes a potential solution to help address the patient safety problem, it should be acknowledged that an intervention by itself has limited value, unless it can be successfully implemented in practice.

The rest of this Chapter will provide an overview of the study and contents of this thesis. Figure 1.1 provides a graphical summary of the timeline of this study, the history of patient safety in Scotland and the Trigger Review Method (TRM).

1.2. General practice and patient safety (Chapter 2)

The patient safety literature can be classified into one of three interlinked groups, depending on what type of knowledge they generate (47). The first group of studies increases our understanding of the 'problems' associated with patient safety and includes knowledge about the epidemiology and nature of patient safety incidents (PSIs). This group of knowledge will be discussed in Chapter two. A chronological summary of sentinel events, reports and national patient safety improvement initiatives that have been implemented in the UK, and particularly in Scottish general practice will be provided and the concept of safety culture will be introduced.

1.3. The Trigger Review Method (Chapter 3)

The second of the three groups of studies are those concerned with developing and testing complex health care interventions, including different improvement methods and tools. These studies produce evidence that increases our understanding about potential 'solutions' to patient safety problems. Chapter three will describe the strengths and limitations of five different types of patient safety improvement methods that are currently available for use in the general practice setting. One of these, the Trigger Review Method (TRM), is the main focus of this study.

Figure 1.1. A timeline of this study, the history of patient safety in Scotland and the Trigger Review Method (TRM)
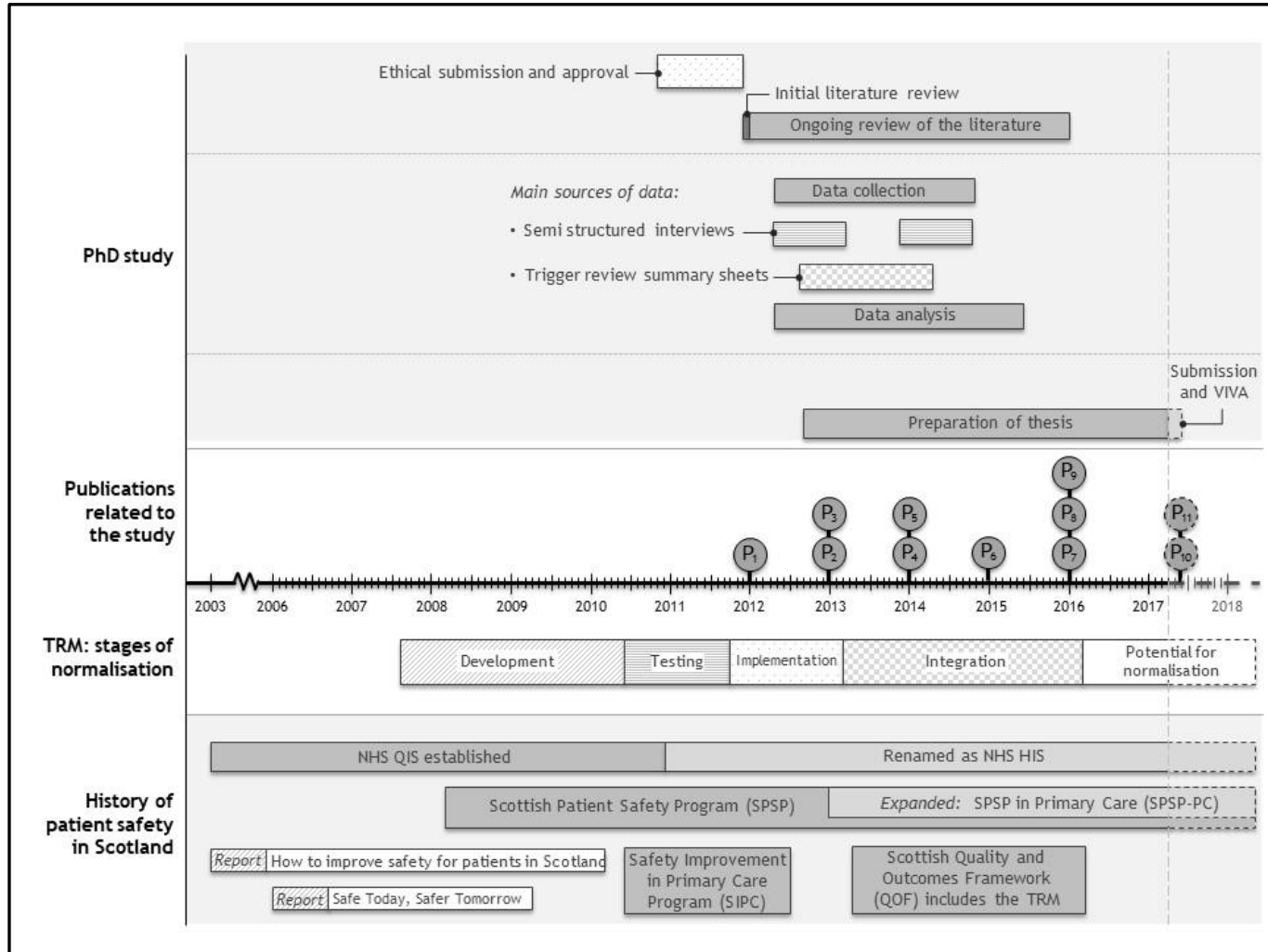
P1 – P11 are listed as Appendix 10 (page 304)

1.4. Implementation science and Normalisation Process Theory (Chapter 4)

Building on the knowledge of the previous two groups, we need to understand and evaluate how complex health care interventions – e.g. the potential 'solutions' to problems such as suboptimal healthcare safety - are implemented and why they are effective (or not). This group of literature also includes knowledge about the factors that hinder or facilitate implementation and normalisation processes. The narrative in Chapter four will therefore be about the science of implementation and the many different theories that are currently available for describing and explaining implementation processes and phenomena, some of which are summarised. Of these, Normalisation Process Theory (NPT) was selected to be the theoretical underpinning for much of this study.

NPT was developed in and for the UK primary care setting, which makes it eminently suitable for the purpose of this study. As a middle-range social theory, NPT enables researchers to describe the work participants do individually and as teams to implement, integrate and embed an intervention, which is the main focus of this study. Chapter four concludes with a dedicated section about the NPT framework and a description of the main study aims.

1.5. Methods (Chapter 5)

Chapter 5 describes the mixed-methods study design, sampling and recruitment strategies. The different methods that were used to collect and analyse the qualitative and quantitative data are then described. Finally, specific ethical considerations are discussed.

1.6. The study participants' perceptions of patient safety (Chapter 6)

The main study findings are described in chapters 6 to 9. In each chapter the findings are compared with the international patient safety literature where relevant, some of the important practical implications are described and the main points are summarised.

The first of the results chapters (Chapter 6) describes the perceptions of a range of general practice staff about the concept 'patient safety'. In particular, participants considered safety to be an important and integral part of the care they routinely deliver. However, most participants perceived a proportion of PSIs as inevitable, and therefore not preventable. Despite this, they unanimously agreed that many high-risk processes and systems *are* amenable to improvement efforts.

The other sections of the chapter describe the factors participants perceived as most important in relation to PSIs; the wide range of formal and informal improvement methods that participants were aware of or already using; and the importance of the prevailing safety culture at the time of the study.

1.7. Main outcomes from implementing the TRM (Chapter 7)

The concept of 'complex health care interventions' and their three main components: 'actors', 'objects' and 'contexts' has already been introduced (Page 24). Chapter 7 focuses mainly on the third component – the 'object' – which in this study is the TRM. In general terms the chapter describes how the TRM was enacted and the outcomes that resulted from this. From a NPT perspective, the main work that is considered is that of 'collective action' and in particular its component of 'interactional workability'. In other words, how did the clinician reviewers apply the TRM, were they able to detect triggers and patient safety incidents (PSIs) and what actions (if any) did they subsequently take?

Throughout the chapter the main findings are discussed when they are reported in order to raise a number of directly relevant issues, and they are compared with the patient safety evidence-base where applicable. In addition, the main findings are compared with the aggregated data from the general practices in three Scottish NHS Health Boards who implemented the TRM subsequent to this study as a Quality and Outcomes Framework (QOF) requirement for the financial year April 2013 to March 2014 (48). These data are referred to as the 'QOF study' and provide additional context for interpreting and discussing the main findings of this study.

1.8. How the TRM worked (Chapter 8)

Chapter 8 explains how the TRM worked. In essence, trained clinicians performed structured trigger reviews of samples of patient records with a patient safety 'mindset', ideally as a single uninterrupted activity during protected time allocated specifically for this purpose. The importance of detecting PSIs was that it created potential 'learning moments' (49). The value of learning moments was in turn determined by clinicians consciously or unconsciously choosing to either accept 'ownership' of PSIs or not. This pivotal decision was crucial to the eventual outcomes of the TRM. The potential outcomes from detecting PSIs and accepting ownership for them are described and include: clinicians and teams taking specific actions to help reduce similar PSIs in the future; increased vigilance and awareness of potential safety threats; and identifying learning needs and points.

1.9. Factors that facilitated or hindered the implementation of the TRM (Chapter 9)

This chapter describes the factors that facilitated or hindered the implementation of the TRM in general practice. The results are presented according to the four main constructs of the Normalisation Process Theory (NPT) framework, which are: understanding (coherence); the work required (collective action); engagement of key actors (cognitive participation); and monitoring and appraisal (reflexive monitoring). The chapter also considers the potential implications of the barriers and facilitators that were identified and compare and contrast them where relevant with the international literature.

1.10. Discussion (Chapter 10)

In the final chapter, four questions in relation to the study are considered. The first two questions are directly relevant to the study aims: '*Should the TRM be normalised* and W*hat is the likelihood of it being normalised in general practice in Scotland?* In answering these questions, the potential implications of the main study findings will also be described.

The third question is: *What are the strengths and limitations of this study?* In answering this question, the implications of selecting NPT as a theoretical framework will be considered as a separate subsection. The relative strengths and weaknesses of the TRM will also be described. The fourth question is: *Can recommendations be made as a result of this study?* The short answer is 'yes' – a number of specific recommendations will be made in relation to implementation processes and improvement interventions; the TRM; and current and future research priorities.

Chapter 2. Patient safety and general practice

The aim of this chapter is to distil the literature and practical experiences of the last two decades and provide a short yet cohesive summary of the state of patient safety in UK general practice. The chapter begins with the terminology of patient safety and defines common terms in this study, including 'error', 'harm' and 'patient safety incident' (PSI). Next, the incidence of error and harm in general practice is considered.

Current estimates of preventable harm vary widely and are dependent on study designs and methods, but provide compelling evidence of room for improvement. The two high-priority areas in general practice which are implicated in the vast majority of PSIs are identified and discussed, e.g. medication and diagnoses-related processes. Two other types of patient safety incidents (PSIs) are also considered: ordering and processing of investigations and communication, clinical handover and care transitions. The chapter then summarises influential UK patient safety programmes and initiatives, reports and sentinel events in chronological order before discussing those most relevant to this study, including: the Safety Improvement in Primary Care programme (SIPC); the Scottish Patient Safety Programme (SPSP) and the Quality and Outcomes Framework (QOF). The chapter concludes by explaining the importance of safety culture and how it affects all improvement efforts and initiatives.

2.1. The terminology of patient safety

Patient safety has its own vocabulary, just as any other scientific discipline. However, because it is a relatively new field of research, the same terms often have different definitions and different words are used interchangeably. New terms are regularly being added and the meanings of words evolve. As an example, a review of 'medication safety' in 2005 found 25 different terms relating to the same concept, with 119 different definitions for these terms (50). Even everyday terms that may seem self-explanatory and simple can be challenging to definitively define as demonstrated by a qualitative survey of general practitioners (GPs) who provided 25 different definitions of the common word 'error'. The lack of consensus was attributed to them considering the term

from different perspectives relating to three sets of factors: process vs. outcome errors, rare vs. common occurrences and system vs. individual responsibility for errors (51). The different perspectives of participants in this study will be discussed in Chapter 6.

This ambiguity can be frustrating for researchers who feel patient safety terms are '*difficult to pin down*' and also give the wrong impression that we are investigating and dealing with unbounded '*relative concepts*' (52). Semantic differences in terms and lack of coherence around their functional meanings make direct comparison between studies difficult and reduce the potential of evidence to be generalized wider than its initial setting (53). Developing and validating an international, standardized patient safety vocabulary was therefore recognised as an essential requirement for effective patient safety research and improvement (54).

In response, the World Health Organisation (WHO) developed and published an International Classification for Patient Safety (ICPS) in 2009 (3). The definitions of common patient safety terms that are used throughout this thesis are taken from the ICPS and they are listed on page 13. The four terms that are most relevant to this study are defined and discussed below. They are: 'patient safety', the discipline within which this study was conducted; 'patient safety incidents', one of the study's main outcome measures; 'harm' and more specifically avoidable harm; and 'error' because, despite its strong correlation with harm, important differences between the two terms should be explicitly distinguished.

Patient safety: The reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum (3). A short, practical explanation is that when things go right, nothing bad happens.

Patient safety incident (PSI): An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient (3). This broad definition includes a large number of related terms such as: adverse events, adverse drug events, adverse incidents, near misses, error, harm event and significant events.

Harm is defined as the impairment of structure or function of the body and/or any deleterious effect arising there from (3). It can be considered to have occurred if a patient's health or quality of life is negatively affected by any aspect of their interaction with health care. A pragmatic interpretation of harm is that it is anything that you would not want to happen to you or your relatives while receiving care. The severity of harm ranges from transient inconvenience and self-limiting symptoms, through prolonged admissions, disabling injuries, permanent functional impairment and even death. It is also crucial to distinguish between preventable harm and harm as a recognised complication of evidence-based care. In practice it is often challenging to make these subjective distinctions between different degrees of harm severity and whether harm was avoidable or not. This is further complicated by the lack of a validated and reliable classification system or definitions of either concept (55).

Error is the failure to carry out a planned action as intended or application of an incorrect plan. Errors are always *unintentional* and therefore differentiated from violations, negligence or recklessness. These terms are not included or implied in the following chapters unless expressly indicated otherwise. Three main types of errors have been described: slips (incorrectly executed plans), lapses (a plan or part of plan is not executed) and mistakes (choosing or executing the wrong plan) (1).

Observation studies in high-risk medical specialties such as anaesthesia and cardiac surgery have shown that health care errors are common, but that most errors are recognised and ameliorated before harm occurs (56). However, the same errors may go undetected on a different day and then result in harm to varying degrees. The current consensus is therefore that error and harm are clearly associated, but the type of error and the severity of harm are usually not; only some errors lead to harm; and harm does not necessarily imply an error (57). A practical example is the study of the association between the severity of intercepted medication errors in an accident and emergency setting and the probability of patient harm. 82% of errors were rated as 'significant' or 'serious' yet the probability of harm was considered 'medium' (17%) or 'high' (1%) for a minority only (58).

2.2. The incidence of error and harm in general practice

Until recently, there have been no large-scale epidemiological studies to reliably quantify the harm rate in primary care, although a number of these studies are now being planned or have just been concluded (21, 22, 59, 60). Our knowledge of patient safety in the general practice setting were therefore about specific care processes and systems or types of error and harm and were derived from small studies. Consequently, the task of identifying how big an issue safety really is has been described as being akin to '*looking at mountains in the clouds – it is hard to tell where one thing begins and another ends*' (61). Just as it can be difficult to separate mountains and clouds, there are significant methodological, cultural and practical challenges in understanding and differentiating between, for example: contributing factors, causative factors and chance; preventable and non-preventable harm and perceptions; and intentions and objective outcome measures. The challenges include: a historic perception that general practice is low-risk and by implication not a research priority; a lack of validated methods that can feasibly and reliably detect all or most PSIs; procuring and allocating the required time and resources to undertake the necessary research; and reaching consensus about what the research priorities should be in general, and as described above reliably differentiating between 'harm' and 'preventable harm'.

Irrespective of these and other challenges, the importance of assessing and improving patient safety in general practice is increasingly being recognised and understood. There are at least three reasons for this. The first reason is that the vast majority of all health care is delivered in this setting. There were more than 300 million face-to-face consultations in general practice in the UK in 2009, which is approximately 90% of all patient encounters in the NHS (62). Since then, there has been a substantial increase in consultation rates, with average consultation duration and total clinical workloads recently described as '*reaching saturation point*' in English general practice (63). The same pattern of year on year increases in workload can be observed in NHS Scotland's general practices, with more than 24 million face-to-face consultations in 2012 alone (64). Primary care clinicians and their representative bodies are arguing strongly that the significant increases in workload have not been matched with

commensurate increases in the workforce or resources and in some instances have declined (65). This argument strongly influenced the context and findings of this study and will be examined in detail in chapters 6, 9 and 10.

The second reason why patient safety in general practice is important is because of significant changes over the past 20 years or so in the way health care is delivered, which in turn have increased the risk for PSIs to occur in this setting (66). For example, patients are discharged from hospitals earlier than in the past; GPs increasingly prescribe and monitor high-risk medications; time pressures in consultations are increasing with complexity relating to an ageing population, multimorbidity and polypharmacy; and services and continuity of care are fragmenting (63, 67-70). The third reason relates to the nature of general practice as a discipline concerned with '*incremental longitudinal processes*' that is '*founded on decisions concerned with managing uncertainty and marginalizing risk*' (52).

There has been a substantial increase in the last five to ten years in the number and quality of studies about the incidence and nature of safety threats and deficiencies in general practice. As a result, it is now widely accepted that healthcare errors are relatively common in primary care settings worldwide and that a substantial minority result in preventable harm to patients (20). We also know that the majority of harm incidents are minor or moderate in severity, but that some have serious consequences, including hospital admissions and even death. (17) Five examples are provided below as further evidence in relation to these general findings. The first two studies were selected because they provided the first known estimates of error rates in UK primary care, the third example was selected because it suggested that the patient safety problem in primary care was much more serious than previously suggested, and the fourth and fifth example was selected because of its relevance to this study.

The first example is the literature review by Sandars and Esmail who aimed to describe the frequency and nature of medical error in primary care in 2003 (71). Their study was the first known review of its kind, and they found only 12 suitable studies for inclusion. The estimated rate of error was between 5 and 80 per 100 000 consultations and the authors described how different methods and

terminology made it challenging to understand the state of patient safety at that time. The outcomes or potential preventability of the errors were not described. The authors acknowledged that this rate was likely an underestimation of the true error rate as most of the studies had used voluntary incident reporting by clinicians. This was confirmed in that same year when Rubin et al (example two) reported their findings of an error rate almost 100 times higher (75.6 errors per 1000 consultations) in UK primary care. This rate was derived from a voluntary incident reporting system they had implemented in UK primary care (72). These early studies highlighted the need for further research, rigorous methodology and reliable metrics.

The third example is the controversial study by Woods et al who reviewed the discharge documentation of patients in the USA in order to detect the number of preventable adverse events originating in ambulatory care and the severity of their outcomes (73). They estimated that these preventable adverse events resulted annually in as many as 75 000 hospital admissions and 2 587 deaths in the USA. While this study has been widely cited since, it is important to acknowledge its potential limitations and assumptions. The authors reviewed a large sample of 14 700 hospital discharge records and detected 587 adverse events. However, only 31 of these events were judged to be preventable *and* originating from ambulatory care, which they defined as 'outpatient settings' and included family practice, internal and emergency medicine. It was from this small number of cases that they generalized and calculated rates for the wider USA context. It has since been argued that '*implausible estimates of deaths due to medical error will do more to erode the cause of patient safety than headline-friendly figures will do to help it*' (74).

The fourth example is the study by de Wet and Bowie who performed a trigger review of a sample (n=500) of electronic patient records from Scottish practices in 2008 (40). They found that harm occurred on average at a rate of one event per 48 consultations. Of these, 42% of adverse events were judged to potentially be avoidable. While the estimated harm rate of 9.4% in general practice was comparable to that in hospitals, it was derived from a small sample of records, with no attempt to calculate inter-rater reliability or verify the adverse events. In addition, some of the detected incidents had originated in secondary care.j

The fifth and final example is the systematic review (n = 109 studies) undertaken in 2016 by Panesar et al in order to answer the question: 'how safe is primary care (22)?' They found rates of from <1 to 24 PSIs per 100 consultations, of which a small minority were associated with severe harm.

2.3. Common types of PSIs

Most PSIs in general practice belong to one of the following four category types: (i) medication and medication-related issues; (ii) diagnoses and diagnostics; (iii) organisational, which includes systems, procedures and managing investigations; and (iv) communication, which includes clinical handover and patients' care transitions between different health care providers and agencies (75). In many instances more than one category may be relevant as demonstrated through the summarised example in Box 2.1 of a PSI that was submitted to NHS Education for Scotland (NES) as a significant event analysis (SEA) report. Each of the four patient safety areas are discussed below and illustrated further through a small selection of studies. Whenever possible, systematic reviews or 'pivotal' studies were selected. However, some examples are included because of their particular interest or relevance to this study. In all instances however, the selected studies are comparable to the wider literature about that topic.

2.3.1. Medication errors

Adverse drug events (ADE) are estimated to affect up to 20% of patients worldwide in primary care settings (19, 76-78). The majority of prescribing errors cause only minor or moderate harm (79), but the small proportion that results in more serious harm, including hospital admissions, is still considerable, given the sheer volume of many millions of prescriptions issued (80). Unfortunately, the true incidence of avoidable medication-related PSIs is not yet clear. Depending on the study design, definition of ADE and specific patient population investigated, the proportions of these events that are potentially avoidable have been reported from as low as 10% to as much as 50%.

Box 2.1. Example of a PSI with multiple categories

A patient presented with progressive shortness of breath to her general practitioner and was admitted to hospital with presumed acute exacerbation of her known heart failure. After extensive investigations she was diagnosed with 'nitrofurantoin lung', a rare pulmonary complication of the antibiotic (nitrofurantoin) she had been prescribed as prophylaxis against urinary tract infections. The hospital discharge summary did not contain this information or the results of the investigations they had conducted, the patient was unaware of the cause of her deterioration and the medication was not discontinued in general practice. As a result, her symptoms returned and she was readmitted to hospital. The patient's experience and this admittedly rare complication demonstrate medication-related, diagnostic, organisational and communication deficiencies.

While the exact number of medication-related errors or the proportions of avoidable ADEs may not yet be known, we do have high quality evidence about the causes and contributing factors to ADEs. Garfield et al were the first to map out the whole UK primary care medicines management system and to systematically review the evidence of cumulative medication errors in it (81).

They found that ADEs are usually caused by complex and multifaceted errors that commonly occur in all stages of the medication systems, including prescribing, dispensing, administration and monitoring. According to them the implication is that only a minority of patients (4 to 21%) achieved optimum benefit from their medication. They recommended routine monitoring of adherence, clinical effectiveness and related hospital admissions as the first steps to improve the quality of the medication system.

This may seem like a daunting task – and it is. However, a useful starting point may be the handful of high-risk medications that are associated with the majority of all ADEs (82). These are the cardiovascular drugs, non-steroidal anti-inflammatory drugs (NSAIDs) and anticoagulants (83). Other groups of drugs that are also commonly associated with ADEs include the anti-infective agents, drugs used for the treatment of diabetes mellitus and analgesia (84-86). Conversely, some drugs such as anti-anginals and asthma preventers may cause preventable hospital admissions if they are *not prescribed*. An alternative starting point may be to consider the specific risk factors that increase the likelihood of suffering ADEs. These are: increasing age; female gender; very young age (< 4years old); polypharmacy (e.g. multiple prescription items); number of daily doses; multimorbidity; and high consultation rates (78, 79, 83, 84, 86-89).

The risk factors of medication-related PSIs may be well known but there is still a paucity of validated interventions to reliably and cost-effectively reduce them. Zermansky et al conducted a randomized controlled trial in English general practice more than fifteen years ago to determine the potential impact of an experienced pharmacist conducting clinical medication reviews of elderly patients with repeat items. Adverse drug events were not measured but there was no significant impact on mortality, hospital admissions or number of consultations (90). A subsequent systematic review and meta-analysis found

'weak' evidence to indicate that pharmacist-led medication reviews may be effective in reducing hospital admissions but this benefit was not demonstrated when analyses were restricted to RCTs only (91). More recent systematic reviews were conducted in 2013 (92) and again in 2015 (93). They found that some information technology (IT) interventions were able to successfully reduce medication errors in two specific instances: (i) when pharmacists effectively collaborate with prescribers about unsafe prescribing; and (ii) when clinical decision support (CDS) systems (informed by prescribing-safety indicators) target only a limited number of clearly defined medications and specific patient groups. They also found that at least half of IT interventions were unsuccessful or paradoxically associated with e-iatrogenesis (94).

2.3.2. Diagnostic errors

Despite the relative frequency and potentially devastating consequences of diagnostic errors for patients and clinicians alike they remain underreported by doctors and have only recently been acknowledged by the wider patient safety research community as an important area of study (95, 96). Current estimates of diagnostic error rates are highly dependent on the study design and methods. Trigger reviews of medical records detected rates ranging from 5% (97) to 16% (98) of primary care consultations while patients have reported errors in up to 30% of their and their families' diagnoses (99). Diagnostic errors are the most common reason for medico-legal claims against GPs in modern health care systems, including the UK (100).

A review of 25 years' worth of settled primary care medico-legal claims in the USA found that only a small minority were due to negligence (15) and no single clinical condition accounted for more than 5% of the claims. However, some conditions were associated with a disproportionately higher risk of generating a complaint compared with the relative frequency with which they occur in general practice. For example, a missed diagnosis of appendicitis was 25 times more likely to generate a claim than a delayed diagnosis of breast cancer (101). It is unclear why this is the case, but may be due to patient and public perceptions that some diagnoses are 'easier' to make than others. Studies of medico-legal claims also tend to focus only on delayed or wrong diagnoses.

While these are important subtypes of diagnostic error, the potential harm from over-diagnoses are increasingly being recognised (102, 103).

Incomplete history taking and clinical examinations contribute to the majority of diagnostic errors (98). Unfortunately, while some of the contributing factors may seem simple and apparent – especially in retrospect - diagnostic errors are even more challenging to understand and reduce compared with medication, organisational and communication related issues (104, 105).

There are at least three reasons for this (106). The first reason is that diagnostic errors are not condition specific. They only appear that way because certain conditions such as cancers, myocardial infarctions and meningitis (100) are more memorable or lead to litigation more often than others. The second reason is that various patient and condition-specific characteristics combine in infinitely unique clinical scenarios. Some of the more important factors are atypical and non-specific presentations; very low prevalence of some diseases; multimorbidity; polypharmacy; and physiological variation (107). The third reason is the inherent susceptibility of all clinicians to err. The more obvious and better known reasons include: availability bias (108); physical and psychological limitations to human performance; cognitive errors (109); and lack of knowledge (110). However, another crucial reason is that the very same cognitive processes and adaptive behaviours that enable them to provide efficient care most of the time, occasionally and paradoxically predispose them to err.

It is worth examining this final challenge to reducing diagnostic error in a little more detail because of its relevance to this study and as an example of the practical implication of the influential principle of Efficiency-Thoroughness-Tradeoffs (ETTOs) in patient safety. The ETTO principle provides an important perspective to understand the causes and contributing factors of PSIs and will be described in detail in Chapter 6. For now, it is considered from the perspective of clinicians and diagnostic errors.

The 'right' diagnosis is mainly the product of clinicians' conscious and unconscious cognitive processes. Many different processes have been identified and described. Two of these are sufficient to help illustrate the ETTO principle,

namely 'hypothesis generation' and 'pattern matching' (also known as 'satisficing'). When clinicians use 'hypothesis generation' they list a wide range of possible diagnoses and then systematically consider and investigate each one in turn to either confirm or reject it. It is a time-consuming and resource-intensive strategy but the benefit is that it helps to reduce diagnostic errors. On the other hand, when clinicians choose to 'pattern match' they will accept the first diagnosis that satisfactorily explains the majority of the available clinical information at that point in time. Pattern matching is time and resource efficient but associated with a higher diagnostic error rate compared with the hypothesis generation approach. The ETTO principle recognises that neither approach is essentially 'right' or 'wrong' and both may be needed in different clinical scenarios. It is only once a diagnostic error had been made and resulted in harm that the need for greater thoroughness becomes apparent in retrospect. In these instances, it is true that the conscious or unconscious decision to select one approach over the other lies with the clinician. Also, contextual, cultural and organisational factors are more often the crucial drivers of clinicians' choices and strongly incentivise efficiency (pattern matching) over thoroughness (hypothesis generation). However, consciously slowing down and reflecting on every case will not necessarily eliminate diagnostic error either (111).

From this perspective, it may therefore be more accurate and helpful to conceptualize and refer to diagnostic errors as 'missed opportunities in diagnoses' (112). For the purpose of this study the more conventional term 'diagnostic error' will still be used but include this expanded definition, unless stated otherwise.

2.3.3. Investigation-related errors

Laboratory tests and imaging are common and essential tools in modern primary health care and help clinicians to diagnose, monitor and screen a very wide range of treatments, symptoms and conditions. Unfortunately, some recommended tests for monitoring chronic conditions and medications are not requested (113) or, once requested, significant results are lost, missed or not followed-up (114). Three examples are provided to help illustrate this safety problem. The first is Casalino et al who reviewed more than 5000 primary care

records and found 7.1% of clinically significant outpatient test results had either not been relayed to patients or if they had been discussed, this had not been documented (115).

The second example is Elder et al who used a multi-method approach to intensively study the management of test results in family medicine. They also found that patients had not been notified about the results of a proportion of tests (0 to 13%). However, in their study only 28 to 55% of abnormal results had been followed-up (116). According to them the likelihood of investigations being managed appropriately were associated with two main factors: safety awareness (leadership, communication, teamwork and having policies and procedures in place) and technological adoption (electronic health records and connections between the practice and testing facilities, forcing functions in the software and facilitation of communication with patients through technology).

The third example is Walsh et al's survey of primary care clinicians in which 37% reported consulting with at least one patient in the two week study period who either had a missing test result, or whose treatment in response to a test result had been delayed (117).

From these three examples it might seem that the most common error – or at least the most easily identifiable error – is failing to follow up on significant results. However, this is only one process in the larger system of managing investigations. Other processes include: ordering tests; implementing tests (e.g. taking the right samples at the right time); reporting results to clinicians; clinicians responding to results; notifying patients of results; and general administration (e.g. coding and filing results). Errors have been detected in every single process and are associated with specific system hazards (118, 119). Bowie et al identified four hazard types that are particularly relevant in UK primary care: system variations and weaknesses (e.g., lack of a tracking process); unclear communication between clinicians and administrators; administrators informing patients of test results; and challenges in maintaining patient confidentiality (120). The most error-prone processes were 'implementing' tests (one third of errors), reporting test results to clinicians (one quarter of errors) and administrative errors such as misfiling (one fifth of

errors). This is why laboratory testing in general practice has recently been referred to as the 'blind spot' (121) of patient safety and why it is a priority to standardize and enhance the ordering, tracking, patient notification and follow-up processes to help reduce avoidable investigation-related errors (114). Important progress has been made in this regard with the development and recent publication of a safe laboratory testing 'good practice guidance' by the pan-European LINNAEUS collaboration. It contains 77 statements relating to 10 safety domains and provides a practical starting point for primary care teams who wish to implement safe systems and processes for ordering tests and managing results (122).

2.3.4. Interface and transition-of-care errors

The peri-discharge period has been shown to be a particularly high-risk time for PSIs to occur, of which many are potentially ameliorable or preventable (123, 124). They include: adverse drug reactions, drug omissions and inconsistencies, unjustified medications and drug discrepancies when discharge items are compared with those prescribed before admission or with what was intended by the hospital clinicians (125). Errors and harm relating to procedures and the results of investigations being lost or not followed-up have also been reported, but the most common type of errors are related to medication management and incomplete documentation (126).

There is some evidence that medication discrepancies can be reduced significantly if primary care providers communicate with patients within 24 hours of their discharge from hospital (127). However, a recent systematic review found most unintentional medication discrepancies had 'no clinical significance' and medication reconciliation did not reduce hospital use within the first 30 days post-discharge (128), although significant reductions in readmissions and emergency department visits were found during longer post-discharge follow-up periods (129).

Notwithstanding the lack of consensus about medication reconciliation's usefulness, primary care clinicians still require accurate and timely information about individual patients when they are discharged from hospital settings to

ensure care continues and is safe. The discharge documentation should therefore be legible, adequate and include medication lists, relevant investigation results and information about follow-up arrangements (130). It has been argued that effective clinical handover requires not only such standardized information exchanges but that there should also be direct interaction between clinicians (131). Ideally, this would occur with every transition and actively involve patients and their families/carers (132, 133). If we are to achieve this care aspiration there is still much to do as even basic notifications do not reliably happen for every patient. For example, Bell et al found in their multi-centre trial in the USA that only 42% of primary care clinicians had received discharge documentation within a fortnight of their patient being discharged and concluded that there was 'much room for improvement' in communication between hospitals and GPs (134).

The intuitive association between improving hospital-GP communication and improved patient safety outcomes including mortality, hospital readmission and emergency department visits has also not been demonstrated (134). In a recent, large study Oduyebo et al reviewed more than 6000 hospitalizations. Direct communication between inpatient and outpatient providers was reported for 36.7% of patients but again not associated with decreased 30-day readmission rates (135). In fact, Coller et al reports that improving communication may paradoxically have increased readmission rates in a cohort of paediatric patients (136).

In addition to secondary care, patients from general practices also interface with and transition to and from out-of-hours (OOH) services. It is well known that errors and harm do occur in this setting, and it is an important area of research (137, 138). However, for the purposes of this study, interface and transition-of-care errors are arguably less important than the other three error types that were described. This is because, from a general practice perspective, they are usually not preventable. Also, most studies about interface-errors have focused on hospital-GP communication, rather than GP-hospital communication. A recent review (n=20 studies) aimed to address this issue and found no association between the quality of GP communications with hospitals when admitting patients and the subsequent 30-day admission rates (139).

2.4. Patient safety improvement programmes and initiatives

The patient safety literature that have been described so far indicate the need for health care organisations to better identify and act on PSIs. In recognition of this need, there have been several organised attempts in the last decade to develop structured programmes of patient safety in the UK. The key programmes and initiatives will now be discussed.

Table 2.1 chronologically lists improvement programmes and initiatives, reports and sentinel events relating to patient safety in the UK and especially NHS Scotland and Scottish general practice. The initiatives or programmes that are most relevant to this study are then described in more detail. They are: the Health Foundation's Safer Patients Initiative (SPI) and Network (SPN); the Scottish Safety Improvement in Primary Care (SIPC) programme; the Scottish Patient Safety Programme (SPSP); and the Scottish Quality and Outcomes Framework (QOF) for general practice.

2.4.1. The Safer Patients Initiative

The Safer Patients Initiative (SPI) was the first large-scale, complex improvement programme aiming to improve patient safety in the UK. It was commissioned by the Health Foundation and focused on reducing preventable harm in secondary care. Twenty four hospital sites participated during two consecutive phases that ran from 2004 until 2008. The aim of phase one (n=4 hospitals) was to reduce the number of adverse events in the pilot hospital sites by 50%. The initial four sites were to achieve this aim through a 'change package' designed by the Institute for Healthcare Improvement (IHI). This included three core components: (i) implementation of evidence-based interventions in specific clinical areas that are known to be high-risk for PSIs, e.g. critical and peri-operative care and medicines management; (ii) training staff in quality and safety improvement methodologies; and (iii) establishing specific roles for the Chief Executives and senior executive teams in relation to patient safety. The aims of phase two (n=20 hospitals) were to reduce the

Table 2.1. A timeline of the recent history of patient safety in the UK

Year	Patient safety improvement programmes, initiatives, reports and sentinel events
1998 – 2001	The public inquiry into the Bristol Royal Infirmary paediatric cardiac surgery services led by Prof Ian Kennedy QC makes 200 recommendations for improving patient care and condemns the prevailing 'club culture' which contributed to iatrogenic harm at that time (140)
2000	The Department of Health (DOH) publishes 'An Organisation with a Memory' in England. The key theme of the report is that health care organisations and staff should identify and learn from PSIs. (27)
2001	The DOH publishes 'Building a safer NHS for patients' which describes the practical steps to improve care safety. The report identifies specific, high-priority safety threats, proposes the first steps to implement a formal incident reporting system and acknowledges the importance of patient safety research. (141)
2001 – present	The National Patient Safety Agency (NPSA) is established and tasked with improving patient safety in the NHS in England and Wales. In 2012 the NPSA's key functions were transferred to the NHS Commissioning Board Special Health Authority. Patient safety related work was transferred again in April 2016 to NHS Improvement.
2001 – 2009	The DOH launches the Patient Safety Research Portfolio (PSRP), a national program that funds research (n=36 studies) about healthcare error, including how it can be measured and prevented in secondary and primary care settings in England (142).
2003 – present	NHS Quality Improvement Scotland (NHS QIS) is established with the formal remit to improve the quality and safety of healthcare in Scotland. QIS was renamed in April 2011 to NHS Healthcare Improvement Scotland (HIS)
2003	The Scottish Executive Health department publishes 'Learning from Experience: How to Improve Safety for Patients in Scotland'. The report recommends raising awareness of iatrogenic error and harm and building a positive, blame-free safety culture. (143)
2004	The NPSA publishes 'Seven steps to patient safety'. They are: 1. Build

a safety culture; 2. Lead and support your staff; 3. Integrate your risk management activity; 4. Promote reporting; 5. Involve and communicate with patients and the public; 6. Learn and share safety lessons; 7. Implement solutions to prevent harm (144).

2004 – 2008	The Health Foundation implements the 'Safer Patients Initiative' (145).
2005	The House of Commons Committee of Public Accounts publishes 'A Safer Place for Patients: Learning to improve patient safety'. It concludes that some progress had been made in learning from PSIs and building a safety culture, but that there is much room for further improvement (146).
2006	NHS QIS publishes 'Safe Today, Safer Tomorrow'. It recognises the need for co-ordinated senior organisational leadership, additional resources and the active involvement of patients and clinicians in improvement initiatives (147).
2008 – present	The Scottish Patient Safety Programme (SPSP) is introduced in selected hospital specialties. It is subsequently expanded into other settings which are described in more detail below (148).
2008	Mr. David Gray dies after an inadvertent administration of a lethal dose of Diamorphine during a routine out-of-hours consultation (30).
2009 – 2011	The Health Foundation establishes the 'Safer Patients Network' (149).
2010 – 2012	The Health Foundation funded Safety Improvement in Primary Care (SIPC) programme is implemented in Scotland (41).
2010 – 2013	The public inquiry into the Mid Staffordshire NHS Education Trust care failings led by Robert Francis QC makes 290 recommendations (29).
2013 – present	The Scottish Patient Safety Programme in Primary Care (SPSP-PC) is launched with a focus on general practice. In 2014 it is extended further to include pharmacy and dentistry (42).
2013 – 2016	The Scottish Quality and Outcomes Framework (QOF) specify 'quality and safety' as one of its four domains. General practices are financially incentivised to comply with specific patient-safety related indicators including the Trigger Review Method (TRM) (43, 150).

mortality rate by 15% and adverse events by 30% over a twenty month period from 2006 to 2008 (145).

The internal evaluation found evidence that the SPI had an overall positive influence on patient care. The initial four sites measurably improved on a range of processes. As a result, the rates of ventilator associated pneumonia, central line catheter bloodstream infections and surgical site infections all reduced. The twenty sites in the second phase all demonstrated improvements in at least some process and outcomes measures but with substantial inter-site variation.

The external evaluation found evidence that the organisational climate had improved but concluded that there had been no significant reduction in mortality or morbidity and that the quality of prescribing remained unchanged during the study period compared with the control group (145). They acknowledged this might be due to the relatively short study period and because interventions were implemented in individual units while the main outcomes were measured at the organisational level.

Despite the lack of quantitative evidence that the SPI significantly improved patient safety, it remains an important and influential programme that provided valuable experience and lessons about complex health care interventions and implementing change at an organisational level in the UK. The evaluation identified important factors that hinder or facilitate successful implementation. Of these, the most important factor is arguably allocating adequate and appropriate resources. This issue will be considered again in Chapters 9 and 10.

The evaluation also identified important learning points, including:
- It is essential to raise awareness of the patient safety problem amongst staff before implementing improvement programmes, i.e. assess the readiness of an organisation for change and ensure clinicians' engagement;
- The majority of health care workers will likely require additional training before they are able to contribute effectively to quality improvement initiatives, i.e. it is necessary to build capacity and capability;

- It is important for researchers and policy makers to understand the unique contexts and environments within which they implement their initiatives and accordingly adapt their improvement methods;

- The right data need to be collected reliably to evaluate the impact of an intervention and this may require developing or adapting existing reporting systems. The SPI used the Global Trigger Tool (GTT) for this purpose and this method will be discussed further in Chapter 3.

2.4.2. The *Safer Patients Network*

The Health Foundation envisaged an organic network of likeminded individuals and organisations who would independently and collectively continue to build on the work of the SPI and share their experiences and learning. They therefore launched the Safer Patients Network (SPN) in June 2009. The vision for the network was to create a self-sustaining, member-driven community that would spread improvement throughout their organisations and further afield. One of the key findings of the in-depth evaluation of the SPN is that this vision was unfortunately not adequately promoted and potential members therefore did not understand the value of joining or remaining in the network. The launch of the network also coincided with a number of other national and regional initiatives which created competing priorities for organisations. In addition, inadequate resources were provided for maintaining the network and members were dissatisfied with the seemingly unstructured nature of the network compared with the clear plan and processes of the SPI. Consequently, there was a gradual attrition of sites after the SPI concluded. Eighteen of the original 24 sites joined the network. Of these, 10 participated in 'pass it on' collaboratives and only four took part in Innovation projects. The SPN experience is a powerful example of the many challenges inherent in sustaining complex health care interventions for a sufficient period of time to allow their integration and embedding into routine care. This important issue will be considered further in chapters 9 and 10 (149).

2.4.3. The *Scottish Patient Safety Programme (SPSP)*

The SPSP was launched in 2008 with the ambitious aims to reduce secondary care mortality and harm by 15% and 30% over a five year period. The secondary aims were to reduce healthcare associated infections, adverse surgical incidents and adverse drug events, improve critical care outcomes and build a strong and positive safety culture. The internal evaluation found a reduction in the Hospital Standardised Mortality Ratio (HSMR) of 16.5% between 2007 and 2016. There was also evidence of harm reduction relating to specific conditions or processes. One example is the number of cardiac arrests during hospital admissions that were reduced by 19% (n=11 hospitals) between 2012 and 2015 (148).

The programme design was a collaborative approach with regular regional and local events for staff to learn about quality improvement and share their experiences. For the first few years the programme was supported by the Institute for Healthcare Improvement (IHI) and much of their methodology were incorporated in the SPSP, including the global Trigger Tool and PDSA method. Other important partners were NHS Scotland, NHS Quality Improvement Scotland (now NHS Healthcare Improvement Scotland); NHS Education for Scotland (NES); and the Health Foundation. The initial focus of the programme was acute hospitals in Scotland. However, as the programme became more established it was expanded into primary care (SPSP-PC). The SPSP-PC is described in its chronological place below.

2.4.4. *Safety in Primary Care (SIPC) programme*

The Health Foundation-funded Safety in Primary Care (SIPC) programme was launched in May 2010 and concluded in June 2012. In the first phase (year one) twenty general practice teams in three regional health authorities in Scotland participated. The second phase commenced in May 2011 with the recruitment of a further four health boards and another 50 practices. One of the main aims of the programme was to test and evaluate a number of potential quality and safety improvement methods and tools in a general practice context. The four main methods and tools were: (i) a proto-type version of the Trigger Review Method (TRM); (ii) GP-SafeQuest, a validated instrument enabling serial

measurements of perceptions of safety culture; (iii) the plan-do-study-act (PDSA) method; and (iv) a care bundle approach to improve the reliability of chronic disease management *(41)*.

The SIPC programme was positively received by the majority of participants who gained new theoretical and experiential safety knowledge and reported improvements in practice safety systems, team working and communication with colleagues and patients. However, while the evaluation found anecdotal examples of benefits there was no quantifiable evidence of significant improvements in patient safety (41). Many participants also reported a significant mismatch between their multiple competing workload priorities, the larger than expected amount of time and resources that was required to participate in the programme and the comparatively inadequate levels of backfill funding for staff participation. As a result, three practices disengaged from the programme citing lack of time and increased staff stress due to unmanageable workloads. For them, participation in the programme paradoxically and unacceptably compromised their time to deliver a clinical service. Other practices expressed doubts about future participation in similar initiatives unless their resource concerns were addressed.

2.4.5. Scottish Patient Safety Programme in Primary Care (SPSP-PC)

The Scottish Patient Safety Programme in Primary Care (SPSP-PC) was developed from the SIPC programme by using, and adapting, the same collaborative approach, tools and methods. It was implemented in March 2013 with the aim to measurably improve the quality and safety of care in those general practices who volunteered to participate. At that time SPSP-PC had three core components: (i) detecting, learning from and reducing PSIs by applying the Trigger Review Method (TRM) to samples of patient records; (ii) measuring and building a strong and positive safety culture; and (iii) improving chronic disease and medication management by using a care bundle approach. The TRM component was subsequently removed from the SPSP-PC because Scottish practices were financially incentivised to implement the TRM through the QOF which meant duplication of effort. This will be discussed in more detail below (35).

An internal evaluation found that the vast majority of general practices are now involved to some degree in the SPSP-PC and have started implementing the different methods (42). There is emerging evidence that medication management may be improving but it is still too early for a definitive assessment of the programme's overall utility. The intention is to expand the SPSP-PC to dentistry, community pharmacy, district nursing and care homes from late 2016 and to optometry in 2017.

2.4.6. GP Quality and Outcomes Framework

The Quality & Outcomes Framework (QOF) was a major component of the General Medical Services (GMS) contract between UK general practices and the NHS. It was introduced in April 2004 to help address longstanding variation in the quality of primary care provision (151). The QOF was the most ambitious, comprehensive and largest pay-for-performance scheme in international healthcare and one of the most important, influential but also controversial initiatives ever to be implemented in UK general practice. The QOF was essentially a pay-for-performance scheme that financially incentivised practices to reliably provide standardized, high-quality care. The QOF measured participating practices' performances annually against a range of evidence-based or pre-agreed 'point-in-time' indicators. Practices 'earned' points according to their level of achievement for each indicator, with payment starting at a minimum threshold (usually 40%) rising to a maximum (usually 90%). Points were weighted according to the practice list size and were worth from tens to hundreds of pounds each. From 2004 until 2013 practices could achieve a maximum of 1000 points a year. In the 2013/14 financial year the maximum number of points was reduced to 923 points. In the 2014/15 and 2015/16 financial years the number of points were reduced further to a maximum of 659. (43, 150)

Although the QOF has been studied extensively, there is still no consensus about its overall utility, its effect on clinical outcomes or whether it had a significant and positive impact on patient safety (152). Only 'small and inconsistent' associations have been found between QOF indicators, all-cause mortality and

emergency admissions (153). On the other hand, there is evidence of improved quality of care for patients with specific chronic diseases and a trend towards improvement in some processes and outcomes which can at least partly be attributed to QOF (154-156). However, there is no evidence of any discernible effect on hypertension-related outcomes (157) and depression indicators failed to improve disease detection or treatment (158). Overall, however, the QOF was 'likely' a cost-effective use of resources (159).

Participation in the QOF was voluntary but in reality most practices would not have been viable business concerns if they had opted out. As a result essentially all Scottish general practices participated in the QOF as it was one of their main potential sources of income. However, following increasing dissatisfaction with the contract and its impact on workload, it was decommissioned in Scotland in 2016 (160). From April 2016 the financial investments previously associated with QOF were transferred into Scottish general practices' core funding. Performance data will still be extracted to support the new peer led GP Cluster Continuous Quality Improvement process as part of the latest GMS contract agreement but will not be used for payment purposes. The other UK home countries are currently considering its future viability. From the perspective of this study only the Scottish QOF will therefore be considered.

The QOF indicators changed considerably over time. In the 2013-14 financial year a 'quality and safety' domain was created with specific indicators financially incentivizing practices to improve this aspect of their service (43, 150). In particular, they were tasked with: reviewing outpatient referrals, reducing avoidable emergency hospital admissions, creating anticipatory care plans for high-risk patients and implementing specific safety-related tools and methods (see Table 2.2, page 56). One of the new quality and safety indicators - Indicator 'QI001(S)' - is of particular importance to this study. Practices who complied with this indicator could earn a maximum of six points. In 2014-15 the indicator was renamed 'QS007' but the requirements remained the same. The 'validated tool' the description refers to was the Trigger Review Method (TRM).

Table 2.2. QOF Quality and Safety indicators for 2013-14

Indicator	Description	Points
QI001(S)	*The practice **conducts two case note reviews**, using a validated tool, to detect patient safety incidents, meets to discuss the results, and shares a reflective report on actions and themes that arise from this with the NHS Board*	6
QP001(S)*	Review data on secondary care outpatient referral	5
QP002(S)*	Participates in an external peer review... to compare its secondary care outpatient referral data with that of the other contractors	5
QP003(S)*	...follows 3 agreed care pathways...to avoid inappropriate outpatient referrals	11
QP004(S)*	Review data on emergency admissions	7
QP005(S)*	Participates in an external peer review...to compare its data on emergency admissions and to share the learning from at least 25 per cent of the Anticipatory Care Plans (ACPs)	17
QP006(S)*	Produces a list of 5% of patients in the practice, who are predicted to be at significant risk of emergency admission or unscheduled care	5
QP007(S)*	...Creates Anticipatory Care Plans	30
QP008(S)*	Holds at least 4 meetings during the year to review the needs of the relevant patients in the practice ACP cohort	10
QP009(S)*	Produces and submits a report to the Board on internal practice and wider Board system changes that may benefit patients with ACPs	10
QS002(S)	The practice conducts a safety climate survey with all staff, clinical and non-clinical, using a validated tool, meets to discuss the results, and shares a reflective report on actions that arise from this with the NHS Board.	5

*Abridged

The QOF was initially received with great enthusiasm by general practices but with time there were increasing concerns about the validity of some of the additional and modified indicators that were added annually and the perceived incessant tightening of targets by policy makers. Other concerns were that it created a de-personalising 'box ticking culture'; that it was vulnerable to data distortion and potential gaming; that it accelerated a transition to nurse-led primary care; there were tensions between the different QOF roles as quality improvement tool, regulatory framework or remuneration mechanism; and that the Framework promoted simplicity over complexity and measurability over meaningfulness (161-163). The concerns and perceptions of general practice staff about the QOF are important because they could influence their understanding about new quality initiatives and whether and to what degree new indicators such as 'QS007' are 'enacted' in practice. This has important implications for this study and will be considered in detail in Chapter 9.

2.5. Safety culture

There is strong agreement that safety culture is a highly important concept, not least because it is such a decisive factor in many organisational performance and safety failures (164). Safety culture is important because organisations with a positive safety culture are more likely to learn openly and effectively from failure and adapt their working practices appropriately (165). The converse is true for a weak safety culture, which has been implicated as a causal factor in many catastrophic organisational incidents, for example the Piper Alpha oil-platform explosion, the space shuttle Challenger disaster, and the Zeebrugge ferry incident (164). Comparable NHS incidents where a poorly developed safety culture was cited as a contributory factor would include the failings highlighted in Stafford hospital (high mortality rates from emergency admissions) (29), Bristol Royal Infirmary (high infant surgical mortality rates) in England (28) and the Vale of Leven hospital (potentially avoidable deaths associated with Clostridium difficile) in Scotland (166).

What the aforementioned major incidents have shown us is the influence of high level organisational factors on safety performance and related failures, rather than much of the previous (simplistic) focus in decades past which was often on

improving local systems or technical designs or eradicating frontline human error issues (164). It is really only in the past decade that we have begun to look seriously at how we can assess safety culture in healthcare settings to identify related issues of critical importance (such as the strength and effectiveness of team working, communication, leadership, and commitment to safety improvement and so on) and consider their implications in relation to practice systems, performance and safer care.

Safety culture can be defined as '*the sub-facet of organisational culture that is thought to affect members' attitudes and behaviour in relation to an organisation's ongoing health and safety performance*' (165). The concept is organic in that culture evolves over time and is influenced by many factors, including the working environment, health & safety policies and practices, the workforce and management as well as leadership characteristics (164). The measurable 'surface' components of safety culture are collectively referred to as the safety climate – '*the individual and group values, attitudes, perceptions and patterns of behaviour that determine how seriously safety management is taken in the workplace*' (167).

Assessing the perceptions of the workforce about patient safety can provide a 'snapshot' of the prevailing culture at a given moment in time and is now a widely used and accepted approach amongst many diverse high risk industries, including nuclear power, aviation and healthcare (167). Safety climate instruments are used to measure the values, attitudes, norms, behaviours and perceptions of individual members of a workforce. In this way, the implicit and shared understandings about '*the way we do things around here*' can be rendered visible to the team in the first instance, but also potentially to others such as safety managers and clinical leaders in the organisation. Three examples of validated instruments that are commonly used are: (i) the Manchester Patient Safety and Assessment Framework (MaPSaF) in English primary care (168); (ii) the Safety Attitudes Questionnaire (SAQ) which has been translated and applied in many international secondary care settings (169); and (iii) SafeQuest, a survey with 30 questions (170).

SafeQuest was developed and tested in Scottish general practices, underwent further testing in the SIPC programme (41) and is now one of two key components of the SPSP-PC (42). All participating Scottish general practice teams periodically complete the surveys, meet in groups to discuss and act upon the survey findings, and then submit a summary report of the improvement outcomes to the local health authority.

The issue of safety culture will be considered again in more detail in chapters 6 and 10. For now, the important implication is that the prevailing safety culture (or conversely the lack of a safety culture) influences clinicians and staff to choose behaviours that enhance - or compromise - safety practices and thinking (171). Consequently, safety culture is not only an important contributing factor to PSIs but also to successful improvement efforts, interventions and initiatives.

Conclusion

A thought-provoking editorial by Dr Wachter asked the following, pithy question just over a decade ago now: 'I*s ambulatory patient safety just like hospital safety, only without the "stat"* (172)?' The answer to this question is an emphatic 'no'. There are many important differences, including: the nature and incidence of errors; patient-clinician relationships; organisational structures and resources; the types of activities and outcome measures that are regulated and rewarded; and the capacity and potential for change. While we can learn much from the patient safety research and improvement initiatives in secondary care settings, it is therefore important to remain mindful that general practice is in some ways a '*whole different world*' (172). The aim of this chapter, consistent with this perspective, was to provide an introduction to key patient safety concepts in relation to general medical practice in the UK only, rather than the whole discipline.

The first half of this chapter summarised the epidemiology of patient safety in general practice. More specifically, four common patient safety terms that were particularly relevant to this study were defined. Next, the incidence of error and harm in this setting were reported and the most common types of PSIs were described. The key messages from this section were the wide variation in the

available estimates of preventable harm and the absence of effective interventions to reduce well-known safety risks. However, while there may be reliability concerns about some of the studies' results, there are also incontrovertible evidence of unacceptable levels of preventable, iatrogenic harm in general practice.

The second half of the chapter summarised the patient safety improvement programmes, initiatives, reports and sentinel events in the UK. Selected initiatives or programmes were described in more detail because of their relevance to and strong influence on this study, including: the SIPC program; the SPSP and SPSP-PC; and the Scottish QOF. This section also introduced the concept and importance of safety culture. Safety culture is a core component or outcome measure of many safety improvement programs and is thought to be one of the essential success factors when implementing complex health care interventions. The key message from this section was that the safety of health care, including in the general practice setting, has been and remains a national priority in Scotland. However, despite considerable investment and effort, there has been no reliable evidence so far that care is becoming significantly safer.

Overall then, this chapter described the current state of patient safety in UK general practice and formulated it as a discrete 'problem' of sufficient importance to justify increased efforts and additional research to improve care standards. However, it is unclear how this may be achieved in a cost-effective and feasible manner, or which methods are effective and acceptable for this purpose. The next chapter will therefore continue the narrative by considering the second of three main groups of knowledge we can derive from patient safety research, which are potentially reliable metrics and effective improvement tools and methods with which to address the patient safety problem.

Chapter 3. The Trigger Review Method

Chapter 2 began the narrative summary of the patient safety literature from the perspective of UK general practice. Common patient safety terms were defined, estimates of the incidence of error and harm were provided and the main types of patient safety incidents (PSI) were described. A chronological summary of sentinel events, reports and influential improvement initiatives and programmes in the UK were provided and the concept of safety culture was introduced.

The main message of chapter 2 was that there is irrefutable evidence of avoidable iatrogenic harm in general practice affecting a substantial proportion of patients. Our understanding of the extent of the problem and potential contributing factors continues to increase but remains incomplete and there is a need for further research in this discipline. Until recently, the aim of the majority of patient safety research has been to produce epidemiological knowledge and increase our understanding of why PSIs occur. This is an appropriate focus for initial research in health care, because effective interventions are derived from agreement, understanding and prioritising of a problem. However, while large-scale epidemiological studies are important there is now arguably an even greater need for research to develop effective improvement strategies, methods and tools to measurably improve safety or mitigate error in all health care settings.

This chapter continues the narrative by considering the second main group of patient safety knowledge, which is about the specific methods and tools that are available for measuring and improving health care in general practice. There are four main sections. The first section describes the practical application, relative strengths and weaknesses and intended utility of five main approaches of measuring and improving patient safety. They are: (i) safety learning systems with the examples of Incident Reporting Systems (IRS), Significant Event Analysis (SEA) and Failure Mode and Effects Analysis (FMEA); (ii) Patient safety checklists; (iii) Cyclical improvement methods, e.g. clinical audit, care bundles and the plan-do-study-act (PDSA) method; (iv) mortality data and medico-legal claims analyses; and (v) clinical record review, including Trigger Tools and the Trigger Review Method (TRM).

Of these methods, the TRM is the main focus of this study and the rest of the chapter. Section two explains the practical application of the TRM and describes its three sequential steps and minimum implementation requirements. Section three describes the potential value of the TRM and how its main purpose was intentionally conceptualized as improvement rather than measurement of health care performance. This shift in emphasis was strongly supported by original research that formed a part of this study and is therefore described in some detail in the fourth and final section.

3.1. Methods for measuring and improving patient safety in general practice

3.1.1. Safety learning systems

A safety learning system is a method of monitoring the occurrence of PSIs and developing improvement strategies to address the contributing factors (7). Safety learning systems include different types of incident reporting systems, but also methods that allow analyses and learning from adverse events. The two examples of analyses-type methods that will be considered are significant event analysis (SEA) and Failure Modes and Effects Analysis (FMEA), but first a brief overview of incident reporting systems (IRS).

Voluntary IRS have been a popular patient safety research method for many years (173). They harness the unique and personal perspectives of many different health care staff groups but also patients about the care they deliver and receive. IRS are also comparatively cheaper to implement and maintain than some of the other quality improvement methods such as clinical record review. However, they do have a number of well-recognised limitations which include: selective disclosure of incidents (49); variable and poor clinician engagement (21); a perceived disconnect between the reporting, learning and improvement aspects of IRS (174, 175); and the estimated harm rates lack reliability and validity. This will be illustrated further by one secondary care and two primary care examples.

The secondary care example is the mixed-method study by Olsen et al who compared the number of adverse events detected through incident report, pharmacist surveillance and 'real-time' record review of 288 hospital admissions (176). The IRS received 11 reports. None caused significant harm and only one was reported by a doctor. Pharmacists identified 30 potential adverse events in the same cohort of patients while the record review method detected 26 adverse events and 40 potential adverse events. There was very little overlap between the three methods; each method mainly detected different PSIs, but the record review method detected the most incidents, the widest range of issues and provided the most detail about contributing factors.

The second example is a mixed methods study to identify adverse events in 4095 patients who visited their general practices during a five month period in the Netherlands (177). General practitioners reported 20 events or approximately one adverse event for every 200 patients who visited their practices. Pharmacists reported six adverse events. There were four adverse events associated with the 28 deaths during the study period. Finally, a retrospective assessment of 150 medical records by external reviewers found 11 adverse events which is approximately one adverse event for every 15 patients who visited the GPs. Again, there was little or no overlap between the detected adverse events but the record review method detected significantly more incidents.

The third example is the implementation of a general practice safety learning system in Alberta, Canada (7). Participating practices (n=19) submitted an average of 1.4 reports per month, with the number of reports decreasing over the study period. Unlike secondary care, the majority of reports were submitted by doctors, and 50% of incidents were associated with patient harm. The authors concluded that IRS provided only a '*glimpse of the scope of the [patient safety] problem*' and was not an effective method to determine the types and frequency of PSIs in general practice. They also identified a number of important barriers and several reasons for the 'low reporting rates', including: lack of time to submit reports; clinicians not recognising or interpreting incidents as reportable; practice teams not understanding the value of reporting; and the prevailing practice culture not being conducive to reporting.

3.1.1.1. Significant event analysis

Significant event analysis (SEA) is well established as a safety improvement intervention in general practice in Scotland, where its importance to the patient safety agenda cannot be overstated (8). Documentary evidence of participation was a contractual requirement of the Scottish Quality and Outcomes Framework; it remains a key element of the GP specialty training curriculum; and it is a core element of professional appraisal and medical revalidation (178). SEA has also been successfully introduced in other countries. A recent, notable example would be the inclusion of SEA as one of the core components of the RCGP patient safety toolkit (179, 180).

The SEA method is applied by clinicians and care teams to investigate and learn from sub-optimal care or any other issues of 'significance' that are highlighted for attention, but in reality the great majority of significant events are patient safety incidents (181). The process requires care teams to hold structured meetings to analyse significant events and helps them to identify learning needs and plan effective remedial action together. When undertaken constructively, these meetings provide a forum for meaningful reflection, discussion and analysis in what should be a non-threatening and empathic environment. If done well, SEA can enhance team working and morale, and improve communication and understanding between team members, all of which helps to build a more positive safety culture in GP surgeries (182).

However, there is strong evidence to suggest that many investigations into safety incidents in primary care are poorly conducted (178, 181, 182). There are several key issues that contribute to this problem. For clinicians and others, being involved in a significant event is similar to receiving a form of negative feedback. The subsequent emotional reaction to this type of feedback can interfere with the personal ability to assimilate and process the information beyond the 'self' level (183), thereby potentially impeding an objective and constructive approach to significant events and their analyses. There is also evidence that the health and emotional wellbeing of clinicians involved in these types of events can suffer (the so-called 'second-victim' syndrome) leading to increased stress and anxiety levels and feelings of guilt, helplessness, frustration

and anger (184-186). This will be discussed in more detail in Chapter 8, page 217. Additionally, a prevailing 'blame culture' is still widely perceived within health care, which impacts on the preparedness of clinicians to highlight patient safety issues because of concerns about punitive action and professional embarrassment (187). The implications are that many clinicians are highly selective in the types of safety incidents they raise for team-based discussion and analysis, potentially ignoring those of a complex, serious or highly sensitive nature and opting instead for less controversial examples, or even for non-engagement in this learning activity overall (188).

Therefore, while there is strong engagement with SEA in UK primary care, the evidence for its impact on improving the quality and safety of patient care remain mixed (178). The standard of reflection and critical analyses of such events is poor in a substantial proportion of SEAs with many teams seemingly lacking an understanding of the systems and organisational factors contributing to these incidents. Indeed, a recent review of SEA reports showed that most clinicians tend to view the causes of incidents as being mainly attributable to their own actions (181). This will be discussed in more detail in Chapter 6. For now, the important implications are that there may be numerous missed opportunities for individual, team-based and wider organisational learning from PSIs in order to minimise their risks of recurrence and there is wasted time and financial resources associated with participating in (frequently predictable) sub-optimal learning and improvement efforts.

3.1.1.2. Failure mode and effects analysis

Incident reporting systems, SEA and root cause analysis (RCA) are all examples of health care risk assessments using a structured *retrospective* review of PSIs. A complementary approach in high-risk industries is *prospective* risk assessment of complex processes to systematically identify possible ways in which they may fail, the likely impact of such failures, and proactively mitigate these risks. One of the most widely used prospective risk assessment approach in health care is Failure Mode and Effects Analysis (FMEA). FMEA includes the multidisciplinary activities of mapping out processes and systems, quantifying risks according to their probability, severity and detectability, calculating risk priority numbers

(RPN) and then intervening to reduce the RPNs. FMEA is increasingly being used as a research and quality improvement tool and serial RPN measures are held as proof that care processes are becoming safer. While this application of FMEA makes sense conceptually, a recent non-systematic review of FMEA found a lack of standardisation, '*no evidence that its outcomes are valid and reliable*' and that it is very time consuming. The review also described several mathematical challenges associated with ordinal scales and warned that '*the use of numerical scores gives an unwarranted impression of objectivity and precision*' (189).

Retrospective and prospective risk assessment approaches such as incident reporting systems, SEA and FMEA can therefore not be recommended for quantitative assessment of risk or as a reliably metric of harm. However, they do have great potential benefits as qualitative approaches to improve patient safety, particularly when multidisciplinary teams are involved and contribute to analyses and mapping of shared processes and systems.

3.1.2. Patient safety checklists

Checklists are strongly promoted as an effective way to standardize processes, increase the reliability of health care delivery and as cognitive aids to ensure task completion by clinicians and care teams (190). The expectation is that this will support workforce safety performance and provide further systemic defences against error and preventable harm to patients (191). In addition to widespread support from clinical champions the checklist approach is also underpinned by a more robust evidence base compared with many other quality improvement methods (192). A large group of international patient safety experts recently published the findings of their comprehensive assessment of the literature to identify potential patient safety strategies. They conducted a three-stage review over a four year period and identified ten patient safety strategies that are ready for immediate adoption in health care (193). Three of the ten measures hospitals were encouraged to implement relate to checklists of some kind: preoperative checklists and anaesthesia checklists; checklists to prevent central line associated bloodstream infections; and 'do-not-use' lists for hazardous abbreviations. The other seven strategies apply to specific clinical conditions and secondary care settings: interventions to reduce urinary catheter

use; care bundles to reduce ventilator-associated pneumonia; hand hygiene; multi-component interventions to reduce pressure ulcers; barrier precautions to prevent health care associated infections; real-time ultrasonography for central line placement; and interventions to improve prophylaxis for venous thrombo-embolisms.

At first glance, none of these strategies or specific checklists seems directly applicable to UK general practice. However, the conceptual benefits of a checklist approach are clearly desirable: a safety checklist provides a method to engage front-line staff in the timely and consistent checking of important issues that can impact on the safety, health, and wellbeing of people and practice performance. Bowie et al recently took the first step to this goal by developing and validating a preliminary safety checklist for general practices. The list has 78 items and six domains: medication management; housekeeping; information systems; practice team; patient access and identification; and health and safety. The preliminary checklist has potential as an intervention to measure, monitor, and improve elements of general practice safety and performance, but it is too early to know what the uptake or utility of this list will be, whether it will be associated with improved patient outcomes or the specific barriers to its implementation. However, it seems reasonable that the same barriers (i.e. competing priorities for time, inadequate training and lack of incentives) and facilitators (i.e. a mandate for compulsory use) identified by Shapiro et al to the implementation of checklists in USA procedural primary care would at least have to be considered (194).

In addition to the new general practice safety checklist, there is at least one type of secondary care checklist that may also be useful for the general practice setting – the 'Never Event' list. Never Events are '*serious, largely preventable patient safety incidents that should not occur if the available preventable measures were implemented by healthcare workers*' (195). An unambiguous example of a Never Event in the acute hospital context is performing a surgical procedure on the wrong limb. The rationale for devising and implementing lists of Never Events in healthcare, therefore, is to mitigate or eliminate the risks associated with these types of serious but preventable occurrences. There is now emerging evidence that Never Event lists and policies are delivering on this

promise in selected hospital settings (196). Consequently, a preliminary list of ten Never Events was recently developed for the UK general practice setting with the intention to help improve patient safety (Box 3.1) (197).

Before the list is implemented it may be prudent to first consider and address three important and unresolved concerns about secondary care Never Event policies in case they are equally applicable to general practice. The first concern is that some 'Never Events' currently included on lists may not in fact be preventable in every instance despite the best efforts, intentions and adherence to clinical guidelines of the healthcare workforce (198). A second concern pertains to the proliferation and 'broadening' of the Never Events concept with additional items periodically being added to lists (199). The potential risk is that the core essence of the Never Event concept as a means of focusing attention on relatively rare but serious patient safety incidents may be diluted in this process. The third concern is that Never Event policies may have unintended and unwanted consequences, not least being that Never Event lists may become synonymous with medical negligence (200).

Even if these concerns are addressed, there remain a number of important challenges in addition to those mentioned already for the safety checklist approach that will first have to be overcome for the Never Event approach to be successfully implemented in general practice. For example, how do you enforce mandatory reporting in general practice settings where engagement in voluntary incident reporting systems is minimal and inconsistent? A second challenge is whether the specified Never Events can be detected reliably by every general practice. Recent research on the effort required to identify adverse events shows, unsurprisingly, that the rarer the event, the greater the number of patient records to be reviewed to identify such events (201). Other challenges include determining who should be responsible for implementation of such a policy and how this would be resourced, promoted and prioritised.

Box 3.1. Preliminary list of Never Events for UK general practice (197)

1. Prescribing a drug to a patient that is recorded in the practice system as having previously caused her/him a severe adverse reaction

2. A planned referral of a patient, prompted by clinical suspicion of cancer, is not sent

3. Prescribing a teratogenic drug to a patient known to be pregnant (unless initiated by a clinical specialist)

4. Emergency transport is not discussed or arranged when admitting a patient as an emergency

5. An abnormal investigation result is received by a practice but is not reviewed by a clinician

6. Prescribing aspirin for a patient <12 years old (unless recommended by a specialist for specific clinical conditions for example, Kawasaki's disease)

7. Prescribing systemic oestrogen-only hormone replacement therapy for a patient with an intact uterus

8. Prescribing methotrexate daily rather than weekly (unless initiated by a specialist for a specific clinical condition, for example, leukaemia)

9. A needle-stick injury caused by a failure to dispose of 'sharps' in compliance with national guidance and regulations

10. Adrenaline (or equivalent) is NOT available when clinically indicated for a medical emergency in the practice or GP home visit

3.1.3. Cyclical improvement methods

Criterion audit, care bundles and PDSA are three quality improvement methods that may appear similar to healthcare professionals because of their cyclical nature. Criterion audit and care bundles are both methods that can be used to measure clinical performance and quality of care. If performance is found to fall short of a set standard, the individual or team is encouraged to implement change in order to improve care. The PDSA method is one possible method to achieve this aim. It requires measurement as part of this process, which is underpinned by the same considerations as criterion audit and care bundles. Each of these three methods are briefly discussed below.

3.1.3.1. Clinical audit

Criterion-based clinical audit is a widely accepted method for monitoring, assessing and improving care quality (202), particularly in UK general practice where a defined method was developed and successfully implemented by Lough and colleagues (203). A Cochrane systematic review of audit (n=140 studies) concluded that the overall strength of evidence for this type of approach to improve quality and standards of care was moderate. In terms of 'success' as a quality improvement (QI) intervention this ranked highly as an effective strategy (>10% increase in appropriate care or equivalent measure) compared with many other approaches (204, 205).

Research strongly suggests that small, highly focussed audits often lead to a much better chance of meaningful improvements in patient care being implemented and sustained (204). In general practice, there is good evidence via external review by trained peer colleagues that many GPs can implement a defined method of criterion based audit and successfully demonstrate potentially sustainable improvements in patient care, although a significant proportion can struggle with this approach (206). A review of the standard of 336 criterion audit reports found a number of 'application of method' issues which impacted on the potential for effective change and care improvement. For example, 119 projects (35.4%) were judged to have at least one methodological

deficiency in the data analysis and change management stages of the audit (207).

3.1.3.2. Care bundles

The 'care bundle' approach is promoted as a method that may be particularly useful to achieve the aims of improving the reliability of evidence-based care delivery and hence clinical outcomes (208). A care bundle is simply a small number of health care interventions grouped together which normally has a synergistic relationship that impacts on clinical outcome for patients. Bundles usually contain three to six components which may include clinical interventions such as care processes, procedures, or diagnostic tests, but are not deemed suitable to act as comprehensive lists of all possible care. Selection of appropriate bundle components is based on best evidence and/or local considerations and may change with time and experience (209).

There are many similarities between the care bundle and the criterion-based audit method. In fact, a simple way to conceptualize a care bundle is to imagine it as a group of audit criteria (209). However, there are also a number of key differences:

- The care bundle method typically focuses on specific clinical areas or conditions, while the focus of audit is typically on specific processes of care.
- The care bundle involves a composite 'all or nothing' compliance measure, while criterion audits typically report singular compliance measures for individual criteria.
- Every individual component in the bundle should be recognised as an intervention that is routinely delivered or considered for every patient within a specified time period. Compliance with a care bundle and its components is measured on an 'all or nothing' basis, whereas the performance achieved for any given audit criterion does not affect the result of any other criterion (assuming more than one criterion was specified).

Specific care bundles have been implemented in a range of secondary care settings such as paediatric and adult ICU, medical and surgical wards and Accident and Emergency departments in North America and the UK (210, 211).

Reported clinical outcomes have included: significant reductions in health care acquired infections; lower condition-specific and all-cause mortality; reduced re-admission rates of elderly patients; and decreased length of ICU stay and number of ventilation days (212). Although higher compliance rates with bundles are associated with improved outcomes (213), these are difficult to sustain because of organizational and human-system performance factors which often result in rates below 50% (214). In UK secondary care settings, reported compliance with a variety of clinical care bundles ranges from 19-52% (214, 215). Low compliance rates have important safety implications, as a positive and significant association has been found between compliance rates and clinical outcomes such as mortality (210, 215). The care bundle approach has recently been piloted in UK general practice and is included as a core component in the SPSP-PC (216). There is emerging evidence of improvements in specific, high-risk processes such as drug-monitoring but not (yet) of significant reductions in iatrogenic harm in this setting (42).

3.1.3.3. The PDSA method

The Institute of Healthcare Improvement popularized the PDSA method as a key intervention in quality and safety improvement collaboration in the early 2000s. Since then it has been used as a standalone intervention or as a key component of many different quality improvement (QI) programmes in healthcare settings worldwide (217-220).

The PDSA method is an improvement tool that can be used by individuals or teams to plan and test multiple, small and incremental changes to their everyday work practices and systems in a structured manner and then evaluate the impact over time to determine whether improvements in work quality are apparent. A single PDSA cycle consists of the four steps 'Plan, Do, Study and Act' which are performed sequentially. Any number of PDSA cycles can be undertaken sequentially, with the aims of trying different or adapted change interventions (potential improvements) and to increase the number of patients affected by the change per cycle. Cycles often build on the results of previous efforts so that improvement gains accumulate in an incremental manner (221).

The PDSA method has a number of potential benefits. Using this approach potentially enables frontline staff to test out planned care or system changes in their own local environment. This increases understanding of the potential feasibility, costs and impact of an intervention before change is implemented on a larger scale, and allows for the opportunity to adapt or abandon the changes if they do not work as planned. As each test (cycle) is small and rapid, the method can provide 'real time' feedback and is therefore relatively safe and resource efficient. The PDSA method may also help to overcome initial resistance to change from other practice colleagues who may be sceptical about the planned change.

However, like all other QI methods, the PDSA approach is not a panacea. A recent systematic literature review found that the reported application of PDSA cycles varied significantly, with many studies failing to comply with the basic principles of the method (222). A key conclusion was that there was much room for improvement in the application and use of the PDSA method and it remains unclear why, when, for whom and in what contexts it is effective (223, 224).

3.1.4. Mortality data and claims analysis

3.1.4.1. Mortality data

Baker et al reviewed the literature (n=53 studies) to determine how mortality data are currently used in the general practice setting (225). They found evidence of increasing interest in this approach in quality improvement activities with exploratory studies conducted about the roles of practice 'death' registers, monitoring and audit and critical incident reviews. However, these activities are hindered by a lack of access to timely and relevant data. In addition, no association between mortality data, quality improvement initiatives and subsequent reductions in mortality rates have been found in general practice (so far). This may be because: the relative numbers of deaths per practice are small; only a tiny proportion of deaths may be avoidable; and quality improvement efforts focusing on structures and processes may not directly affect mortality, or the effect may only become evident after longer periods of study.

3.1.4.2. Medico-legal claims

A large peer-reviewed study (n= 26,126 cases) of settled primary care medico-legal claims in the USA have important implications for patient safety and UK general practice (101). The main finding was that different proportions of claims can be due to negligence (in this case 23%), clinical errors or are the unavoidable result of appropriate care. Conversely, many errors (especially those with trivial or no consequences for the patient) and instances of negligent care are not included in medico-legal data estimates. The distinction between negligence, error and unavoidable harm is critical as there are different potential solutions and approaches depending on this differentiation. Medico-legal data analyses and studies therefore provide estimates of 'claims risk' and not 'error risk'. However, medico-legal claims data remain valuable in extending our understanding of patient safety, especially when combined with data from other methods. In particular, these types of studies have significantly increased our understanding about the incidence, nature and contributing factors to diagnostic errors, as was discussed in Chapter 2. They also provide evidence of the relative frequency of error and harm in general practice settings and the complexity of the associated and contributing individual and systems factors.

3.1.5. Clinical record review

Clinical record review (CRR) is a well-established approach of detecting and quantifying sub-optimal care issues. In fact, it is considered the gold standard approach in patient safety (226). It allows estimation of harm rates for specific patient populations at given points in time and, if repeated, allows comparisons to detect significant changes across time, whether they be deterioration or improvement. The key strength of CRR compared with the other available research, measuring and improvement methods is that it detects a significantly greater proportion of all harm incidents (227). In fact, CRR harm rate estimates are currently the closest approximation a single method can provide of the 'real' epidemiological state of patient safety.

Unsurprisingly, the original landmark studies about the prevalence of adverse events in hospitals in the USA (11), UK (14), Australia (12), Canada (228) and

New Zealand (229) therefore all used some form of CRR. However, while the studies all used CRR, their methods were typically adapted to include a 'stepped' process and included the application of various predefined screening criteria and different groups of clinician reviewers with specific tasks commensurate with their clinical experience (227).

A further strength of CRR is therefore its flexibility. Over the years there have been many examples of different successful adaptations. Different versions of CRR may involve an automated or manual process; retrospective or prospective reviews; reviewing every section or only some sections of medical records; using internal or external reviewers to the organisation; and having one, two or a team of clinicians review records. There is no single 'correct' adaptation (230).

It is important to acknowledge that using the CRR approach to detect patient safety incidents (PSIs) and measure harm does not provide information about their aetiology and contributing factors, nor does it automatically lead to improvement. It is also time consuming and expensive (177, 231, 232). In addition, the reliability (and therefore potential usefulness) of the harm rates detected with any adaptation of CRR is dependent on the method's many constituent parameters (or factors) such as: the quality of the clinical records; individual reviewer factors; and specific characteristics of the review process (227). The parameters will be considered again in more detail later. However, of all the currently available methods, the clinical record review (CRR) is, arguably, the least affected by these barriers and therefore has the most potential as a metric. This will be considered in more detail in the following sections of this chapter.

One of the better known examples of an adaptation of the CRR approach is the 'global trigger tool' popularized by the Institute for Healthcare Improvement (IHI) in recent years as a means for frontline clinicians to estimate harm rates using a rapid, focused and structured approach to record review. Their rationale for the trigger tool method in secondary care settings is its ability to quantify harm accurately with relatively small samples of medical records and to longitudinally track changes in harm rates (233). However, the term 'trigger tool' predates the IHI and was first used in 1974 to describe sentinel words that

may help to identify adverse events in medical records (234). Then, in the early 1990s it was adopted by Classen et al to describe their method of using trigger phrases to search for adverse drug events in patients' electronic records and the hospital pharmacy system (235). Specific trigger tools are now routinely used in many hospital settings worldwide (85, 233, 236, 237) and in ambulatory primary care settings, including Scottish general practice, where it is known as the Trigger Review Method (TRM). Given the relevance the TRM has for this study, the following sections will describe its practical application and potential value.

3.2. Practical application of the TRM

The TRM allows primary care clinicians (e.g. GPs, GP trainees, practice nurses and pharmacists) to review small samples of patient records for previously undetected patient safety incidents (PSI) in a structured, focused, rapid and active manner:

- Structured – clinical reviewers consider each of the five sections of a primary care record in turn (Table 3.1.).
- Focused – a specific search for pre-defined 'triggers' (e.g. sentinel phrases or words) is conducted. Triggers are prompts or 'signs' in the record that *may* indicate the occurrence of PSIs (Table 3.1.).
- Rapid - a maximum of 20 minutes is allocated per record and only a pre-specified period in each record is reviewed (usually three calendar months) (39).
- Active – clinical reviewers are encouraged to reconstruct each patient journey and should probe, analyse and critically appraise the record for evidence of PSIs and latent risks hidden in it.

Table 3.1. The five sections of primary care records and associated, pre-defined triggers (39)

Section of the record	Trigger (must be present during the review period)
Clinical encounters (face-to-face, telephone or house calls)	• ≥3 clinical encounters in any given 7 day period
Medication	• 'Repeat' medication item discontinued • Optional triggers, e.g. acute prescription of NSAIDs or opiates
Clinical codes	• A clinical READ code for an adverse drug event and/or allergy was added • Any new 'high priority' clinical code added
Correspondence (referrals, clinic letters, discharge summaries, reports)	• Any out-of-hours health care contact (out-of-hours service or Accident & Emergency) • Emergency hospital admission for ≥ 1 day
Investigations (imaging, laboratory)	• Haemoglobin ≤ 10,0 g/dl. • Optional triggers, e.g. INR > 5 or < 1.7 or AST/ALT > 100 IU/L

Clinical reviewers are encouraged to record their findings, reflections and actions on a '*Trigger Review Summary Sheet*' (SS). The SS is a double-sided template for collecting and summarizing data on the number of detected 'triggers', the details of any PSIs uncovered, any learning needs identified and actions that were or should be taken as a result of the review process. There have been many versions of the SS because it is periodically adapted to incorporate the feedback from its users. The version of the SS that was used in this study is included as Appendix 10. The definition of a PSI is provided on the SS to remind reviewers that the TRM's key focus is on detecting a circumstance where harm occurred (physically or psychologically and regardless of severity) or could have happened but was prevented (a near miss) or could happen at some point in the future.

The TRM has three consecutive steps which are described in more detail below:
(1) Planning and preparation;
(2) Review of records; and
(3) Reflection and action.

3.2.1. Planning and preparation

The first step is to define the specific patient population or medical condition from which a small random sample of clinical records will be sampled for review. Although *any* patient population or medical condition could conceivably be selected, the records of frail elderly patients and those with multiple co-morbidities and polypharmacy are more likely to contain evidence of PSIs and latent risks. Examples of potential high-yield patient sub-populations are shown in Box 3.2. Specific patient population characteristics may suggest optional triggers. For example, a trigger of 'INR >5' would be suitable for a sample of patients prescribed Warfarin.

The next step is to decide the number of clinical records to sample and what period of time is to be reviewed in each record. Practical experience suggests that reviewing three recent consecutive calendar months in each of the 25 records (randomly sampled from the chosen patient population) is feasible for the vast majority of clinicians.

Box 3.2. Examples of specific 'high risk' patient groups that could be selected for review (39)

1. Specific, Shared Patient Characteristics	2. Chronic Disease Areas	3. High Risk Medications
Nursing Home Patients	COPD	Insulin
>75 years	Stroke/TIA	Morphine
Last 25 Attending Out-of-Hours	CVD	Warfarin
Last 25 Hospital Referrals	Diabetes	NSAIDs
Housebound patients	Heart failure	Diuretics (x2)
Last 25 Hospital Admissions	CKD	>5 Repeat medication items

4. Combinations of Groups 1 to 3

e.g. Patients over 75 years, taking 5+ medications, who attended in previous 12-weeks; nursing home patients prescribed NSAIDs; patients with heart failure and who are prescribed 2 or more diuretics.

5. Choose Your Own Sub-Populations

e.g. Patients discharged after emergency hospital admission (review the period before and after admission); a random selection of any 25 patients registered with the practice.

3.2.2. Reviewing records

Once the sample of records has been identified, a clinical reviewer screens each record, searching for previously validated pre-defined 'triggers' (Table 3.1.) which may point to the existence of an unknown PSI or latent risk to the patient. For example, the reviewer finds an INR >5 (trigger) and, on further examination of the record, detects that the patient was treated for an associated bleed in secondary care. There is no 'correct' number of triggers. Instead, the number of triggers should be decided by considering the available time and resources (less triggers) and the number of PSIs to detect (more triggers). In practice, only a few triggers will be 'positive', e.g. lead to the detection of a PSI. On the other hand, one trigger may lead to the detection of more than one PSI. A maximum time of 20 minutes is allocated per record and only three calendar months are reviewed in each record. Trigger review studies have consistently found that this amount of time is sufficient (85).

When PSIs are detected, a brief summary of the event should be recorded on the SS. Reviewers are also encouraged to rate the perceived severity and preventability of each detected PSI on a scale from 1 to 4. The dual scoring system was developed by CdW and PB in response to the lack of published guidance on how to judge the 'preventability' of detected PSIs and is described further in Chapter 5. Unfortunately, but inevitably, some patients will be unavoidably harmed as a result of their interactions with healthcare for a range of highly complex reasons. This is a critical and often overlooked issue in the patient safety literature. The key focus from the patient's and the clinician's perspective should therefore be on detecting and learning from those incidents which are judged to be *preventable* e.g. there is consensus that they should not have occurred if the appropriate preventative strategies had been in place.

3.2.3. Reflection and action

In the third step of the TRM, reviewers document any clinical actions they performed during the review (this option is left to their own discretion) and indicate which further actions they intend to take on their SS. A selection of possible actions is offered (Box 3.3) but with the flexibility to consider any

action they considered appropriate. They are also encouraged to reflect on their findings and write down any learning points and needs on a professional and practice level.

Once the SS is completed, the reviewer should consider who they should share the findings with. The ideal forum for sharing the finding is during a practice meeting involving all staff. Finally, the reviewer should consider when they are going to conduct another trigger review. At present, the requirements of QOF are for two trigger reviews during a 12-month period. The first time the TRM is used, a clinician reviewer requires, on average, about two hours of protected time to complete all three stages and the SS - although this may range from around one hour to a maximum of four hours.

3.3. Potential value of the TRM

3.3.1. Appraisal and revalidation

In terms of regulatory and educational policy in the United Kingdom, 'safety and quality' is one of four professional domains describing the expected duties and standards of every doctor registered with the General Medical Council (GMC). Specifically, registered doctors are expected to '*take part in and respond constructively to the outcome of systematic quality improvement activities (eg audit), appraisals and performance reviews*' (238). The TRM is perfectly aligned with this expectation and could therefore play an important role in helping to achieve this standard.

The TRM was therefore included in the GP Appraisal process in Scotland in 2012 as a potential Quality Improvement Activity (239). In Scotland, GPs' participation in the annual appraisal process is mandatory and a prerequisite for their successful revalidation every five years. GPs have to submit supporting

Box 3.3. Suggested actions that could be performed after the review (39)

- Significant event analysis

- Criterion audit

- Implement change for improvement and how this will be achieved

- Provide feedback to a colleague

- Add SS to appraisal documentation

- Submit a formal incident report

- Update or develop a protocol

- Discuss with a GP educational supervisor

evidence of ongoing learning and 'good practice' in four domains: (i) knowledge, skills and performance; (ii) safety and quality; (iii) communication, partnership and teamwork; and (iv) maintaining trust. Each domain has core elements and minimum requirements. The minimum requirements for the 'safety and quality' domain are that GPs will submit ten SEAs and three Quality Improvement Activities in a five year cycle (239). The effect of including the TRM in the GP appraisal process is discussed further in Chapter 9.

3.3.2. Educational value

In response to the recognised patient safety problem, medical educators have started to integrate safety-related topics and issues into undergraduate education and specialty training programmes. The UK Royal College of General Practitioners (RCGP) – which has responsibility for the content of the specialty training curriculum - has developed a curriculum statement on 'patient safety' (240). They also defined specific learning objectives which require GPSTs to demonstrate a whole range of problem-solving skills aimed at improving the management of clinical risk and enhancing the patient experience of care. The TRM is one of the potential quality improvement activities they could undertake that would fulfil these requirements. The TRM also has potential educational value for non-GPST general practice staff. The findings from trigger reviews may help to pinpoint individual and team learning needs and points where patient safety may have been avoidably compromised. The educational value of the TMR is discussed in more detail in Chapter 8.

3.3.3. Improving patient safety

In general practice, safety incidents are typically reported by patients, identified directly by clinicians or highlighted by colleagues as part of routine practice. However, some incident types are not detected so easily – in fact, there is evidence that the majority of incidents remain undetected because they are not reported by patients or clinicians. Systematically reviewing clinical records for previously undetected incidents and potential threats using the Trigger Review Method (TRM) therefore provide care teams with a new perspective on patient safety, by offering valuable opportunities to take pre-

emptive action before harm occurs. The potential value of the TRM as an improvement approach to care in general practice will be discussed in detail in Chapters 7 and 10.

3.3.4. Measuring health care performance

There are at least two important reasons why harm *should* be measured and why harm rates should be calculated in health care, including in the general practice setting. The first reason is that knowledge of the scale of the patient safety problem helps to guide decisions about the amount of resources required to invest in or re-allocate to the potential problem and can inform the design and implementation of improvement initiatives. The second reason is that safety improvement initiatives and interventions need to be formally evaluated to determine whether they are cost-effective and leading to safer care (or not) and robust evaluation requires reliable serial measurements.

The original purpose of the 'trigger tool' approach as applied in secondary care settings was to reliably measure rates of harm detected in the records of specific groups of hospitalised patients over time. There, external reviewers 'objectively' determine and monitor harm rates for individual clinical wards, units and hospitals. Only the aggregated results (harm rates) are typically shared with the care teams. This application of the trigger method has two major drawbacks: the first is that frontline staff do not have ownership of the data and the second is that no attempt is made to investigate why the detected incidents occurred or how they may best be prevented in future. The general practice TRM was adapted to address both these drawbacks.

The TRM has the potential to reliably measure harm in general practice at the regional and national level, providing certain caveats that will be described shortly are observed. However, measuring harm rates at the individual practice level is a potential distraction from the arguably greater benefits to be accrued from applying the method to enhance learning and facilitate improvement activities. This approach is consistent with the explicit understanding that Trigger Tool data should not be used for 'benchmarking' purposes between institutions (241).

There are three important reasons for shifting the focus of the TRM from 'measurement' to 'improvement'. The first reason is that, when this study commenced in 2011, the available resources at the time seemed inadequate to recruit sufficient practices and clinician reviewers to review enough records in order to estimate harm rates with adequate precision or to detect changes in harm rates over time with acceptable power. As a result the decision was taken by CdW to prioritise the TRM's improvement potential over its measurement function.

The second reason relates to the philosophical question of 'how much harm is too much?' In 2011 there was already sufficient evidence to suggest that the safety of care in all health care settings, including general practice, was suboptimal and that there was great potential for improvement (174). A simple clinical analogy would be to consider morbidly obese patients. While measuring and recording an exact weight before implementing reduction strategies is recommended and would be helpful, the absence of a scale should not be used as an excuse for inaction. Similarly, detecting PSIs and becoming aware of patient safety threats in your own practice should be enough motivation for health care professionals to take remedial action, irrespective of what the true incidence of harm may be. These issues will be considered again in Chapter 10.

The third reason was of a more personal nature and informed by anecdotal feedback from clinicians and colleagues during the development and testing of the TRM. While many clinicians understood the importance of measuring harm, they reported a 'disconnect' between 'measurement' activities and what they perceived as the more important task – improving the standards of care they deliver. From their perspective, the overall number of harm incidents, the reliability of estimates and how harm rates compared across practices were unimportant or even irrelevant.

The most common feedback we received during TRM testing can be paraphrased as a question: '*what do we do after we detect harm incidents*?' The answer to this question is considered in more detail in Chapter 7. It seemed to me that unless the TRM could be adapted and made more relevant to the individual clinicians and practices who were expected to implement it, it would have no

realistic chance of ever becoming part of normal care. The best way to achieve relevance seemed to be through simplifying the method further, emphasizing the TRM's potential for learning and improvement, encouraging clinician reviewers to use their own initiative when applying the method and for them to accept 'ownership' of their findings. This approach was recently endorsed by the authors of a systematic review of the Global Trigger Tool (GTT). They recommended that the purpose of the TRM should be re-framed, as it was in this study, to understand and characterize PSIs, rather than just count them (242).

Conclusion

This chapter summarized the second group of patient safety knowledge, focusing on the specific methods and tools that are available for measuring and improving health care in general practice. The chapter began by describing five methods that can be used to measure and improve patient safety in general practice. Of these, the TRM is the main focus of this study and its practical application through three consecutive steps were described. Next, the potential value of the TRM was considered in relation to GP appraisal and revalidation, GP specialist training, as an approach to improve the safety and quality of care and as a metric for estimating harm rates.

In conclusion - Chapter 3 described the potential value and practical application of the TRM and provided a rationale for allocating time and resources to its implementation and study. However, successfully developing and testing a method – while important first steps - are not sufficient to ensure its successful implementation or eventual 'normalisation' into routine care. The next chapter will therefore review the different theoretical perspectives and approaches to implementation. In addition, a rationale for selecting normalisation process theory (NPT) as this study's theoretical framework to describe, understand and explain the implementation of the TRM will be provided. Chapter 4 will conclude with a description of the main study aims.

Chapter 4. Implementation Science and Normalisation Process Theory

Introduction

This chapter begins by introducing Implementation Science and summarizing some of the different models, frameworks and theories applied to health care, with specific reference to Normalisation Process Theory (NPT). Next, the main constructs, components and potential utility of NPT are described and illustrated with a small selection of practical examples of its use in other studies and the rationale for choosing NPT as the theoretical framework for this study is provided. The chapter concludes by formulating the main study aims.

4.1. Implementation Science

Conducting rigorous research, building a sound evidence base to inform high-quality care and designing and developing useful interventions, methods or tools for complex health care settings are all challenging tasks. However, successfully disseminating this evidence into practice or implementing an intervention and ensuring it is used long enough to become embedded into routine care processes are arguably even greater challenges. In fact, there are often 'translational gaps' as much research and many interventions are never implemented at all, or only partially adopted or not sustained despite their potential utility (243, 244). This is true across health care, but a particular exemplar in respect of quality and safety initiatives (45). As a result, precious time and resources are often squandered on unsuccessful projects while the alluring promise of efficiency and quality gains remain unfulfilled.

Unsurprisingly, researchers and policy makers are very keen to avoid this waste and are interested in identifying the facilitators of improvement initiatives as well as overcoming the multiple barriers to the transfer of knowledge in order to build research-policy-practice links (245). Implementation science was borne out of this desire and is defined as the scientific study of methods to promote the systematic uptake of research findings and other evidence based practices into routine practice to improve the quality and effectiveness of health services and

care (246). A more practical description of this 'relatively young science' (247) is that it aims to open the 'black box of change' (248).

Our current knowledge about implementation dates back more than half a century and has its roots in many disciplines, including sociology, behavioural economics and psychology. Over the years, a diverse range of implementation models, frameworks and theories have been developed and proposed, offering researchers a rich selection to choose from. However, much of the early research in health care was empirically driven without consideration of the theoretical underpinnings of implementation. This has been likened to '*an expensive version of trial-and-error'* and made it difficult to understand or explain how and why interventions succeed or fail, or to identify the determining factors of successful implementation efforts (249).

There are at least two main reasons why explicit theoretical underpinnings are desirable for designing and implementing interventions. First, theory provides a generalizable framework enabling the comparison of effectiveness of interventions in different contexts and settings and opportunities for incremental accumulation of knowledge. Second, there are almost always multiple factors at different levels that determine health care outcomes. Applying theoretical frameworks may help to reduce the risk of important determining factors being overlooked (248).

Seeking to address this 'theoretical vacuum' (250) in the intervention designs of empirical studies, the MRC issued guidelines which strongly recommend the explicit and active application of theory in order to proactively enhance the transfer of research findings into clinical practice (251). The implications of the MRC recommendations are that researchers should aim to: establish the nature of associations between an intervention and observed outcomes; recognise the potential interactions between an intervention and the setting in which it is introduced; and consider the mechanisms through which the intervention and interactions improve care or, conversely, fail to improve care. In other words, determining whether and to what extent new methods, tools, guidelines or interventions are successful in particular health care settings requires that the factors hindering and facilitating their implementation be identified and

understood. These necessary processes are greatly facilitated by judiciously selecting and applying appropriate models, frameworks and theories from which interventions' main determining factors can be derived and/or described (248).

Before considering the potential options, it is necessary to first define four common terms in this chapter: theory; model; framework; and implementation. A common definition of 'theory' is a system (or set) of analytical ideas, principles or statements held as an *explanation* or account of a group of facts or phenomena (252, 253). The terms 'models' and 'frameworks' are often and inappropriately used interchangeably with 'theories'. Models are deliberate simplifications of phenomena and are descriptive, but not explanatory. Frameworks consists of descriptive categories that provide outlines, structures or overviews of the concepts, constructs and variables that presumably give rise to specific phenomena but without explanations (254). 'Implementation' is defined and understood for the purposes of this study as '*the process of putting to use or integrating new practices within a setting*' (254). It is part of a diffusion-dissemination-implementation continuum, but should be differentiated from these related terms. Diffusion refers to the passive, untargeted and unplanned spread of new practices, while dissemination implies the active spread of new information to target audiences using specific strategies.

4.2. Models, frameworks and theories of change in health care

A review in 2004 of the available theories relating to innovation in health care at that time concluded that the literature was complex, diverse and large and articulated the challenge of describing and understanding change as the product of multiple, unpredictable interactions between interventions, specific contexts and settings (255). The different theories, models and frameworks of change in health care can be classified into five different groups, depending on whether their main focus is on: (i) stages of change; (ii) individuals; (iii) social contexts; (iv) organisations; or (v) political and economic contexts (248).

From the perspective of the 'stages-of-change' models and theories, change happens as a result of individuals and teams taking 'steps' to progress through consecutive stages. Each stage is characterized by different determining factors

and therefore requires unique strategies for change. In Roger's innovation-diffusion theory there are: innovators; early adopters; early majority; late majority; and laggards (256) while the stage-of-readiness-to-change model describes levels of motivation by distinguishing between: precontemplation; contemplation; preparation; action; maintenance; and completion (257).

The different theoretical approaches focussing on individuals as the main agents of change can be further subdivided into cognitive, educational and motivational theories.

- *Cognitive theories:* Rational decision-making theories assume the behaviour of clinicians is the result of considering evidence and balancing the relative advantages and disadvantages of different choices in an objective and impartial manner. In reality, the decisions of many clinicians may not be rational but are instead based on contextual information, previous experience and cognitive structures which combine to create so called 'illness scripts' (258).

- *Educational theories:* Adult learning theories state people are more motivated to change problems they identify themselves, compared with those that are presented to them. However, clinicians have different learning styles, e.g. activist; reflective; theoretical; and pragmatic learning styles (259). Consequently, not all clinicians will have the inclination to undertake self-directed learning. Even when clinicians do undertake self-directed learning, self-assessment is notoriously challenging (260).

- *Motivational theories:* The theory of planned behaviour states behaviour is influenced by intentions, and intentions are in turn influenced by perceptions of social norms (e.g. peers), self-efficacy (e.g. perceived control in relation to the behaviour) and the individuals' attitudes (261). Attitudes are determined by the expected outcomes of the behaviour and the clinicians' appraisal of these outcomes.

From a social context perspective, there are models and theories of communication (e.g. the persuasion-communication model; elaboration likelihood model; and heuristic systematic model), professional development and leadership, social network and influence theories and social learning theories. The different types of theories focusing on organisations include: theories of organisational culture and integrated care, organisational learning culture, complexity theory and the theory of quality management. Finally, examples of theories with an economic /political focus include reimbursement theories and the theory of contracting.

An alternative taxonomy with five categories was recently proposed based on the application of the different types of models, frameworks and theories in implementation science. The categories are: (i) process models; (ii) determinant frameworks; (iii) classic theories; (iv) implementation theories; and (v) evaluation frameworks (254). However, the author acknowledges that there is considerable overlap between these categories.

Taxonomies of models, frameworks and theories are interesting and satisfying from a scientific perspective, as is recognising and applying specific 'labels' to individual implementation approaches. However, there is a more important and serious rationale for this explicit differentiation, which is the acknowledgement that models, frameworks and theories all have different assumptions, aims and characteristics which strongly influence their potential relevance and usefulness for specific research designs.

A third and admittedly oversimplified taxonomy of the different theories, models and frameworks is therefore to categorize them into one of two main groups depending on whether they consider implementation as the product of 'institutionalization' or 'individual action' (5). 'Institutionalization' theories are those with the theoretical perspective whereby implementation is understood as the product of organisational activity. From this perspective, the 'actors' and 'contexts' are considered to interact in a predictable and rational manner during implementation processes. In contrast to 'institutionalization', theories with an 'individualized' perspective describe implementation and implementation outcomes from the perspective of the 'actors'. A central assumption of these

theories is that individuals have 'free will' and actively choose to implement an intervention (or not). Current evidence supports this perspective - at least to a degree – with a general consensus that 'individual' factors are indeed important determinants of successful implementation, but that they only account for an estimated quarter of the observed outcomes (262, 263).

Several decades of research and the anecdotal experiences of many clinicians strongly suggest that, while these two perspectives of implementation are helpful, neither fully describe or 'capture' the complexities of developing, successfully implementing and evaluating complex health care interventions. Organisational innovations and new health care interventions are often imposed and individuals and teams have to work creatively to flexibly configure their existing practices to accommodate the changes according to their own specific requirements and local contexts. If there are workability issues with an intervention that they cannot resolve it leads to problems with integration. The majority of models, frameworks and theories also only describe and explain implementation processes retrospectively, e.g. they either lack predictive power or it may be that they have not been used in this way.

Given the relative limitations of existing theoretical perspectives about implementation, the need for a new and different theory of implementation became apparent that can mediate between macro (e.g. diffusion, institutionalization and organisational level factors) and micro (cognitive and individual action) levels of analysis (46). In response to this challenge Normalisation Process Theory (NPT) was developed. While there are many similarities between NPT and other, existing theories, NPT expands our understanding of implementation by offering a third potential perspective: successful implementation is the product of the 'work' health care staff have to do individually and collectively to implement research, a new method or a complex health care intervention. This, arguably, makes NPT a useful theoretical approach with which to explore the implementation of patient safety initiatives, such as the TRM. Before considering this, NPT is first described in more detail below.

4.3. Normalisation Process Theory (NPT)

The Normalisation Process Model (NPM) was developed and validated while conducting telemedicine and chronic disease management research in UK primary care settings in order to better understand the work required to implement such interventions in primary care across multiple studies conducted between 1995 and 2005 (44). This model consisted of four components that allowed barriers and facilitators in relation to the work of implementation of complex healthcare interventions to be identified, described and evaluated. However, it does not explicitly consider what the intervention is trying to achieve; who needs to be involved; and how the impact of the intervention is monitored. Innovation and change are recognised as often arising from external sources or being imported into local contexts but, because the departing point of the model is 'normalisation', the focus is on the '*creativity imbued in everyday professional work*' (46).

Recognising that implementation work is greater than the actual activities and resources required, NPM was subsequently further developed into the Normalisation Process Theory (NPT) (5, 243, 264). The most significant changes to the model were grouping the four original components together as a single construct – 'collective action' – and then adding three additional constructs focused on understanding, engagement and monitoring (264). NPT is a formal and verifiable theory with the purpose of empirical application rather than abstract critique. It is defined as an '*explanatory framework for investigation of the routine embedding of material practices in social contexts' (5).* Material practices are regarded as all of the things people do when they implement complex health care interventions (245).

NPT is a middle-range theory of social action making it amenable to the development of testable questions and propositions. Theories are considered 'high', 'middle' or 'low' depending on their place in an abstraction level continuum. The 'high' level theories have a universal or almost unlimited scope of application, while 'middle' level theories explain limited sets of phenomena (253). There is currently no 'high' level theory of implementation. It is possible in some disciplines to build a higher level theory from lower abstraction level

theories (analogous to building a wall from bricks). While a general theory of implementation has recently been proposed (265) the general consensus is that it is very unlikely there will ever be a grand theory of implementation because implementation is too multifaceted and complex to allow universal explanations (254).

NPT is a theory about the 'work' people do collectively and as individuals to implement and sustain an intervention – in the instance of this study, the intervention is the TRM and the main agents of change are primary care clinicians. From this perspective, 'work' is defined as '*purposive social action that involves the investment of personal and group resources to achieve goals*' (5). In other words, NPT is more concerned with understanding what people do than in their attitudes or beliefs.

The term 'normalisation' is defined as the embedding of a technique, technology or organisational change as a routine and taken-for-granted element of clinical practice (46). It includes all of the stages from design, development and testing of an intervention, through to its implementation, embedding and finally integration (5). Normalisation should be differentiated from adoption (e.g. an intervention is accepted and is used from time to time) and rejection (e.g. an intervention is spurned). Just because some innovations and interventions become normalised do not necessarily imply that they were effective in achieving their intended outcomes, nor that they are of high quality or that they are permanent, e.g. they may become de-normalised with time (44). The converse is also true – an intervention may be useful and meet the organisational criteria for success and yet not become normalised (266). This is why 'proof of concept' studies add little value to the evidence base in implementation science and are unlikely to do so (267, 268). However, despite this conceptual problem much research still focuses on 'can it work/does it work?' questions rather than asking 'how' interventions should be implemented.

4.3.1. NPT constructs and components

NPT focuses attention on the different types of implementation work as described and categorized according to four main interactive constructs termed:

coherence; cognitive participation; collective action; and reflexive monitoring. NPT postulates that for evidence and innovation to become routine practice ('normalised'), work has to be done to understand and organise the method (coherence), staff have to be enrolled into using it (cognitive participation), the method has to be enacted (collective action) and work has to be done to organise, collect and interpret data about the method's effects (reflexive monitoring) (5).

The four main constructs are characterised by specific types of 'investments' required from implementers, without which successful normalisation becomes highly unlikely. Each construct is further divided into four sub-constructs or 'components', which allows the specific nature of the work to be described in more detail. The components have been referred to as 'generative mechanisms' because aggregating their different and specific 'work'/tasks produces the outcomes from implementing an intervention (5).

Although the constructs and components describe different types of 'work', they are highly synergistic, fluid, dynamic and often exist concurrently (5). In practical terms, this means that constructs and components constantly 'interact' with the potential to influence and change each other. The relative importance of each of the constructs and components fluctuate over the implementation period but also between particular empirical contexts. A simple analogy of NPT would be that 'components' are atoms and 'constructs' are molecules. Just as atoms and molecules may potentially interact, influence each other to varying degrees and change over time, the constructs and components affect each other and are also affected by external factors. An example would be the work of 'enrolment' of staff and 'initiation' of a project which are clearly related in a practical and temporal sense. These tasks are particularly important during the early phases of implementing a new initiative.

The NPT constructs and all of their components are described next in more detail (5, 243, 264). The NPT coding framework that was used in this study are summarised in Table 4.1.

Table 4.1. The NPT Framework

NPT constructs and components	Description
Coherence	The work participants have to do to understand the TRM
• Differentiation	The work participants do to understand the differences and similarities between the TRM and their existing methods, tools and practices.
• Communal Specification	The work required by all those involved to understand the purpose, aims and potential benefits of the TRM.
• Individual Specification	The work of considering and quantifying the expected 'effort', time and resources that will be required by the individuals involved to successfully implement the TRM. This work helps to determine whether the TRM is perceived as feasible.
• Internalization	The work participants do to understand and interpret the TRM in relation to their own principles and beliefs and also the prevailing culture in their team or organisation. This work helps to determine whether the TRM is perceived as acceptable.
Cognitive Participation	The relational work required to build and sustain a community of practice around TRM.
• Initiation	The work of preparing for the implementation of the TRM. This includes identifying and involving key participants willing to 'drive forward' the identification of the TRM.
• Enrolment	The work of recruiting participants who will implement the intervention and keeping them engaged in the process.
• Activation	The continuing support work that is necessary to sustain the use of the TRM
• Legitimation	The work required by everyone involved to legitimize and justify their involvement with the TRM to themselves and each other
Collective Action	The operational work required to enact the TRM and requires participants to invest effort
• Interactional workability	The work of applying the TRM in practice (e.g. what respondents actually did) and the time and effort this required (as opposed to what they perceived it would be). What effect (if any) did implementing the TRM

	have on their routine work?
Relational integration	The work of building and maintaining confidence, trust and accountability in the TRM and in each other's ability to successfully implement it. To be effective, this work requires formal and informal sharing of trigger review findings
Skill-set workability	The work of dividing tasks and allocating resources so that the TRM can successfully be implemented in practice
Contextual integration	The work of integrating the TRM into existing structures, contexts and policies; the level of organisational support and resources at local, regional and national level.
Reflexive Monitoring	The work of assessing and appraising the individual and communal worth of the TRM
Systemisation	The work of collecting and organizing adequate and reliable data about the TRM to enable evaluation and to identify the benefits or problems of the TRM
Individual appraisal	The work participants do to evaluate the TRM's worth for them
Communal appraisal	The work of participants to collectively evaluate the TRM's worth, including to others
Reconfiguration	The work participants do to modify the TRM, themselves or their contexts

4.3.1.1. Construct: Coherence

Coherence (CO) is the *work* individuals and teams have to do in order for them to make sense *of* an intervention - in this case, the TRM. This includes the work required to understand an intervention as something new and worthwhile. In other words, they need to create 'a cognitive and behavioural ensemble' of the TRM (5). In practical terms this means working to package the TRM so it becomes a unique and recognizable entity that can 'stick' within specific contexts. Participants' understanding typically increases and evolves over time and requires them to invest meaning in the TRM. Coherence has four components: differentiation; individual specification; communal specification; and internalization.

Differentiation

Differentiation is the work participants do to understand the differences and similarities between the proposed method, tool or intervention and their existing methods, tools and practices. In the case of the TRM participants may have to do work to compare and contrast the TRM with formal and informal review processes of medical records they currently undertake and with existing QI methods such as SEA and clinical audit they already routinely applied. They also need to understand how the 'steps' of the TRM relate to each other and how a first and subsequent reviews may be different.

Communal specification

Communal specification is the required work to understand the *purpose* of the intervention (the TRM). What is the TRM's likely value for them collectively, for the practice and for their patients? In other words, do they think the TRM is useful? Participants' understanding of the aims and benefits may be different from the intervention's intended aims and benefits. If this difference is small, there is a 'high degree' of 'communal specification', which is desirable as it helps to facilitate normalisation.

Individual specification

Individual specification (IS) is the work of considering and quantifying the expected 'effort', time and resources that will be required by the individuals involved to successfully implement the intervention, and how this could best be done. In other words, how feasible would it be to implement the TRM? While a sound understanding of the task requirements are important, it does not necessarily mean that the resources or appropriately skilled, trained and experienced staff are available or willing to participate. Allocating adequate resources and effectively recruiting (the work of 'enrolment') and engaging clinicians in the project require the additional work of 'skill set workability' (discussed later).

Internalisation

Internalisation describes the work participants do to understand and interpret the TRM in relation to their own principles and beliefs as well as the prevailing culture in their team or organisation. In other words, is the TRM acceptable to them and do they see the benefits of using it? Internalisation also includes the work they have to do to interpret the findings from the trigger reviews in relation to their own contexts.

4.3.1.2. Construct: Cognitive participation

The cognitive participation (CP) construct describes the relational work that is required to *build and sustain a community of practice* around an intervention and requires participants to invest commitment. This involves identifying *who* should be involved with the TRM, *recruiting* and organizing them and keeping them *engaged* throughout the implementation process. CP's four components are: initiation, enrolment, activation and legitimation.

Initiation

Initiation (IN) is the initial work of successfully 'bringing forth' an intervention and requires key participants who are capable of 'driving forward' an

intervention. Examples of initiation work include promoting and raising awareness of the TRM and planning and delivering educational events.

Enrolment

Enrolment (EN) is the work of recruiting participants who will implement the intervention and keeping them engaged in the process. In other words, EN describes *who was involved* with the TRM and when, in what capacity and to what degree they contributed. In particular, it addresses the degree of 'buy-in' that individuals show towards the intervention. However, the work of determining *who* should be involved in implementing the TRM is described by the 'skill set workability' component.

Activation

The activation (AC) component describes the *continuing support* work that is necessary to sustain the use of an intervention. From a TRM perspective, 'activation' work includes the different improvement actions reviewers and teams considered or undertook after trigger reviews. For this work to be successful, participants needed to remain actively involved in the process. This, in turn, depends on whether they feel 'empowered' to enact change and they consider ongoing participation as 'right' for them (the work of Legitimation – see below).

Legitimation

Legitimation (LE) is the work clinicians and general practice staff have to do, but also the work of policy makers and professional organisations, in order to legitimise and justify their involvement with the TRM to themselves and each other. In other words, it is the work that is necessary so participants believe implementing the TRM is the 'right' thing to do.

4.3.1.3. Construct: Collective action

Collective action (CA) is the operational work required to *enact* the TRM and requires participants to invest effort. The CA construct describes the organisational, external, immediate and internal factors that may hinder or facilitate the implementation process. The four components of CA are: interactional workability, relational integration, skill-set workability and contextual integration.

Interactional workability

Interactional workability (IW) is the work of applying the intervention and, in particular, whether the intervention makes the 'day job' easier or harder for individuals. In the case of the TRM it therefore involves screening samples of electronic patient records for PSIs. It is important to consider whether informal work-place rules may be affecting this work, and if the intervention helps or hinders clinicians' 'normal' work. The IW component includes the actual time and effort the work required, whereas participants' perceptions of the time and effort they invested is described by the 'individual specification' component (part of the coherence construct).

Relational integration

Relational integration (RI) is the work of building and maintaining confidence, trust and accountability in an intervention and in each other's ability to successfully implement it. In other words, RI is the work of incorporating the TRM within existing relationships. This component should be differentiated from the work of 'legitimation', which is the work participants and external parties do in order to agree that they should be enacting the intervention. Are TRM findings being shared and, if yes, how and with who?

Skill-set workability

The Skill-set workability (SW) component describes the work of dividing and allocating resources so that an intervention can successfully be implemented.

This requires division of labour, e.g. 'who does what?' In the case of the TRM, records may only be screened by trained clinicians. The SW component also includes the work of deciding who has the power to make the decisions about resource allocation and work delegation. To be effective, skill-set workability requires consideration of the knowledge, skills, attitudes and capacity of staff.

Contextual integration

Contextual integration (CI) is the work of integrating the TRM into existing structures, contexts and policies: the Quality and Outcomes Framework (QOF); Local Enhanced Service (LES); appraisal and revalidation; GP Specialist Training (GPST) curriculum; regional and national Quality improvement initiatives such as SIPC and SPSP-PC. In addition, there is work to incorporate the TRM within the prevailing safety culture (work that is shared with the 'initiation' component) and professional roles (work that is shared with the relational integration component). The work of CI depends on the availability of adequate and appropriate resources and therefore also includes: provision of new resources or re-allocating existing resources; senior leadership support; restructuring current policies and infrastructure to include, promote and support the TRM.

4.3.1.4. Construct: Reflexive monitoring

Reflexive monitoring (RM) is the work of assessing and appraising the individual and communal worth of the TRM. It has been defined as: '*the work of understanding and evaluating a complex intervention in practice*' (269) and requires participants to invest comprehension. This work requires adequate time, reliable metrics and sharing of results. The four components of RM are: systematisation, individual appraisal, communal appraisal and reconfiguration.

Systematisation

Systematization (SY) is the work of collecting and organizing adequate and reliable data about the TRM to enable evaluation and to identify the benefits or problems of the TRM. This work is normally undertaken through a combination of formal and informal methods. This component is therefore also concerned with

the methodological formality with which implementers derive value-judgements about the TRM's usefulness.

Individual appraisal

The individual appraisal (IA) component describes the work participants do to evaluate the TRM's worth for them, e.g. the clinician reviewer, the reviewer's practice team and their patients. IA is typically informed by data derived from informal methods and relies on 'experiential and unsystematic practices of judging the value and outcomes of practice'.

Communal appraisal

This component describes the work of participants to collectively evaluate the TRM's worth, including to others, *e.g.* clinicians, practices and specific professional and patient groups other than their own. Communal appraisal is typically informed by data derived from formal methods (at least in comparison with IA).

Reconfiguration

Reconfiguration (RE) is the work participants do to modify the TRM, themselves (e.g. their attitudes, skills, knowledge, tasks) or their contexts (practice procedures, policies and infrastructure).

4.3.2. The rationale for selecting NPT for this study

NPT has at least three important 'strengths' which help justify its selection to inform the study design and analysis in this work. First, it was developed in the UK primary care setting with methodological rigour, its design process was transparent and it was subsequently validated through practical application in 'real life' settings. Second, because NPT is about 'workability in practice' (269) it can be applied iteratively to study temporal changes in perceptions, actions and outcomes. Third, it is transferable to different healthcare settings and can be applied to a wide range of innovations, methods, tools and interventions.

Even though NPT is relatively young in research terms – it was developed only a decade ago - it has already been successfully used in multiple studies and settings.

For example, in the UK, NPT has been used to study the implementation of nutrition guidelines for elderly patients in residential care homes (270), to evaluate the integration of Telecare management of chronic diseases in the community (268, 271), as a framework for generating and analysing data relating to the management of early chronic kidney disease in primary care (272) and to assess the treatment burden among patients with chronic heart failure in general practice (273). In Australia, the barriers and enablers to initiating insulin in primary care were identified (274) and a conceptual NPT framework was used to design a new model of depression care in general practice and study its effective implementation (275). A similar approach was adopted in the Netherlands to implement a stepped-care approach to the management of depression in primary care (276). Finally, NPM was used in South Africa to analyse provider experiences of a new tuberculosis treatment programme (277) and a provider-initiated HIV testing and counselling intervention (278).

This small selection of studies help to demonstrate some of NPT's multiple potential applications. Its main use so far has been as a validated, conceptual framework for *describing*, *understanding* and *evaluating* complex health care interventions. However, it can and has been used to help design, develop and test complex interventions and to optimize trial parameters (269, 279). In this way, NPT allows implementers to focus through a socio-technical lens on areas likely to be problematic and direct their efforts accordingly (243). Another important application is to help 'bridge the translational gap' between research and innovation and their practical implementation by identifying possible barriers and facilitators to these processes (245).

While post-hoc explanations and interpretations of events are important, an 'ideal' theory overcomes the significant methodological and theoretical challenge inherent in predicting future outcomes with at least a modicum of reliability and success. This holds true in the field of implementation science because, no matter how complex and emergent implementation processes may

appear, they are subject to normative and structural constraints that are usually not arbitrary. Consequently, the '*trajectory of a practice can be anticipated within certain limits*' which in turn enables '*prospectively assessing the potential of practices to normalise*' an intervention (5). In other words, NPT can be applied to determine the more likely outcomes of an intervention, e.g. whether it will be successfully normalised or not. At the very least, NPT can be applied to judge the implementation potential of an intervention. The practical implication is that NPT may therefore have utility as a potential 'trial killer' (243, 269). Applying the NPT framework to a study proposal would help to determine the likelihood of that intervention being successfully normalised, and hence whether it is worthwhile to proceed with the study or not (245).

4.4. Study aims

This thesis describes the study of the implementation of the TRM in the general practice setting in Scotland. There are four main study aims.

- *To describe the perceptions and understanding of general practice clinicians and staff about the concept of 'patient safety' prior to the TRM being implemented*. Perceptions powerfully influence and create the unique contexts within which health care interventions are implemented. The current consensus is that the successful implementation of interventions is strongly associated with the degree to which the planners consider and take into account the contextual factors and the setting into which they transfer their interventions (243, 250, 251, 280). Becoming aware of and understanding pre-existing perceptions and contexts are therefore important to understand the outcomes from implementing the TRM, and are described in Chapter 6. Considering the perceptions of the participants in the design and planning stages of the study helped to increase the likelihood of the TRM being understood as acceptable, feasible and potentially useful.

- *To evaluate the usefulness of implementing the TRM by describing its main outcomes*. Chapter 7 considers the questions related to this aim: how did the general practice staff implement the TRM, what did they find and what did they do next? More specifically, how many trigger reviews were undertaken,

what number and types of patient safety incidents were detected, which improvement actions were considered or undertaken and how much effort did this require? In addition, the degree to which the study participants perceived the TRM as feasible, acceptable and useful is also described. The qualitative and quantitative results that are presented in Chapter 7 provide evidence of the different aspects of the usefulness of the TRM. The study findings therefore help to answer an important question which is raised in Chapter 10: should the TRM be normalised?

- *To explain how the TRM works.* Chapter 8 explains how the TRM produced the results that were observed – whether positive or negative. It also describes the related issue of the learning that occurred as a result of the trigger reviews.

- *To identify and describe the main factors that facilitated or hindered the implementation of the TRM in general practice.* Understanding what the main factors are that determine whether interventions are successfully implemented and normalised extends the potential impact of the study from a single intervention in a single setting. However, for this potential to be realized, a structured assessment of potential factors that may facilitate or hinder these processes are required, which is provided in Chapter 9. The study findings also help to inform recommendations about future improvement interventions and application of the TRM; whether the TRM should be normalised or not and how the process may best be facilitated; and which areas of research should be prioritised (Chapter 10).

Before the main findings are presented, the different methods that were used to achieve the four main aims are first described and discussed in the next chapter.

Chapter 5. Methods

This chapter begins with an overview of the study design and a description of the sampling and recruitment strategies. The two main data sources are described: semi-structured interviews with practice managers (PM), practice nurses (PN) and GPs; and (iii) Trigger Review Summary Sheets (SS). In particular, the data collection strategies and the methods that were used to analyse the qualitative and quantitative data are described. The chapter concludes by considering data protection issues and ethical requirements.

5.1. Study design

The study design was a mixed-methods approach comprising semi-structured interviews with a range of general practice clinicians and staff at two different points in time and a cross-sectional review of electronic patient records by trained clinicians who applied the Trigger Review Method (TRM).

Some of the early studies about patient safety in general practice have been likened to '*picking low hanging fruit'* because they were opportunistic, the results could not be generalised from the original to other settings and they often provided only a narrow perspective of certain types of harm and error (177). In reality, patient safety incidents (PSIs) have complex and diverse contributing causes that can be understood from different perspectives (281). Four specific perspectives of the contributing causes of PSIs will be described in Chapter 6, page 163. For now, the important implication is that different improvement approaches and interventions only provide information about specific aspects of patient safety. Similarly, different research methods can only provide patient safety-related data from specific perspectives.

One of the key benefits of a mixed-methods study design is therefore that the different, complementary perspectives about PSIs that they provide can, in combination, enhance our overall understanding of patient safety. A second benefit of this approach is that, by combining different methods, their respective limitations are compensated, at least to some degree, while the veracity of the main findings are enhanced (282). In this study quantitative

methods were used to collect data about the incidence and nature of PSIs and the range of improvement actions considered or undertaken during and after the trigger reviews. Simultaneously, qualitative methods were used to explore and describe the perceptions of general practice staff and clinicians about the TRM, the contexts within which it was being applied and the related implementation processes. Combining the results from the different sources of data provided more complete and reliable answers to the questions posed in Chapter 10 about the potential usefulness of the study and how generalizable its findings were than would have been the case if only a single source of data had been available.

5.1.1. Setting and sample

The study was undertaken in the West of Scotland region in two NHS Health Boards (henceforth BOARDS): Greater Glasgow and Clyde (GGC) and Ayrshire and Arran (A&A). The BOARDS contain 262 and 57 general practices respectively and cover a wide range of settings from severe socioeconomic deprivation to areas of affluence, with practices located in urban, suburban and rural areas.

A range of different types of general practice staff was included in the study to allow exploration and comparison of clinical and non-clinical perceptions of patient safety in general and the trigger review method in particular. The decision to include multiple staff groups was also motivated by the multidisciplinary nature of general practice and its strong ethos of working in teams.

The study sample was obtained from two main sources. The first source was a convenience sample of 12 GP practices from GGC (n=10) and A&A (n=2) BOARDS. In each surgery, at least one GP and the practice manager actively participated, while participation by a practice nurse was strongly encouraged. The second source was a convenience sample (n=25) of GP specialist trainees (GPSTs) from the West of Scotland.

The pragmatic choice of a convenience (or non-probabilistic) sampling strategy was motivated by time and resource constraints and ready access to an

established network of general practices with an interest in quality improvement and research. The sample size was informed by the need to collect sufficient qualitative and trigger review data, to allow for a proportion of practice teams potentially withdrawing during the study period and the budget that had been allocated to this specific research project.

The GP teams and GPSTs were not involved in any other research projects during the study period. However, some of the practices were participating in two Local Enhanced Service (LES) Quality Improvement projects. The projects were medication reconciliation; and improving the reliability of care delivered for patients prescribed disease-modifying anti-rheumatic drugs (DMARDs) by applying a Care Bundle approach.

5.1.1.1. The 'QOF study' sample

The inclusions of the TRM in the Scottish QOF and as an integral component of the SPSP-PC were described in Chapter 2. These events occurred shortly after the data collection phase of this study had been concluded and before the analysis had been completed. A timeline of the events were provided in Figure 1.1, page 27. The implication was that virtually all general practices in Scotland implemented the TRM from April 2013 onwards, using essentially an identical approach as in this study. Consequently, thousands of patient records were reviewed in Scotland, and more than a thousand Trigger Review Summary Sheets (SS) were submitted to the BOARDS in the 2013-14 financial year.

CdW was commissioned to evaluate the implementation of the TRM as part of QOF by NHS Education for Scotland (NES) on behalf of the BOARDS. The final, approved evaluation reports were subsequently rewritten, submitted for peer-review and published (48). CdW also provided informal support and advice to a third BOARD, NHS Lothian. Direct access to the aggregated trigger review data from the three BOARDS (with their express permission) provided a unique opportunity for comparative analysis with the data collected for this study. In Chapter 7, when the quantitative results of this study are presented, the aggregated data from the BOARDS will also be presented for comparison and

context. The results from the BOARDS will henceforth be referred to as the 'QOF study' to differentiate it from this study.

5.1.2. Recruitment

Potential participants for this study were identified from two different NHS Education for Scotland (NES) 'lists'. The first list consisted of the contact details of approximately 21 practices that had previously supported NES research projects, including the implementation of other quality improvement interventions, and who had provided invaluable feedback about their perceived utility.

The second list was the e-mail addresses of all of the active general practice educational supervisors in the West of Scotland. NES maintains this database to help support its core business, which is postgraduate medical education, including the delivery of GP Specialist Training in Scotland. The strategies that were used to recruit general practices and GPSTs for this study are described below.

5.1.2.1. Recruitment of practices

Practice managers (n=21) were sent written information about the proposed study, its rationale and an invitation to participate via e-mail in April 2012. The invitation letter is included as Appendix 2, page 293. There were three main requirements:

(i)   The designated clinician reviewers and the practice manager would undergo TRM training;

(ii)   The general practitioner, practice nurse and practice manager would each participate in *two* individual, semi-structured interviews. The first interview would be scheduled before the training event and trigger reviews. The second interview would be conducted after all of the SS had been submitted;

(iii)   The practice would submit four SS, with at least two of the four prepared by a GP reviewer.

The first 12 general practices who responded affirmatively to the invitation were selected. Each practice nominated at least two clinicians, one of which had to be a GP, to receive TRM training. Each participating practice received an equal professional fee paid once they had agreed to participate in order to help recompense them for the time spent on the project. The amount was equivalent to that of one practice manager, three GP and three practice nurse sessions and was calculated from the sessional payment rates NES agreed at that time.

5.1.2.2. Recruitment of GPSTs

In April 2012, all GP Educational Supervisors in the West of Scotland Deanery were e-mailed (n=322) with details of the study and were asked to discuss this with their trainees. The invitation letter is included as Appendix 3, page 295. There were two main requirements of participants:

    (i)   They would undergo TRM training;

    (ii)   Each participant would submit one SS;

The number of participants was restricted to the first 25 GP trainees to indicate a willingness to participate via email response. The GPSTs did not receive a professional fee but could claim their travel costs incurred in relation to the TRM training event.

5.1.3. TRM training

The TRM training sessions had a number of key components, which are shown in Box 5.1 These components were developed and refined over several years prior to this study through practical experience and participant feedback during initial TRM pilot work and the SIPC programme. The components are flexible and can be tailored to the size of the group of learners, their specific learning needs and the available time.

The aim of a TRM learning session is to help prepare clinicians to successfully apply the TRM. The two main objectives are that, as a result of the training sessions, reviewers will be able to: (1) review their own clinical records in a rapid, structured and focused manner in order to detect PSIs and potential

Box 5.1. Components of the TRM training intervention

- A *patient safety quiz* with feedback to introduce the evidence base for the epidemiology of error and harm in primary care.

- A *group work exercise* on matching a range of patient safety terms to their definitions in order to help increase participants' shared understanding of key terms such as 'patient safety incident'.

- A short PowerPoint *presentation* about the Trigger Review Method (TRM)

- Provision of a TRM *educational support package* consisting of: (i) a step-by-step implementation guide; (ii) simulated patient records with 'worked out' solutions; (iii) the Trigger Review SS template; and (iv) practical examples of how to rate PSI severity and preventability.

- Opportunity for individual participants to *practice* performing 'trigger reviews' of simulated patient records, followed by discussions in small groups and then feedback in an open forum. The objective is for reviewers to identify at least four of the PSIs contained in the examples within 20 minutes, and to make judgements on the severity and preventability of these incidents.

- *Clarification* of the study's expectations, including informing participants about the 'high risk' patient groups from which they were to select their sample of clinical records for trigger reviews and where to send their completed SS documentation.

safety-critical issues and; (2) learn from and act on the findings in order to improve the quality and safety of the care they deliver.

5.1.3.1. Training of practice teams

The nominated clinicians from each participating practice were trained to use the TRM by CdW at a time of their choice. Any number of additional team members was able to attend. Training lasted up to three hours and was delivered on the practice premises. All of the training components were delivered, but the duration of each component was adjusted according to the needs of each practice team.

5.1.3.2. Training of GPSTs

A dedicated three-hour training session was offered exclusively to participating GPSTs. They were offered two possible dates in May 2012 in a central Glasgow location to give some attendance flexibility to the volunteer participants. The two training sessions were delivered by the same facilitators (PB and JM).

5.2. Data collection

The data in the study were collected with two different methods, semi-structured interviews and Trigger Review SS templates, and are described below.

5.2.1.Semi-structured interviews

Two different interview schedules were developed – one for the first round interviews scheduled before the TRM training session - and the other for the second round interviews undertaken after the practice teams had concluded their reviews and submitted their SS. The schedules were derived from patient safety literature, previous experience of research in this discipline and through discussion with PB and COD (283). In addition, the second interview schedule was based on the NPT framework. The interview schedules are included in Appendix 6 and 7, pages 299 and 300.

The first interview with each participant was conducted *before* the training session and aimed to explore in confidence participants' awareness, experiences and perceptions of the state of patient safety in primary care and how safety may be addressed. The second interview was conducted *after* all SS had been submitted. The second interview aimed to explore the potential acceptability, feasibility and usefulness of the trigger review method.

The interviews were conducted in the participating GP practice premises at a time convenient to the participants. Informed consent was obtained before commencing interviews. The practice and individual consent forms are included as Appendix 4 and 5, pages 297 and 298. Following written consent, interviews were recorded using a digital recorder and supporting field notes were made. The number of interviews, their duration and the types of individual participants are summarized in Table 5.1.

Only one participant was unable to commit to a time for the first round of interviews (GP12). A minority of participants were unable to participate in the second round of interviews. This was because two PMs had developed significant health problems, while PN07 had left the practice and her position had not been filled by the end of the study period.

5.2.2. Trigger reviews

Each practice was asked to conduct four trigger reviews in total during the period of time from June 2012 to July 2013, with at least two of these performed by a GP. GPSTs were given a four-week period after their training session to undertake the TRM and submit one completed SS each. Each Trigger Review was conducted on a random sample of medical records (n=25).

After the data collection phase of the GPST component of the study had concluded, the trigger review process was slightly adapted. Reviewers in the GP component of the study were advised to stop searching for PSIs once they had detected five. Instead, they were encouraged to use the remaining time to consider how to act on their findings. The reason for 'capping' reviews at five

Table 5.1. Summary of the number and duration (in minutes) of individual interviews

ID	GP interviews			PN interviews			PM interviews			All
	1st	2nd	Both	1st	2nd	Both	1st	2nd	Both	
1	45	*	45	58	*	58	NA	NA	-	103
2	66	52	118	57	45	102	46	19	65	285
3	56	57	113	58	27	85	54	22	76	274
4	59	54	113	49	30	79	58	x	58	250
5	54	62	116	49	28	77	45	x	45	238
6	53	49	102	55	30	85	60	35	95	282
7	57	50	107	38	X	38	60	x	60	205
8	48	62	110	73	70	143	76	x	76	329
9	54	15	69	56	41	97	64	41	105	271
10	57	44	101	58	54	112	52	28	80	293
11	58	54	112	44	22	66	43	x	43	221
12	x	41	41	49	21	70	59	x	59	170
All	607	540	**1147**	644	368	**1012**	617	145	**762**	**2921**

*GP01 and PN01 requested a group interview in lieu of a second, individual interview. Its duration was approximately 90 minutes and is not included in Table 5.1.

NA = PN01 was also PM01. She indicated her preference to be assigned as PN rather than PM for this study.

X = participant unavailable for an interview

PSIs was pragmatic as it is possible that GP teams would not be able to feasibly deal with all incidents detected during a review, given time and resource constraints.

Reviewers were asked to complete a trigger review SS after reviewing each sample of records (n=25). The SS template is described in more detail in the next section and is included as Appendix 8, page 301. Reviewers were also strongly encouraged to 'fix' any obvious problems that could be achieved quickly and without much effort while conducting the reviews, e.g. updating a patient's allergy coding status. Participants were advised that the total review process (collecting and reviewing a sample of 25 records and completing the SS) should take approximately two to four hours and that no more than 20 minutes should be taken for any single record.

The recommended number of reviews, the study period and recommendation of a maximum number of PSIs per review were informed by feasibility concerns and reflected how the TRM could practically be implemented as part of the QOF. It had been the intention all along to propose that the TRM be included in the QOF if the findings indicated that it was an acceptable, feasible and useful intervention. As it turned out, the TRM was included in the QOF before the study was concluded.

5.2.2.1. Selection of patient record samples for trigger reviews

The recommendation to clinicians was that they should select their random samples of patient records to review from a specific high-risk patient group - patients who were older than 75 years *and* had a record of confirmed cardiovascular disease. This 'high-risk' patient group is particularly prone to error and harm (as described in Chapter 3) and therefore increases the likelihood of detecting PSIs. However, reviewers were informed that they had the final say in deciding which patient group to select. The decision to allow reviewers discretion in relation to their choice of patient population was pragmatic, to account for the professional requirements and attitudes of some reviewers and because, based on previous experience with the TRM, increasing the flexibility of the TRM had improved its acceptability. The reviewers were therefore also

provided with a pre-selected list of alternative 'high-risk' patient populations group (Box 5.2).

5.2.2.2. The 'review period' for records

The 'review period' was defined as any three consecutive calendar months in each patient record before the review date, as this period of time arguably offered the most efficient compromise between yield of triggers and time spent by the healthcare professional examining the notes [1]. It was left to each practice to decide which three-month period clinicians would review.

5.2.2.3. The Trigger Review Summary Sheet (SS)

The trigger review SS is a structured, two page template guiding reviewers through the three steps of the TRM, which are: (1) planning and preparation; (2) reviewing a sample of patient records and (3) reflection and action. The SS were used to collect and summarise anonymised data. It contained a number of tick-boxes as well as free-text data fields for clinicians, including those in the GPST group, to: record triggers and details of detected PSIs, including their perceived severity and preventability; describe the improvement actions and intended actions undertaken during and after the trigger reviews; record their own learning needs and points and those of their practice teams; and reflect on or provide feedback about the trigger review process.

In addition to the eight validated, pre-defined triggers on the SS template, reviewers could add optional triggers, depending on the characteristics of the specific 'high-risk' patient population they selected to review. For example, 'prescription of a NSAID' might have been a useful optional trigger to add to the list of validated triggers when screening the records of patients with cardiovascular disease. The SS continued to evolve and a number of minor edits that were made as a result of and subsequent to this study are described in Chapter 9, page 240.

Box 5.2. Potential high-risk patient groups from which samples of records could be selected for Trigger Reviews

- Patients on DMARD therapy;
- Patients with diagnosis of Left Ventricular Systolic Dysfunction;
- Patients on Warfarin therapy;
- Patients with a higher SPARRA score, e.g. >40;
- Recent admissions with COPD;
- Care home residents;
- Patients on chronic district nursing caseload;
- Patients aged >75 years on 6 or more medications

5.2.2.4. Severity and preventability of detected PSIs

The dual scoring system included on the SS to allow reviewers to judge the perceived severity and preventability of detected PSIs is shown in Table 5.2. The severity classification system was adapted from previously published work to suit the general practice context (284).

5.3. Data analysis

5.3.1. Quantitative data analysis

The quantitative data from the submitted SS were extracted and coded in an Excel spreadsheet and included: (i) the numbers of individual triggers and PSIs identified; (ii) the severity and preventability ratings of Patient Safety Incidents; (iii) actual or proposed improvement actions resulting from the trigger reviews; and (iv) the time required to conduct the reviews.

In general, data can either represent measurements on a continuous scale or information about categorical (discrete) characteristics. For example, age is 'continuous' and gender is 'categorical' data. Some variables may be considered as one or the other. For example, the ratings of PSI severity on a 4-point scale may be considered as either continuous or categorical data. In this study, all ratings were considered to be categorical data. The characteristics of the quantitative data collected during the study and the statistical methods to analyse them are summarized in Table 5.3.

5.3.1.1. Descriptive statistics

The clinician reviewers were classified into one of *three groups* according to their professional roles. The three groups were: 'GP', 'nursing' and 'GPST'. The nursing group included practice nurses and nurse practitioners.

Table 5.2. Severity and preventability rating scales for detected PSIs (39)

Severity	Scale	Preventability
Any incident with the potential to cause harm	1	Not preventable and originated in secondary care
Mild harm: inconvenience, further follow-up or investigation to ensure no harm occurred.	2	Preventable and originated in secondary care OR not preventable and originated in primary care
Moderate harm: required intervention or duration for longer than a day	3	Potentially preventable and originated in primary care
Prolonged, substantial or permanent harm, including hospitalization	4	Preventable and originated in primary care

Table 5.3. Summary of the quantitative data derived from the trigger review summary sheets

Description	Type of data	Descriptive statistics	Statistical tests
Reviewer characteristics	Categorical, nominal	Counts, percentages	
Triggers	Continuous, ratio	Counts, percentages, means, SD, range	Comparison of means and proportions: two-sample t-tests, ANOVA, Chi-square
Number of PSIs	Continuous, ratio	Counts, percentages, means, SD, range	Comparison of means: two-sample t-tests, ANOVA
PSI Severity / Preventability ratings	Categorical, ordinal	Counts, percentages	Comparison of proportions: Chi-square
Classification of PSI types and commonly implicated medications	Categorical, ordinal	Counts, percentages	Comparison of proportions: Chi-square
Number and types of actions or intended actions	Continuous, ratio	Counts, percentages, means, SD, range	Comparison of means and proportions: two-sample t-tests, ANOVA, Chi-square
Time taken for reviews	Continuous, ratio	Counts, percentages, means, SD, range	Comparison of means: two-sample t-tests, ANOVA

Microsoft Excel was used to perform simple descriptive statistical calculations, including: counts, percentages, means, standard deviations and ranges of the relevant study variables. All other statistical tests, e.g. comparison of means (section 5.3.1.2) and proportions (section 5.3.1.3), were performed with MedCalc Version 14.1.

5.3.1.2. Comparison of means

Two statistical methods were used to compare means: two-sample t-tests and ANOVA.

Two-sample T-tests: This test is used to compare the means of two study populations (groups). More specifically, t-tests are used to compare *one continuous variable* between *two* groups. To compare how *two* variables vary together, correlation and regression should be used. If one variable is compared for *more than two groups* ANOVA should be used.

The validity of T-tests is based on two assumptions. The first is that the populations being studied have a normal distribution. Although the variance within each group is unknown it is assumed to be the same. The second assumption is that the samples of data from the two groups are independent.

T-tests were used to compare the aggregated mean scores of this study with the aggregated mean scores of the QOF study for the following data:
- Time required to complete Trigger Reviews and SS;
- Numbers of detected triggers;
- Numbers of detected PSIs;
- Numbers of improvement actions and intended actions undertaken during and after Trigger Reviews.

In other words, t-tests were used to determine whether, for example, significantly more (or fewer) PSIs were detected in this study compared with the QOF study. In each instance when t-tests were used, the following were calculated: t-value, p-value, degrees of freedom (DF), 95% confidence interval (CI) and the standard error of difference

ANOVA: This test was used to compare the mean scores of three or more groups. In addition, post-hoc t-tests were performed to further analyse observed intra-group variation. ANOVA tests were applied to the following data of the three reviewer groups (GP, GPST and PN):

- Time required to complete Trigger Reviews and SS;
- Numbers of detected triggers;
- Numbers of detected PSIs;
- Numbers of improvement actions and intended actions undertaken during and after Trigger Reviews.

In each instance when ANOVA was used, the following were calculated: Sum of squares, F-ratio, p-value and degrees of freedom (DF)

5.3.1.3. Comparison of proportions

Chi-square (x^2) tests: The Chi-square test is used to 'test' how likely it is that an observed distribution is due to chance. It is also called a 'goodness of fit' statistic because it measures how well an observed distribution of data fits with the expected distribution if study variables were independent. Chi-square tests may only be applied to categorical data. The validity of the test is based on the assumptions that data were randomly and independently gathered from the populations (groups) and that there are at least five study participants in each group that is being compared. These minimum requirements were exceeded in this study.

Chi-square tests were applied to the following data to compare the difference in proportions for:

- Reviewer groups (GP, nursing and GPST) who selected their samples of patient records from the recommended 'high-risk' patient group.
- The severity and preventability ratings applied by the reviewer groups in the study and the BOARDS;
- The different PSI types in the preliminary classification;
- The most commonly implicated medications in detected PSIs;
- Actions and intended improvement actions undertaken during and after

trigger reviews.

In each instance when chi-square tests were used, the following were calculated: the difference in proportion (%), the 95% confidence interval (CI) of the difference, the chi-square value, p-value and degrees of freedom (DF).

5.3.2. Qualitative data analysis

Analysis of the qualitative data commenced shortly after the first interviews had been conducted in 2012 and continued until the second half of 2016. This section describes the different qualitative data analysis processes and strategies that were used in order to achieve the aims of this study. Table 5.4 provides a summary of the main points.

5.3.2.1. Assignment of unique identifiers to practices and participants

All interviews were carefully transcribed verbatim in order to preserve colloquialisms, repetition and other important aspects of communication, e.g. 'pause', 'giggle', 'laugh', 'cough' or 'a knock on the door'. The transcripts were anonymised by removing all names from them. Each of the twelve participating practices was assigned a unique, double digit identifier, commencing with '01' through to '12'. The same unique identifier was applied to every participant within a given practice. Participants from the same practice were differentiated by adding a further, unique identifier as a prefix, derived from their professional role: general practitioner – GP; practice nurse – PN; and practice manager – PM.

The results chapters (chapters 6 through 9) include a large selection of verbatim quotes from the interview data that are presented in a similar way to the following example:

> *'I like nothing more than going back over notes, and reviewing and researching what we have or haven't done'* (GP06)

The unique identifier at the end of the quote in the example, e.g. 'GP06', indicates that this exact phrase was spoken by a general practitioner (GP) from

Table 5.4. Summary of the study's qualitative data analysis strategies and processes (285)

Processes	Analysis strategies	
	Thematic analysis	**NPT framework application**
Sources of data	• All of the data from the first round of semi-structured interviews with PNs, GPs and PMs • Free-text entries by clinician reviewers on the Trigger Review SS • Some of the data from the second round of semi-structured interviews	• The majority of the data from the second round of semi-structured interviews
First cycle coding	The data were coded using: • Grammatical methods (attribute and simultaneous coding); and • Elemental methods (descriptive and structural coding)	The data were coded according to the main NPT constructs
Second cycle coding	The initial codes and data were analysed further through pattern and focused coding	The data were sub-coded to the NPT components
Derive categories, themes and main study findings	The findings relate to: • Perceptions of patient safety (Chapter 6) • Classification of PSIs (Chapter 7) • How the TRM works (Chapter 8)	The findings relate to: • Factors that facilitated or hindered implementation of the TRM (Chapter 9)

practice six of the twelve participating practices. In order to reflect the reality of modern general practice, which is that it is delivered by teams, the qualitative data included 'matched' interviews within each practice, e.g. a practice nurse, GP and practice manager, who were interviewed (where available) using the same schedules. In this example, data from the practice nurse and manager from the same practice as GP06 would be indicated by the unique identifiers 'PN06' and 'PM06' respectively.

5.3.2.2. Thematic analysis

The first round interview transcripts were read and re-read to provide an overview of the contents and as a primer for the 'first cycle' of coding (285). The two main tasks during the first cycle were to: (i) develop and apply codes to the data and; (ii) to write reflective memos about the codes and initial impressions of the data. An exemplar reflective memo is provided in its original format in Box 5.3 for interest. The memo was written while analysing the first interview with PM08.

For the purposes of this study, a 'code' was understood to mean '*a word or short phrase that symbolically assigns a summative, salient, essence-capturing and/or evocative attribute for a portion of language-based data*' (285). The majority of the first cycle coding was performed using pen and paper, as this was found to be easier and also more conducive to reflection than using Computer-assisted qualitative data analysis software (CAQDAS).

After initial experimentation with various coding methods, I found the grammatical (e.g. attribute and simultaneous coding) and elemental (e.g. structural and descriptive coding) methods to be the most useful and intuitive for application to the first round interview data (285). A brief description of these methods is provided in Box 5.4.

Once first cycle coding had been completed for the majority of transcripts, the second cycle of coding were commenced. During 'second cycle' coding, the memos and codes from the first cycle were searched for patterns and categories and were combined, re-combined and reconfigured. The codes were then

Box 5.3. Example of a reflective memo

12/01/2013; 10:00 am

'I selected PM08 to code, as I hoped it would be a little 'easier' than another GP/PN. So far, quite a few 'memorable quotes'. She is clearly a very enthusiastic person, and just about the only one so far enthusing about QOF. Not surprising, as it gave her a number of opportunities, including becoming a QOF practice inspector. However, after a few years the health board 'didn't need us anymore'. I really like her philosophical, no-nonsense response to being fired: '…anyway that was that [chuckle] and this is now…' No wasted self-pity here! Reminded me about the well-known poem 'if' …' if you can meet success and sorrow the same…' (I paraphraze)

11:40: Still coding PM08: The longest passage is when I ask her about 'culture' (ethos) - more unstructured than semi-structured interview? One of the reasons she left her previous practice was because she was 'frustrated' and it was the only way she could implement change. What a loss to the previous practice! Interesting, that the PM from the previous practice retired?? The 'new' PM came to her and has now adopted some of the systems (access/triage) that she put into place! Excellent example of cross-practice relationships and learning. How can this be captured better, and disseminated?

I've come away very impressed by the 'flat' hierarchy in this practice. They don't 'vote', just reach consensus. Lots of different, regular meetings, with standing items on their agenda. All meeting minutes are disseminated to 'everyone'. Attached staff are involved in meetings and considered part of the team. Having said that, the GPs still seem to have all of the 'power'. As far as the 50:50 split of types of PMs, I think she slightly misunderstood what I asked and insinuated. For all that the PM has autonomy, she very much seems to leave decisions to GPs. It was clear that she doesn't censure information for them.

Of all the PM transcripts I've read so far, I'm most impressed by her - very positive, practical attitude, good systems in place - in one word, I'll describe her as a 'fixer'.

Box 5.4. Summary of selected coding methods (285)

Qualitative data coding methods	Description
Grammatical methods:	Grammatical methods are used to enhance the organisation and texture of qualitative data. The word 'grammatical' refers to the principles of the specific coding techniques and not to the grammar of language.
• Attribute coding:	Attribute codes are used for basic, descriptive purposes. They typically relate to a study's setting and the demographics and characteristics of participants. Examples from this study include: 'teaching practice' and 'salaried GP'
• Simultaneous coding:	Two or more different codes are applied to describe a single piece of text. For example, a participant's description in this study of sharing a mistake with his colleagues during a dedicated SEA meeting was simultaneously coded as: 'positive safety culture', 'SEA' and 'practice meeting'
Elemental methods	Elemental methods are the 'foundation' approaches and focused filters for coding qualitative data
• Structural (or utilitarian) coding:	Structural codes are used to categorise data and help to identify their commonalities, differences and relationships. Examples from this study include the codes 'assumptions', 'distractions', 'lack of knowledge' and 'fatigue' to describe some of the reasons clinicians gave for making errors.
• Descriptive (or topic) coding:	Descriptive codes summarise the topic (not content) of text passages in a single word or short phrase. An example from this study would be the descriptions participants provided of patient harm, that were descriptively coded as 'patient safety incident'

gathered into related categories and themes, which were mapped and displayed with NVivo version 9.2.81.0. The codes were therefore not simply labels for the data but the '*critical links*' between the interview data and the explanations of what the data were understood to mean (286). This is why, although coding and analysis may not be synonymous, '*coding is a crucial aspect of analysis*' (287). The number and nature of the themes are described in detail in Chapters 6 and 8. However, overall, the analysis identified 21 broad themes relating to the different study aims.

Two specific, related strategies were used to reduce bias: double coding and coding clinics (288). The double coding was performed at the beginning of the first cycle by CdW and JF, who independently analysed the same interview transcripts of GP05, PN05, PM05 and GP06. During a series of coding clinics, they then compared their initial codes, preliminary understanding of the data and any differences in interpretation. However, because '*all coding is a judgement call*' and dependent on the researchers' '*subjectivities, personalities, predispositions and quirks*' *(289)* any unresolved disagreements about coding were subsequently discussed with either COD or PB. In this way, the different perspectives were triangulated to inform the generation and application of suitable codes.

5.3.2.3. Application of the NPT framework

In thematic analysis, as described in Section 5.3.2.2, codes are constructs generated by the researchers themselves, in order to symbolise and summarise attributed meaning to data. In contrast, theoretical frameworks provide a-priori codes for researchers to apply to their data. In this study, the majority of the qualitative data from the second round of interviews were coded using the constructs and components of the NPT framework. The four main constructs are: coherence (sense-making work); collective action (operational work); cognitive participation (relational work); and reflexive monitoring (appraisal work). The NPT framework has previously been described in detail in Chapter 4 and is summarised as Table 4.1, page 96.

The sequential processes that were involved in analysing the data using the NPT framework are described next, and illustrated through the practical example of

the following verbatim quote (a datum) from GP05: '*I think it's useful as a learning tool to learn about your own systems and a way of trying to improve those systems and a way of learning as a team with the results*' The quote is also shown in Box 5.5 with the original highlights, first and second cycle codes and written notes that were made while analysing the data.

Preliminary, first cycle coding was performed independently by CdW and JF, who used coloured pens and paper copies of selected interview transcripts (GP05, GP06, GP02, PN02) for this purpose. They held data clinics to compare and evaluate the consistency of their coding, to discuss their interpretations of the data and understanding of the NPT coding framework and to identify exemplar quotes for each construct and component. They discussed any differences or uncertainties with COD in order to reach a shared understanding of the meaning of the NPT constructs and components. Once this has been achieved, all further coding were performed by CdW in NVivo version 9.2.81.0.

During first cycle coding, most data were coded using one of the four main NPT constructs. However, some data clearly related to a more specific component, and could therefore immediately be coded accordingly. In the example of GP05, the participant's words, '*I think'*, was interpreted as him doing the work of trying to understand the potential value of the TRM. The quote was therefore coded as 'coherence', which is one of the four main NPT constructs. The validity of this code was examined by CdW in a related memo. If the words '*it's useful'*, rather than '*I think'*, had been considered in isolation, they could have been coded as 'reflexive monitoring', one of the other four main NPT constructs. However, when the rest of the quote is considered, it is clear that the participant was doing 'sense-making', rather than 'appraisal' work, which is why this piece of text was coded as 'coherence'.

Four informal, aide-memoires questions were used to help differentiate between the main NPT constructs. The questions were:
- Coherence - what do participants think the work is?
- Cognitive participation - do people join in to do the work?
- Collective action - how do people do the work?
- Reflexive monitoring - how do we know the work is happening?

Box 5.5. An example of a datum after the first and second coding cycles
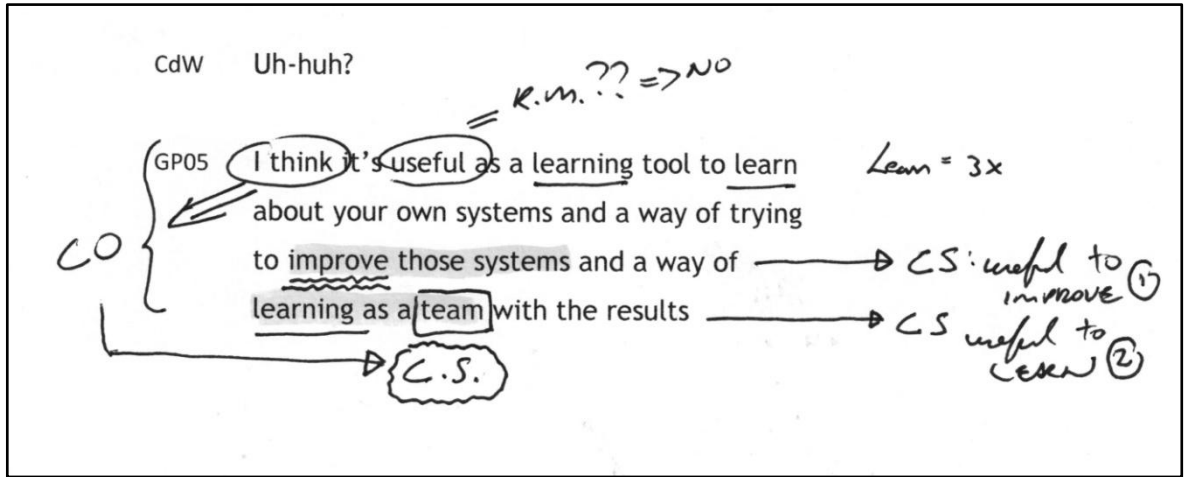
During second cycle coding, data were coded in more detail by using the NPT components. In the example above, the participant's words '*trying to improve those systems*' and '*learning as a team*' were interpreted as him doing a specific kind of coherence work, which was to try and understand the potential value of the TRM. This kind of coherence work is described by either the 'individual specification' or 'communal specification' components. Because GP05 described his understanding of the potential value of the TRM in terms of a practice team, rather than in relation to himself or another individual, the datum was coded as 'communal specification'. The other kinds of coherence work GP05 might have done were: comparing the TRM with improvement methods he already used (the 'differentiation' component of coherence); or considering how the TRM would fit within the existing culture of his practice (the 'internalisation' component of coherence).

The first and second cycle codes, in combination with their related, reflective memos, were then analysed further in order to extract and summarise their meaning, which produced the results that are reported in Chapter 9. In the example of GP05, CdW considered the original quote, its first cycle code (coherence) and second cycle code (communal specification) before describing the result as: '*one GP participant thinks the TRM is useful because of its potential for helping practice teams learn*'. Then, through a process of constant comparison, this result was compared with the rest of that participant's data *and* with the related results of all of the other participants, e.g. the data relating to the 'communal specification' component of the NPT framework. In many instances the results from the other study participants provided additional insights and allowed more nuanced interpretations that helped to enrich the preliminary results and refined them until they became the study's main findings.

In the example of GP05, many other participants shared his perception about the usefulness of the TRM, and no one fundamentally disagreed with this viewpoint. When all the different perceptions were combined, the preliminary result was expanded and refined into a main study finding, which is that the majority of participants perceived the TRM as useful, because it helped them identify

specific learning needs and points relevant to them and their practice teams. This finding will be discussed in more detail in Chapter 9.

5.3.2.4. Development of a preliminary classification of PSIs

The PSIs that had been detected, recorded and submitted in this study, as well as the QOF study, were coded and thematically analysed by CdW, SL and CB. Initially, CdW, SL and CB independently coded the same 100 PSIs. They met to compare their codes and agree which categories of types of PSIs were emerging from the data. Next, CdW, SL and CB coded 100 additional PSIs each, before meeting for a second time to clarify any remaining discrepancies and to further refine the categories describing the different types of PSIs. CdW then double coded two samples, different from the aforementioned 200 PSIs, that were also coded by SL (n=50 PSIs) and CB (n=50 PSIs) respectively. No further discrepancies or new types of PSIs were identified. Consequently, the remaining PSIs were coded individually by either SL, CdW or CB.

The nine categories of different types of PSIs that were identified through this analytical process provided a preliminary classification of the types of PSIs that were detected with the TRM in this study and the QOF study. The classification and the proportions of PSIs in each category are reported in Chapter 7, page 187.

Classification systems are valuable tools in patient safety research. They provide a systematic and potentially transparent approach for describing health care processes and systems; support reliable analyses of PSIs and clinical outcomes; and allow integration of data from heterogeneous data sources. Consequently, there is considerable interest in this concept and a wide range of patient safety classification systems and taxonomies have been proposed. However, the vast majority of these were considered unsuitable for direct application in this study. This is because: (i) they were developed for application in secondary care settings; (ii) describe related yet fundamentally different concepts to PSIs such as 'error', 'harm' or 'adverse event'; or (iii) had not been appropriately validated.

One of the first taxonomies of medical error in primary care was developed fifteen years ago in the USA (290). It consisted of eight categories: administrative failures, investigation failures, treatment delivery lapses, miscommunication, payment system problems, error in execution of a clinical task, wrong treatment decision and wrong diagnosis. Shortly after, an international taxonomy of general practice errors was proposed. It was developed from voluntary incident report data and was more detailed with five different levels and 171 different types of error (291). A few years later taxonomies of medical error in general practice were developed in Canada (six error categories: administrative; communication; diagnostic; documentation; medication; and surgical/procedural) (292); New Zealand (three levels: 'patient', 'clinician' and systems' with 70 types of errors) (293); and the UK (six error categories: prescriptions, communication, appointments, equipment, clinical care and 'other') (72).

A comparison of general practice 'error' taxonomies suggests that the main source of their differences may be attributable to the development approach the researchers selected rather than their content. There are two main approaches when developing taxonomies – 'lumping' or 'splitting' categories, referring to the predilection of researchers to merge or subdivide categories (292). Therefore, while some taxonomies have now been superseded by more recent, validated instruments, the categories they describe remain relevant.

One example of a new and validated classification system that will be of particular importance to future primary care patient safety research is the LINNEAUS collaboration's recent, comprehensive and multi-dimensional patient safety incident classification-system which they developed specifically for this purpose (294). The system provides definitions of dimensions and classes of PSIs, and is independent of data sources and accounts for the different organisations and professions involved in care episodes.

If the LINNEAUS system of classifying PSIs had been available at the time this study was designed or when the data were analysed, it would have been applied in preference to the method that was used. The classification of PSIs in this study is therefore relatively simple in comparison to the LINNEAUS framework,

but the overall approach, content and PSI classes are still compatible with the newer, validated system.

5.4. Ethical approval and considerations

The study was submitted to and approved by the Glasgow University's College of Medicine, Veterinary & Life Science's Ethical Committee, reference number 2012054. The ethical approval letter is included in Appendix 1.

5.4.1. Consent

The practice team agreed to participate in writing. They gave consent to allow the researchers supervised access of the premises and medical records at arranged times. Every individual participant (GP, PN, PM, GPST or any other) was asked to indicate their consent to participate in the study in writing - separately to the practice - to actively participate in the training, reviewing of medical records and before any research-related activity commenced. The surgeries, individual team members and GPSTs retained the right to withdraw from the study at any time. The consent forms are included in Appendices 4-6.

5.4.2. Analysis of risk

Prior to commencement of the study, a risk-analysis was performed. The potential risks associated with the study were considered to be very low. However, a separate concern was whether and what risk there may be from implementing the TRM and clinician reviewers finding previously undetected PSIs. Practical experience with the trigger review method in Scotland during the previous four years suggested that the vast majority of detected patient safety incidents would be of low or moderate severity. Only in exceptional cases would an incident of severe patient harm have gone undetected. However, this possibility was considered and reviewers were encouraged to deal with it in an appropriate manner through disclosure to the patient and family, reporting the incident (if relevant) and significant event analysis. Reviewers who may have experienced emotional difficulties as a result of the trigger review method would have been provided with contact details of a health care professional to

discuss their concerns in private but this eventually did not arise during the study period.

5.4.3. Data storage, access and handling

All data were stored securely on NHS Education for Scotland IT systems in accordance with the Data Protection Act of 1998. CdW, PB and HB had access to all of the data. COD could request access to any data considered relevant and had access to selected transcripts for analysis purposes. Data were anonymised and stored on an internal network for the duration of the study and will be stored for five years after its completion.

Conclusion

This chapter described the study design and the methods that were used to collect and analyse the data. The two main sources of data were:

1. Two rounds of *semi-structured interviews* with practice managers, practice nurses and GPs. The first round of interviews were analysed thematically and the results are provided in chapter 6. The majority of data from the second round of interviews were coded to the NPT framework, although some data were also analysed thematically. The results are presented in chapters 7 to 9.

2. *Trigger Review summary sheets*, containing both numerical and free-text data. The quantitative data were counted and percentages were calculated. Means, standard deviations and ranges were calculated for continuous and ratio-type data. Comparisons of means were performed with t-tests (two variables) and ANOVA (three variables) and comparison of proportions with Chi-square tests. The qualitative data were analysed thematically. The results of the quantitative analysis are reported in Chapter 7 and the qualitative analysis results in Chapters 7 and 8.

The specific strengths and limitations of the study design and methods are described in Chapter 10, from page 269.

Chapter 6. Participants' perceptions of patient safety

This chapter describes the results that relate to the study aim of describing the perceptions and understanding of general practice clinicians and staff of patient safety. The main source of data for this chapter was the first round of interviews with practice managers, general practitioners and practice nurses. The data were thematically analysed.

Introduction

Chapter 2 described how patient safety incidents (PSIs) commonly occur, and that a substantial minority result in preventable, iatrogenic harm to patients. From a patient safety perspective, the main priorities in modern health care systems are therefore to improve standards of care, reduce the risk of avoidable harm and remove (or contain) latent safety threats from systems where possible. Consequently, a number of improvement initiatives ranging from small-scale, informal actions in single units or teams to formal collaborative-type programmes at regional and national levels have been implemented in the UK, including in general practice. Chapter 3 described five main types of improvement methods - including the TRM - that were specifically developed or adapted for use in patient safety research and in these improvement programmes.

However, despite more patient safety initiatives interventions and research than ever before, there is still very little evidence that health care safety standards, including in general practice, have been substantially improved as a result (35). There are many potential reasons for this, including some that are still unknown at this time. Arguably, the most pressing question right now is therefore whether the safety improvement methods available to us are actually useful? It is challenging, if not impossible, to provide a short and clear answer to this deceptively simple question. The reality is that the utility of a method or intervention is determined by a range of emergent, complex and interlinked factors that are typically absent when its performance is evaluated during testing or pilot studies. Three of these factors that are particularly important are described to help illustrate this point further.

The first factor that helps to determine the practical usefulness of improvement methods is the reciprocal effect of the diverse, dynamic and complex health care contexts within which interventions are implemented (295). The same method produces significantly different results depending on when, where and how it is implemented. The second factor is the perceptions of the intended users. If health care staff perceive methods as acceptable, feasible and useful they are more likely to implement and use them. However, positive perceptions about the utility of a method do not necessarily imply a willingness or ability to use it. The third factor is therefore whether the knowledge, skills and attitudes of the intended users are sufficient to enable effective use of the method.

Before health care policy makers and researchers attempt to implement complex health care interventions, it is therefore important, and possibly essential, that they first consider and understand whether and how frontline clinicians and staff perceive related problems and their potential solutions. This is because perceptions about the nature and scale of the problem, and the need for, and characteristics of, interventions will largely determine how they are received, interpreted and applied in practice. In fact, this may be more important than the potential or actual 'technical' value of the intervention. However, the perceptions of general practice staff about patient safety are currently largely unknown.

The aims of this chapter are therefore fourfold:
- To explore the perceptions and experiences of a range of general practice staff about the concept of 'patient safety';
- To list and describe the factors they perceive as most important in contributing to patient safety incidents (PSI);
- To identify which improvement actions, methods and tools are known or currently being used by practices, which areas they perceive as important for further improvement and the requirements to do so; and
- To consider the safety culture that was prevailing in the general practice teams when the TRM was implemented.

Throughout this chapter, the main findings are discussed when they are reported to raise a number of directly relevant issues, and to compare them with the patient safety evidence-base where applicable. The chapter concludes with a summary description of the four main perspectives of the contributing factors to PSIs, and explain how each perspective helps to inform the selection of different approaches to health care improvement (296).

6.1. Perceptions and experiences of 'patient safety'

6.1.1. Patient safety definitions and perspectives

Only a few participants were able to provide a definition of patient safety. Others felt that a formal definition of patient safety had little value for them and could, paradoxically, even distract them in their efforts to provide high quality care. One practice nurse said: '*sometimes it can feel in health care like we just define things that we are already doing and you're not sure why. Who is doing the defining? It would be people higher up... sometimes it can feel like it's quite divorced from where we are.*' (PNO2) However, all participants were able to clearly articulate their understanding of patient safety through practical examples and rich descriptions.

Despite the seemingly disparate nature of the patient safety narratives, three themes clearly emerged during analysis, based on the different perspectives from which participants initially understood and explained patient safety. The perspectives were related to: (i) patients; (ii) clinicians and health care staff; and (iii) systems and processes. The different perspectives are summarised in Table 6.1 and illustrated with a selection of verbatim quotes.

Those participants who interpreted safety from a 'patient' perspective, typically talked about 'harm' or 'journeys' and thought patients could actively contribute to their own safety, but also to PSIs. Other participants had a predominantly 'clinician and staff' perspective of safety. They were more likely to describe patient safety in terms of 'responsibilities' and 'duty of care' and considered the actions of health care workers, whether intentional or not, as particularly important determinants of PSIs. The remaining participants had a third

Table 6.1. Participants' patient safety narrative perspectives

Perspective	Verbatim quotes
Patients	I always put myself in the patient's point... if that's the way I was treated how would I feel about that? I suppose I always do that and it's just natural for me (PM07) I don't think it [patient safety] is as simple as making sure you are prescribing the right drug - it is looking at the patient as a whole and thinking outside the box (PN06)
Clinicians and staff	It's about taking personal and professional responsibility for that patient... not passing the buck, taking responsibility for each patient (PN02) As practice manager I have to make sure that when the patients come in to the health centre they are protected throughout (PM02)
Systems and processes	Double checking, checking, double checking. I think that keeps everybody safe. That's how I view it [patient safety] (PN11) It just makes me think about clinical safety - I think to make sure that prescriptions are correct, and referrals are dealt with properly and that patients are followed up (PM11)

perspective of patient safety, namely that it is about 'systems and procedures'. Their narratives typically included terms such as 'protocols' and 'guidelines' and they perceived organisational factors, systems and processes to be the main drivers of patient safety.

The three different perspectives from which participants shared their patient safety narratives were not associated with their professional roles. Being in the same practice team did not increase the likelihood of participants having the same perspective either. Rather, the specific perspectives from which participants understood patient safety in this study seemed to be mainly derived from their own, unique and individual experiences.

These study findings, i.e. that the vast majority of participants were able to explain patient safety in practical terms, even though they were unable to provide formal definitions of the concept, and that their patient safety narratives were delivered from different perspectives, are similar to the international literature. In a qualitative study of GPs (n=22) and practice nurses (n=7) in the Netherlands, none of the respondents provided a definition of patient safety, but they were also able to offer a wide range of descriptions and perceptions of this concept when asked (297).

One implication of this finding is that the way in which researchers and policy makers define patient safety may not have any practical meaning for frontline staff. In order for improvement interventions to be successfully implemented, it may therefore be necessary to first align how patient safety is understood by *all* stakeholders, and especially their intended users, to ensure overall consistency of purpose and application. From an NPT perspective, the work to achieve this goal is described by the 'coherence' construct. This will be considered in more detail in Chapters 9 and 10.

6.1.2. Patient safety perceptions and experiences

The experiences and perceptions participants had of patient safety could be summarised as four main themes. They are, that patient safety is: (i) *important*; (ii) *integral* to care; (iii) characterized by *impermanence;* and (iv) *imperfect*,

but amenable to improvement. The themes are discussed below and summarized in Table 6.2 with a selection of verbatim quotes.

6.1.2.1. Patient safety is important

All participants agreed that patient safety is important, and for some of them, it was *the* most important characteristic of the care they aim to deliver. However, the majority acknowledged that there are a number of equally important

priorities competing for increasingly limited time and resources. As a result, the relative importance they placed on patient safety could change in response to internal and external factors. Two examples of the relative importance of patient safety increasing would be after detection of a significant PSI in the practice, and in response to the promotion of a safety improvement initiative by a local Health Board.

6.1.2.2. Patient safety is integral to care

The vast majority of participants expressed the opinion that patient safety had been an integral part of their practice for many years, even if this had not been explicitly acknowledged. According to them, the significant change had been that external agencies had started taking an interest in it too. As a result, many felt patient safety had become '*fashionable*' and '*sexy*' (GP04) and also: '*…anything that's got a government initiative becomes a buzz word*' (GP08). This perception was re-enforced by the fact that patient safety *had* been formally prioritised and improvement programmes were promoted by policy makers at around the time of the study. Arguably the best example of this was the launch of the national Scottish Patient Safety Programme (SPSP) in 2008 and the subsequent expansion to include general practice in 2013 (42). Participants recognised the importance of this aspect of the care they deliver being newly labelled as 'patient safety' by external agencies. In NPT terms this legitimised their involvement in the improvement initiatives – a factor that helped to facilitate the TRM. This issue is discussed further in Chapter 9.

Table 6.2. The four main patient safety themes participants described

Theme and description	Verbatim quotes
Important: Patient safety is important, but one of several priorities competing for limited time and resources	• [Patient safety] is almost the 'be all and end all'. Whatever you do you have to make sure that patient safety is your highest priority (GP11) • When things come along we should be grabbing them and taking the opportunity to look at things and how you do things and how you're going to change things for the better ... it's just I suppose for most practices, it's just something else to do in your already crammed up day (PM10)
Integral: Patient safety is and has been integral to care delivery for many years, but was only recently formally prioritised	• We've been doing this same thing under different names for years. It has been going on for years. It's just been called different things (PM04) • I think [patient safety is] the next big thing really, and somebody in government's decided to throw money at it, so that's what we're doing now. That's not to say it's a bad thing or that it shouldn't have been done years ago, but I think it is [pause] today's big thing (PM11)
Impermanence: Patient safety is the dynamic and emergent product of the many health care processes that shape patient journeys	• I suppose [GP X] has changed my view of patient safety from things that happen from a sort of medication or a medical point of view, wrong diagnosis, error in prescribing that sort of thing. So now I look at patient safety from that point of view, as opposed to the view that I had (PM06)

- It's a whole kind of journey, and we're involved in so many aspects of it. There's safety in the physical viewing, there's safety in the medical assessment, medical administration and then the ongoing care, and I suppose secondary care. You know, you can talk about the journey into it secondary care as well. So yes, it [patient safety] covers everything really (GP07)

Imperfect: the quality of safety can – and should – be improved further. However, it is unlikely that it will ever be 'perfect'

- Nothing can be 100% safe. You can always aim for that as an ideal but, for anybody that thinks they're going to be 100% safe all the time – they are fooling themselves and probably missing what they are doing wrong… When I say inevitable, I didn't mean it in the sense of 'well it's inevitable so just live with it' I mean it's inevitable so don't accept that it [PSIs] doesn't happen (GP01)

- Total patient safety is [pause] will I say unachievable? I don't think it's ever going to be achievable, but I think there's a lot of things can be done to change things, but I don't think you'll ever get 100% perfect - you've got too many ingredients for that, too many ingredients (PN08)

6.1.2.3. Patient safety is characterized by impermanence

The majority of participants explained that they understood patient safety not only as the state of care at important moments, such as when PSIs occur, but as the dynamic and emergent product of many different and variable processes in health care, all in temporal (and sometimes contradictory) relationships with each other. They were aware that, just as levels of relative safety risk fluctuates, their own understanding and experiences of the prevailing levels of safety changed too. There were many potential reasons for this, such as: direct or indirect involvement in PSIs – not only as clinicians but also as patients; personal reflection; feedback from patients and colleagues; and the degree to which national policy prioritises safety. A practical example of how a participant's recent, personal experiences as a patient informed her perceptions of care safety is provided in Box 6.1. Many participants explained the impermanence of patient safety by referring to patient journeys, both within primary care but also interfacing with hospital care, and how they are often unpredictable with many twists and turns and may include a range of health care staff able to influence the different potential endpoints.

6.1.2.4. Patient safety is imperfect but can be improved

All but one of the participants thought that PSIs were the inevitable consequence of clinical care and even if infinite resources were theoretically available to try and prevent them, they could never be completely prevented. This perception is widely shared by other clinicians worldwide and fits with what we know about the inevitability of failure at some point in highly complex socio-technical systems (281, 298, 299). Some participants therefore described the possibility of 'perfect' patient safety as a 'pipedream' or a 'wish'. Despite this perception, all participants agreed that this was not an excuse for not attempting to reduce PSIs and that much could still be done in this regard. They also all agreed that improving patient safety was an ethical and professional responsibility for every health care worker, for general practice teams and also organisations. However, according to them, the expectations about the results of these efforts should be tempered by the acknowledgement that clinicians are 'human' and therefore imperfect and prone to err.

Box 6.1. Example of a participant's personal experience as a patient

I was an inpatient just for, well, for two nights. I had a thunderclap headache and I had to have an ehm CT and an LP. Anyway, it happened on a Friday, which was unfortunate ehm and I had to go to A&E was so sick, got reviewed, bloods, CT, all within an hour, so impressive. Sent over to medical assessment unit, waited about five hours to be seen then was seen by the consultant who said: 'okay, your CT's fine, we need to do an LP. We'll get that done, we'll get the results tomorrow and if it all is okay, you can get away.' Well, so I was like 'oh, that's fine'.

So then nothing happened the next day. It was so loud overnight - there was an old demented lady who was so agitated and they were speaking quite [firm voice] 'Shh, come on shhh' in the middle of the night. It was ehm quite upsetting. Anyway, she got moved to another ward in the middle of the night. I think probably cause she was quite hard work. There was another lady who was really wheezy who they also moved in the middle of the night and I was going to go and say I think she needs a nebuliser, I think she needs reviewed. None of this was done on the acute medical ward ehm and anyway, they did the LP too late, they sent the samples off, they told me they hadn't arrived. Turns out they don't process at the labs after twelve o'clock on a Saturday. Had to wait til the Sunday. They wouldn't let me go home even though it was less than a mile from the hospital, so I had to wait another twenty four hours but they kept me because I was independent and self caring...

I was not impressed at the level of nursing and care... there's not enough time nursing anymore I don't think, and I think we need to get back to good caring, nursing, that's my rant [chuckle]. I was, I was very saddened by my stay, and it actually makes me think I don't want to admit people to the [hospital X]. I think patients might be better dealt with at home. So nursing, more nursing time, more nurses on the wards so they can do their job fantastically but also care for the patients...if they don't increase the number of nurses you're going to have people having acute LVF [heart failure] or people going off with COPD, people arresting and no-one else noticing...we've lost the human aspect of it and I think that's a big loss... you're not meant to move old delirious, demented patients in the middle of the night cause it increases delirium, it increases that [whispering] we all know that. They should have moved me but they moved the one who was hard work, short of breath, not being reviewed. I mean, I, was just about to go and say 'look, can you get this person', then they wheel her, but I was 'oh'? It was quite bad from the other side (GP07).

There are at least three practical reasons that support the perceptions of the participants that patient safety will always be imperfect. The first reason is the variable quality and timeliness of information. Clinicians often have insufficient information or the wrong information and increasingly also have to contend with information overload and information 'chaos' (300). Even when they are familiar with all the latest evidence-based information and have access to reliable investigations they may still not understand or know all the relevant contexts and patient-specific issues. For example, some medication side effects and serious drug interactions may be known but cannot reliably be predicted for every patient; and rare and occult diseases may go undetected or unrecognised. The second reason is that clinicians are in many instances only one contributing factor to PSIs. Technology can fail without human involvement and patients contribute to some PSIs too. The third reason is that, even if clinicians worked with 'perfect' patients in 'perfect' systems, their own psychological and physiological limitations predispose them to error. These factors will be considered in more detail next.

6.2. The main contributing factors to patient safety incidents (PSI)

Participants felt PSIs were most likely to occur in medication and medication-related processes, such as prescribing, dispensing, administration and monitoring: '*our biggest area where things can go wrong is generally through prescribing, and it's where you can do the most harm as well' (GP03).* Three specific examples of medication-related risks participants identified were: patients intentionally and unintentionally varying from prescribers' intended use of their medication; a lack of reconciliation of medication items between different health care settings; and the sheer volume of prescription requests that made effective monitoring a challenge. One GP explained: '*the way that the service is set up, we as prescribers aren't the ones that are doing the monitoring' (GP10).*

Another important practice system participants identified as high-risk for PSIs was ordering investigations and managing results, e.g. '*I'm really worried I put the wrong label on things - that's awful easy done' (PN11).* Many clinicians recounted personal experiences of specimens, requests and reports being

mislabelled, lost or not followed-up appropriately. Despite this, the vast majority thought the volume of data made it unfeasible to implement a monitoring system, e.g. *'We don't have any processes [to monitor investigation requests] and a lot of that is about capacity you know. The practice just doesn't have capacity to manage everything' (GP08).* Participants also identified the processes of sharing, storing and accessing information as important safety risks: *'the ability for error is huge. I mean I scan something and then you drop and drag it into a patient's records. How do you know you've put it into the correct patient?' (PM02).*

Elderly and housebound patients and nursing home residents in particular were considered to be at increased risk of PSIs and more likely to suffer harm. Participants explained this risk was because of relatively higher levels of multimorbidity, polypharmacy and reduced physiological reserves compared with other patient populations, but also because elderly patients often struggle with access to appointments and clinicians have insufficient time for pro-active management of physical and social problems.

The specific patient characteristics and practice processes the study participants identified as being particularly 'high-risk' for PSIs are almost identical to those identified through years of patient safety research and which was summarised in chapter 2. A further, specific example from the international literature is a web-based survey of GPs in the Netherlands. The two risk factors they perceived as most frequently constituting safety threats were, similar to this study, prescribing and monitoring of medication and patient age over 75 years. In addition, they identified polypharmacy, poor doctor-patient relationships and insufficient continuing education by GPs as important (301). The recommendation to practice teams in this study was to select the records of high-risk, elderly patients for trigger reviews. One of the pre-defined triggers required reviewers to screen for medication changes, while several others were related to specific laboratory results. In terms of NPT, the high degree of congruence between the perceptions of the study participants, the international literature and the TRM helped to facilitate its implementation through the work of coherence.

All participants were able to identify a range of contributing factors to PSIs. The factors were related to five main themes: (i) inadequate time and resources to deal with increasing workloads; (ii) lack of care continuity; (iii) patient-related factors; and (iv) clinician-related factors; and (v) chance. The participants explained that all of the contributing factors were potentially relevant to *all* types of PSIs and could affect any practice system, process or patient. The implication is therefore that, in order to improve the safety of care, it is necessary to adopt a holistic, systems-perspective rather than simply attempting to 'fix' each factor in turn. These themes are discussed below and summarized in Table 6.3 with a selection of verbatim quotes.

6.2.1. Inadequate time and resources to deal with increasing workloads

All of the participants described how they, and the rest of their practice teams, were struggling to safely manage their existing workloads and that their workloads continued to increase. They responded to the increasing workloads with a range of formal and informal adaptive behaviours. Four practical examples of adaptive behaviours provided by the participants were: intentionally deviating from policies and procedures (e.g. violations); working additional, unpaid hours; choosing to forego breaks and meals; and re-prioritising the urgency of competing tasks and making changes to their appointment systems.

Despite these behaviours – in a sense their best efforts to adapt - they remained aware of potential safety threats in the practice which, in some instances, had even increased. For example, some patients may have been inappropriately triaged, prescriptions were often signed without being reviewed and reception staff sometimes offered patients appointments with team members who were not clinically appropriate to their needs. One nurse explained: *'we can't see these types of patients'* but because *'there's no appointments [reception staff is] putting it in for us just to get them really off the phone'* (PN09).

Participants clearly understood the potential risk of increasing workloads and relative lack of time, but were unable to find an alternative solution that was acceptable and feasible in practice. Procuring additional time (whether through

Table 6.3. Factors perceived as contributing to patient safety incidents (PSIs)

Main factors	Specific examples	Verbatim quotes
Inadequate resources	Excessive workload	It was almost getting really too dangerous - we're talking sixty people in that hour and a half every morning (GP02)
		The pressure that is on practices to churn out patients and churn out facts, figures, returns - it's phenomenal (PM02)
	Time constraints	At my lunch break I'm putting information on the computer (PN03)
Clinician factors	Distractions	If you're doing that while you're trying to do six million other jobs, your phone's ringing and everything else then you could miss it. Discharges are particularly bad - we've had it one or two incidents with the discharges [deep breath] (PM04)
	Assumptions	I don't really remember what I was doing at the time. I do remember seeing it, but I made an assumption. Assumptions aren't good for safety (GP02)
	Difficult 'personalities' in the team	[There is] huge variance from practice to practice and I guess it's all about the GPs that you work with (PM08)
	Lack of knowledge or skills	I think the biggest threat to patient safety is the fact that loads of people do things that they don't actually know how to do in nursing (PN02)
	Stress	You get stressed; you're kinda rushing against the clock all the time. So because you're rushing it's probably more stress…which in itself isn't a great thing either from a safety point of view (PN03)

Main factors	Specific examples	Verbatim quotes
Clinician factors... *continues*	Being unaware of personal limitations	Nobody is perfect ever, so you have to be aware of your limitations (PN09)
	Violations	The systems are there. People either don't follow the systems or don't have time so try to cut corners with the systems, and that's why things fail (PM07)
Loss of care continuity		Sometimes we've had issues over the last few years and I think really it's because people are darting in and out and don't really know what's going on (PM12)
Patient-related factors	Patient expectations	I think they [patients] have some real unrealistic expectations of what doctors can and can't do (PM03)
	Compliance	If you sat down and you've agreed that's what you're going to do, it's then the patient's responsibility to keep their part of the deal in inverted commas (GP11)
	Diversity of presenting problems	We have such a big remit as practice nurses that we're expected to be, to at least a degree, experts in, that you can sometimes feel like you're drowning a wee bit (PN02)
	Multimorbidity	People come in with a shopping list you know (PN08)
Chance		It's really just luck when bad things don't happen (GP08)

employing new staff or increasing the hours of existing team members) reduces the income and livelihood of the partners and would in some instances make the business non-viable. One GP explained how they: '*obviously have a set amount of money. If you employ too many doctors you're not going to have a practice because it won't be financially viable and it will close*' The challenge is '*getting the right balance of what you can afford and what you can do*' (GP03). This important issue will be considered in detail in Chapter 10.

Inadequate resources and high workload were not only perceived as important safety threats by the study participants, but were also understood to have a negative impact on the performance and wellbeing of clinicians and staff. These key findings are comparable with the international literature (302). In a focus-group study of primary care physicians (n=32) in the USA, the lack of resources and time pressures were perceived as particularly important impediments to care quality. In fact, inadequate resources '*often force physicians to compromise standards of care*' (303). Other important factors that were identified in that study included: lack of control over work environments and inflexible and unclear policies and procedures.

Insufficient time to provide all of the necessary care patients require is a well-recognised and important contributing factor to PSIs. A framework identifying specific types of 'time problems' or 'tempos' in general practice was recently proposed (304, 305). One of the five components of the framework is the 'office tempo' and quantifies the amount of time clinicians have available to provide care for patients. All participants identified this tempo as a particularly important risk factor for PSIs. The other four tempos relate to: (i) 'diseases' (estimated evolution and response to treatment times); (ii) 'patients' (wide variability in compliance with management plans and follow-up); (iii) 'out-of-office coordination' (obtaining investigation results and access to specialists); and (iv) 'knowledge' (misinterpretation of initial symptoms or having to acquire new information). However, the study participants were less likely to identify these four tempos when discussing the importance of time.

6.2.2 Lack of care continuity

Participants explained continuity meant ensuring that relevant, correct information accompanied the patient throughout their journeys and that named clinicians were involved in their care. Continuity was generally perceived as an important contributing factor to safe care. Conversely, a lack of continuity was perceived to negatively impact on patient safety, particularly during care transitions between health care providers and at the interface between different organizations. One participant explained: '*I refer them [patients] to hospital. They see two different consultants [pause] it's a system it's a patient pathway but it doesn't necessarily mesh like that. It could butt up against each other like that and that's where the problems lie. They don't know what I'm doing and I don't know what they're doing*' (GP04).

Many participants were also concerned that care continuity was being eroded at a practice level, which they attributed to increasing workloads; patient expectations of same-day consultations; and use of locum staff. However, one participant felt continuity paradoxically decreased patient safety in some instances. She explained that: '*sometimes it can be the other way. It can put a lot of demand on you because they know you*' (PN05). In response, clinicians might be more inclined to accede to the requests of the patients who are well-known to them or try and fit in additional issues within a single consultation.

6.2.3. Clinician-related factors

Participants described a wide range of 'clinician' factors that may contribute to PSIs (Table 6.3). However, they recognised that some behaviours intentionally (for example violations) or unintentionally (for example assumptions) ensured patients received an effective and ongoing service despite distractions, competing priorities and having to deal with large workloads. What the participants were describing are clear examples of 'efficiency thoroughness trade-offs' (ETTOs), although they did not use this term. ETTOs and the ETTO principle are therefore important in relation to this study and will be discussed on page 166.

One of the more insidious clinician factors that was identified by some participants was 'personalities' in their teams. They used the word 'personality' euphemistically to explain how specific characteristics of some clinicians increased the risk of PSIs occurring in the practice. These characteristics included clinicians being afraid to ask for help; lacking insight about their own knowledge and skill deficiencies; interpersonal relationships and communications skills that made it challenging for others to raise concerns about potential safety threats with them.

6.2.4. Patient-related factors

The majority of participants – and especially the practice managers - felt the expectations of patients about their care, of GP practices and the NHS had increased to the point where it was difficult or impossible to meet. This feeling was compounded by the perception that some patients take very little or no responsibility for their own health, but also by the increasing clinical complexity and prevalence of multimorbidity. One practice manager described her perspective: *'we are becoming an older generation. I think there's more and more, three or four things that people are wanting to discuss, where you just can't do that in ten minutes'* and then there is the additional workload of *'all the paperwork that comes behind that as well'* (PM02).

The clinicians reported struggling and often failing to effectively and safely manage the *'shopping lists'* (PN08) of their patients in the ten minutes allowed for consultations. However, while some patients were perceived as *'demanding'*, participants acknowledged that the majority of patient requests and expectations were appropriate and that clinicians and practices were responsible for meeting them.

The first four groups of contributing factors to PSIs the participants in this study identified (sections 6.3.1 through to 6.3.4) are comparable to those reported by clinicians in other health care settings and countries. Three of many possible examples are provided as evidence. The first example is a qualitative study conducted in the USA more than twenty years ago. The authors explored the recollections of family physicians (n=53) of their most memorable errors and the

perceived causes through in-depth interviews. Similar to this study, many different possible contributing factors (n=34) were considered, which the authors categorized into three groups: physician stressors and characteristics; process-of-care factors; and patient-related factors. Some of the more important, common and specific factors within these categories included distractions, 'hurry', lack of knowledge and premature closure of the diagnostic process (306).

The second example is a survey of clinicians (n=848) working in outpatient settings in the USA that identified many cognitive and systems factors felt to be related to diagnostic errors. Some of the more common factors reported by clinicians were: inadequate knowledge, detection or perception of clinical problems; excessive workload; issues in relation to investigation and information systems; and patients' lack of adherence to physician recommendations (110).

The third example is the qualitative study by Slight et al about the perceived causes of prescribing and monitoring errors in English general practice. They identified seven high-level categories, each containing a number of error-producing conditions. The categories are: the prescriber; the patient; the team; the working environment; the task; the computer system; and the primary-secondary care interface (307).

In addition to these well-known contributing factors to PSIs, the participants in this study also identified a fifth group, 'chance'.

6.2.5. Chance

The vast majority of participants considered 'chance' or 'luck' to be the most important contributing factor to safe care or, alternatively, whether PSIs occurred and the resultant harm severity. One GP explained how '*things that could have gone wrong but didn't*' was because of '*the grace of God and good luck*' (GP10*)*. Consequently, many participants expressed feeling helpless and unable to prevent these types of PSIs in the future because, as another GP explained, '*if she were to have that same day again, probably the same thing would happen again. It's just a set of circumstances… you might be lucky, you*

might be unlucky' (GP02). However, all participants acknowledged that chance was not always implicated or the main contributing factor for every PSI.

This perspective of PSIs may seem negative, pessimistic or fatalistic to some. However, given the vast majority of participants share this understanding about at least some PSIs, their perception should at least be acknowledged, and its veracity examined. If we accept for a moment that some PSIs truly occur by random chance, what type of method or improvement initiative could we propose that would be acceptable for clinicians? How do we best safeguard clinicians and patients alike? This issue will be considered further in section 6.5, from page 166.

6.3. Existing improvement actions and potential for future interventions

6.3.1. Existing improvement actions

Participants were aware of many different formal and informal methods that could be used to help improve the standards of care they deliver. Table 6.4 lists specific examples of methods and verbatim quotes. The methods ranged in scope from small changes for a single patient to system-wide re-organisation of practice systems. For example, a practice nurse (PN04) was able to recollect three recent improvement actions she had undertaken: (i) covering the light bulbs and fixing in place the examination lamps to prevent them falling or shattering on patients during cervical screening tests; (ii) convincing her practice to procure a hydraulic bed to facilitate the physical examinations of disabled patients; and (iii) she had designed and implemented a protocol for travel vaccinations to standardize management. This finding, that many clinicians develop informal, unique and successful solutions to safety risks in their own working environments, are consistent with the literature (308).

A significant minority of participants, and many from the practice nurse group in particular, perceived the active involvement of patients as an important approach to deliver high-quality, safe care. For them, patient involvement meant involving patients in their own management plans through shared decision-making, providing patients with clear information about their conditions

Table 6.4. Examples of improvement methods participants already used

Action or method	Selected verbatim quotes
'Formal' actions	
Significant event analysis (SEA)	We do significant events regularly... we will meet to discuss it (PM06)
Clinical audit	We do lots of audits around [access] and check that it's still as good as we think it is, and we occasionally have to tweak the amount of triage (PM08)
Protocols	Over the last few years with being a training practice we have tried to put a lot of protocols and systems in place to protect it (PN05)
CPD, appraisal and revalidation	Individually you are doing the best for the patient that you have and that is your responsibility, so there is a bit about professional development, CPD and maintaining your knowledge and recognising your weaknesses (GP08)
'Formal' and informal actions	
Involving patients	We're calling it 'complaints, comments and compliments' and what we're asking, we'll go out regularly and speak to the patients and say 'how do you feel about how we're doing? Is there anything we can improve on?' How do we know we're completely safe? I think this is maybe a way of us checking are we doing enough (PM02)
Informal actions	
Raising awareness of safety critical issues	People are making others aware of what has happened and that is the way forward and we will just continue to do that, and hopefully we will get better and better at it (PM06)
Sharing information / peer feedback	I think being able to discuss things with my nursing colleague - on a Wednesday I start at one, we have an hour's handover - I find that really useful (PN02)
Mitigation, esp. pharmacists and patients	I think there are lots of sources that stop us from falling short more of the time, to be honest (GP03)

and treatments, pro-actively planning for future events (e.g. exacerbations of their chronic conditions) and eliciting patients' feedback about the standard of care they received. One practice nurse explained that when she's consulting: *'you're hoping that they're [patients] going to give you a wee bit of feedback as well... they're the first ones to say: 'hey wait a minute!'* (PN07)

Many participants recognised or referred to instances where PSIs or their impact had been mitigated. This happened through the intervention of a wide range of potential factors, but the most important were other practice team members, pharmacists and patients. In other words, 'people' were responsible for creating patient safety. Specific instances of mitigation were considered to occur mainly through chance, but the overall likelihood of mitigation increased when there was effective teamwork and communication in the practice. One participant described how: *'there is a whole team, you know - GP, staff, pharmacists. If everybody works together as a team then these things can be resolved before they get to the critical stage'* (PM06). This issue will be considered again in Chapter 10.

6.3.2. Potential for future improvement initiatives

When asked to suggest high-priority patient safety areas for future intervention, the majority of participants identified two specific issues. The first issue was medication and medication-related processes. Participants were concerned about the very large volume of repeat prescriptions generated on a daily basis, usually by administrative team members, which were signed without review by GPs: *'If you see the amount of repeat prescriptions that wait to be signed, it can be two inches thick [this] puts a lot of stress on the doctors, because then it becomes a machine. So all you're doing is you're signing through the prescriptions and not actually looking at the prescriptions. How safe is that?'* (PM02). For them, the implication was that more, and more thorough, medication reviews would be useful to help prevent PSIs. The perceptions of the study participants are consistent with the international literature that have also identified the management of repeat prescriptions as an *'important source of risk'* (309).

The second issue was ensuring housebound patients receive the care they require. One participant described how *'housebound chronic diseases get neglected'* because *'you can tick a box to say they're housebound so therefore you don't have to achieve targets for them'* (PN08). A substantial minority of participants therefore thought it might be helpful to create nursing roles specifically aimed at providing care to these patients, similar to how public health nurses care for children or incentivizing practices to provide this service. A practice nurse explained: *'if the funds were there, that would be a good idea'* (PN12).

In addition to these two issues, a substantial minority of participants also suggested: improving the reliability of their clinical coding and computer software usability; reducing the number of interruptions during specific tasks by allocating protected time for staff; and collectively learning from PSIs.

Despite recognising potential areas for improvement, the study participants unanimously agreed that they had no time, resources or spare capacity to consider implementing these suggestions, or *any* other new interventions. They also doubted whether any other team in the general practice setting could feasibly undertake any additional, unfunded work. Some participants also expressed concern that quality improvement interventions may increase workload and paradoxically decrease patient safety by reducing time to provide clinical care. One participant explained that this was why *'it can be seen as hassle for some'* because *'it takes us out from the day to day practice when I have still got other patients and normal work carries on'* (GP06).

Perhaps unsurprisingly then, most participants identified externally funded, additional clinician and staff time as the most important determinant of patient safety, and whether they would be able to implement additional improvements. One practice manager described that *'what we need is another body in the practice who'll see another hundred patients a week, which would make a tremendous difference'* because *'it means they [admin staff] can get on with the safety aspects of downloading blood results instead of answering a patient's phone call four times when one would do if we had appointments to give them'* (PM12).

A small minority of participants disagreed, and thought increasing staff levels could actually decrease patient safety. They reasoned that this would be because of loss of care continuity, increased use of locums and the likelihood that patient demand would keep outpacing any additional capacity. They argued that rather than employing additional staff, existing team members could work more efficiently instead: '*what you need is a good dependable well trained staff rather than more bodies on the ground*' (PM06).

Participants also recognised a need for additional training, new quality improvement tools and IT support if they were to successfully implement further improvements. However, these factors were relatively less important than workload, time and resources. One practice manager made it clear that '*we don't have the money for the other options [time, staff] so therefore we'll take the tool*' (PM11). This key finding is reflective of the wider patient safety literature. In a survey conducted by Sarkar et al in the USA clinicians provided open-ended recommendations to reduce diagnostic errors. The vast majority suggested addressing workload issues and time constraints, improving investigation management systems and strengthening collaboration and communication between different health care providers. A tiny minority (3%) cited 'training opportunities' as a potential improvement strategy (110).

6.4. Participants' perceptions of safety culture

All participants thought culture was an important determinant of patient safety in their practice but also in the wider health care service. They understood culture as a dynamic and evolving construct and were able to provide many examples of how cultures in different parts of the health service interacted to produce positive, but also negative, outcomes for staff and patients (Table 6.5). However, all participants perceived the culture in their own practices and, with a few exceptions, other general practices in Scotland as conducive to safe care. They felt the overall culture in general practice was characterized by effective teamwork, communication and leadership, but that this was not necessarily the case for other parts of the health service. The sentiment of PN02 that '*there's a very open communicative atmosphere [and] we're all fairly aware of the*

Table 6.5. Examples of the potential effects (positive or negative) when different cultures interact in health care

Providers	Verbatim quote
District nurses	There was a little bit of a stand-off between the receptionists and the district nurses but I don't think, you're not going to resolve that (GP03)
General Medical Council	At some level there is the big bad witch called GMC that must have some impact actually, if you end up making a lot of errors... that is one driver for people to not end up in trouble with GMC (GP06)
NHS Health Boards	There is always this suspicion as well of Health Board managers. Real suspicion from a lot of GPs... that engagement that you can actually work together - they don't believe that that is what is happening (GP08)
Secondary care referrals	I think a lot of the systems that have been put in place to improve the flow of information haven't really done that well. They've done it on one level but what we used to have in place - the sort of personal relationships that we used to have between primary and secondary care - that's all been broken down, but it's not been replaced by anything so I see that as a real problem (GP09)
New practice staff	I think it's hard when you come in somewhere new to you. You've worked a certain way before. There is a tendency to want to come in and change everything but you have to obviously respect other people's working practices as well (GP02)
Accident & Emergency departments	A&E letters at the moment from [x] hospitals gives a disclaimer that drugs are not included in the letter which to me seems like a shocking admission in any kind of a clinical correspondence but we live with it, for the time being (GP01)
Improvement initiatives (SPSP-PC)	These [GPs] are independent contractor communities. We have to engage with them on that basis. We can't tell them what to do (GP04)

threats to patient safety' was representative of the perceptions of the study participants.

Participants also recognised that the prevailing culture is an important determining factor of any new initiative's degree of success. One GP explained that an essential prerequisite for the successful implementation of change is to '*get the culture right'* so that '*there'll be an appetite for the tools'* (GP04). Another participant agreed '*the fundamental thing is culture'*. According to him the specific methods were secondary to the overall success of a venture: '*you are just using the tools to try and emphasize and drive and direct people'* (GP06). The importance of culture will be considered again in Chapters 9 and 10.

While participants were aware of culture changing over time, few were able to describe how or why these changes occurred. A number of participants attributed a strong, positive safety culture simply to 'luck': '*maybe we're just a lucky practice because we all more or less sing from the same hymn sheet'* (PM08). However, one factor they felt did affect their culture (in a positive or negative way) was team members leaving or joining the practice: '*we'll have someone new in the practice and that kind of gives everyone a bit of a buzz really'* (PM08).

The characteristics and personality traits of team members also affected the culture. Some team members – usually one of the GPs and/or the practice manager - seemed to have a disproportionally large impact on the prevailing culture. These team members strongly influenced the practice safety culture through their actions, examples and leadership. GP06 was one of many participants who was identified by his team as being influential and important to their culture. The following verbatim description of how he approached PSIs provides evidence of how he helped to build a positive and open culture: '*if I haven't done something correct, I have always first to be self effacing and fall on the sword and say: 'that was my fault, I made that mistake. I apologize, how do we make it better from here?' Also being accepting of when other people say 'oh this didn't go quite right' - I won't be likely to hit them over the head with a stick about it. I would far rather that I knew about it and then you can adapt'* (GP06). The issue of leadership will be considered again in Chapter 10.

Many participants were aware that the culture in health care had changed over the years and continues to change. While some of the changes were incremental and barely perceptible at first, other changes had been more dramatic and rapid. For example, some participants described being aware of a prevailing 'blame and shame' culture' in health care for a long time, but how this had changed for the better in more recent times. One participant thought: '*the culture within medicine is far more open than it used to be, and everybody knows that they make errors (GP06).* Another participant described '*a big culture shift*' in the willingness of clinicians to admit their errors and interpret them as '*opportunities to learn and make positive changes'* (GP10).

There is corroborating evidence for the perceptions participants had about the prevailing safety culture in general practice in Scotland and England. A safety culture survey of general practices in England with the 'Competing Values Framework' instrument just over a decade ago found the majority of teams had a 'clan' culture type, which is characterised by high levels of teamwork (310). For the last few years perceptions of safety climate in general practice have been measured annually in Scotland with SafeQuest, a validated 30-item questionnaire (170, 311). The quantitative survey data suggest the safety climate in primary care is generally positive, although a small minority of practices has significantly less positive perceptions of safety climate than the main group (41, 42, 170, 311).

6.5. Different perspectives of the causes and contributing factors to PSIs

This section describes four main perspectives about the contributing factors to PSIs in the international literature (296). They are that PSIs result from: (i) individual human errors; (ii) systems and technical failures; (iii) weak safety cultures; and (iv) Efficiency-Thoroughness-Trade-Offs (ETTOs). These perspectives were reflected in the wide range of patient safety experiences and perceptions reported by participants in this study. The practical importance of the different perspectives is that they strongly influence which type of improvement approach individuals and teams are likely to select.

6.5.1. Individual human error

The first perspective of the causes and contributing factors to PSIs is that they are the product of individual human failures and errors. Human error is considered a natural phenomenon and an important mechanism through which we learn. The phrase 'to err is human' is well-known and recognises the existence of finite physiological (e.g. attention span, short-term memory) and psychological (e.g. resilience, motivation) resources that will eventually limit the ability of even the most skilled and talented human being to continue to function effectively and safely (312). For example, an inexperienced, tired and hungry GP specialist trainee (GPST) working in a busy and unsupported practice and who is often interrupted is more likely to make a diagnostic or prescribing error than her well-rested and experienced colleague working in a supportive environment.

The implications from this perspective are that *all* health care workers are susceptible to err; that the likelihood of error increases as the number of 'demands' on finite human abilities increase; and that the frequency and types of clinical errors are largely predictable. From this perspective, the contributing factors to PSIs can be conceptualised as simple linear cause-and-effect models. A practical example is that interrupting a clinician causes a lapse in concentration which results in a diagnostic error (effect). These models implicitly or explicitly implicate health care professionals in PSIs and may inappropriately and sometimes unintentionally be used to justify the 'blame and shame' culture that still prevails in some health care organisations.

There are at least three reasons why individual clinicians may be inappropriately blamed for certain PSIs. The first reason is that, from a legal perspective, it is easier to prosecute an individual than an organisation. The second reason is that disciplining individual employees are more convenient for some health care organisations than analysing and improving their systems. However, the third reason is arguably the most pervasive and important, yet also the most challenging to overcome. As individuals and societies we are psychologically predisposed to attribute blame for unfortunate events to those visibly and directly involved in them.

Two examples of psychological predispositions are: 'hindsight bias' and the 'just world' hypothesis. Hindsight bias creates the 'I-knew-it-all-along' effect. This means knowledge of an action's outcome makes warning signs appear more obvious and consequences more foreseeable than they were to those involved in the PSI (313). The 'just world' hypothesis is the (often unconscious) assumption that 'bad' things happen because of 'bad' people (312). Unfortunately, the reality is that it is often the 'best' people who make the worst errors as they are more likely to be performing the most difficult tasks (164).

From the perspective of 'human error', certain improvement initiatives will appear more appropriate than others. Examples of interventions that are strongly associated with this perspective include: (i) continuous professional development (CPD), providing educational resources and promoting (or mandating) specific training activities; (ii) increasing professional regulation and implementing a revalidation system; (iii) taking disciplinary actions against individual clinicians who are involved in PSIs; (iv) incorporating human factors engineering in health care organisations; and (v) clinical decision support systems (109, 314).

6.5.2. Systems and technical failures

The second of the four patient safety perspectives is that health care systems and technical failures contribute to PSIs. Health care organisations consist of many highly complex systems, and even relatively straightforward and common processes have multiple, interacting steps (281). The inherent active and latent safety risks in these systems and processes are often graphically depicted by the admittedly oversimplified metaphor of the 'Swiss-cheese' model (1). In the model the slices of cheese represent the various system defences between potential hazards and accidents. The holes in the cheese represent active and latent errors in the system and the slices of cheese have to be visualized as being in constant motion. The holes in the cheese rarely form a straight line of openings because at least one slice typically blocks the hazard from reaching patients. PSIs occur when the holes in the slices of cheese temporarily align, which allows hazards to reach patients.

Systems and technical failures can be represented by linear models in which it is possible to identify simple, complex and cascading causes, contributing factors and outcomes (315). In other words, a PSI is conceived as the product of a series of events which occur in a specific and (retrospectively) recognizable manner. The model therefore allows some knowledge about the future which is conceptualized as a mirror image of previous events and conditions. The implication for patient safety is that some PSIs may be prevented by detecting and eliminating potential threats proactively and by designing, incorporating and strengthening health care system defences (316). From this perspective, examples of system defences may include: guidelines; protocols; automating processes or including visual reminders for clinicians; redundancies (e.g. additional steps or duplication of actions); and 'forcing functions' in software.

6.5.3. Safety culture as a contributing factor to PSIs

The third perspective about the causative and contributing factors of PSIs is that the prevailing safety culture in a health care team or organisation helps to determine whether they occur or not. As previously discussed in Chapter 2, organisations and teams with a positive and strong safety culture are more likely to learn openly and effectively from error and adapt their working practices appropriately when PSIs occur. Safety culture will be discussed in more detail in Chapter 10.

6.5.4. Efficiency-thoroughness trade-offs

The fourth perspective about the causes and contributing factors of PSIs are that they are the inevitable by-products of efficiency-thoroughness trade-offs (ETTOs). ETTOs are the approximate performance adjustments individual clinicians make in order to manage expected and unexpected variability in their environments and tasks (317, 318). The effectiveness and appropriateness of ETTOs can only be evaluated retrospectively, once patient outcomes are known. The implication is that ETTOs are not intrinsically 'right' or 'wrong'.

An example of the ETTO principle in general practice is the challenge of GPs to balance their available time between taking complete histories and performing thorough examinations, and offering appointments to all the patients who request them. Taking incomplete histories and conducting partial examinations would allow GPs to see more patients. This approach prioritises efficiency over thoroughness. Alternatively, GPs may decide to take complete histories and conduct full examinations (increased thoroughness) but will then be able to offer fewer appointments or have to work longer hours (decreased efficiency). The benefit of maximum efficiency is that more patients will receive at least some care. On the other hand, it may increase the risk of diagnostic errors and only the most pressing problems may be dealt with. The benefit of maximum thoroughness is that rare or dangerous clinical conditions are more likely to be identified. However, fewer patients will receive care and other, equally important tasks, may be neglected.

The stark reality in present-day UK general practice is that resources and time are at best finite but more typically scarce. The information available to GPs with which to diagnose and plan care is always underspecified. This is because undifferentiated patient populations present with complex, diverse and often atypical symptoms and signs and medical records are often incomplete or unavailable. To provide effective patient care despite the challenge of ever-changing demands, clinicians have to make approximate adjustments to their performance. In other words, they have to adjust (consciously or unconsciously) the efficiency in relation to their thoroughness. The adjustments are based on their interpretations of the requirements of their patients and the available resources (of all types) at given points in time. It is 'performance variability' that allow clinicians to balance the demand for resources with what is actually available and possible to do in practice (319). The challenges inherent in this balancing act will be considered in detail in Chapter 10.

From an ETTO perspective, performance variability is therefore not only considered normal, but necessary, and the origin of *both* successful *and* unsuccessful health care outcomes. The ETTO approach to improve patient safety is by learning from positive deviance and increasing the resilience of clinicians and systems (6, 319-321).

Conclusion

This chapter began with a description of the perceptions of a range of general practice staff about the concept 'patient safety' in Section 6.1. All participants considered safety to be an important and integral part of routine care. The vast majority also perceived it as impermanent and imperfect. However, they recognised an ethical and professional duty to continue to improve the standards of care in their practices and felt that there was potential to do so. The TRM should therefore be acceptable to the participants, as the main reason for its development was to provide frontline staff with a practical method to examine their own records in order to detect and learn from PSIs and identify and address latent safety threats in their systems and processes.

Section 6.2 described five groups of factors participants identified as causing or contributing to PSIs. In addition, they identified medication and medication-related processes and elderly, housebound patients as being particularly at risk for PSIs. Most participants perceived a proportion of PSIs as inevitable, and therefore not preventable. However, they unanimously agreed that many contributing factors and high-risk processes and systems are amenable to improvement efforts. The TRM is compatible with these perceptions as it recommends selecting high-risk patient groups and the predefined triggers are consistent with the contributing factors to PSIs.

Section 6.3 listed a range of improvement methods the study participants were aware of or already using. The implementation of the TRM may potentially be facilitated through its association with some of these tools. However, there is also the possibility that implementation may be hindered if participants are unable to differentiate the TRM from their existing tools. This issue will be explored in Chapter 9. The vast majority of participants also indicated that additional resources would be required as a critical prerequisite before they would consider participating in future improvement initiatives. This issue will be considered in Chapters 9 and 10.

Section 6.4 described the prevailing safety culture in general practice in Scotland, which was perceived as 'positive'. The NPT work of 'internalization' is facilitated when interventions and practice cultures are compatible. The TRM should therefore be of interest to clinicians and staff. This issue will be considered in more detail in Chapter 9.

The final section described four different perspectives from the international patient safety literature about the contributing factors to PSIs. Each perspective helps to inform the selection of specific strategies to improve the safety of care. For example, the ETTO principle helps to explain the perception of many participants that some PSIs occur by 'chance', and suggest increasing the resilience of clinicians, systems and organisations.

In summary, this chapter provided an overview of the perceptions study participants have about patient safety. More specifically, it described what participants perceived as important patient-safety related problems; whether they believed the issues were amenable to change and their responsibility to deal with; and what they were already doing about potential safety threats. It also considered the prevailing cultures in the practice teams as an important determining factor for successfully implementing complex health care interventions.

The main findings are that the all participants considered patient safety an important and integral part of their 'jobs'. They were aware of many predisposing factors to PSIs and conceded that there are potential improvements that could be made in their systems and procedures. The implications are that the TRM should be: acceptable to the study participants and compatible with their perceptions about patient safety; compatible with the prevailing cultures within the teams; and suitable for contextual integration in the general practice setting. Chapters 7, 8 and 9 will present evidence in support of these assumptions.

Chapter 7. Main outcomes from implementing the TRM

This chapter describes the results that relate to the study aim of determining the usefulness of the TRM by describing the outcomes from its implementation. The main source of data for this chapter was the Trigger Review Summary Sheets (SS). The data were analysed using the statistical methods described in Chapter 5.

Introduction

Chapter 3 introduced the concept of complex health care interventions and their three main components: 'actors', objects' and 'contexts'. The results that were presented in the previous chapter mainly related to the 'actor' and 'context' components. This chapter will focus mainly on the third component – the 'object', which in this study is the TRM - how it was enacted and the outcomes that resulted from this. From a NPT perspective, the main work that will be considered is that of 'collective action' and in particular its component of 'interactional workability'. In other words, how did the clinician reviewers apply the TRM, were they able to detect triggers and patient safety incidents (PSIs) and what actions (if any) did they subsequently take?

This chapter has four main sections. The first section describes the characteristics of the clinician reviewers and participating general practices, the types of electronic patient records that were selected for review and the number of completed Trigger Review Summary Sheets (SS) that were submitted during the study period. The second section lists the number and types of predefined triggers. The third section reports the number of detected patient safety incidents (PSIs) and their severity and preventability ratings. The different types of PSIs are then described and a preliminary classification of the main types is provided. In the fourth and final section of this chapter the actions and intended actions of the reviewers and their teams during and after the trigger reviews are discussed.

Throughout this chapter the main findings are discussed when they are reported in order to raise a number of directly relevant issues and to compare them with the patient safety evidence-base where applicable. In addition, the main

findings are compared with the aggregated data from the general practices in three Scottish NHS Health Boards who implemented the TRM subsequent to this study as a Quality and Outcomes Framework (QOF) requirement for the financial year April 2013 to March 2014 (48). This data will henceforth be referred to as the 'QOF study' and provide additional context for interpreting and discussing the main findings of this study.

7.1. Characteristics of clinician reviewers and trigger reviews

7.1.1.Reviewers

A total of 47 clinician reviewers participated in the study. The professional roles of the reviewers were: general practitioners (n=12), practice nurses (n=11), a community pharmacist (n=1), GPSTs (n=22) and a nurse practitioner (n=1). They were recruited through two different strategies, as described in Chapter 5. The first strategy recruited 26 clinician reviewers from ten NHS Greater Glasgow and Clyde (Health Board 'A' - HBA) and two NHS Ayrshire and Arran Health Board (Health Board 'B' - HBB) general practices and exceeded the initial aim of recruiting two reviewers from each of twelve practices. The characteristics of the twelve participating practices, the reviewers and the number of Trigger Review Summary Sheets (SS) they submitted are summarized in Table 7.1.

Through the second strategy, 25 GPSTs from the West of Scotland region were recruited and all of them attended the Trigger Review training sessions. 21 (84%) of the participants subsequently implemented the TRM and submitted SS that were suitable for analysis.

The reviewers were classified into three main groups according to their professional roles. They are: (i) a GP group (n=12); (ii) a GPST group (n=22); and (iii) a nursing group (n=12). The data from the community pharmacist's reviews were included in the overall analyses but not in the group analyses.

7.1.2. Trigger Review Summary Sheets

A total of 67 SS were submitted, comprising 1659 individual electronic patient records. Clinicians from the general practice teams reviewed 1139 individual patient records and submitted 46 SS (see Table 7.1). The West of Scotland GPST group reviewed 520 individual patient records and submitted 21 SS. A three-month period was reviewed in each of 1659 individual electronic patient records.

Data were recorded and summarized by the clinical reviewers along with their actions, intended actions, learning points and needs, reflections and feedback on the trigger review summary sheets (SS) that were provided.

The expected total number of SS for the study had been 73 - 48 from the practice teams (four SS from each of the twelve practices) and 25 from the West of Scotland GPSTs (one SS per GPST). The overall response rates for submitted SS were therefore 91.8% (67/73), with response rates of 96% and 84% from the practice teams and GPST groups respectively.

The evaluation of the subsequent implementation of the TRM as part of the QOF for the financial year from 2013 to 2014 involved analysis of 755 submitted SS. The SS summarized the findings from reviewing a total of 18826 individual patient records from three NHS Health Boards in Scotland. The overall response rate for the general practices from the three Boards could not be calculated from the available data, but the response rate for Health Boards 'A' and 'B' were 66.1% and 88.2% respectively.

The response rate in this study was higher than in the QOF study. There are a number of possible reasons for this finding. The practices and most of the reviewers in this study were essentially a self-selected group who were highly-motivated to implement the TRM. The vast majority of the practices and many of the reviewers had participated in previous research projects and improvement initiatives. The participants invariably described their prevailing culture as proactive and took pride in being 'early adopters'. In addition, participants were offered one-to-one, tailored training in the use of the TRM at a time and place of their choice and had direct access to external 'expert' support. They were also offered a slightly more generous financial remuneration for their time. These facilitating factors will be considered in more detail in chapter 9.

Table 7.1. Characteristics of the participating general practices

Practice no	Patient list (n)*	GPs in practice (n)		Area	Training practice	Clinician reviewers (n)	SS (n)
		Partners	Other				
1	2100	1	-	Suburban	No	1 PN 1 GP	4
2	4300	3	1 salaried	Urban	Yes	1 PN 1 GP	4
3	3200	1	1 salaried 1 long-term locum	Urban	No	1 PN 1 GP	4
4	4100	3	1 Retainer	Urban	Yes	1 PN 1 GP	4
5	11000	8	-	Suburban	Yes	1 PN 1 GP 1 Nurse practitioner	4
6	5900	4	1 Salaried	Urban	Yes	1 PN 1 GP	3
7	8200	7	-	Urban	Yes	1 Community pharmacist 1 GP	4
8	6800	3	2 Salaried	Urban	Yes	1 GP 1 PN	4
9	6400	3	1 Salaried	Urban	No	1 PN 1 GP	4
10	9900	6	1 Retainer	Urban	Yes	1 PN 1 GP	4
11	3000	4	1 Retainer	Inner City	Yes	1 PN 1 GP 1 GPST	4
12	7500	6	1 Salaried	Urban	Yes	1 GP 1 PN	3
All	**72400**	**49**				**26**	**46**

*rounded to nearest 100

Abbreviations: GP=General practitioner; PN=Practice nurse; GPST=GP specialty trainee; SS=Summary Sheet

7.1.3. Selection of patient records

The vast majority of trigger reviews (57/67, 85.1%) were performed by applying the TRM to the records of the specific 'high risk' patient group that had been recommended, i.e. patients aged >75 years and with confirmed cardiovascular disease. Reviewers from the GP, nursing and GPST groups indicated selecting this high-risk patient group on 22/24 (91.7%), 15/19 (78.9%) and 18/22 (81.8%) SS respectively. The differences between the reviewer groups were not statistically significant (chi-square 1.518, DF=2, p=0.151). Examples of alternative patient groups the remaining reviewers selected were: 'patients prescribed warfarin'; 'patients with COPD'; and 'patients seen in consultation in March'. One reviewer expressed an interest in the management of patients with diabetes mellitus and therefore applied the TRM to a selection of records from that patient group.

7.1.4. Review time

The mean reported time reviewers in the study required to conduct a trigger review and complete a SS was 138.3 minutes (min), SD 48.3, range 60 to 240. The mean times of the GPST, nursing and GP groups were 148.4 min/SS (SD 49.6, range 60 to 240), 140.7 min/SS (SD 52.3, range 65 to 240) and 126.3 min/SS (SD 46.7, range 70 to 240) respectively. The difference between the group means was not statistically significant (p=0.351, DF=2, Sum of squares 5159.8 and F-ratio 1.068).

An alternative way to quantify the reported time requirements would be that reviewers required, on average, approximately five minutes to review a single patient record. This is well short of the recommended maximum of 20 minutes per record. It is also considerably less than a trigger review study in ambulatory primary care in the USA in which reviewers required approximately 20 minutes to screen each record (322). However, the different study methods mean the results are not directly comparable.

The mean time to conduct a trigger review and complete a SS for reviewers from the QOF study was 165.7 min (SD 62.1, range 30 to 300, n=656/755 SS). The difference of 27.4 min is significantly longer than reported by reviewers in this

study (p=0.001, T=3.3, df=712, 95% CI -43.8 to -11.0, standard error of difference 8.371). In other words, reviewers in this study spent on average approximately two hours conducting a trigger review and completing the associated SS, while reviewers in the QOF study reported taking about two and a half hours. It is unclear what the practical implication (if any) of this difference may be or the reason for it. One potential explanation may be the difference in training between reviewers in this study (face-to-face) and the QOF study (in groups). The reported difference intuitively seems small, but the issue of time (or lack thereof) was repeatedly and strongly identified as a key barrier to the implementation of the TRM. This issue will be considered again in more detail in Chapter 9.

A small minority of reviewers indicated requiring more than four hours to complete the trigger reviews. It is possible they may have overestimated the actual time required, but this seems unlikely as there were no formal or informal incentives or assessments associated with the duration of reviews. It seems more likely that this finding is reflective of the characteristics of individual reviewers. Alternatively, it may indicate the need for further training to re-emphasize that the TRM should be structured and focused. It is also possible that some trigger reviews, PSIs and further actions are more complex than others and therefore required additional time.

7.2. Triggers

Overall, a total of 1407 triggers were detected, with a mean of 21.0 per Summary Sheet (SD 13.7, range 0 to 66). Reviewers from the QOF study detected a mean of 17.5 triggers/SS (SD 11.9, p=0.023). The GP, nursing and GPST groups detected a mean number of triggers of 24.3 (SD 15.1), 15.4 (SD 9.3) and 21.4 (SD 14.6) per SS respectively. The comparative differences between calculated means were not statistically significant (p=0.104). The most commonly detected trigger was 'repeat medication item discontinued' (n=290, mean 4.3/ SS, SD 4.4, range 0 to 18). The frequencies, proportions, means, standard deviations and comparison of means between groups and between this study and the QOF study are shown in Table 7.2.

Table 7.2. Number, type and comparison of triggers detected by reviewers in this study and the QOF study

Trigger	This study											QOF study		Comparison of means		Comparison of proportions
	GP		Nursing		GPST		Comparison of means (ANOVA)		Total*							
	n (%)	Mean (SD)	n (%)	Mean (SD)	n (%)	Mean (SD)	Sum of squares, F-ratio (p-value) and DF=2		n (%)	Mean (SD)		n (%)	Mean (SD)	t-value (p-value) and DF=820	95% CI (Std error of diff)	Difference in proportion (%), 95% CI, chi-square (p-value) and DF=1
>3 consultations	74 (12.7)	3.1 (3.2)	40 (13.7)	2.1 (2.3)	121 (25.7)	5.5 (6.2)	128.1, 64.1 (0.037)		249 (17.7)	3.7 (4.4)		1348 (10.2)	1.9 (2.5)	5.2 (<0.001)	1.1 to 2.5 (0.345)	7.5, 5.5 to 9.7, 72,4 (<0.001)
New high priority clinical code	128 (22.0)	5.3 (3.9)	55 (18.8)	2.9 (2.5)	75 (16.0)	3.4 (3.5)	71.3, 3.073 (0.053)		271 (19.3)	4.0 (3.5)		2185 (16.6)	3.1 (3.1)	2.3 (0.025)	0.1 to 1.7 (0.400)	2.7, 0.6 to 5.0, 6.421 (0.011)
Allergy read code	19 (3.3)	0.8 (1.7)	12 (4.1)	0.6 (1.0)	22 (4.7)	1.0 (1.1)	1.6, 0.461 (0.633)		59 (4.2)	0.8 (1.3)		310 (2.3)	0.5 (0.8)	2.8 (0.006)	0.1 to 0.5 (0.109)	1.9, 0.9 to 3.1, 18.178 (<0.001)
Repeat medication item discontinued	146 (25.0)	6.1 (6.0)	71 (24.3)	3.7 (3.0)	64 (13.6)	2.9 (2.8)	127.7, 3.429 (0.039)		290 (20.6)	4.3 (4.4)		2458 (18.6)	3.4 (3.0)	2.3 (0.025)	0.2 to 1.7 (0.400)	2.0, -0.2 to 4.3, 3.203 (0.074)
OOH / A&E attendance	96 (16.5)	4.0 (2.0)	52 (17.8)	2.7 (2.3)	70 (14.9)	3.2 (2.5)	18.7, 1.817 (0.171)		229 (16.3)	3.4 (2.8)		2335 (17.7)	3.2 (3.7)	0.4 (0.666)	-0.7 to 1.1 (0.463)	1.4, -0.7 to 3.4, 1.626 (0.202)
Hospital admission	75 (12.9)	3.1 (2.0)	34 (11.6)	1.8 (2.0)	66 (14.0)	3.0 (2.6)	21.2, 2.148 (0.125)		178 (12.7)	2.7 (2.2)		2461 (18.7)	3.4 (3.7)	1.5 (0.128)	-1.6 to 0.2 (0.459)	6.0, 4.0 to 7.8, 30.444, (<0.001)

Hb < 10	8 (1.4)	0.3 (0.5)	4 (1.4)	0.2 (0.5)	19 (4.0)	0.9 (1.4)	6.1, 3.706 (0.030)	32 (2.3)	0.5 (0.9)	365 (2.8)	0.6 (0.8)	1.0 (0.332)	-0.3 to 0.1 (0.103)	0.5, -0.5 to 1.3, 1.008 (0.315)
Optional trigger(s)	37 (6.3)	1.5 (1.3)	24 (8.2)	1.3 (1.2)	33 (7.0)	1.5 (2.6)	20.5, 0.081 (0.923)	99 (7.0)	1.5 (1.8)	1731 (13.1)	2.3 (3.1)	2.1 (0.038)	-1.6 to -0.0 (0.384)	6.1, 4.5 to 7.5, 42.663 (<0.001)
Total	583	24.3 (15.1)	292	15.4 (9.3)	470	21.4 (14.6)	855.5, 2.352 (0.104)	1407	21.0 (13.7)	13193	17.5 (11.9)	2.3 (0.023)	0.5 to 6.5 (1.535)	

*Includes data from a community pharmacist

Abbreviations: OOH=out of hours; A&E=Accident and Emergency

There are at least two explanations why the 'repeat medication item discontinued' trigger was detected the most. The first is the relatively high incidence of polypharmacy and multimorbidity in the high-risk patient populations that were selected. The second reason is that during the study period a number of medication reconciliation initiatives were underway locally and involved the participating general practices. Two examples of medication changes that were being promoted at that time were: (i) decreasing the dose of simvastatin or prescribing an alternative lipid-lowering drug for patients concurrently prescribed amlodipine; and (ii) changing omeprazole to lansoprazole for those patients concurrently prescribed clopidogrel.

The second most common trigger in this study (and the third most common in the QOF study) was 'new high priority clinical code added'. This finding may indicate the increasing prevalence of chronic disease detection; the increasing workload of general practices; and the fact that coding clinical conditions have become a routine part of day-to-day work because of the QOF. From an NPT perspective, it would seem that coding has been 'normalised' through its contextual integration with QOF.

The predefined trigger that was detected least in both studies was 'haemoglobin (Hb)<10' (n=32, mean 0.5/SS, SD 0.9, range 0 to 7). Reviewers were also encouraged during the training sessions to add the trigger 'prescription of a non-steroidal anti-inflammatory drug (NSAID)'. The rationale for adding this trigger was that elderly patients and patients with heart disease are at increased risk of adverse drug events if prescribed NSAIDs. In fact, Morris et al previously found NSAIDs were the drug most commonly associated with adverse drug events in UK general practice (323). However, in this study the NSAID trigger was least detected. This finding may indicate a high level of awareness of this potential patient safety threat amongst the clinical workforce and might provide indirect evidence of improved, safer prescribing.

Selecting the optimal number of pre-defined triggers was discussed in Chapter 3. Despite much research, the choice of triggers essentially remain at the discretion of researchers and reviewers and require reaching a compromise between the greater sensitivity afforded by more triggers and the improved

efficiency of fewer triggers. As a result, the numbers of triggers in different studies range from two (324), six (325) through to 72 (326). A study of preventable adverse drug events in primary care found the majority (60%) were detectable by four triggers only (323). In general practice, increasing the numbers of triggers may help to detect additional PSIs, but with variable and diminishing returns which are not commensurate with the increase in research/review effort this requires. Given that the intention of the TRM is to facilitate rapid record reviews, larger numbers of triggers may in fact decrease the effectiveness of this method.

The overall number of triggers that arguably provide the best compromise between feasibility and likelihood of detecting PSIs seem to be approximately ten – at least for ambulatory and primary care settings. The overall number comprises a combination of 'global' (non-specific) and specific triggers. A practical example is Kaafarani and colleagues' systematic development of a trigger tool for detecting adverse events in ambulatory surgery. Their study design used the 'gold standard' for trigger tool development and incorporated literature reviews, end-user preferences and expert opinion to derive ten triggers, half 'global' and half specific (327). A further example is Singh et al's experience with a trigger tool for identifying adverse drug events among older patients in primary care. They found nine of their 39 triggers accounted for approximately 95% of the adverse drug events they detected (322).

7.3. Patient safety incidents (PSI)

7.3.1. Incidence of PSIs

A total of 216 PSIs were detected and recorded by the clinicians in this study, with a mean of 3.2 PSIs per SS (SD 2.0, range 0 to 9). Reviewers in the QOF study recorded a total of 2753 PSIs, with a mean of 3.6 PSI/SS (SD 1.5, range 0 to 5). The difference in means between the two studies is statistically significant (t=2.0, df=840, standard error of difference=0.197, 95% CI -0.8 to -0.0, p=0.042). The GP, nursing and GPST groups respectively recorded: 75 PSIs (mean 3.1 PSIs/SS, SD1.8, range 0 to 5), 46 PSIs (mean 2.4 PSIs/SS, SD1.9, range 0-5) and 85 PSIs (mean 3.9 PSIs/SS, SD2.3, range 0 to 9). The differences between the

means of the three groups were not statistically significant (p=0.065). Selected examples of PSIs detected during the study are included in Tables 7.3 to 7.6.

Five of the 67 Summary Sheets did not have any PSIs recorded (7.5%). The number of SS without a PSI from the GP group (1/24, 4.2%), nursing group (3/19, 15.8%) and GPST group (1/22, 4.5%) was comparable (p=0.289). In the QOF study 32/755 (4.2%) of SS did not have a single PSI recorded. A comparison of the difference in proportions of SS without PSIs in this and the QQOF study were not statistically significant (Chi-square results: difference 3.3%, 95% CI -2.0 to 12.5, chi-square=0.892, DF=1 and p=0.345).

The majority of participants agreed that 'finding nothing' is a potential barrier to the implementation of the TRM. This will be considered in more detail in Chapter 9. For now, it is important to consider two different reasons why some reviewers may have failed to detect a single PSI. The first reason is that there were no PSIs to detect in their random sample of records. This argument is supported by the fact that a similar, small proportion of reviews in both studies failed to produce any PSIs. The other reason is that reviewers did not recognise or report a PSI that was in fact detectable in the record. Without external or at least additional reviews of the same sample of records it is not possible to explore this option. From a purely personal perspective it seems likely that both reasons can be true.

It is possible to express the number of detected PSIs in this study (216) as estimated rates, including: one PSI per 7.7 reviewed records; one PSI per 7.7 patients; one PSI for every 23 months of documented care; or 13.0% of the patients whose records were reviewed. While the estimated incidence of PSIs in this study may help to inform our understanding of the safety of care in general practice, it is important to recognise that *all* rates have limitations. Rates are highly dependent on the numerator. If 'PSIs' had been replaced with alternative numerators such as 'adverse drug events' or 'incidents of avoidable harm' the estimated rates in this study would have been lower. Another limitation is that estimated rates are normally calculated for specific patient populations, in this case 'high-risk, elderly patients'. They should therefore not be generalized to other patient groups and are not suitable for direct comparison with the

estimated rates of error and harm in other studies. The potential value and limitations of estimated harm rates are considered in detail in Chapter 10.

7.3.2. Severity of PSIs

The proportions of PSIs – as rated by reviewers in this and the QOF study as being of severity '1' through '4' - are shown and compared in Table 7.3. The severity of the majority of PSIs in this study were rated as '1', i.e. having the 'potential for harm' (n=78 PSIs, 36.1%) or '2', i.e. leading to 'mild harm' (n=75 PSIs, 34.7%). The minority of PSIs were rated '3' or '4', i.e. judged to have caused 'moderate' or 'severe harm' (n=63 PSIs, 29.2%).

There was no significant difference in proportions of the ratings of PSI severity between this study and the QOF reviewers (chi-square 3.924, DF=3, p=0.2698). However, the severity ratings of PSIs between the three different reviewer groups in this study were significantly different (chi-square 21.259, DF=6, p=0.002). The GPST group rated fewer PSIs as having a severity of '1' (potential for harm) and were more likely to rate PSIs as '3' (moderate harm) or '4' (substantial harm) compared with the GP and nursing groups.

The key finding is therefore that the majority of detected incidents have low-to-moderate severity or are 'near misses'. This finding is consistent with the international general practice patient safety literature and independent of the research method (33-35). Two further practical examples are provided. The first example is a study of medication errors reported by family practice teams in the USA. A minority (16%) of errors resulted in adverse drug events. The authors used a 5-point scale to rate the severity of adverse events: (i) 'did not reach the patient' – 41%; (ii) 'reached patients but did not require monitoring' – 35%; (iii) 'required monitoring' – 8%; (iv) 'required intervention' – 13%; and (v) 'resulted in hospitalization' – 3% (76).

Table 7.3. PSI (n) severity and preventability ratings recorded by reviewers

Rating scale	Scale item description	Selected examples of PSIs from study	This study				QOF study n (%)	Comparison of proportions Difference in proportion (%), 95% CI, chi-square (p-value) and DF=1
			GP n (%)	Nursing n (%)	GPST n (%)	All* n (%)		
	Severity							
1	Any incident with the potential to cause harm	Diagnostic read codes from hospital discharge (aortic stenosis, postural hypotension and osteoarthritis) were added to record, but with low priority, so not present on summary	35 (46.7)	21 (45.7)	19 (22.4)	78 (36.1)	1090 (40.4)	4.3, -2.7 to 10.9, 1.366 (0.243)
2	Mild harm, inconvenience, further follow-up or investigation to ensure no harm occurred	Verapamil stopped as could have been causing constipation, exacerbating underlying gastro-intestinal problems	25 (33.3)	17 (37.0)	29 (34.1)	75 (34.7)	788 (29.2)	5.5, -1.1 to 12.5, 2.645 (0.104)
3	Moderate harm: required intervention or duration for longer than a day	A delay in monitoring after an increased dosage of nephrotoxic medicine leading to a significant decrease in renal function with increased monitoring requirements	8 (10.7)	1 (2.3)	19 (22.4)	31 (14.4)	454 (16.8)	2.4, -3.2 to 7.0, 0.667 (0.414)
4	Prolonged, substantial or permanent harm, including hospitalisation	Delayed diagnosis of ischaemic heart disease led to avoidable admission	7 (9.3)	7 (15.2)	18 (21.2)	32 (14.8)	367 (13.6)	1.2, -3.5 to 6.8, 0.153 (0.696)

Preventability

1	Not preventable and originated in secondary care	77 year old with IHD and paroxysmal AF admitted to hospital for elective pacemaker insertion. Post procedure, required two courses of antibiotics and repeated contacts with GP surgery due to medication side effects and slow recovery	6 (8.1)	7 (16.7)	5 (5.9)	20 (9.6)	379 (14.2)	4.6, -0.4 to 8.5, 3.044 (0.081)
2	Preventable and originated in secondary care OR not preventable and originated in primary care	Elderly patient did not have her vitamin B12 injection in over 6 months. The receptionist contacted the patient's daughter and asked her to make an appointment, but this was never done	23 (31.1)	7 (16.7)	41 (48.2)	74 (35.6)	995 (37.3)	1.7, -5.5 to 8.5, 0.172 (0.679)
3	Potentially preventable and originated in primary care	Failure to initiate prophylactic treatment for or follow up a patient with gout resulted in a hospital admission	20 (27.0)	15 (35.7)	22 (25.9)	59 (28.4)	732 (27.4)	1.0, -5.3 to 7.9, 0.0532 (0.818)
4	Preventable and originate in primary care	Patient given inappropriate dosages of anti-diabetic medication with resultant renal injury	25 (33.8)	13 (31.0)	17 (20.0)	55 (26.4)	562 (21.1)	5.3, -0.8 to 12.0, 2.907 (0.088)

*Includes a community pharmacist

The second example is a mixed-method study of adverse events in general practice in the Netherlands. Adverse events were detected prospectively by GPs and through a retrospective record review. Approximately half of the events were not associated with any harm, which is comparable with a severity rating of '1' in this study. Approximately a third of the detected adverse events led to worsening of symptoms (severity ratings '2' and '3') while a few resulted in hospital admissions (severity rating '4'). However, the majority of events were associated with the risk of harm (328). The implication of these findings is therefore that improvement efforts in general practice should focus on reducing the risk from avoidable PSIs irrespective of the severity of harm associated with them.

There are at least three reasons why the TRM is more likely to detect PSIs associated with no or mild harm rather than with moderate or severe harm in general practice. The most obvious reason is that there may simply be fewer incidents associated with moderate to severe harm to detect. The second reason is that trigger reviews are conducted on relatively small samples of records and focus on specific periods of care only. The potential windows through which PSIs may be detected are therefore relatively narrow. The third reason is that more serious incidents are less likely to go undetected. Depending on the severity of harm patients experience, they may re-present to the practice, attend accident and emergency, be admitted to hospital or make formal complaints, thereby alerting clinicians of a potential problem.

Even in those few instances when PSIs with moderate to high severity are detected in general practice, they often originate in secondary care. Three clinical examples would be: patients presenting to their GP with urinary sepsis after being discharged from hospital with an indwelling catheters; patients presenting to their GP with phlebitis after intravenous cannulation during their hospital admissions; and patients with post-operative wound infections presenting to primary care clinicians. This does not necessarily imply that the majority of hospital-related PSIs have serious consequences for patients. The proportions of detected PSIs associated with moderate to severe harm may be relatively higher in hospitals than in general practice when the results of

individual trigger reviews are compared. However, the majority of hospital PSIs is still associated with low to moderate harm. A practical example is Forster et al's study to detect adverse events in an obstetric service through trigger-based clinical surveillance. They found serious adverse events occurred 'infrequently' and there were no instances of permanent harm or death. However, they commonly found 'quality problems' which they felt could (and should) be addressed (326).

In other words, the perceived severity of PSIs should not (and do not) automatically correlate with their usefulness in relation to informing subsequent improvement actions. Despite the relative low impact of the majority of PSIs, they still provide many opportunities to tackle issues that can be addressed by the practice team or a clinician reviewer (326, 329). However, many participants associated more severe PSIs with relatively higher importance and usefulness. From an NPT perspective this issue has to be addressed by doing the work of coherence in order for clinicians to understand that the value of PSIs should be measured by their potential to inform subsequent improvement actions rather than the severity of harm associated with them. This work was performed to some degree through the TRM training sessions. Still, participants' perceptions of the importance of the severity of PSIs strongly influenced the implementation of the TRM and will be discussed in more detail in chapter 9.

7.3.4. Preventability of PSIs

The potential preventability of detected PSIs ranging from '1' through '4' - as rated by the reviewers in this and the QOF study - are shown and compared in Table 7.3. The preventability of 8 (3.7%) PSIs were not rated. 114 PSIs (54.8%) were rated by the reviewers in this study as being preventable or potentially preventable, compared with 1294 PSIs (48.5%) in the QOF study. There was no significant difference in the proportions of preventability between the studies (chi-square 5.745, DF=3, p=0.125). However, the ratings of PSI preventability of the three different reviewer groups in this study were significantly different (chi-square 16.300, DF=6, p=0.012). The GPST group were less likely to consider PSIs as being preventable or potentially preventable compared with the GP and nursing groups. The key finding from both studies is therefore that

approximately half of all detected PSIs may be preventable. This seems to be a consistent finding in the international literature in different health care settings (33-35).

The importance of the concept of 'preventable' harm was previously discussed in Chapter 2. This is a critical and often overlooked issue in the patient safety literature: unfortunately but inevitably some patients will be unavoidably harmed as a result of their interactions with healthcare for a range of highly complex reasons. The key focus from the perspective of patients and clinicians should therefore be detecting and learning from those incidents which are judged to be preventable.

A literature review published after this study had commenced found there is still insufficient empirical evidence to support a specific definition of 'preventable harm'. However, the most common definition is the '*presence of an identifiable, modifiable cause of harm*' (55). The authors suggest three ordinal categories for the degree of preventability: 'definite', 'probable' and 'plausible'. These categories seem intuitively sensible and may prove to be more sensitive and useful compared with the two categories ('preventable' and 'potentially preventable') that were provided in the trigger review template in this study. However, the intrinsic challenges of subjectivity and inter-rater reliability are arguably more important than the type of rating scale reviewers use (330).

The basic preventability rating scale used in this study was specifically developed to assist participants in making professional judgements, e.g. whether identified PSIs had modifiable causes. The rating scale also encouraged them to consider whether it was feasible for them to address modifiable causes, hence the distinction between 'originate in secondary care' and 'originate in primary care'. Consequently, PSIs rated as '3' or a '4' were more likely to be amenable to corrective actions.

It is unclear whether the relatively small differences in PSI severity and preventability ratings between reviewer groups in this study had a discernible impact on their subsequent actions. The difference between the preventability

ratings of the GPST group and the other two clinical groups in this study is consistent with their severity ratings and may therefore be a consequence of applying the rating systems to different PSIs, rather than indicative of disparate interpretations of key concepts. In general, more severe PSIs (as detected and rated by the GPST reviewers) tend to be associated with secondary care. From a general practice perspective, the corresponding preventability rating of '2' signals that, even if modifiable causes could be identified, it is unlikely for primary care to feasibly address them. However, the potential importance of reviewer characteristics, e.g. number of years of clinical experience, and differences in TRM training on the reliable application of the rating scales should also be considered and may be a focus for future research.

7.3.5. Classification of PSI types

The iterative development of a preliminary classification system for the different types of detected PSIs was described in Chapter 5. The nine types of PSIs are: (1) medication and medication-related activities; (2) communication and correspondence; (3) record keeping and coding; (4) care monitoring, access and continuity; (5) diagnoses; (6) medical equipment including IT; (7) investigations; (8) healthcare acquired infections (HAI); and (9) insufficient information to classify. The proportions of each of the different types of PSI are shown and compared in Table 7.4. There were significant differences between the proportions of PSIs detected by the reviewers from this and the QOF study for the following types: care monitoring, access and continuity (p=0.004), diagnoses (p<0.001) and 'unclear' (p<0.001).

Table 7.4. Preliminary classification of types of PSIs (n)

PSI types	Selected examples of PSIs from this study, taken verbatim from the submitted Trigger review summary sheets	This study n (%)	QOF study (2 Boards) n (%)	Comparison of proportions Difference in proportion (%), 95% CI, chi-square (p-value) and DF=1
Medication	Two different strengths of co-codamol prescribed for patient. [Also] on repeat NSAID - elderly patient with renal impairment.	88 (40.7)	650 (34.7)	6.0, -1.0 to 13.2, 2.795 (0.095)
Communication	Bisoprolol increased from 5mg to 10mg at admission. Medication not altered on repeat script. Increase NOT highlighted by secondary care (and CCU and Ward doctors different [doses])	12 (5.6)	108 (5.8)	0.2, -3.9 to 3.1, 0.0012 (0.972)
Record keeping and coding	Same diagnosis recorded twice, discharge letter filed 3 times with different dates - potential for confusion regarding dates	18 (8.3)	145 (7.7)	0.6, -3.0 to 5.3, 0.0316 (0.859)
Care monitoring, access and continuity	Elderly lady with heart failure on ramipril. Bloods not done for 2 years. Letters sent but not attended	55 (25.5)	324 (17.3)	8.2, 2.3 to 14.8, 8.223 (0.004)
Diagnoses	Chest x-ray 'non-specific opacity' - repeat in two months. Patient presented one week later with nausea, then dysphagia. Oesophageal CA. Died.	16 (7.4)	46 (2.5)	4.9, 1.7 to 9.3, 14.307 (<0.001)

PSI types	Selected examples of PSIs from this study, taken verbatim from the submitted Trigger review summary sheets	This study n (%)	QOF study (2 Boards) n (%)	Comparison of proportions Difference in proportion (%), 95% CI, chi-square (p-value) and DF=1
Investigations	Unlabelled specimen bottle sent for FBC check	6 (2.8)	54 (2.9)	0.1, -3.2 to 2.1, 0.0173 (0.895)
Medical equipment including IT	Female patient age 88, terminal Ca. Problems with syringe driver. No number for district nurses. Pump alarming - unable to fix	2 (0.9)	15 (0.8)	0.1, -0.9 to 2.5, 0.0603 (0.806)
Insufficient information to classify PSI	Anaemic - required transfusion	17 (7.9)	512 (27.4)	19.5, 14.6 to 23.3, 37.857 (<0.001)
Healthcare acquired infection	83 year old developed chest infection and cellulitis after discharge from [hospital] post hip dislocation	2 (0.9)	18 (1.0)	0.1, -2.3 to 1.1, 0.0495 (0.824)

7.3.6. Medication-related PSIs

The majority of detected PSIs were of the 'medication' type in both this (n=88 PSIs, 40.7%) and the QOF study (n=650 PSIs, 34.7%). A selection of the ten most common types of medications implicated in PSIs and their relative frequencies are shown in Table 7.5. The most common medication involved in this and the QOF study was Warfarin and seven of the top ten medications were the same in both studies. The key findings of this study are consistent with the international literature: the most common types of PSIs in general practice are related to medication and medication-related processes; and a small number of medications are associated with the majority of medication-related adverse events (77, 78, 83, 87, 88). A systematic review of the international literature (n=19 studies) was recently conducted to study the incidence of inappropriate medication prescribing (IMP) to elderly patients in primary care (331). The authors found a median rate of IMP among the elderly of 20%. The four most commonly prescribed inappropriate medications were from the following groups: analgesia (propoxyphene, a type of NSAID); antihypertensives (doxazosin); anti-histamines (diphenhydramine); and anti-depressants (amitriptiline). The availability of these drugs differs widely between countries and the findings can therefore not be directly generalized to Scotland. However, it is striking that six of the ten types of medications identified as high-risk in this study also belong to the analgesia and antihypertensive groups.

7.4. Actions and intended actions of the reviewers and practice teams

This section describes the actual and intended actions of reviewers and their practice teams as a result of the trigger review process. These actions can be divided into two distinct groups, depending on their temporal relation to the trigger reviews. The first group includes any action that was undertaken while the trigger reviews were being conducted. These types of actions do not necessarily require detection of PSIs. For example, a clinician reviewer may have updated the clinical codes for a patient while reviewing the record or clarified a clinical entry. The second group includes actions intended or undertaken after the trigger reviews were concluded. These actions typically required detection of one or more PSIs.

Table 7.5. The 10 most common medications associated with PSIs

Medications	Selected examples of PSIs from this study, taken verbatim from the submitted Trigger review summary sheets	This study		QOF study (2 Boards)		Comparison of proportions
		n (%)	Rank	n (%)	Rank	Difference in proportion (%), 95% CI, chi-square (p-value) and DF=1
'Top 10' medications, This study						
Warfarin	Patient's INR > 5 after Warfarin dose changed. Patient unsure of what dose he was meant to take and didn't know what he had been taking	10 (11.2)	1	139 (19.5)	1	8.3, -0.6 to 14.8, 3.075 (0.080)
Calcium Channel Blockers	Ankle swelling secondary to amlodipine. No allergy coded	9 (10.1)	2	13 (1.8)	13	8.3, 2.8 to 16.6, 17.555 (<0.001)
ACE / ARB	Trial of ramipril 1.25mg started. Patient already on ramipril 10mg which had been withheld but not discontinued on repeats. Nurse at an appointment printed 1.25mg from 'acutes' and also all repeats, including Ramipril 10mg. Patient noticed and called for advice	8 (9.0)	3	45 (6.3)	7	2.7, -2.7 to 10.9, 0.549 (0.459)
Diuretics	Diuretics discontinued completely instead of dose reduced	7 (7.9)	4	47 (6.6)	5	1.3, -3.8 to 9.2, 0.0561 (0.813)
NSAIDs, including aspirin	Chronic cardiac failure admission. Had been getting as required diclofenac. Apparently told that prn ok by cardiology. May have exacerbated underlying heart failure	6 (6.7)	J5	52 (7.3)	4	0.6, -7.0 to 5.3, 0.000122 (0.991)
B-blockers	Given atenolol 100mg by chemist instead of allopurinol 100mg. Already on metoprolol - felt unwell. Checked by GP stopped himself	6 (6.7)	J5	15 (2.1)	12	4.6, 0.2 to 12, 4.896 (0.027)

Opiates, e.g. codeine, morphine, tramadol	Injured back - was given co-codamol. Co- codamol made her sick.	5 (5.6)	J7	27 (3.8)	J8	1.8, -2.3 to 8.9, 0.281 (0.596)
DMARDs including methotrexate	Female patient age 76. GP discovered her medication had not been collected for 5 months. This was missed when patient attended for routine monitoring bloods. Resulted in flare up of arthritis. Pt stopped due to side effects which could have been easily treated with an additional tab.	5 (5.6)	J7	78 (11.0)	2	5.4, -1.9 to 9.9, 1.930 (0.165)
Antidepressants and antipsychotics	Prescribed citalopram when already on sertraline. GP did not check. Patient did not start and phoned her usual GP	5 (5.6)	J7	20 (2.8)	10	2.8, -1.3 to 9.9, 1.233 (0.267)
HMG-CoA reductase inhibitors (statins)	Patient with GI upset following prescription of simvastatin. Adverse reaction to simvastatin not coded and simvastatin restarted 18 months later as patient's cholesterol noted to be elevated at CHD annual review.	4 (4.5)	10	9 (1.3)	J15	3.2, -0.3 to 9.9, 3.203 (0.074)
'Top 10' medications, QOF study						
Unspecified	Ordering medication every month and getting 2 months' supply. Why has no-one noticed this, and why has the pharmacist not noticed this?	2 (2.2)	J12	56 (7.9)	3	5.7, -0.2 to 8.7, 3.015 (0.083)
Antibiotics	Diarrhoea following antibiotic treatment for chest infection. This worsened haemorrhoids. Had further 2 courses in Nov & Dec. Referred to surgeons for haemorrhoids	2 (2.2)	J12	46 (6.5)	6	4.3, -1.6 to 7.1, 1.880 (0.170)
Oral anti-diabetic drugs	Proteinuria as code, taking incorrect glicazide and metformin dose.	2 (2.2)	J12	27 (3.8)	J8	1.6, -4.2 to 4.2, 0.212 (0.645)

*Abbreviations: INR=international normalised ratio; ACE=Angiotensin-converting enzyme (ACE) inhibitors ; ARB=Angiotensin II receptor blockers ; NSAID=Non-steroidal anti-inflammatory drugs ; DMARD=Disease-modifying anti-rheumatic drugs ; J=Joint.

7.4.1. Actions undertaken during trigger reviews

Clinicians in this study indicated undertaking specific actions relating to patient care and practice processes in 44/63 SS (69.8%). Reviewers in the GP, GPST and nursing groups indicated performing one or more actions while conducting reviews in 21/24 (87.5%), 11/20 (55.0%) and 12/19 (63.2%) SS respectively. The differences are statistically significant (Chi-square statistic 13.431, DF=2, p=0.001).

Reviewers in the QOF study recorded undertaking one or more actions during the trigger reviews in 654/755 (86.6%) of the SS. This is comparable to the GP group in this study but significantly more than the nursing and GPST groups (difference in proportions=16.8%, 95% CI 5.6 to 29.9%, Chi-squared 11.787, DF=1 and p<0.001). Essentially all reviewers in the QOF study were GPs, which is probably why their proportions of actions undertaken during reviews were comparable with those of the GP group in this study.

The implication of this finding is that GP reviewers are more likely than other clinical groups to take some kind of action relating to patient care during trigger reviews. This is understandable as GPs would typically have more clinical autonomy and a wider range of responsibilities for care delivery compared with GPSTs and practice nurses. It should be recognised though that GPST and nurse reviewers are able to make meaningful contributions to improvement efforts as borne out by the fact that more than half of them reported taking some patient care related action while conducting their reviews. However, at the very least this finding raises the question of who ideally should be performing trigger reviews in general practice to help maximize its potential for improving care. This question will be considered again in Chapters 9 and 10.

The actions reviewers undertake during trigger reviews can be classified into one of four main types, depending on whether they relate to: (i) record keeping and coding; (ii) medication; (iii) communication, e.g. with the patient, carers or other health care providers and could be telephonic, face-to-face or via correspondence; and (iv) providing or arranging additional care such as

investigations or consultations. Each of these has a number of more specific actions that are summarized and illustrated with selected quotes in Table 7.6.

7.4.2. Actions and intended actions after trigger reviews

A total of 203 specific actions were taken or intended by reviewers and their practice teams after the trigger reviews were completed. These actions were typically prompted by the PSIs they detected. A mean of 3.1 actions or intended actions were taken or intended after completion of each trigger review in this study (SD 4.2, n=65/67, range 0 to 27). The means for the GP, nursing and GPST groups were 2.7 (SD 3.1, n=24/24, range 0 to 12), 1.8 (SD 1.8, n=19/19, range 0 to 7) and 5.2 (SD 6.0, n=20/22, range 0 to 27). The differences in group means were statistically significant (DF=2, sum of squares 123.2, mean squares = 61.6, F-ratio = 3.837 and p=0.027s) with post-hoc tests finding significant differences between the GPST and GP (p=0.046) and GP and nursing (0.012) groups. The specific types of actions undertaken after the trigger reviews are summarized and compared in Table 7.7.

Reviewers and practice teams from the QOF study indicated taking or intending to take a total of 3124 actions after completing their trigger reviews, with a mean of 4.1 actions or intended actions per trigger review (SD 3.4, n=755/755, range 0 to 21). This was significantly more than in this study (difference of means=1.0, standard error 0.45, 95% CI 0.1 to 1.9, t-value 2.230, DF=818, p=0.026).

However, there were no statistically significant differences when each specific action is compared, apart from 'discuss with educational supervisor', which is expected, given this study had a much larger proportion of GPST reviewers than the QOF study. The difference in reported actions between the two studies can be partly explained by small but potentially significant adaptations that were made to the SS between this study and the subsequent QOF study. The additional option of 'other' was added in 'step two' of the SS and the 'discuss with educational supervisor' was changed to 'formal submission of incident' in at least one Health Board. In other words, reviewers in the QOF study had more options to record their actions or intended actions. However, it is unclear

Table 7.6. The types of actions reviewers undertook during trigger reviews

Main type of action	Specific examples of actions	Selected quotes from Trigger Review SS
Record keeping and coding	Update coding (disease registers, QOF, medical history of clinically important procedures and diagnoses)	Low priority codes from recent discharge were upgraded to 'active' so they are present on the patient summary (GP02) Add code 'deteriorating renal function' to patient (with declining eGFR) record (PN01)
	Correct coding / records	Duplicate code removed (GP11)
	Add a clinical entry, allergy or set a task 'reminder'	Coded [that] ACE-inhibitor not tolerated (GP05)
Actions related to medication	Changes to medication items (commence new drugs, change or discontinue current drugs)	A handwritten note from secondary care outpatient clinic was overlooked. Request to start vitamin D as adcal D3 not tolerated. Contacted pharmacy to see what cholecalciferol preparations are available and commenced [patient] on it (GP02) I changed a patient's antidepressant and added it to his repeat script. Chemist and patient notified to avoid confusion (GP03)
	Perform medication reviews	Medication reviews carried out on all patients reviewed (GP08) Two medication reviews updated (GP04) Medication reviews done / medication adjustments made (GPST9)

Communication (monitoring, clarification, review, education)	Clarify management plan and responsibilities with other health care workers, including secondary care	Patient contacted about INR – district nurses requested to do [patient's] fasting glucose (PN02)
	Clarify patient understanding of management plan	NSAID on repeat [despite] myocardial infarction - looks like patient taking it, but not actually, so stopped: confirmed with phone call (GP07)
	Provision of information / education to patients	Telephoned patient about repeat blood tests, including inflammatory markers (GP02)
	Confirming that intended actions (e.g. scheduled monitoring) took place	Follow up abnormal chest x-ray (patient had been seen at respiratory clinic) (GP11)
Additional care (Investigations and follow-up)	Arrange an appointment with the reviewer or another practice team member	Noted antihypertensive compliance poor. Last BP nine months ago was high. Not ordered calcium channel blocker for four months. Called [patient] in early for home blood pressure review diary and entry in case notes to query at review (GP02) Called patient overdue annual review (GP12)
	Refer to another health care provider	[I send a] letter to cardiology and to a patient (GP10)
	Arrange repeat or further investigation for a patient	>14 point drop in eGFR not noted three weeks ago. Distracted by the increased glucose and new diagnosis of type two diabetes mellitus. [Patient] 92 [years old] with dementia and frail. Arranged bloods [to be] rechecked (GP02)

Table 7.7. Specific actions relating to patient care and practice processes that were taken or intended after completion of trigger reviews*

| Description of action | This study | | | | QOF study | Comparison of proportions |
| | GP | Nursing | GPST | All$^\$$ | | Difference in proportion (%), 95% CI, |
	n (%)	n (%)	n (%)	n (%)	n (%)	chi-square (p-value) and DF=1
Significant event analysis	10 (15.4)	3 (8.8)	12 (11.5)	25 (12.3)	372 (11.9)	0.4, -4.0 to 5.8, 000344 (0.953)
Clinical audit	5 (7.7)	2 (5.9)	5 (4.8)	12 (5.9)	173 (5.5)	0.4, -2.5 to 4.7, 0.00692 (0.934)
Make a specific improvement	5 (7.7)	2 (5.9)	7 (6.7)	14 (6.9)	352 (11.3)	4.4, -0.1 to 7.7, 3.325 (0.068)
PDSA cycle	1 (1.5)	0 (0.0)	1 (1.0)	2 (1.0)	61 (2.0)	1.0, -1.6 to 2.0, 0.546 (0.460)
Feedback to colleagues	29 (44.6)	14 (41.2)	28 (26.9)	71 (35.0)	1265 (40.5)	5.5, -1.7 to 12.3, 2.176 (0.140)
Discuss with Educational Supervisor	0 (0.0)	3 (8.8)	27 (26.0)	30 (14.8)	2 (0.1)	14.7, 10.1 to 20.4, 402.564 (<0.001)
Add to appraisal documentation	8 (12.3)	6 (17.7)	12 (11.5)	26 (12.8)	496 (15.9)	3.1, -2.4 to 7.6, 1.159 (0.282)
Protocol update	7 (10.8)	4 (11.8)	12 (11.5)	23 (11.3)	297 (9.5)	1.8, -2.4 to 7.0, 0.519 (0.471)
Other**	N/A	N/A	N/A	N/A	106 (3.4)	

*More than one option could be selected

$^\$$Includes a community pharmacist

**The 'other' option was added to the SS after this study

whether this relative increase in reported actions in the QOF study had any additional practical value for patients compared with this study.

The most common action taken by reviewers and their practice teams in this and the QOF study was 'feedback to colleagues' and this accounted for, respectively, 35.0% and 40.5% of all indicated actions. They were least likely to apply the 'Plan-Do-Study-Act (PDSA) method'. This may reflect a lack of knowledge of this specific QI method (and indeed other QI methods such as root cause analysis) since there is no formal training on these methods within the current GP curriculum, but would not explain the relatively low numbers indicating their intention to undertake audits and SEA which are formally taught. From a systems perspective of safety improvement this may indicate a training need to help link PSIs to particular improvement methods and tools.

Conclusion

This chapter described the practical implementation of the TRM in general practice, the main findings from conducting trigger reviews and the actions and intended actions undertaken by clinician reviewers and their practice teams. The main results are summarized below:

- A range of primary care clinicians (n=47) were recruited and trained before applying the TRM to review a selection of 1659 high-risk patients' records. They recorded their main findings, actions and reflections on Summary Sheets (SS) and submitted 67 of these for analysis.
- The mean reported time required to conduct a trigger review (25 individual records) and complete a SS in the study was 138.3 minutes (SD 48.3).
- The reviewers found 1407 triggers, with a mean of 21.0/SS (SD13.7). The most common trigger was 'repeat medication item discontinued'.
- 216 PSIs were detected, with a mean of 3.2 PSIs/SS (SD 2.0). A substantial minority of these were considered to have led to moderate or more substantial harm (n=63 PSIs, 29.2%) while the majority (114 PSIs, 54.8%) were rated as being preventable or potentially preventable. However, a small minority of reviewers did not record any PSIs.

- The PSIs were classified by type using a preliminary classification. The most common type of PSI related to 'medication' (n=88 PSIs, 40.7%). The most commonly implicated drug was Warfarin.

- Reviewers undertook specific, patient safety-related actions *during* approximately two thirds of trigger reviews. The types of actions related to improving (i) record keeping and coding; (ii) medication-related processes; (iii) communication; and (iv) providing or arranging additional care for patients.

- A mean of 3.1 actions were taken by reviewers and their practice teams *after* completing their trigger reviews. The most common action was 'feedback to colleagues' but they also conducted SEAs, performed clinical audits, designed protocols, added findings to their appraisal documentation or made specific improvements to their practices.

Chapter 8. How the TRM works

This chapter describes the results that relate to the study aim of explaining how the TRM worked in practice, how it influenced study participants and helped to bring about the outcomes reported in Chapter 7. The main source of data for this chapter was the second round of interviews with the practice managers, general practitioners and practice managers. The data were thematically analysed. A summary of this chapter and its three sections are provided in Figure 8.1.

The first section describes how the TRM enabled the detection of PSIs by providing the study participants with: (i) the necessary 'knowledge' to ensure they were ready to use the method with a patient safety *'mindset'*; (ii) *opportunities* to perform trigger reviews, and to reflect on the findings and implement changes; and (iii) a *structure* of the cognitive and practical steps required for effective implementation of the TRM.

The terms 'knowledge' and 'readiness' are commonly used and require further clarification. For the purposes of this study, knowledge is understood to '*encompass everything that individuals might know, be able to do and value*'. 'Readiness' is defined as '*an individual's ability to learn from what they know, can do [their skills] and value [their attitudes]*'. In other words, different yet interdependent types of knowledge (knowing; doing; and valuing) determine the 'readiness' of individuals to engage with, and learn from, their experiences in any given situation (332).

When all three of these components are present (knowledge/mindset; opportunity; and structure) the likelihood of detecting PSIs with the TRM is greatly increased. The importance of detecting PSIs in this study is that it creates potential 'learning moments' (49). Learning moments are by their very nature emergent and temporal and their value is determined by clinicians consciously or unconsciously choosing to either accept 'ownership' of PSIs or not. This pivotal decision is a key determinant of the nature and degree of impact the PSI will have and is therefore crucial to the eventual outcomes of the TRM, e.g. whether it will result in reflection, learning and improvement-related

Figure 8.1. How the TRM works and the related chapter sections
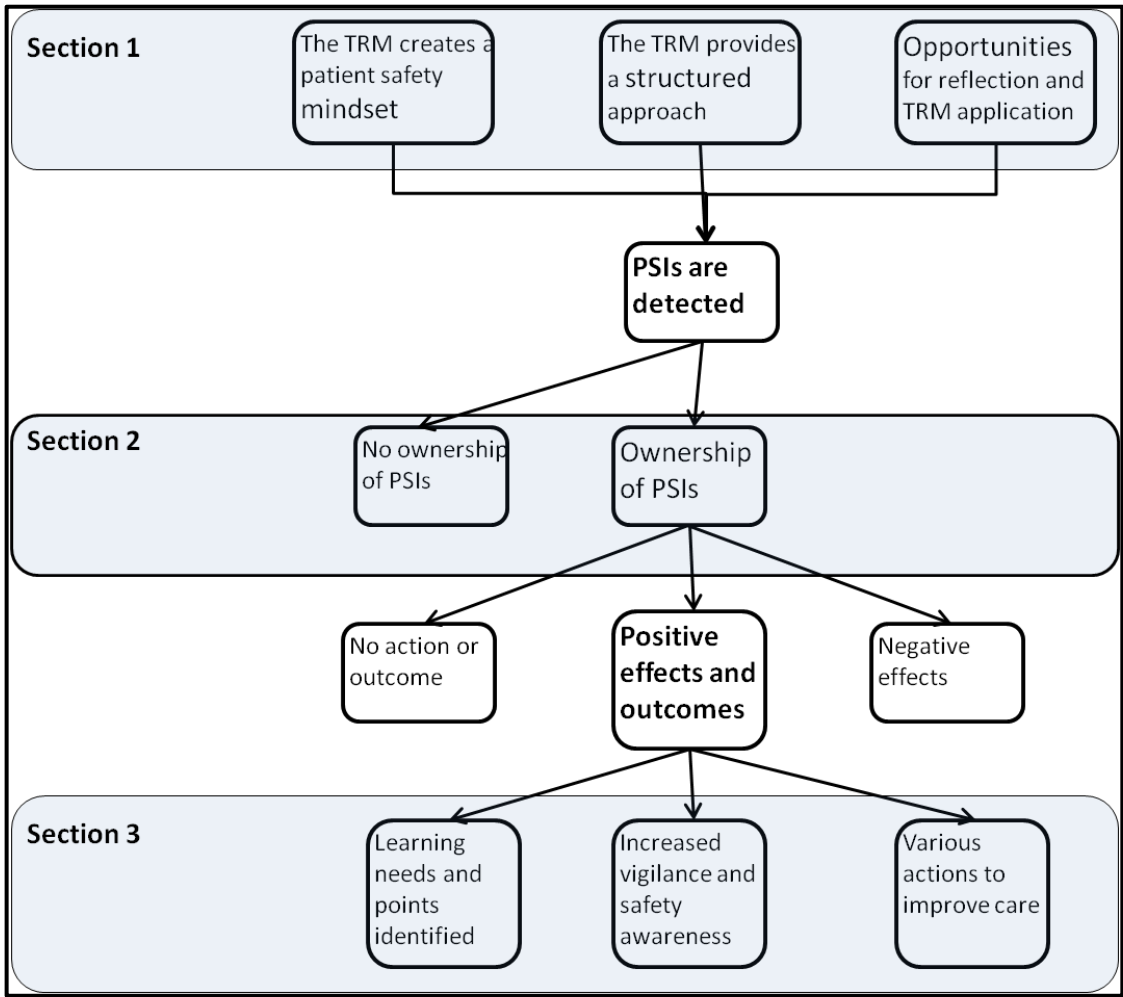
actions or not. The second section of this chapter therefore explains the importance of ownership of PSIs in more detail as well as how this concept influenced clinicians and their teams.

The third and final section describes the potential outcomes from detecting PSIs and accepting ownership for them, ranging from negative emotional and psychological experiences, through none or neutral to very positive effects. Practical examples include: clinicians and teams taking specific actions to help reduce similar PSIs in the future; increased vigilance and awareness of potential safety threats; and identifying learning needs and points.

8.1. The TRM enables the detection of PSIs

8.1.1. The TRM helps to create a patient safety 'mindset'

One of the participants explained how certain tasks created a specific mindset for her, and presumably other health care workers. As a practical example she described how, when she began the daily task of signing bundles of repeat medication prescriptions, she unconsciously went '*into prescriber mode*' (GP03). In the same way, while she was performing trigger reviews, she noticed adopting a 'trigger tool mindset'. Many other participants reported a similar experience of (unconsciously) forming a specific 'mindset' during application of the TRM which made them more vigilant and aware of potential safety-related issues. So, while the patient records were the same ones they had interacted with on a regular basis while providing routine care, when applying the TRM to them this 'mindset' made them feel and appear 'new'.

It is important to note that all reviewers who were aware of this mindset, irrespective of their clinical roles, reported that it developed gradually, over a period of time. The first time they applied the TRM the mindset developed relatively slowly. As they reviewed the consecutive sections in individual records, the 'mindset' started forming until: '*you're looking at the notes from a different view, from a different perspective*' (GP02). As reviewers became more familiar with the method, a focused, patient safety mindset developed quicker: '*by the time you're on the third one [record review] it's just happening*

automatically' (GP04). However, even with experience, reviewers still required a few minutes for the TRM mindset to form.

Once this new perspective (mindset) had been established, participants felt they were more likely to detect PSIs compared with the beginning of the review, or when they were interacting with the record for other reasons during routine care. This mindset was 'built' by reviewing sections in consecutive records in a systematic and focused manner, but could be lost or changed by distractions and interruptions. This is one of the main reasons why implementing the TRM was facilitated by reviewers being provided with sufficient, uninterrupted (protected) time to complete a trigger review as a single activity.

Participants felt these 'mindsets' were beneficial and increased their efficiency as all of their attention could be focused on the tasks in hand: *'it's much easier to achieve one specific aim if you're focused to doing it rather than trying to achieve a hundred different things all at the same time' (GP11).* Unfortunately, while focusing on completing a specific task such as signing a bundle of prescriptions, potential safety threats and opportunities for interventions or additional care probably go unrecognised in many instances. Box 8.1 provides a practical example of a PSI that was detected during a trigger review in this study and describes its impact.

The clinician reviewer who reported the PSI subsequently reflected on the potential reasons why it may have gone undetected. She concluded that, because she had focused all of her available attention on certain clinical tasks, the unintended consequence had been that other opportunities for proactively offering care to the patient had been missed. She explained: *'I had seen that patient and I hadn't mentioned an ACE inhibitor at all and you also think well why did I never mention that? I'd have just completely excluded it, or was my mind thinking along the track of something else?' (GP03)*

It was unclear to the participants exactly how the 'mindset' formed, but they suspected an association with repetitive and routine clinical tasks: *'we're so used to doing things I think in a certain manner' (GP03).* While this explanation seems plausible, an alternative or additional reason may be that participants'

Box 8.1. Example of a detected PSI and the importance of 'ownership'

A GP reviewer (GP03) identified an elderly patient with established chronic kidney disease (CKD) stage three who had not been added to the practice register and had not been offered treatment with a suitable ACE/ARB. In other words, the PSI was suboptimal treatment of a patient with CKD. This was rated as a PSI with low severity and high preventability. The reviewer was surprised at detecting this PSI because the patient had consulted with her on several previous occasions in the preceding months. Her first actions were to add him to the relevant chronic disease register, request a repeat eGFR blood test to check his renal function and arrange a review appointment to monitor his blood pressure and discuss potential further treatment. She identified a professional learning need about the management of CKD while reflecting on this incident and addressed it. The incident was discussed during a practice meeting and the team decided to update the practice protocol for the management of CKD and to perform a clinical audit of the management of their patients with CKD.

'readiness' for the TRM - as determined by their knowledge of it - helped to create the mindset. The TRM knowledge of most participants would have increased as a result of training, increasing practical experience from conducting trigger reviews and evaluating their findings. From an NPT perspective, participants' knowledge - and therefore readiness to learn from PSIs - increased through work relating to coherence and especially its 'internalization' component ('value' or 'attitude' knowledge); collective action ('doing' or 'skills' knowledge); and reflexive monitoring ('knowing' or information knowledge).

8.1.2. The TRM provides opportunities for its application and reflection

Many participants felt that one of the important characteristics of the TRM that made it useful to them was that it not only encouraged reflection and further action, but also provided opportunities to do so. The TRM initiative essentially offered general practice teams a method with potential benefits for them and their patients, an estimate of the time and resources that implementing it would require and an offer of some financial and 'expert' support. During the recruitment stage of this study, participants therefore had the opportunity to decide before the TRM was implemented whether it would be appropriate for them to be involved (or not). From an NPT perspective they had the opportunity to do the necessary work of: initiation, i.e. the preliminary work of deciding they should be involved in its implementation; internalization, i.e. understanding and agreeing whether the proposed intervention (the TRM) was compatible with their prevailing culture; and legitimisation, i.e. feeling justified in allocating and spending time and resources on TRM-related activities.

I really did think [the TRM] was valuable, cause it really does just give you that time out to review patients, just review care and systems, and you know it's something that we often don't have. (GP08)

Chapter 6 described how participants understood patient safety as an important and integral part of the care they provide, and how they perceived a professional responsibility for their patients' safety. It also described how they were able to identify a large number of potential safety threats and contributing factors to PSIs and their willingness to improve their standards of care, provided

they had adequate resources to do so. A key element in the way the TRM works is therefore by providing teams with an improvement method (and supporting evidence of its potential value) *along with* some financial compensation for the required time for implementation. This in turn creates the opportunities (and legitimacy) for clinician reviewers to engage in quality improvement work. The implication from an NPT perspective is therefore that, for an intervention to be successfully implemented in general practices, it is important to ensure that the work of contextual integration is supported, i.e. providing teams with appropriate resources and adequate time. This will be considered again in Chapter 10.

The majority of participants reportedly used the opportunities for reflection to some degree, although it is difficult to quantify the true extent or measure the quality of the reflection. However, the descriptions of some clinicians of how they were able to identify learning needs or points while reflecting on detected PSIs provide some evidence of its usefulness. This is an important outcome of the TRM study and will be described in more detail in section 3 of this chapter. Other participants described how reflection helped them understand the latent risks associated with detected PSIs, how these may affect other patients, and how they may be able to proactively manage risk. A practical example is provided in Box 8.1.

The importance of clinicians being able to reflect on clinical care and their own performances is increasingly being recognised. Reflection is considered a competency in its own right and is promoted as a core professional quality in medical education (333). It is a collective term that includes '*those intellectual and affective activities in which individuals engage to explore their experiences in order to lead to a new understanding and appreciation*' (334). It should be recognised that, while the TRM strongly promoted and provided opportunities for reflection, it cannot *make* people reflect or more reflective per se. This issue will be considered in more detail in chapter 9. The implication of this finding from an NPT perspective is therefore the importance of identifying and recruiting those clinicians who are naturally more reflective to perform trigger reviews, e.g. effectively performing the work of skill set-workability.

Another way in which the general practice TRM approach created opportunities for learning and reflection in this study was by encouraging clinicians to consider *all* PSIs as potentially important, irrespective of whether they considered them 'acts of omission' or 'acts of commission'. This is a key difference compared with the Institute for Healthcare Improvement's secondary and ambulatory Global Trigger Tools (GTT) that only record and measure 'acts of commission'. However, the authors of a recent systematic review of the GTT challenged this approach, and recommended inclusion of 'acts of omission' in all settings (242).

The decision to purposefully exclude acts of omission may be justified and considered reasonable for many study designs, as it reduces the subjectivity of the external reviewers' findings, improves inter-rater reliability and therefore also improves the reliability of harm estimates. This is less of an issue when reviews are conducted by internal reviewers where the intention is to improve their own care standard, rather than simply measure clinical performance. This issue, and the other potential strengths and limitations of the TRM will be considered in detail in Chapter 10.

In this study, a relatively large proportion of detected PSIs could be attributable to omissions of care. A practical example would be the suboptimal treatment of a patient with confirmed chronic kidney disease (CKD) who was *not* prescribed an ACE/ARB even though this is recommended by current evidence-based guidelines (see Box 8.1). The implication is that there are potentially many minor safety threats or quality issues detectable in general practices that either go unrecognised or are recognised but not prioritised or acted on while delivering routine care. If so, it is likely the result of significant time constraints and the need to prioritise more urgent medical concerns and the patient's agenda during consultations that are typically scheduled for a maximum of ten minutes. One clinician explained that *'unless it's something glaringly dangerous [we] might just sort of gloss over it and move on cause you don't have time'* (GP02). A practical example would be an elderly patient presenting with symptoms and signs of an acute and significant respiratory tract infection. In a typical ten-minute consultation agreeing and implementing a suitable management plan is prioritised over medication reconciliation or coding. In effect, the clinician is making an ETTO – which was described in Chapter 6.

Unfortunately, these minor issues remain as latent risks in practice systems and could manifest later, potentially as serious incidents (1).

Perhaps unsurprisingly then, many of the detected patient safety incidents in this study were the result of latent safety risks or 'hazards' in the wider practice systems that were already known to many of the reviewers or their teams, but had not been addressed before because of lack of opportunity or perceived urgency. This may also be one of the reasons why the vast majority of study participants indicated they were willing to consider, search for and report PSIs (Chapter 6). In this context, the TRM simply provided the final or necessary impetus (by providing practical examples through detected PSIs of breaches of system defences) for reviewers and teams to implement improvement actions and a little protected time and opportunity to do so. Conceptually, how the TRM worked during its implementation and subsequent application can be likened to a catalyst: it enabled and accelerated existing processes.

8.1.3. The TRM provides structure to the review and improvement efforts

Chapter 3 described the three consecutive steps of the TRM In detail, which are: planning; reviewing records; and action and reflection. Each step has a number of clear and specific recommended tasks which reviewers should perform or consider. The TRM therefore provides a structure for reviewers to follow and apply when reviewing their patient records and taking or considering subsequent improvement actions. Some participants described how the structure and steps of the TRM helped to focus their attention and efforts and they felt this increased their likelihood of recognising PSIs in the records they may otherwise have overlooked, or may have overlooked while providing routine care: e.g. '*the same patient I'd seen regularly, well I didn't make that jump at all [to detect a PSI] until I applied the structure to it [the record]' (GP03)*. Another clinician agreed that '*the structure helps [reviewers] to process it [PSIs] if you like, and make it a bit more tangible' (GP12)*. This finding is consistent with international evidence that unstructured reviews are inefficient, inaccurate and highly variable compared with structured approaches (233, 335).

The vast majority of reviewers indicated that they preferred the structured approach of the TRM over the alternative, which would have been to simply conduct an unguided review of the same sample of records: *'I think for people just looking through records, they often don't know what to look for and I think the trigger tool at least gives you a kind of core information' (GP08)*. The structure of the TRM also required clinicians to focus on performing tasks consecutively. One participant understood the value of the TRM in the following way: *'I think the benefit of doing it as a bundle if you like or as a as a trigger tool exercise is that you're much more likely to be focussed on looking for it [triggers]' (GP12)*. The structure and focus of the TRM helped a few of the participants who recognised that they were easily 'side tracked' or 'bogged down' when reviewing clinical information such as, for example, correspondence and investigation results. This is why one participant recommended the TRM to her colleagues and advised them: *'well, that's why you might find the structure of this [the TRM] more helpful than just randomly going through it all' (GP10)*.

These study findings illustrate the work of at least four different NPT components: 'differentiation' – the participants performed work to increase their understanding of how the TRM is different from alternative clinical record review approaches; 'interactional workability' – they had to enact and interact with the method to produce results; 'relational integration' – the work they did to build trust and confidence in the method and in their ability to apply it correctly; and 'individual and communal specification' – the work they did to increase their understanding through practical experience of how to apply the method more effectively, thereby increasing their perceptions of its feasibility and acceptability.

On the other hand, some reviewers detected PSIs that were not directly associated with triggers. These PSIs were still detected in the proximity of triggers, or while searching for triggers in specific sections of records. A practical example would be the detection of the PSI of an elderly patient who suffered a preventable adverse drug reaction after being prescribed different opiate analgesia concurrently. The reviewer detected the PSI while searching the medication section for the presence of the trigger 'medication discontinued'. One of the participants explained the value of the TRM's

structured approach in the following way: '*even if there isn't a problem in the crux area, 'cause you've looked at that area there might be something juxtaposed to that that you see because you've actually taken the time to look at it [a specific part of the record] more carefully*' (GP06).

8.2. The importance of 'ownership' of PSIs

A crucial difference between the IHI trigger tool method and the TRM approach in this study is 'ownership' of PSIs. In secondary care, external reviewers conduct trigger reviews on samples of records from patients who are unknown to them with very little or no chance of clinician and patient ever meeting in the future. The main findings are estimated harm rates and these are typically 'owned' by researchers and managers. Even when findings are shared with clinical teams they tend to be in aggregated data and chart format. In contrast, primary care clinicians in this study performed trigger reviews on records of patients that, in most instances, were very well known to them. They had usually provided at least some of the care during the periods of review and there was a very high probability that they would continue to do so in the future. Consequently, participants from all clinical groups felt they 'owned' the PSIs they detected.

However, the difference in ownership should not be considered a proxy of reviewer motivation, ability and thoroughness. External reviewers are typically highly-experienced clinicians with additional training in the trigger review methodology. Many of them may also have a personal interest in patient safety and could be expected to do the best job they can. Conversely, some internal reviewers may lack the necessary experience, training or attitude to effectively apply the TRM. Notwithstanding potential differences in reviewer characteristics, ownership of PSIs (or not) was an important determinant of the outcomes in this study as will be explained below, with the implication that it may also be an important factor to consider in other trigger review studies.

How the TRM seemed to work in general practice was that, once potential safety threats became apparent in the practice through the detection of PSIs, the personal relationships with and knowledge of the patients made them difficult to

ignore. In other words, the PSIs detected in general practice seemed to evoke a powerful moral, professional and personal imperative to take further remedial actions that were reportedly felt by the vast majority of participants. The importance, emotional dimension and impact of PSI ownership was graphically described by a participant who thought implementing the TRM had '*certainly started the hares running*' in his practice. He explained this was because detecting PSIs had felt like '*you've been pricked*' *(GP04)*.

The initial actions and intended actions were therefore typically, and unsurprisingly, targeted at individual patients and problems. Once the first few, small actions were taken, this sometimes led to larger and more significant changes or at the very least increased the probability of further improvements to other systems or reducing latent safety threats at practice level. In this way a single incident affecting one patient potentially became the starting point and spark for further assessment and actions at the wider patient population or practice levels. A practical example is provided in Box 8.1 in order to further illustrate the key findings of how the TRM works. The example describes the responses of the reviewer and her practice team to the detection of a single PSI.

In this example, applying the TRM had had the benefit of improving the management of patients with CKD of the practice because of four different sets of actions: (i) immediate actions during the trigger review relating to the specific patient with the PSI; (ii) the team performed a clinical audit to measure their current CKD management performance and to assess the likelihood of a similar incident occurring in the future; (iii) the reviewer undertook self-directed learning about the management of CKD as part of her continuous professional development; and (iv) the team updated the practice's CKD management protocol.

This example helps to illustrate key findings from chapter 7, namely that the degree of severity and preventability of PSIs are not associated with their usefulness. It also illustrates a key finding from this chapter, which is that reviewer characteristics are important determinants of the TRM's outcomes. In this instance the ability and willingness of the clinician to reflect on her findings determined the outcome and value of the TRM.

From an NPT perspective, this example illustrates the work of 'enrolment' and 'activation' – the reviewer had to recruit and engage additional team members (enrolment) to help her implement the desired actions, including the audit and updating the CKD protocol (activation). It also demonstrates the work of reflexive monitoring, and more specifically 'individual and communal appraisal' – the reviewer and practice team had to evaluate the importance of the findings and the potential value (or not) of taking subsequent actions.

Another way ownership of PSIs (and therefore the TRM) works is by generating findings that have personal importance and relevance to the clinicians and teams who apply the method because '*no one else is in the same boat*' (GP04). The value of the TRM is therefore not necessarily only in finding undetected or new types of PSIs but simply the fact that a PSI – or PSIs – was uncovered in the practice at all, and that it occurred to a patient known to them. Once PSIs are detected, the TRM essentially becomes open-ended in the sense that the type and degree of learning and whether and what type of improvement actions are undertaken are left completely to the discretion of the individual clinician reviewer. GP reviewers in particular valued this approach: '*looking for the problem and sorting it myself I felt a degree of empowerment' (GP06)*. The same participant went on to explain his understanding of the TRM and its potential value (e.g. the NPT work of coherence) as: '*allowing you to take some control and ownership over stuff again and make a difference.'*

Some of the key differences between the TRM and many other quality improvement methods are, therefore, that it provides participants with highly personal, practical and patient-specific information and can enhance clinician autonomy.

Up until now, the discussion about ownership was from the perspective of a professional relationship between patients and clinicians or patients and other general practice staff. There is a second form of ownership of PSIs that were recognised by many participants, but especially the GP group and practice managers. This type of ownership is inferred from the general practice business model and relates to the responsibility of an organisation and organisational

leadership to assure patient safety and compliance with clinical governance obligations. The (abridged) narrative of PM11 in Box 8.2 provides a representative example of the perceived importance of ownership.

The ubiquitous business model of general practice in Scotland is a contractual agreement between the NHS and independent contractors to provide defined health care services on their behalf. GPs and some non-GP partners typically own the business concern and, in many instances, the care facilities. Participants understood the implication, namely that business partners had overall responsibility for the practice, the care it delivered and the repercussions from actions – whether positive (e.g. profit sharing, accumulating assets) or potentially negative (e.g. patient complaints, PSIs). Consequently, many GPs and some PMs were strongly motivated not only from a personal and professional, but also from a business perspective to provide high-quality, safe care. One of the participants explained: '*I sit here in this practice and think, what's happening in this practice? Because the buck stops with me, or with [GP partner x] or with [GP partner Y]' (GP04).*

This is a key difference between general practice and NHS acute care settings, as clinicians working in hospitals arguably have less of a vested financial interest in preventing PSIs. Even when hospital clinicians and staff are directly responsible for managing department budgets, their decisions rarely if ever directly affect their own personal incomes in the way it does general practice.

Box 8.2. Example of the perceived importance of 'ownership' to participants

I've been here seventeen years. I've been a partner for seven or eight of those now and basically I run the business of the practice...I manage everything from buying the envelopes to [pause] to agreeing the contract with the health board. Ehm well at the end of the day if anything goes wrong it's the partners that are going to to [pause] take the can for it... I never felt outside the partnership anyway. I was very taken aback to be offered partnership. It'd never even crossed my mind. I think it crosses more people's minds nowadays, but then it didn't ehm and it was very flattering. I think the only thing that's changed for me is [deep breath] you definitely do feel a much bigger weight of responsibility... I took a year to accept... because I wasn't sure it was really what I wanted, and I was giving up all my employment rights and that was scary, and I was becoming self employed, which was scary. I mean it's my practice, but then I probably felt that way as a manager as well (PM11).

8.3. Outcomes from PSI 'ownership'

There are three main types of outcomes from detecting and assuming ownership of PSIs (Figure 8.1). They are: (i) no impact or change; (ii) positive; and (iii) negative outcomes. Examples of positive outcomes include the different actions and intended actions undertaken by clinician reviewers and theirs teams during and after the trigger reviews as a result of the PSIs they detected and were described in detail in chapter 7. In addition, a practical example illustrating some of the potential and different positive effects of ownership of a single PSI was provided in this chapter (Box 8.1).

This section describes three further potential outcomes from PSI ownership: increased vigilance and awareness of patient-safety related issues; identifying learning needs and points; and their emotional impact on clinicians and their teams.

8.3.1. Increased patient safety awareness

Many participants thought that applying the TRM had increased their awareness of safety-critical processes at the time and a minority felt that this effect was sustained for at least several months after each trigger review. One GP said: *'having done the trigger reviews [we are] more aware of looking for things'* (GP02). Some clinicians also reported that their confidence in their wider practice systems and the standards of the quality of care they delivered had increased after conducting the reviews. From an NPT perspective, this reflects the work of relational integration (increased confidence) but also reflexive monitoring (evaluating their levels of safety) being performed successfully.

It is unclear exactly why the TRM increased awareness of patient-safety related issues and why this occurred to varying degrees for different reviewers. However, a similar effect has been reported in the international literature as far back as 1991, when Wu et al found many junior doctors' vigilance increased as a result of their (known) mistakes (336). Some of this study's participants thought there was an association between the TRM's structured approach, specific triggers and ongoing safety awareness. This perception is supported by the fact

that a few months after the trigger reviews had been completed, a minority of reviewers reported still approaching patient records section-by-section and screening for triggers in a structured manner even during their routine consultations. This was particularly true for the group of PN reviewers, who were initially less confident than the GP group about using the TRM, but found the structured approach and predefined triggers particularly useful. A nurse practitioner explained: *'personally, the trigger review of patient notes did change my mind-set and I look for certain triggers now as part of my practice. You tend to memorise certain triggers and look out for them with all patients - it tends to become imbedded into practice'* (PN0X).

8.3.2. Learning needs and points

The majority of participants thought that the TRM was useful, because it helped them to identify new learning needs and points. Learning needs were identified at the individual and practice team levels: *'there are always things to learn if you're keen to learn'* (PN12). Some reviewers also described how they met or planned to meet these learning needs. At the individual practitioner level, learning needs often related to management of patients with chronic disease. An example would be updating knowledge on the management of atrial fibrillation.

There are three ways general practices and organisations can respond to and learn from PSIs. The first is *'doing the quick fix'*. This is the most common and superficially attractive response. The second is *'going into a black hole'*, e.g. clinicians report a PSI, but 'nothing' seems to change. The third is *'closing off the Swiss-cheese holes'*, when sustainable changes are made to systems in order to prevent recurrences (175). Options one and three are appropriate. The challenge is determining when to use which.

At the practice level, reviewers frequently identified the need for: improving communication between primary and secondary care, consistent coding of clinical conditions and 'protocols' for the management of specific high risk medication, e.g. monitoring of nephrotoxic drugs. Further examples with selected quotes are provided in Table 8.1.

Table 8.1. Educational value of the TRM: selected examples of individual and practice teams' learning needs and points

Educational value of the TRM	Examples recorded on the Trigger review SS	
	Individual (clinician) level	Practice team level
Identifying learning needs	• 'I need to review CKD 3 management as I could not remember specific contraindications for ACE inhibitors'	• 'Several patients overdue annual reviews - should we check notes and call patients via telephone rather than just letters?'
	• [I need to] update my diabetic knowledge - online module'	• 'Liaise with colleagues who do bloods to ensure the correct tests are carried out and to reduce the need for the patient to return unnecessarily'
	• [What is the] target heart rate for AF? Read editorial from NEJM	• 'Should discuss and agree how to prioritise read codes. In DOCMAN we should probably advise the staff what priority we want given to codes. Confusing for staff as lots of options.'
	• '[Find out] how to liaise with social services about respite [care]'	• 'Protocol for monitoring potential nephrotoxic [and hepatotoxic] drugs'
Identifying learning points	• 'Awareness of need to ensure warfarin is stopped pre-operative where appropriate'	• 'That, whilst as a practice we are fallible, we do have reasonable processes in place. The missed increase in bisoprolol was a concatenation of events between primary and secondary care at the discharge interface. This is a fraught area.'
	• 'Be aware and proactive if investigation results do not fit with clinical picture'	'Positive learning that disease monitoring systems work well (COPD) [in this practice]'
	'[I] need to give more attention to out of hours summary sheets'	• As a team we need to be more aware of encourage those patients with chronic disease to attend for review

Whether and to what extent learning from PSIs occurs is determined by many factors (337) and will be considered in more detail below.

8.3.3. Emotional impact of PSIs

The potential adverse impact of PSIs on clinicians is increasingly being recognised and studied (186, 338-341). In fact, a study to determine the factors that influence how students and residents learn from medical errors found even imagining themselves committing errors caused the participants 'significant stress' (299). Twenty-five years ago Christensen et al likened their experience of conducting in-depth interviews with community physicians (n=11) about the impact of their perceived mistakes on them as '*equivalent to a descent into the underworld of medicine. It is a journey into a place of shame, fear and isolation*' (298). The authors described the wide range of negative emotions ('dysphoric feelings') the clinicians experienced and how, in many instances, these feelings of frustration, guilt, fear, anger, self-doubt, anxiety, humiliation, shame and embarrassment remained unresolved for months and years. These findings have since been replicated in larger studies, different clinician groups and settings (186, 339, 340, 342).

The different coping strategies clinicians reported using – if indeed they even consciously committed to deal with the effects of PSIs on them – typically belonged in one of two groups, depending on whether the focus of the strategy was on the 'emotion' or 'problem' (298). This is in some ways analogous to the two different tasks clinicians face in response to a PSI or medical error: '*How do I deal with this*?' And '*How do I learn from this*?' (338) Examples of helpful 'emotion-focused' strategies include disclosing errors to peers, patients and family; and re-establishing and re-affirming their professional identities (e.g. self-forgiveness). On the other hand, participants with a 'problem-focused' approach attempts to analyse the event, learn from it and take remedial actions. Consequently, there is hope in the '*heart of darkness*' for '*this landscape of fallibility contains the spirit of wisdom that can guide the rebuilding*' (298). All but one of the participants in Christensen et al's study reported learning from their mistakes and had subsequently taken specific actions to improve their clinical performance in some way.

In some ways little has changed in the quarter century since this study was published: patients still suffer avoidable, iatrogenic harm; and clinicians still err despite their best and ongoing efforts to provide safe care. As a result, we should acknowledge that the emotional cost of PSIs can be high (338). This is why clinicians involved in serious PSIs have been referred to as 'second victims' (185).

One thing that has changed dramatically in health care, and especially in general practice, is the disclosure rates of medical errors. In the study by Christensen et al, only a tiny minority of physicians admitted to disclosing their mistakes, and those that did only confided in close relatives (298). In contrast, all of the participants in this study unanimously agreed that disclosing errors was not only appropriate but that they felt able to do so, and were confident of the support of their colleagues, should this be required. While it is possible that this may be the unique perception of this study group, consider that significant event analysis (SEA) is ubiquitous in UK general practice, the prevailing safety culture tends to be 'open' and positive in this setting (Chapter 6) and patient safety research is now encouraged in many modern health care systems. This may also be the reason why there were no reported or known instances of detected PSIs having significant or enduring *negative* emotional impact on participants in this study.

There is some evidence that patients also prefer disclosure of medical errors (343). A questionnaire study of German GPs' management of serious medical errors and subsequent outcomes found most errors had been disclosed to patients. The majority of patients continued to trust their GPs despite them disclosing serious errors, especially if the GP had discovered the problem and disclosed it themselves, or if other health care providers also contributed to the PSI (344). The implication is therefore that the TRM recommendations to discuss PSIs within the practice team and disclose errors early are acceptable to clinicians and patients alike.

A common perception is that clinicians learn 'better' from their own mistakes, from those errors they accept responsibility for and from PSIs that result in severe harm (299, 337). The findings from this study that participants consider

PSIs with higher severity ratings as more important seem to support this perception, and were described in Chapter 7. However, if there is indeed a link between severity of PSIs and subsequent learning, it has not yet conclusively been shown. In fact, current evidence seems to suggest that clinician characteristics are equally or more important determinants of whether and to what degree learning occur (187, 339). Two other factors that are strongly associated with learning from PSIs are: creating opportunities for critical reflection on incidents; and formal discussions of incidents and providing constructive feedback (49, 337, 342). These findings support the emphasis of the TRM in this study on clinician reflection and the recommendation of formal meetings to discuss trigger review findings in a structured manner within teams.

A recent systematic review (n=24 studies) of the effects of medical errors on clinicians found consistent and widespread evidence of negative psychological and emotional effects on them (186). However, a 'disproportionate' amount of this research was conducted in the hospital setting and the authors admit it remains unclear how error outcomes vary between setting and clinical groups. There is, for example, emerging evidence that PSIs have an emotional impact on all general practice staff, and not only clinicians (7, 187). For now, it remains unclear what the implications of this finding may be. Of interest though, is that the review also found some evidence of positive outcomes from medical error. Examples include: increased assertiveness and confidence; improved relationships with colleagues; and corrective and improvement actions taken from the individual patient through to the organisational levels (186). Constructive feedback and effective learning in the aftermath of a serious PSI or error seems to make the difference between clinicians 'thriving' rather than simply 'surviving' (185). This deceptively simple yet powerful observation resonates strongly with the findings of this study. A key priority for future research is therefore to examine the longer-term impact of PSIs and increase our understanding of how to maximize the positive and reduce their negative effects.

Conclusion

This chapter explained how the TRM worked. In essence, trained clinicians performed structured trigger reviews of samples of patient records with a patient safety 'mindset', ideally as a single uninterrupted activity during protected time allocated specifically for this purpose. In combination, these three factors (structure; mindset; and opportunity) greatly increased the likelihood of detecting PSIs compared with unstructured reviews of clinical records or opportunistically identifying them during routine care.

The detected PSIs in this study had personal and professional relevance for the clinicians and the practice teams involved, because they affected or may have affected patients known to them. Many PSIs also provided specific, uncontroversial information about the standards of delivered care.

Consequently, many participants were willing, and felt a responsibility, to accept ownership of the PSIs they detected, thereby seizing the metaphorical 'learning moments' and extracting value from them in the form of subsequent reflection, learning and further action. The different and important positive outcomes from detecting and taking ownership of PSIs in this study were therefore discussed in more detail. In particular, the different types of learning needs and points that participants identified were listed and the increase in some participants' awareness of safety-related issues were described. Although negative outcomes from PSIs were not an issue in this study, they are potentially important and were also discussed.

The key study findings are therefore that the TRM worked because of specific factors (mindset; structure; opportunity; and ownership of PSIs) and that these factors helped to determine the TRM's positive outcomes (detecting PSIs; increased safety awareness; identifying learning needs and points; taking specific improvement-related actions).

The findings may seem simple or self-evident, but they have potential important implications for other quality and safety improvement efforts. Each factor is related to a more generic and essential requirement for successfully

implementing complex health care interventions. They are, in no particular order:

- '*Mindset*' - frontline staff must have the necessary *knowledge* to implement the intervention;
- '*Opportunity*' - participants require adequate and appropriate resources and time to implement interventions;
- '*Structure*' - the aims, applications and potential benefits of interventions have to be clearly understood by participants;
- '*Ownership*' –interventions and implementation require ongoing clinician engagement.

From an NPT perspective, each of these factors is associated with work relating to specific constructs and components of the framework. The likelihood of an intervention being successfully implemented and eventually becoming normalised is dependent on how much of this necessary work is effectively performed in practice. For example, the work of identifying and agreeing the resource requirements, and which team members have the necessary knowledge to implement the intervention, is described by the 'skill-set workability' component of the NPT framework. The work of providing the resources, recruiting the staff and keeping them engaged are described by the 'contextual integration', 'enrolment' and 'activation' components respectively. Similarly, each of the other factors described in this chapter can be described by applying the NPT framework.

The next chapter will describe these factors in more detail and consider whether they facilitated or hindered the implementation of the TRM. The additional factors that were identified as important facilitators or barriers in this study through application of an NPT framework will also be discussed.

Chapter 9. Factors that facilitated or hindered the implementation of the TRM

This chapter describes the results that relate to the study aim of identifying and describing the main factors that facilitated or hindered the implementation of the TRM in general practice. The main source of data for this chapter was the second round of interviews with practice managers, general practitioners and practice nurses. The data were coded and analysed according to the Normalisation Process Theory (NPT) framework.

The chapter sections correspond to the four main constructs of the NPT framework, which are: coherence; collective action; cognitive participation; and reflexive monitoring. Each of the four sections describes the factors relating to that specific construct, and how they are associated with the other elements of the NPT framework. The fifth and final section considers the main study findings and the potential implications of the identified barriers and facilitators, comparing and contrasting them where relevant with the international literature.

9.1. Coherence - The sense-making work individuals and teams did to understand the TRM

The main findings are summarised in Table 9.1 and illustrated with selected quotes:

- *Implementation was facilitated when participants understood that the TRM was a new QI method, but intended to be complementary to existing methods such as SEA;*
- *Participants were concerned that they would have insufficient time and resources to implement the TRM. However, the vast majority found the method was feasible;*
- *The vast majority of participants perceived the TRM as acceptable and compatible with the prevailing safety culture in general practice.*

Table 9.1. A description of the four components of the 'Coherence' construct with selected quotes

NPT component, with a description relating it to the TRM	Success factors and their effect (facilitating or hindering) on implementation of the TRM	Selected quotes
Differentiation: The work of understanding the differences and similarities between the TRM and existing practices (informal record review) and QI methods (SEA, clinical audit).	Implementation was facilitated when participants understood the TRM as a new QI approach, but complementary to existing methods such as SEA and clinical audit.	I mean essentially what [the TRM] does is a kind of retrospective audit of a cohort of patients looking for any potential areas of harm (GP08) [The TRM] is essentially looking to pick up an SEA I suppose. That's the way that you could look at it - if you need an SEA that's a good way to find one (GP07)
Communal specification: Understanding the intention and potential benefits of the TRM.	When participants understood the TRM's intended aims, potential benefits and limitations they were more likely to use it, use it as intended and report positive outcomes.	I think it's useful as a learning tool to learn about your own systems and a way of trying to improve those systems and a way of learning as a team with the results (GP05)
Individual specification: Understanding the required effort and tasks of individual team members to implement the TRM, e.g. is the TRM considered to be feasible and a priority?	All participants were concerned that the available time and resources would be insufficient to implement any new intervention, including the TRM. However, the vast majority found the TRM to be feasible, which then facilitated its further use.	I think the first time doing the first couple of patients was a bit slow and because it's different and you're not quite sure where you're at. So it took a wee while, a couple of patients really to get into the swing of it. I did it again just last week and found it very quick and very easy to go through (GP02)
Internalization: the work individuals and teams have to do to understand how the TRM 'fits in' with the prevailing culture and processes in the practice, e.g. whether it is acceptable.	The vast majority of participants perceived the TRM as acceptable and compatible with the prevailing safety culture in general practice. The closer the TRM fits with the practice culture and the team's existing tasks, the easier its implementation.	You have to have systems in place that make a safe journey for the patient. So I guess that's why we think we should be doing [the TRM], whether it's a project or an incentive or not, because that's what we're all about really, bottom line (PM08)

In the UK, general practices have been incentivised for years to apply QI methods such as SEA and clinical audit (chapter 3) at regular intervals. As a result, most primary care clinicians will have at least some experience with these tools. All primary care clinicians and many non-clinical staff also regularly interact with patients' medical records. Examples of informal and opportunistic interactions may include checking and comparing investigation results and clinical entries while more formal reviews are required to prepare medical reports. The TRM includes references to known and normalised QI methods and its design was based on existing, formal and informal review processes which were adapted to provide a structured approach and a specific purpose, i.e. to detect PSIs. In fact, the structure of the TRM was identified as one of reasons why it was effective, as was described in Chapter 8.

Consequently, the TRM was recognizable to all of the participants, and many of them explained their understanding of the TRM by comparing it with QI methods that were already known to them, such as clinical audit and SEA. Furthermore, they understood the TRM as being complementary to existing QI methods. For example, detecting PSIs with the TRM often required subsequent application of other methods, such as SEA or audit, to better understand or quantify the extent of the problem. Being able to interpret the 'new intervention' in terms of existing approaches and methods helped to facilitate its implementation overall.

On the other hand, when the TRM was perceived as being too similar to existing practices or other interventions, it potentially created confusion and paradoxically decreased the motivation of a tiny minority of participants to implement it. Implementation was therefore further facilitated by participants being able, despite similarities between the TRM and other QI methods, to also recognise important characteristics that differentiated it as being 'new'. The main difference for them was that the TRM aimed to *proactively* detect and prevent PSIs, whereas the aforementioned QI methods were typically *reactive* in nature. One GP explained how '*mistakes usually are only picked up when they've blown up rather than going looking for them*' which is why he thought the TRM was '*better because actually I was fishing for things*' (GP06).

In terms of NPT, the work of differentiation is an important facilitator of implementation because it helps participants to think through how they define, categorize and divide the tasks associated with implementing the TRM appropriately – which is complementary to the work of 'skill-set workability' and essential for effective 'enrolment'. It also helps participants understand how changing aspects of the TRM may affect its outcomes. In NPT terms, it helps to inform the work of 'reconfiguration' of the TRM. For example, selecting different patient populations will affect the type and numbers of PSIs that are detected, e.g. high-risk groups are predisposed to PSIs so their selection will increase the estimated PSI rates. In addition, if new interventions are 'recognizable' to participants it facilitates their work of coherence (sense-making). Participants are able to use their existing skills and previous experience and potentially gain early confidence when using the method effectively. From an NPT perspective, this would be described as 'relational integration'.

Most participants initially expressed concerns that implementing the TRM would increase their workload and require substantial additional resources and time. This perception was moderated as their understanding of the TRM increased through practical experiences with it, so that the vast majority of clinicians conceded that the actual workload and time requirements were lower than they initially expected. For example, GP11 described getting 'bogged down' during the first trigger review, learning from his experience and applying the method more effectively the second time. However, while reviewers typically experienced their second trigger reviews as being quicker and easier than the first, their findings were not necessarily more important or helpful.

The finding that the perceived feasibility of the TRM changed during the study period is the result of the work of 'individual specification', e.g. reviewers changed their perceptions of the TRM so that they came to understand it as being quicker and easier than they thought at first. This was informed by the work of interacting with and experiencing the TRM (e.g. interactional workability) and evaluating its outcomes (e.g. individual appraisal). The implementation of the TRM was facilitated by practice teams understanding the necessary steps to implement the intervention and perceiving the requirements as being feasible. From their perspective, feasibility meant that the TRM

required minimum additional resources, time or increase in workload. The implication is that the degree of perceived or actual 'effort' required to implement an intervention is a powerful determinant of its eventual success (less effort, increased feasibility) or failure (more effort, decreased feasibility). Implementation can be facilitated further if the intervention can be assimilated into existing procedures and practices and participants expect it to reduce their workload.

Implementation of the TRM was also facilitated because its intended users clearly understood its aims, potential benefits and limitations. Initially, their understanding varied widely, but after the training sessions the vast majority understood that the main objectives were to search samples of medical records for previously undetected PSIs and implement improvement actions. For some, their understanding of its benefits expanded during the study period as they identified additional applications, such as using the TRM during one-to-one training sessions with GPSTs.

All participants thought the TRM was compatible with the prevailing culture in general practice and understood how it could be incorporated into their existing safety systems and procedures. This perception facilitated the implementation of the TRM as the participating practice teams reported having a strong, positive safety culture which in large part motivated them to participate in this study in the first place. The implication from this study finding is therefore that the more compatible an intervention is with the prevailing culture and existing work practices of a team or organisation, the more likely that its implementation will be successful and that it will become normalised over time.

The degree to which interventions are perceived as being acceptable and feasible to their intended users largely determine whether they will be implemented successfully in the first instance and subsequently become integrated into routine work. The acceptability and feasibility of interventions are in turn determined by the product of the different types of 'coherence' work. The vast majority of participants perceived the TRM as acceptable and feasible and could: (i) clearly differentiate it from other QI methods; (ii) understand how to apply it; (iii) discern what potential benefits it would have

for them and their patients; and (iv) understood how it 'fit' within the prevailing cultures in their teams.

9.2. Collective action - The operational work of enacting the TRM and integrating it with existing practices and contexts

The main findings are summarised in Table 9.2 and illustrated with selected quotes:

- *Implementation of the TRM was facilitated when PSIs were detected quickly and the PSIs were unambiguous, serious, preventable and originated in primary care;*
- *Implementation was facilitated by allocating adequate resources and time;*
- *Inclusion of the TRM in the QOF was an important facilitating factor.*

The majority of reviewers conducted the trigger reviews as a single activity by themselves. However, in a small minority of practices the reviewers worked in pairs – at least initially – and felt this helped to improve their confidence in the method and their own ability to apply it. A small minority of practices decided to divide the trigger reviews among several clinicians, so that each reviewed only five or six records from the sample, but this strategy was perceived as ineffective. Similarly, when clinicians interrupted their trigger reviews by only searching a few medical records opportunistically during the day or days, they also reported less benefit compared with those that performed reviews as a single activity. One of the reasons for these findings was discussed in Chapter 8, namely that the TRM works by creating a patient safety 'mindset' which required time to form.

Many reviewers considered the PSIs with greater severity to be more deserving of and amenable to improvement actions compared with those that had resulted in little or no patient harm. The small minority of reviewers that were unable to detect a single PSI or only detect a few PSIs of low severity therefore typically perceived this as an important barrier to the TRM's use. This is understandable, as the main value of the TRM in general practice is derived from detecting PSIs and taking ownership for them (Chapter 8). However, some reviewers

Table 9.2. A description of the four components of the 'collective action' construct with selected quotes

NPT component, with a description relating it to the TRM	Success factors and their effect (facilitating or hindering) on implementation of the TRM	Selected quotes
Interactional workability: the work of applying the TRM in practice, the results (e.g. whether and what type of PSIs they detected and what improvement actions they took) and the time and effort this required (as opposed to what they perceived it would be). What effect did implementing the TRM have on their routine work?	Implementation of the TRM was facilitated when PSIs were detected quickly and the PSIs were unambiguous, serious, preventable and originated in primary care. A small minority of reviewers found no PSIs, which was a major barrier to future implementation.	There's safe and there's safe. I mean there's life threatening and there's a slight error on certain things (PM03)
Relational integration: The work of building confidence in the TRM, their own and their colleagues' abilities to effectively apply it and that the findings are valid and useful. To be effective, this work requires formal and informal sharing of trigger review findings.	Practice teams in general accepted that the TRM findings were valid. However, none interpreted the results as reflecting unsafe or poor overall quality care. Implementation was hindered by the concerns of a minority of reviewers about the validity of the results from other practices or that their findings may be inappropriately interpreted and used at regional and national levels.	You can do it properly or you can have a quick scamper through it and not find anything (GP04) If we get information back and you see practices where they've identified a range of issues, that's good - they've identified them. But what else is going on in that practice? (GP08)

Skill-set workability: the work of dividing TRM implementation tasks. To be effective, this work requires the practice leadership to consider each team member's current role, their experience, skills and attitude and the available resources and then appropriately match staff with the required work. If necessary, additional resources or training may have to be procured.

Implementation is facilitated by the allocation of adequate and appropriate resources, balancing competing demands on team members' available time and considering reviewer characteristics when assigning new tasks. The TRM implementation was hindered in those practices that didn't allocate adequate resources and time, or when time was allocated but not protected. The vast majority of clinician reviewers had the necessary skills and experience to perform trigger reviews, but not all of them participated through choice.

Time's the biggest killer. I think every practice could open twenty four hours a day and still not have time. Every single thing that comes out: 'we'll get the practice nurse to do it' but just how thin do you get spread? (PN08)

Coming in in my own time was much better because there was no chance of being interrupted and more time to take. I didn't feel pressure to look at my Docman or look to see what other things were going on in the surgery. So I think probably doing that [the trigger review] complete and everything's closed and you know you're up to date with everything is actually more useful (GP02)

Contextual integration: The work of integrating the TRM within the context of general practice, in particular GPST, appraisal and revalidation. CI work requires the provision of adequate and appropriate resources; visible support from senior leadership and restructuring existing policies or infrastructure to include and support the TRM.

Formal inclusion of the TRM in existing, recognised GP contexts such as QOF, appraisal and GPST is an extremely powerful facilitator. However, some participants felt that including the TRM in QOF may paradoxically decrease its impact, as it may simply become 'another tick box' exercise for some practices.

Will I be putting [the TRM] in my appraisal? Of course (GP01)

 What we were going to do was get the GP trainee involved… I plan personally to use it with our trainees now (GP12)

had an alternative interpretation of 'finding nothing', which is that it provided them with 'evidence' that the care they provide was safe and of a high standard. Implementation of the TRM was facilitated when the participants or practice leadership accurately assessed the resources and time that would be required for each phase of the implementation process *and* ensured that these needs were met. They also had to decide who would do which tasks. In NPT terms, the work involved in this is described by the 'skill set-workability' component. They also had to critically evaluate the knowledge and 'readiness' (as defined in Chapter 8, page 200) of the clinician reviewers and whether these were sufficient to enable them to successfully implement the TRM.

Further work was then required to recruit additional team members and keep them actively engaged in the TRM process (enrolment) and to allocate and provide the necessary resources (contextual integration) to enact the trigger review findings. The potential types of resources included: protected time to implement the intervention; access to external 'expert' support; availability of training; senior leadership support; restructuring current policies and infrastructure to include, promote and support the TRM; and discretionary budgets. The work of 'contextual integration' should be the responsibility of the host organisation, which in this study included the general practices. However, the local health authorities, NHS Health Boards and even the national government also had important contributions to make.

Providing adequate and appropriate resources was one of the most important facilitating factors for the successful implementation of the TRM. While, the participants valued the TRM training, educational material and support from external 'experts', according to them the crucial resource was sufficient, uninterrupted time to allow a trigger review to be completed as a single activity.

While most practices allocated at least some protected time for TRM work, it was seldom adequate or uninterrupted. One GP described the intensity of the workload in her practice as a *'rollercoaster'* and how she had to *'physically hide'* (GP02) to perform trigger reviews. As a result some clinicians performed the reviews in their own time, in-between other tasks or divided the sample of

records between several clinicians, which as stated earlier reportedly decreased its effectiveness. Some reviewers reported being interrupted by team members or by other, more urgent clinical tasks. A minority of participants were also distracted by the constant feeling of other work 'piling up' and a compulsion to keep checking how their workload was increasing while they were performing trigger reviews. For these reviewers, the TRM was perceived as just one more task competing for their limited time.

The personal and professional characteristics of reviewers strongly influenced the implementation of the TRM. Experienced, enthusiastic clinicians who were motivated to use the TRM and able to critically reflect on their findings and the implications for their patients and the practice derived the most value from the method. On the other hand, adopting a strict 'tick box' approach reduced the effectiveness of the TRM. The study participants thought that a substantial minority of the overall general practice workforce would adopt this approach with any intervention including the TRM, and especially those interventions associated with the QOF. From their perspective, the TRM may therefore be less useful when implemented more widely.

This is an important concern given the TRM was incorporated into the QOF shortly after this study commenced and subsequently implemented across Scotland by hundreds of general practice teams. However, a comparison between this study and the larger QOF study did not find any significant differences in the main findings. The perception that some practices simply 'tick boxes' may therefore be incorrect or, alternatively, occur in only a small number of practices.

Most participants thought that including the TRM in QOF was the most important facilitating factor for its implementation. A practice manager explained how *'being part of the contract it [the TRM] just becomes something that has to be done'* (PM03). But for a minority of reviewers it paradoxically decreased their interest in the TRM. This is because they perceived QOF targets as being achievable without discernible improvements in patient outcomes and concerns that targets become harder to achieve year after year. One GP felt that *'it's quite easy to pay, if I'm honest, lip service to some of those changes for the*

paperwork that is required [by QOF]' (GP06). In NPT terms the work of including the TRM in the QOF is described by the 'contextual integration' component. Consequently, participants were able to 'legitimise' their involvement with the TRM and this facilitated its implementation. However, including the TRM in QOF paradoxically also hindered its implementation. Some participants struggled to do the work of 'relational integration' because, as described above, they struggled to build trust in the ability of other practices to effectively apply the method.

Apart from the QOF, the implementation of the TRM was also facilitated by its integration in other general practice contexts, including GP specialty training (GPST) and appraisal. A few participants felt the TRM had potential value in medical education: *I actually used it [the TRM] as a teaching tool' (GP11).* They introduced the method to the GPSTs in their practices, encouraged them to apply it and subsequently discussed their findings in order to identify learning needs and points. Most GP reviewers also indicated that they included or planned to include the TRM as supporting evidence of QI for appraisal purposes. However, these contexts were much less important for the implementation of the TRM compared with the QOF and were not significant facilitating factors.

The vast majority of participants' confidence in the TRM and their own ability to correctly apply it increased with experience and time. However, some participants described a lack of trust in the validity of the findings of reviewers in their own or other practices and a substantial minority of practice nurses doubted their own ability to apply the method correctly (at least initially), e.g.: *'I was just lacking confidence of what I was doing; I think that's what it was. I kept thinking I should go back and I did... I just had to convince myself I wasn't missing anything. I was annoyed with myself for feeling like that cause I felt I shouldn't. I'm experienced enough and it was just something different (PN10).*

Despite this, the vast majority of practice nurses were able to detect PSIs. However, they were less likely than the GP group to formally share their findings with the rest of the team or implement improvements at the practice level. This was at least partly because the majority of nurses were not provided with formal opportunities to report their findings during practice meetings, where limited

time meant competing agenda items were given priority, or meetings were scheduled on days when the nurses were not scheduled to work. Even when the practice nurses were able to attend team meetings, they typically did not set or influence the agenda.

> *'The nurse will do it [trigger reviews] because that's what she's been asked to do, but I'm not sure that it'll then go anywhere, or make anything happen unless someone else is involved with that, and it's brought up... it's going to be quite difficult for me to share those findings with other people, because I'm hardly ever at the practice meeting, because they have it on a day I don't work here, and at the other practice I work in I'm never at their practice meetings, so I'm in an oddly peripheral place, you know, and that can be very difficult. I like to feel involved and like I can, you know, influence things and help a practice to work better, but I'm not in that position'* (PN02)

The majority of participants felt confident that the findings of their own trigger reviews were valid and that they had applied the method correctly. They acknowledged that some of the detected PSIs may indicate opportunities to improve specific aspects of future care but no one thought it implied that their overall standards of care were unsafe or of unacceptable quality. The majority of participants informally shared the findings from the trigger reviews with at least some team members. The potential impact and value of the TRM was increased by sharing the findings, particularly when this helped team members to identify and agree on the contributing factors of PSIs and collectively take further action to improve practice systems and processes. However, only a minority shared the results with the whole practice team during dedicated meetings.

A substantial minority of participants had concerns about how trigger review findings would be interpreted and used at a national level. For this group, their concerns, and a general mistrust of more senior NHS management, were a potential barrier to effective implementation of the TRM. One GP felt '*we talk about a no blame culture in NHS [Board X]*' yet '*the first thing everyone does is 'right, who's to blame for this'* and too often the result is that '*we'll hang someone out to dry in a non-judgemental way*' (GP04).

9.3. Cognitive participation - The relational work of engaging participants and establishing a community of practice around the TRM

The main findings are summarised in Table 9.3 and illustrated with selected quotes:

- *Providing flexible training facilitated implementation of the TRM;*
- *The TRM was facilitated through voluntary participation;*
- *The TRM was facilitated when reviewers had sufficient autonomy and opportunities to enact change.*

The period prior to and during the initial implementation of an intervention is crucial, as it helps to determine whether the intended users will accept ownership and continue using it. During this period the work of 'initiation' is an essential part of determining participation, but also influences the degree of 'coherence' (understanding) participants develop about the intervention. Factors that were particularly strong facilitators early in the implementation of the TRM were: (i) identifying and recruiting practices and clinicians with an expressed interest in improving care quality; (ii) providing flexible training sessions; (iii) easy access to 'expert' support and advice; and (iv) detecting PSIs early during the trigger reviews, which helped to increase participants' confidence in the method and their own abilities to apply it. Of these factors, participants considered TRM training as the most important.

Training typically required a minimum of one hour and only rarely exceeded two hours. Characteristics of the training that facilitated implementation were flexibility in delivery and timing, using a range of teaching methods and tailoring the delivery to participants' learning needs. In particular, participants valued the chance to practice the method on simulated records and the educational resources they were provided with were useful reminders during the actual trigger reviews. However, whether clinicians received training or not was a more important factor in determining their success in implementing the TRM than the type of training.

Table 9.3. A description of the four components of the 'Cognitive participation' construct with selected quotes

NPT component, with a description relating it to the TRM	Success factors and their effect (facilitating or hindering) on implementation of the TRM	Selected quotes
Initiation: The work of preparing for the implementation of the TRM, e.g. ensuring that implementers are willing and able to start using it.	Training, formal and informal promotion of the intervention (raising awareness) and access to expert support all facilitated implementation. However, training had to be flexible and use suitable delivery methods.	I've been trying to start the ground level approach of saying 'this is how it should be used', you know, used formatively and using it to look at your systems as well, and things like that (GP05)
Enrolment: the work of identifying and recruiting the necessary people that are required to implement the TRM at the appropriate times. It also involves identifying others who chose to participate and evaluating the contributions of all participants.	Initial recruitment of volunteers facilitated implementation by ensuring clinician engagement. The TRM was facilitated by the vast majority of GPs participating voluntary. However, the majority of practice nurses and administrators were assigned to the TRM which, in some cases, reduced their motivation.	Sometimes you know that, although they're asking you [pause] it's going to come your way anyway (PN09) We decided because I'd already done this last year that one of the other GPs would do the trigger tools this year (GP11)
Activation: The work of supporting and sustaining the TRM individually and as a team. This work required TRM findings to be disseminated and that clinician reviewers had opportunities and sufficient influence to enact the findings.	The TRM was facilitated when findings were disseminated and reviewers had sufficient autonomy and opportunity to enact change.	[The TRM is] easy until you get the 'what am I going to do about this' stage (GP04) I held a practice meeting afterwards to highlight that perhaps we aren't always that good (GP06) I wasn't involved at all (PM10)

Legitimation: The work individuals and teams do to justify implementing and being involved with the TRM. This component also includes the legitimising work other parties do who are not directly involved in the practical implementation of the TRM.

Implementation of the TRM was facilitated when individuals and practice teams were able to justify investing time and resources in its application. Formal inclusion, endorsement and external validation of the TRM by professional and regulatory bodies were particularly powerful facilitators.

I'm not sure if I'd have gone back to [the TRM] if it had disappeared off the horizon. If it was out of QOF, but part of what we do, or it's made an RCGP approved tool or it was something that trainees do, then I could see why people would become lured to the idea that it is a good thing... cause it gives it fruits - there are fruits for your labour. Well, you have to justify the time in order to make it happen (GP06)

I feel I always have to justify every single working minute I have in here and I don't take tea breaks because it's just constant (PN10)

Implementation of the TRM typically began with a GP volunteering to participate in the study or apply the method. These 'early adopter' or local 'champion' GPs described personal and professional reasons for wanting to participate: curiosity, awareness of patient safety as a practice and political priority, and being proactive in this regard. These GPs then enrolled other team members to assist with the work of implementing the TRM in one of three ways. The first was formally assigning specific responsibilities to team members with little or no opportunity to decline the role. This is the way in which the vast majority of practice nurses, managers and administrators were recruited. The second way was to recruit team members opportunistically or wait for them to volunteer their engagement. This is the way the vast majority of other GPs were enrolled. The third and least common enrolment method was formal invitations at practice meetings and GPST training sessions. A few GPs also enrolled non-practice participants, including IT staff, pharmacy colleagues and secondary care clinicians. Perhaps unsurprisingly GPs were - at least initially - more motivated to apply the TRM than PNs. However, the manner of enrolment and initial levels of motivation did not seem to be associated with the relative success (or not) of applying the TRM.

The autonomy (or alternatively 'power' or 'influence') of the reviewers was identified as an essential factor in the TRM's implementation – without it, the potential for improvement was greatly reduced. However, clinicians with little autonomy could still detect PSIs, endeavour to make some improvements at the individual patient level and learn from the trigger review process. Conversely, greater levels of autonomy meant trigger review findings were shared with the rest of the practice team and therefore increased the educational and improvement value of the TRM to the practice and even regional. In NPT terms, the work of 'activating' the TRM required participants to remain 'engaged' with the intervention. This was facilitated when they were provided with sufficient opportunities to enact the intervention and perceived their involvement to be appropriate, e.g. through the complementary work of 'legitimisation' and 'relational integration'.

Implementation was therefore also facilitated when the TRM was perceived as a legitimate activity and participants could justify investing their time and

resources in it. Legitimation of the TRM occurred through three main mechanisms. These are, in descending order of their perceived importance: (i) contextual integration with, for example, QOF; (ii) endorsement and practical demonstration by a peer, e.g. a clinician in the practice performing a trigger review; and (iii) verbal or written promotion by health care and professional organisations, e.g. the RCGP and NES. The vast majority of participants were also aware that improving patient safety in primary care had been declared a priority by the Scottish Government.

However, just because an intervention is perceived as 'legitimate' does not necessarily imply that it is useful or acceptable. Alternatively, an intervention may be very effective and its users may have confidence in it, but it may still not be legitimate. Therefore, the 'confidence' of health care workers in a method, tool or intervention does not only depend on its legitimacy, but also on its perceived value to them and others, i.e. the work of reflexive monitoring, which is discussed next.

9.4. Reflexive monitoring - The appraisal work of adapting and evaluating the TRM

The main findings are summarised in Table 9.4 and illustrated with selected quotes:

- *The Trigger Review Summary Sheets facilitated implementation;*
- *The vast majority of participants perceived the TRM as potentially useful in their practice, and also in the wider general practice setting.*
- *A few clinicians adapted the TRM to better suit their own aims*

The TRM was intentionally designed to be flexible. Training sessions introduced generic principles and suggested high-yield strategies, but reviewers were actively encouraged to make minor adaptations if they considered this necessary in relation to their own individual circumstances. Examples of how the TRM was customized included: the type of patient population selected for review; what period of time to review in each record; whether to add extra 'triggers'; and the order in which record sections were screened for the presence of PSIs. Clinicians

then used their own discretion whether to record a detected PSI or not, and whether and how they address it.

The TRM's relative flexibility was identified as an important facilitating factor for its implementation. However, despite the potential to adapt the TRM, only a small minority of reviewers actually did so. For example, in 57/67 (85.1%) trigger reviews the sample of patient records were selected from the recommended 'high risk' patient group, e.g. patients aged >75 years and with confirmed cardiovascular disease. Another example is that only a tiny minority of reviewers recorded optional triggers and even then there was no evidence that they were useful to detect additional PSIs.

The Trigger Review SS was intentionally designed as a one page (double-sided) data collection template with a series of tick boxes and adjustable text boxes to encourage a structured approach to recording the detection of PSIs, improvement actions and reflection and learning. Clinicians generally found the SS quick and straightforward to use. However, a minority of reviewers were at first unable to complete the electronic version because of incompatible IT systems – a problem which was resolved – and a small minority of reviewers indicated that they had struggled to rate the severity and preventability of the PSIs they detected, despite referring to the rating scales on the SS. A small minority of reviewers also suggested minor changes to further improve the usefulness of the SS. Two examples of suggested edits that were subsequently made were: adding a section to record whether findings were shared at a practice meeting and removing the 'priority' ratings of PSIs. Overall, in NPT terms, the work of 'systematization', e.g. collecting, analysing and sharing data with the SS facilitated implementation of the TRM.

The vast majority of participants perceived the TRM as a useful approach to improve the safety of the care they provide. They also recognised its potential for identifying learning needs and points, encouraging reflection and raising awareness of potential safety threats. Overall, they thought the TRM had at least as much value as their existing QI methods. While the TRM's perceived usefulness was identified as an important facilitator of its implementation,

Table 9.4. A description of the four components of the 'reflexive monitoring' construct with selected quotes

NPT component, with a description relating it to the TRM	Success factors and their effect (facilitating or hindering) on implementation of the TRM	Selected quotes
Systematisation: the work of collecting and analysing information about the TRM, e.g. data about its application, findings and outcomes.	The simple, one-page data collection template facilitated implementation by providing a clear, electronic and structured format. However, some clinicians struggled to rate the characteristics of detected PSIs.	The form's [TRSS] helpful although it's perhaps a reporting tool. It forces you down the route of making you think (GP04) To be honest people will make a judgement for themselves about how important something is and subconsciously will probably use the preventability and the severity in their own head without having to have it written down (GP05)
Reconfiguration: The work of adapting the TRM according to local requirements.	The TRM was intentionally designed to be flexible which facilitated its implementation, with evidence that clinicians modified minor aspects. However, increased flexibility reduces the reliability and validity of inter-practice data comparison.	We used the same list but I don't think we used the same patient's records (GP02)

Individual appraisal: The work of evaluating the usefulness of the TRM for the individual clinician implementing it, her/his practice team and patients.

The vast majority of participants perceived the TRM as a useful approach to help improve the safety of the care they deliver. They also recognised its potential for identifying learning needs and points and encouraging reflection.

I did find it useful… I quite liked it… I thought helpful, clinically helpful… I thought it was worthwhile (GP02)
[We] got some really good outcomes from it: a couple of SEAs and an audit... There's learning for the system in there, so worthwhile, definitely worthwhile (GP04)
I like this [the TRM] as a kind of start. Here's something we can do regularly that can actually show us how good we are or how bad we are or areas that we need to work at or where we need to go (PM03)

Communal appraisal: The work of evaluating the usefulness of the TRM for other practices and their patients.

The vast majority of participants perceived the TRM as a useful approach to improve the safety of care in the wider general practice setting.

I think it's more valuable than QOF QP to be honest... You will probably find things that will then benefit more than that one patient in the practice, because you might be able to then look at wider practices within your own GP practice and then beyond (GP08)

participants were clear that evidence of its usefulness would not be sufficient to ensure its normalisation. Participants also (implicitly) experienced the usefulness of the TRM for others as less important than the perceived value it had for them. The main facilitating value of 'collective appraisal' work therefore seems to be at the regional and national levels. An example of this is the decision to include the TRM in QOF, which was at least partly informed by evidence of its potential usefulness in previous pilot studies (40, 41).

From an NPT perspective, the perceived usefulness of the TRM was mainly determined through the work of 'reflexive monitoring'. Its implementation was facilitated because the vast majority of participants considered the method as flexible, found it easy to collect the necessary performance data and perceived the TRM as being useful for individual clinicians, practice teams, patients as well as the wider general practice community.

9.5. Discussion of the main study findings in Chapter 9

9.5.1. The relationships between NPT constructs and components

Throughout sections 9.1 to 9.4 of this chapter, the relationships between different factors, constructs and components were highlighted. In reality, these effects were emergent, temporal and fluctuated over the course of the study period. While many examples were provided, any of the constructs and components can reciprocally affect all of the others. This is an important point to consider, as the mechanisms, links and associations between the different factors, constructs and components of NPT have not, to the best of my knowledge, been formally considered before. In particular, how and why do the associations between factors change over time? Which of the links, associations and mechanisms are particularly important for normalisation? Do they vary between settings, contexts and with different interventions and implementers?

In terms of the TRM, the following two examples may help to demonstrate the relative importance of associations, links and relationships between NPT constructs and components. The first example is the highly correlated work of relational integration and legitimation. In both cases, the work seems strongly

dependent on confidence – confidence in the method, the reviewers' ability to correctly apply the method, having the support of the rest of the team and confidence that external agencies support the TRM and will not use the results as an indication of substandard care in their practices. However, the work is also different, because relational integration requires actively involving others and legitimisation work requires justification to become and stay involved with the TRM, which is possible to do even when confidence in the intervention may be low.

The second example of highly-correlated work is that of coherence and reflexive monitoring. Being able to evaluate the potential worth of an intervention (individual and communal appraisal) implicitly implies the need of understanding beforehand what its intended aims and potential value are (the work of individual and communal specification). The work of 'communal specification' therefore began prior to the implementation of the TRM as individuals and teams worked to understand its potential worth for them and others. Their initial perceptions then changed as a result of the work of appraisal. The reviewers then (consciously or unconsciously) searched for practical confirmation of their new understanding as they conducted further trigger reviews. In this way, reflexive monitoring and coherence reciprocally influence and shape each other over time.

9.5.2. Comparison with the literature

A systematic literature review (n=47 studies) in 2010 of the influence of context on quality improvement in healthcare identified the most important factors that determined 'success' and normalisation of interventions. They were (are): senior leadership; organisational culture; information systems; previous experience of quality improvement; clinician engagement and resources (345).

A subsequent, narrative review of the Health Foundation's improvement programmes (n=5) by Dixon-Woods et al in 2012 identified ten common challenges when any attempts are made to improve the quality and safety of health care. The ten challenges were related to three broad themes: design and

planning of improvement interventions; organisational and institutional contexts; and challenges related to specific professional groups (346).

More recently, a systematic review (n=57 studies) by Braithwaite et al identified eight common factors associated with successful efforts to improve standards of care: preparing for change; capacity for implementation - setting; capacity for implementation – people; types of implementation; resources; leverage; sustainability; and desirable implementation enabling features (45).

The main findings from the two most recent reviews are summarised and compared in Table 9.5. In addition, the findings from the reviews are 'mapped' to the NPT constructs and components that best describe them. There are three important inferences that can be made from Table 9.5. The first is that a discrete number of factors determine whether complex health care interventions are successfully implemented and eventually become normalised.

Second, the same core set of factors seem to determine whether implementation and normalisation are successful (or not), and these factors can be detected irrespective of the differences in terminology, taxonomies and methodologies of researchers.

The third and final inference is that application of a theoretical framework can facilitate meaningful comparisons of data. More specifically, applying the NPT framework in this study and to the related, international literature, clearly identified the similarities between the key factors that were perceived to strongly influence implementation and normalisation processes. Consequently, it can confidently be asserted that the main study findings reported in this chapter are comparable with the international literature.

Consider, as a practical example, the relative importance of providing adequate resources during implementation. The 'resources' factor is a fairly ubiquitous finding in the international literature, and seems to be independent of geographical location; medical specialty; type of intervention; or scale of improvement initiative (270, 276, 347). In fact, one of the key findings from the review by Braithwaite et al is that 'resources' were the most frequently

Table 9.5. Implementation success factors, quality improvement challenges and the NPT framework

Implementation success factors (n=8) identified by Braithwaite et al (45)	Challenges in quality improvement (n=10) identified by Dixon-Woods et al (346)	Equivalent NPT framework constructs (components)
1 *Preparing for change*: the organisation, team and individuals have planned for the intervention		Cognitive participation (initiation, activation)
	1-3 *Design and planning:* Convince people there is a problem and a solution; match goals and ambitions to what is feasible	Coherence (differentiation; individual and communal specification)
2 *Capacity for implementation – setting*: contextual factors	4 Organisational contexts, culture and capacities	Collective action (skill-set workability, contextual integration)
3 *Capacity for implementation – people*: There are enough people with the necessary skills, knowledge and willingness to implement the intervention	5 Leadership	Cognitive participation (enrolment); Collective action (skill-set workability)
4 *Types of implementation*: the intervention meets the needs of the organisation		Coherence (communal specification)
5 *Resources*: adequate and appropriate resources are available, including discretionary budgets, managerial support, Infrastructure, technology, time and staff		Collective action (skill-set workability)

6	*Leverage*: there is support and momentum throughout the implementation process; clinical champions		Legitimation
7	*Sustainability:* this requires planning and ongoing effort	6-7 Securing sustainability and remaining vigilant for unwanted consequences	Sustainability is the product if the work of all four constructs are done effectively
8	*Desirable implementation enabling features:*		
	• Communication and collaboration		Collective action (Relational integration)
	• Clear implementation strategy		Coherence (individual specification)
	• Teamwork	8 Tribalism and staff engagement	Collective action (Relational integration, skill-set workability)
	• Monitoring, evaluation and feedback	9 Establish data collection and monitoring systems	Reflexive monitoring (systematization, individual and communal appraisal)
	• Incentives	10 Incentivise participation	Cognitive participation (legitimation)
	• Flexibility, tailoring implementations to the local context		Reflexive monitoring (reconfiguration); Coherence (internalization)

identified factor that were considered to be a determinant of successful implementation (45). Similarly, in this study, the vast majority of participants also identified adequate resources as the single most important factor determining whether an intervention will become normalised (or not).

Three additional examples will be provided next to further support the critical inferences from Table 9.5, and the assertion that the main findings from this study are comparable with the international literature. The study designs of all three were informed by NPT, but they were also selected because they are exemplars of: (i) implementing an intervention in the UK, but in a *non-GP* health care setting (270); (ii) implementing *multiple interventions at scale* (347); and (iii) implementing an intervention in general practice, but in a *non-UK* country (276).

The first example is Bamford et al who used NPT and qualitative methods to determine the barriers and facilitators of nutrition guideline implementation in UK residential care homes. They report that '*improving nutrition only appeared to be a priority if it could be achieved within existing resources*' (270). They also found further significant barriers, including: lack of leadership and managerial support and staff perceiving the implementation as threats to their autonomy and expertise (e.g. the work of cognitive participation malfunctioning); lack of feedback from clients to cooks, or feedback mediated by care staff with biased view (e.g. no reflexive monitoring work was or could be done); scepticism over the value of the guidelines which were perceived to be incompatible with existing practices (e.g. much coherence work was required); and the lack of nutritional knowledge or engagement of the cooks (e.g. the work of collective action could not properly be done). Unsurprisingly, the implementation of nutrition guidelines was 'challenging', although some changes did become embedded in routine practice.

The second example is the Delivering Assisted Living Lifestyles at Scale (DALLAS) programme. This was an ambitious programme attempting change at a much larger scale than this study or previous studies underpinned by NPT. DALLAS was a national, pan-UK programme aiming to promote health and well-being through the delivery of a broad range of digital services and products and was evaluated

using a rigorous, mixed methods and NPT approach (347). Some of the key challenges to normalisation in the DALLAS evaluation are therefore less relevant to this study, such as 'branding and marketing issues' or establishing and maintaining 'multi-agency partnerships'. However, other factors such as the 'need for resilience' and 'information governance' are instantly recognizable and equally applicable.

The third example is Franx et al's introduction and evaluation of a stepped-care model for managing depression in primary care in the Netherlands (276). The model had three components: patient differentiation (reliable identification of patients suitable for treatment); stepped-care treatment (being aware of and accessing a range of available treatments); and monitoring patient outcomes. The main facilitating factors were the model itself, which was understood and accepted (the work of coherence), regular structured team meetings (the work of cognitive participation) and positive feedback from patients (the work of reflexive monitoring). However, implementation was hindered by a lack of resources, underdeveloped IT systems and different perceptions of depression in the wider multidisciplinary team (the work of skill-set workability, relational and contextual integration). Consequently, the authors found evidence of '*strides towards utilizing*' the model but not normalisation during the study period. The fact that some improvements were made should be acknowledged and celebrated as '*it seems unlikely that the changes reported by the clinicians would have occurred by itself within the primary care teams*' (e.g. without external intervention).

Conclusion

This Chapter described a large number of factors that were perceived as facilitating or hindering the implementation of the TRM in general practice. Of these, four main factors were identified by the vast majority of participants as being essential for the successful implementation of the TRM. The first and most important factor is provision of adequate resources, and in particular allocating sufficient, protected time to perform trigger reviews. The second factor is legitimising the intervention through incentives and endorsements by the government or a professional body. An example would be the RCGP approving

the TRM for specialty training, appraisal and revalidation purposes. Financially incentivizing the TRM by including it in the pay-for-performance QOF greatly facilitated both these factors ('resources' and 'legitimising'). The third factor is the characteristics of the participating clinicians, e.g. their degree of engagement, autonomy and pre-existing knowledge and skills. The fourth factor is the perceptions of the general practice teams about the TRM's utility.

Normalising innovations and interventions in health care require multiple approaches, which may sometimes appear contradictory: strong leadership is essential, but within a participatory culture; initiatives should have clear aims, but also be flexible and respond to local needs and contexts; performance should be monitored with regular critical feedback, yet without attaching blame; properly designing and planning an intervention is important, yet momentum and pace have to be maintained; clinician engagement is essential, yet some changes will of necessity go against the grain of existing professional cultures and customs. A key message from this study, and also from the international literature, is therefore that '*there is no magic bullet in improving quality in health care*' (346, 348). However, while it is true that implementing change is time consuming and normalisation depends on many, complex factors potentially hindering and facilitating at multiple levels, it is also true that improvement is possible! The final Chapter will therefore consider the likelihood of the TRM being normalised, but also whether the TRM *should* be normalised.

Chapter 10. Discussion

Chapters 6 to 9 described the main study findings, compared them with the international patient safety literature, and identified some of the important practical implications. This chapter begins by summarising the aims and the main findings of this study in Table 10.1. Next, four specific questions are raised in relation to this study, and the most likely answers are provided. The four questions are:

1. *Should the TRM be normalised in general practice?* This is arguably the most important issue to consider from the perspective of this study, which aimed to determine the usefulness of the TRM. The short answer is 'yes', and three reasons will be provided in justification.

2. *What is the likelihood of the TRM being normalised in general practice?* This question relates to the study aim of determining the barriers and facilitators to the implementation of the TRM. The study findings and international literature suggest that normalisation of the TRM would be very likely if all four of the following factors could be guaranteed: practice teams and clinicians have the necessary knowledge to apply the TRM effectively; there is senior leadership support for the TRM; adequate resources (including time) are provided; and it is formally integrated into existing general practice contexts such as GP specialty training (GPST) and appraisal and revalidation. However, given that there are currently no financial incentives or mandatory requirements for practices and individual GPs to use the TRM, normalisation seems unlikely.

3. *What are the strengths and limitations of this study?* This question will be answered by considering the strengths and limitations of the study in general, with additional subsections to consider the strengths and limitations of NPT and the TRM.

Table 10.1. Summary of the aims and main findings of this study

Aims	Chapter	Findings
To describe the patient safety perceptions of general practice clinicians and staff	6	• Participants perceived patient safety as important, integral to care and amenable to improvement. • Medication and medication-related processes and elderly, housebound patients were considered to be particularly at risk for PSIs. • All of the practice teams were already using a range of improvement methods. They strongly indicated that additional resources were critical prerequisites for their future participation in improvement initiatives.
To determine the usefulness of the TRM by describing the outcomes from its implementation	7	• 47 Primary care clinicians performed trigger reviews of 1659 electronic medical records and detected 216 PSIs. • A substantial minority of PSIs (29.2%) were associated with moderate or more substantial harm, the majority (54.8%) were rated as preventable or potentially preventable, and the most common type of PSI related to 'medication' (40.7%). • Reviewers undertook specific patient safety-related actions during and after approximately two thirds of trigger reviews.
To explain how the TRM works	8	• The TRM enabled the detection of PSIs through a combination of three factors: structure; mindset (knowledge); and opportunities. • Detecting PSIs created potential learning moments and the option to accept ownership of the findings. • Ownership of PSIs facilitated subsequent reflection, learning and improvement actions.

To identify and describe the main factors that facilitated or hindered the implementation of the TRM in general practice	9	Implementation of the TRM was facilitated when: • Participants understood that it was compatible with their existing work, and perceived it as feasible and acceptable. • Clinicians had the necessary knowledge to conduct effective trigger reviews • PSIs were detected quickly, and the PSIs were unambiguous, serious, preventable and originated in primary care; • Adequate resources and time were allocated; • It was included in GP contexts such as QOF, appraisal and GPST • Reviewers had senior leadership support and opportunities to enact change • Participants perceived it as useful for them and others

4. *Can recommendations be made as a result of the study?* The answer is 'yes'. Recommendations can be made about implementation processes and improvement interventions in health care settings, in relation to the TRM as well as about current and future research priorities.

10.1. Should the TRM be normalised?

This section provides three reasons why the TRM should be normalised. They are:

(i)   this study contributes further evidence that the TRM is in the main useful, acceptable and feasible as an approach to improve patient safety in UK general practice;

(ii)   For the overall safety of care to improve in health care, a range of complementary methods will be required; and

(iii)   The TRM provides clinicians and researchers with a unique perspective of patient safety incidents (PSI) and how they may be reduced.

10.1.1. The TRM is in the main a useful, acceptable and feasible approach to improve patient safety in UK general practice

All the clinician reviewers in this study were able to perform trigger reviews and submitted Summary Sheets. The vast majority of reviewers detected PSIs and the majority took or intended to take subsequent actions to improve care standards. They also reported learning points and some felt they were more vigilant for potential safety threats. It is highly unlikely that these positive outcomes would have occurred if the TRM had not been implemented. However, it is unclear whether the positive effects had a subsequent, measurable impact on clinical outcomes, and the cost-effectiveness of the method was not estimated. In addition, the safety 'mindset' of some reviewers was temporary and eroded over time because of the need to refocus their attention and efforts on other, competing priorities for their time.

The personal accounts provided by some of the study participants demonstrate how some PSIs can provoke a more powerful learning experience than others. Typically, the more memorable PSIs were the ones that had resulted in serious

harm and were clearly preventable. Given that most of the PSIs detected in this study were of low to moderate severity and only about half were considered preventable, it may help to explain why the increased vigilance for safety threats was transient. However, as was described in Chapter 9, some participants described minor incidents that had caused them significant emotional distress and continued to exert a powerful influence on their clinical practice years later. The recommendation is therefore that clinicians perform trigger reviews regularly to help refresh their safety awareness. By the same reasoning, this recommendation would also apply to other improvement methods. The reviewers in this study felt two trigger reviews a year would be feasible, allow them time to disseminate and act on the findings *and* be frequent enough to retain the required knowledge to apply it effectively.

10.1.2. The overall safety of care can be improved, and this will require a range of complementary methods.

This study contributes to the growing evidence about the potential value of the TRM as an approach to improve patient safety in general practice (40, 41, 48, 349). Most Scottish general practices have now undertaken at least two trigger reviews, detected PSIs and implemented or considered a range of improvement actions. However, even in the unlikely scenario that every reported improvement action had been successful, the reality is that there will still be latent risks within all general practices, and as a result preventable PSIs *will* still occur in the future.

The lack of reliable measures of improvement is not unique to the TRM. Despite more than a decade of sustained attention and considerable investment and research in patient safety, there is still little reliable evidence of widespread reductions in harm rates in any health care setting (226, 350-352). Why is this? One answer that has been proposed is that, compared to traditional biomedical research and initiatives, fewer people have been working in this area for a relatively shorter period of time with only modest resources and without the advantage of many decades of previous evidence. In other words, '*we get what we pay for*' (226).

Another potential reason, which is particularly relevant to this study, is that there are few interventions available that can reliable reduce PSIs. A systematic review by Lorincz et al in 2011 found no credible evidence of effective strategies to improve patient safety in primary care (35). The authors concluded that *'there are no magic bullets'*. It therefore seems obvious that the priority should be to develop new safety improvement methods, or at least further develop and test existing ones. But the question remains - which ones? Evidence-based interventions that target specific complications of care, or more general strategies like the TRM, with the potential to reduce a range of PSIs? Both approaches seem to have merit, but for now it is impossible to objectively recommend one over the other. All of the improvement methods and strategies for the general practice setting that were described in Chapter 3 have specific strengths, but also limitations. Two examples are provided to further illustrate this important issue.

The first example is the study by Tam et al who compared the strengths and weaknesses of chart review, patient surveys and voluntary reporting in detecting medication misadventures in general practice in Hong Kong (83). They found chart reviews uncovered significantly more preventable adverse drug events than incident reporting, but noted the 'pivotal' role voluntary reporting had for drawing attention to sentinel events. The second example is a study comparing clinical record review with four reporting systems in the Netherlands. These were: informal reporting by patients; formal complaints by patients; medico-legal claims; and voluntary incidents reported by healthcare professionals (353). They found only 18/498 (3.6%) of PSIs uncovered through record review were also detected by the reporting systems.

The two main findings and implications from these examples are consistent with the patient safety literature (84, 85, 237, 335, 349). The first finding is that clinical record review detects more PSIs than any other method. Based on this finding alone, the implication seems to be to select it in preference of the other methods. However, the second finding, that there is very little overlap between the PSIs detected with the different methods, negates this implication. For

example, litigation and complaints are predominantly about communication breakdown and missed diagnostic opportunities, while the majority of PSIs detected through the TRM relate to medication-processes. This strongly supports the view that a mixed methods approach is required to improve patient safety.

It is now widely accepted that '*a single measure of safety is a fantasy*' (354). Rather, the different methods are complementary to each other. The implication is that, if the overall safety of general practice is to be understood and improved, the best approach would be to combine the different methods (349, 355-358). Such an approach would also help to mitigate the potential risk of using a single improvement method or measure, which is that, '*given one measure of success, almost any group can be successful in the short term by optimizing that measure at the expense of other important measures*' (359). This approach is already being taken in the UK through, for example, the introduction of the RCGP Patient Safety Toolkit (179, 180). The Toolkit contains a range of improvement methods for the general practice setting, including the TRM, thus offering a choice of methods to clinicians and practice teams.

10.1.3. The TRM provides a unique perspective of PSIs

Patient safety has been compared to an elephant in the well-known Indian fable of the blind men (296, 360). Just as each of the blind men 'saw' only a part of the elephant, specific improvement methods only produce evidence about certain aspects of patient safety. The moral of the fable is that, while each individual perspective may provide useful and unique insights, they are also limited and incomplete. Accordingly, the TRM is valuable because it increases our understanding about the prevalence and characteristics of PSIs, which are important components of the overall safety of care.

The types of PSIs uncovered by the TRM will most likely be familiar to primary care clinicians and are well known and described in the international patient safety literature. The important issue is that they had remained undetected until the TRM review was undertaken. Or, more likely, they may have been

incidentally and opportunistically identified but were not shared or addressed because of a lack of time. As was described in Chapter 8, the TRM worked by creating opportunities and a 'mindset' for detecting and acting on PSIs.

A key finding from this study was that many participants associated the severity and preventability of PSIs with their usefulness (chapter 7). In other words, the outcomes of incidents, rather than the contributing factors to them, seem to influence the subsequent actions and learning of many individuals, teams and organisations. In reality, there can be as much or even more potential for learning and change in some near miss events (326), but this concept is challenging to convey to clinicians and staff. One way to address this issue may be through the culture of the organisation and will be considered on page 264.

Another implication is that a single approach or method should not be promoted as the definitive 'solution' to substandard care. Nor can any method be expected to detect *all* PSIs or create perfect patient safety. That is not to say that all methods are equally useful – they are not. For example, the TRM detects *more* PSIs than any other available metric. In this small study, PSIs were detected and reported at a rate of one incident for approximately every eight records that were reviewed, or approximately one incident for every two years of recorded care. While the precision of this rate is uncertain, it provides an estimate of the prevalence of PSIs in general practice that is comparable with larger studies (48). It also raises important questions. Are the estimated rates of PSIs 'high' or 'low' and do they justify further interventions?

These questions will be considered in more detail in subsequent sections. For now, normalisation of the TRM can be justified in part by the value of the evidence it produces. As our understanding of the nature and frequency of PSIs increase, important questions about the future of health care and the equitable and effective allocation of resources can be more objectively framed and considered.

10.2. Will the TRM be normalised?

The previous section considered the question whether the TRM should be normalised in general practice. The short answer was 'yes', because it is useful. However, while the 'usefulness' of an intervention is an important factor in determining whether it is normalised or not, there are other factors that are equally or even more important. This section therefore describes four additional requirements which, if met, will make normalisation of the TRM very likely. At the time of writing, only some of these requirements have been met. My prediction is therefore that normalisation of the TRM in UK general practice will either be a gradual and piecemeal process or may not happen at all.

10.2.1. Clinicians require sufficient knowledge to apply the TRM effectively

The success of improvement methods, including the TRM, is contingent on the critical assumption that clinicians possess the requisite *knowledge* - as defined in Chapter 8, page 200 - to effectively use them. Moreover, that they are able to apply the technique correctly, produce robust data, analyse and evaluate their findings and then plan and implement meaningful and sustainable improvements. A further assumption is that in those instances where this knowledge is lacking, health and educational authorities are able to up-skill the workforce on the scale necessary to support proposed initiatives. But how realistic are these assumptions? The TRM and this study provide a practical example in helping to answer this question.

Successful implementation of improvement interventions requires clinicians to have knowledge of three specific processes (361). In relation to the TRM, the knowledge is: (i) how to detect PSIs in order to identify a 'problem' or deficiency in care and then define it clearly and correctly; (ii) be able to analyse the problem and correctly identify the main contributing causes and decide whether they are sufficiently important to justify further action, e.g. rate the preventability and severity of PSIs; and (iii) be aware of, select and implement the most appropriate remedial action and evaluate its effectiveness. These processes are consecutive and interdependent, e.g. a process can only be

undertaken if the previous one had been successfully completed. Performing a proper analysis is difficult though, and a skill that often requires training and practice (361). Even when clinicians *are* able to detect PSIs and identify contributing factors that may be amenable to action, they still need to choose or design and implement a feasible solution, evaluate the degree to which this addresses the perceived problem and mitigate any unintended consequences.

Many study participants were able to demonstrate knowledge of all these steps. However, as was described in Chapter 7, a small minority were unable to complete the first step of detecting PSIs, while a few more participants struggled with the third process, i.e. taking action to improve care. The assumption that all clinicians possess the necessary knowledge to successfully implement the TRM – and by extension other quality improvement interventions - therefore seem overly optimistic.

On the other hand, the findings from this study indicate that overall, enough of the participating clinician reviewers had adequate knowledge after training to ensure normalisation of the TRM in general practice. Admittedly, normalisation would be more rapid if the knowledge of a minority of clinicians could be improved further. 'Knowledge' – or lack thereof – is also only one of the factors that determine the normalisation of an intervention. Even so, when safety improvement initiatives are evaluated, the knowledge of participants should routinely be considered as an important contributing factor to the observed outcomes (362).

Given the importance of knowledge, and the fact that some experienced clinicians already have many of the required core safety skills for improvement initiatives (363), should certain clinicians or professional groups be preferentially recruited and trained to use methods such as the TRM? While it is true that in this study the nursing group found fewer triggers and PSIs and were also less likely to document improvement actions or learning points compared with the medical groups, individual nurse reviewers did demonstrate the ability and knowledge to effectively implement the TRM. There was also one GP reviewer who did not detect PSIs. The implication is therefore that practices should select

reviewers with the necessary *knowledge* to conduct TRM, as this is a more desirable characteristic than their professional roles, e.g. GP partner, salaried GP, GPST, practice nurse or nurse practitioner.

Providing suitable training for participants was identified as one of the facilitating factors of the implementation of the TRM in this study (Chapter 9). Training is therefore important and one of the recommendations that are made in relation to the TRM and future implementation initiatives in section 10.4, page 279. However, it is not necessarily synonymous with knowledge. A systematic review (n=39 studies) to determine the effectiveness of teaching quality improvement theory and methods to clinicians found that their self-reported knowledge and confidence improved, but there were little or no evidence that the training had any clinical benefits (364). One interpretation of these findings would be that for training to be truly effective, it needs to occur in conjunction with adequate resources, protected time and opportunities for reflection (365). In fact, it has been suggested that one of the best ways to improve patient safety in primary care may simply be for GPs '*to set aside time and space to be allowed to conduct the required, appropriate reflection effectively*' (52).

10.2.2. Senior organisational and practice leadership support

The support of the practice leadership for the TRM was a key determinant of its successful implementation. In fact, this study would not have been possible without it. It was the practice manager or a senior GP in each practice who agreed to participate, who decided when and how much time and resources to allocate and who recruited additional team members. Furthermore, the practice leadership helped determine through which forums trigger review findings were disseminated and whether proposed improvement actions were implemented at the practice level. The implication is therefore that the practice leadership strongly influence not only whether an intervention is implemented, but also how and to what degree subsequent improvement and learning occur at a local level.

The powerful facilitating effect of leadership on the implementation and normalisation of interventions became even more apparent at regional and national levels (362, 366). Policymakers and senior healthcare executives design the financial (and other) incentives that are linked to the specific performance objectives they set. They also have the authority to mandate a wide range of activities deemed desirable. Individual practices and clinicians retain their clinical autonomy and freedom of choice, but only within predefined parameters. The visible and strong support of senior leadership for an intervention is therefore a key factor in determining whether it becomes normalised or not. This is why Buist and Middleton strongly recommend that clinicians '*in positions of responsibility, need to take ownership of the quality and safety agenda*' and '*claim the agenda*' (367).

The participants in this study were aware of the importance of leadership within their practices but also at higher levels. A GP partner explained the common perception that '*its decision makers actually who normalise things to a certain extent because they mainstream them and they bring them in and support them*' (GP08). This perception seems to be widely shared amongst health care professionals. For example, a qualitative study of chronic disease management in UK primary care found participants thought Telecare would only be normalised if it was made mandatory through a formal policy (268).

An important implication of these findings is that it is the practice leadership who ultimately creates the workplace culture (350, 368). Establishing a 'just' culture that enables the whole team to support and advance patient safety is, therefore, only possible with strong leaders. It is for the practice leadership - GPs, management and senior nursing staff - to facilitate and build a culture of trust that encourages effective team-working, collective learning from patient safety incidents and strong communication across the clinical disciplines and administrative staff. They have both the responsibility and the authority to ensure that there is a continued focus on improving the safety of patient care - in essence, to establish safety as a cultural 'value' as well as a practice 'priority' (350).

All participants in this study described the prevailing culture in their own teams and also in Scottish general practice as overall positive, strong and safety-orientated (Chapter 6). While it may be tempting to speculate whether or not the perceptions of safety culture reflect reality, it is actually the degree of variation between the different staff groups that is of more importance. A consistent finding of safety culture research - irrespective of industry or geographical setting – has been that the larger the variation in the perceptions of different staff groups is, the more likely PSIs become (311). The implication of the homogeneity of the safety culture perceptions in this study therefore suggest some measure of a protective effect against PSIs in general practice.

10.2.3. Normalisation requires adequate resources

A key finding from this study and from the comparable international literature is that normalisation of an intervention requires the provision of adequate resources, including time (347, 366, 369, 370). While this may seem self-evident, in practice many improvement interventions receive funding only for the implementation stage, and even then the initial investments are not always adequate. This study is no exception, as the professional fee offered to participating practices for implementing the TRM were not commensurate with the amount of time that they were expected to allocate for trigger reviews. It is therefore unsurprising than many interventions fail to become normalised despite evidence of their usefulness. On the other hand, interventions may become normalised if there are sufficient incentives to continue using them even when there is little or no evidence of their effectiveness.

The most common business model of general practice in the UK is that of independent contractors to the NHS. In order for practices to be viable business concerns, the partners and managers have to continually balance workload with available resources. They are able to adjust their workloads and increase resources to a degree, but patients and policy makers also exert significant influences – both positive and negative. The inherent challenges in this process can be conceptualised with an analogy of balancing a seesaw (Figure 10.1.).

The 'seesaw' analogy will be illustrated further with two practical examples from this study. The first example was provided by one of the practice managers (PM08). She explained that the practice team understood the importance of correct clinical coding and considered this a priority. There was agreement that the task should ideally be performed by a clinician, but the practice was unable to afford this option. Even if they could have afforded the additional clinical time, there was an even greater need for more consultations. The leaders therefore decided to assign the role of 'coder' to an administrative team member and provided the appointee with additional training and support. They acknowledged there may have been (and will likely be) some instances of incorrect coding, and that this may contribute to PSIs, but they perceived this as the only feasible option for them. Using the analogy of the see-saw, they reached a compromise between risk reduction and resource allocation.

The second example is the TRM and the Scottish QOF. Chapters 1, 2 and 9 described how financially incentivising the TRM through the QOF greatly facilitated its implementation. For practice teams, the relative increase in workload from implementing the TRM was 'balanced' by an increase in their resources, hence their willingness to implement it. When the QOF was discontinued in 2016, the 'resources' for the TRM were also removed (e.g. one end of the seesaw became unbalanced). The most likely response of most practices in Scotland will be to restore balance by reducing the workload, e.g. stop using the TRM. The main implication is therefore that the TRM will not be normalised. However, it is possible that the relative importance of the other facilitating factors, such as senior leadership support and contextual integration, may increase in their relative importance and be sufficient to still ensure normalisation. Nevertheless, even if this happens, normalisation will still require a much longer period of time and will likely occur in a piecemeal manner.

Figure 10.1. The association between 'workload' and 'resources' in general practice

patients   policy makers   clinicians & practice managers
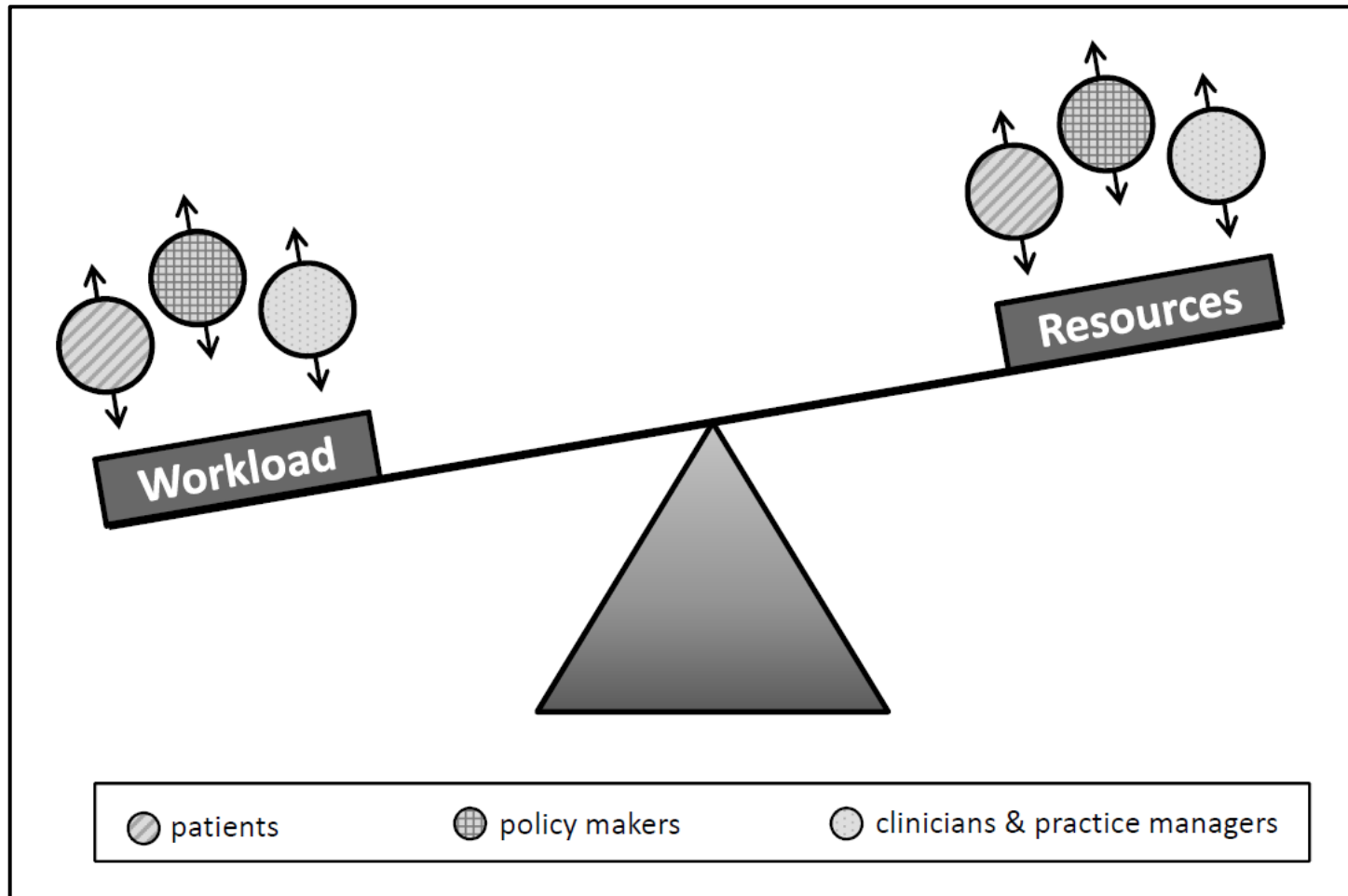
The two examples help to demonstrate the challenges clinicians and staff struggle with in modern health care systems to effectively balance opposing priorities. The importance of resource allocation in these instances cannot be overstated. The stark reality is that practice teams and individual clinicians are deciding - whether consciously or unconsciously – how much patient safety they can afford. If we accept that resources are finite, at least two important questions should be asked (371). The first question is how much safety can we afford in our current health care systems? The second question, strongly related to the first, is who should have the responsibility to make this decision?

These questions are challenging, emotive and currently shrouded in uncertainty (372). Very few patient safety studies evaluate cost-benefit/utility because it requires considerable resources, expertise and often data that are unavailable (373). A recent systematic review of those studies that did perform comparative economic analyses of patient safety improvement strategies in acute care settings found only four were 'economically attractive': pharmacist-led medication reconciliation; ICU intervention for central line-associated bloodstream infections; chlorhexidine for vascular catheter site care; and surgical sponge counts (374). When the same questions are asked about the primary care setting or in relation to this study there are simply no reliable answers. How much effort would be required to reduce the estimated rate of PSIs that were detected in this study? What is an achievable target? What are the opportunity costs to patients, practices and the NHS if practices decided to allocate time to this problem, rather than some other priority?

The different perspectives of why PSIs occur were described in Chapter 6. The main implication was that in socio-technical systems – such as general practice – the number and severity of PSIs may be reduced but can never be completely eliminated, irrespective of how much effort and resources are invested. In fact, *'efforts to reduce uncertainty towards zero result in increasing marginal costs with diminishing marginal returns for patient safety'* (371). Vincent and Amalberti caution that *'primary care practitioners cannot (and emphatically should not) try to minimise all possible risk'* as this would be *'completely unaffordable'* (366). Only once this fact is publicly acknowledged and accepted,

will it be possible to have meaningful discussions of what feasible targets for patient safety should be. Until then, a succession of improvement initiatives may be decried as ineffective, incomplete or inadequate if they are evaluated against unrealistic targets and expectations.

Unfortunately, the notion that patient safety is imperfect is unpalatable, and for a minority inconceivable. So is acknowledging that resources are finite. For now the easiest, and ironically also the safest course of action for many policy makers and senior leadership in the NHS seems to be leaving the 'seesaw' for frontline staff to balance (366). Then, when the inevitable imbalance results in a 'fall' it is all too often individual clinicians who are held to account. In the longer term, the only sustainable solution will be for patients/society and policy makers to accept responsibility for their part in the 'seesaw' problem and actively contribute alongside clinicians to achieve the degree of balance that is acceptable to everyone (375). It *is* possible to improve the standards and safety of care, but it will require perseverance, ingenuity and realistic expectations from everyone (376) and solutions that can '*only be achieved at a national level*' (366).

10.2.4. Normalisation is facilitated by contextual integration

One of the first tasks for researchers in implementation science is to describe the contexts within which they intend to implement an intervention, and consider how contextual factors may influence their proposed interventions (243). Chapter 9 described how implementation of the TRM was facilitated through the work of 'legitimisation' and its 'contextual integration' into existing general practice processes. In this section the potential influence of two particular contexts on further integrating, embedding and eventually normalising the TRM will be considered: GP specialty training (GPST) and medical appraisal and revalidation.

10.2.4.1. GP Specialty Training

UK GP Specialty Trainees are required to spend 18 months in a GP setting as part of a 3 year programme. The teaching required is governed by the Royal College of General Practitioners (RCGP) curriculum, and one area that is increasingly being highlighted is patient safety (240). Specific learning objectives are also defined which require the trainee to demonstrate a whole range of problem-solving skills aimed at improving the management of clinical risk and enhancing the patient experience of care. In response, medical educators have integrated patient safety-related topics and issues into undergraduate education and specialist training programmes.

As was described in chapter 7, the vast majority of trainees in this study were able to use the TRM to detect preventable PSIs directly related to issues within the practice, particularly in high risk elderly patient group (329). All participants were able to demonstrate some element of reflection, document potential learning needs and develop improvement action plans. The detected PSIs were directly related to issues within the practice which enabled focused discussion with educational supervisors and other colleagues, potentially facilitating rapid implementation of learning and remedial actions. The implications are that using the TRM during training may facilitate both formative and workplace case-based discussions and assessments. The TRM may therefore have a role to play in specialty training to help prepare GP trainees for the contractual and regulatory demands of independent clinical practice and future safety improvement expectations. However, in order for the TRM's potential value as an educational to be realised, further research would be required to explore and validate this application and educational supervisors would require additional training and support.

10.2.4.2. GP appraisal and revalidation

In terms of regulatory and educational policy in the United Kingdom, 'safety and quality' is one of four professional domains describing the expected duties and standards of every doctor registered with the General Medical Council (GMC)

(238). All registered doctors are expected to participate in systems of quality assurance and improvement, perform regular reviews of and reflect on their performance and take action to improve the quality and safety of care they deliver if necessary. The TRM is well aligned with this expectation and, given the evidence presented here, can play an important role in helping to achieve this standard. In NPT terms the TRM is also legitimised through its formal inclusion in the RCGP Patient Safety Toolkit for general practice (180).

The study findings also demonstrate the complementary nature of the TRM in relation to established improvement methods in general practice. PSIs that are detected by trigger reviews can serve as topics for SEA and criterion audit. This is particularly helpful given that appraisal and revalidation requires GPs to analyse two significant events per year, with the GMC encouraging these events to be PSIs rather than broader quality of care issues. Identification and analysis of previously undetected PSIs is therefore particularly pertinent to improving the opportunity cost of SEA topics.

10.3. Strengths and limitations of the study

This section begins by considering the strengths and limitations of this study. The specific strengths and limitations associated with the NPT and the TRM in the context of implementation science and patient safety research are then described.

10.3.1. Study limitations

This study has at least five limitations. In addition, a number of specific limitations in relation to NPT and the TRM were identified (Sections 10.3.3 and 10.3.4)

The perceptions patients have of health care and their participation in research and improvement initiatives are widely recognised as important (377-380). The first limitation is therefore that patients could not be actively involved in this research, despite careful consideration of this option. However, all study

participants recognised and supported the crucial roles and responsibility of patients in relation to the safety of their own care (Chapter 6).

The second limitation is that the *sampling strategy* was a pragmatic choice informed by time constraints, available resources and ready access to GPSTs and general practice teams through their association with NES. The study findings are therefore derived from the experiences and perceptions of participants who have previously demonstrated an interest in research and improvement initiatives. The sample may therefore not be representative of general practice or GPSTs in Scotland or, indeed, other countries in the UK or internationally. This potential limitation was mitigated to some degree by ensuring the sample included training and non-training practices, practice size varied from small (a single GP) to large (>10 GPs) and were spread across urban and semi-rural areas. The subsequent QOF data which were presented in Chapter 6 were aggregated from essentially all practices in the two NHS Boards from which the study sample was derived, and did not reveal significant differences compared with the study sample.

From a quantitative perspective, the size of the sample of records that were reviewed was determined beforehand by resource considerations. Applying the formula proposed by de Wet et al for determining the minimum number of records that have to be reviewed in order to ensure the detected PSI rate is reliable, suggests that the sample of records in this study was adequate to determine PSI rates with acceptable levels of precision, but would not have been adequately powered to detect a significant change over the study period (201).

The third limitation is in relation to the GPST component of the study. It is unknown why five of the trainees who attended training workshops were unable to undertake trigger reviews and submit completed summary sheets. Knowing 'why' may have provided us with greater insights into the overall utility of this method and associated implementation issues. However, it seems likely that the reason may have been timing, as the submission date for trigger reviews coincided with the final two weeks of their training programme.

The fourth limitation is that all study data were reported, and therefore subjective. Consequently, it is unclear whether all the improvement actions clinicians indicated they considered were in fact undertaken. A related issue which will be discussed on page 278 is that inter-rater reliability was not measured. It is therefore possible – even likely – that if clinicians all reviewed the same samples of records, they may have detected different PSIs, provided higher or lower PSI ratings and considered or undertaken other improvement actions. However, while the IRR may affect the quantitative outcomes of this study to a degree, e.g. by over or underestimating the incidence of PSIs, it does not meaningfully affect the qualitative data or the main findings. While it must therefore be recognised that direct observation is the 'gold standard' of socio-technical studies, it is seldom feasible to do so. Instead, researchers '*do the best we could*', and accept that, in many instances, 'interviews were the only window into events that happened far from the researcher's gaze' (271).

The fifth limitation is in relation to the analysis of the qualitative data. Despite a concerted effort to minimise researcher bias through the strategies that were described in Chapter 5, analysis of qualitative data is inevitably influenced by the previous experiences and other characteristics of the researchers. The findings must therefore retain some measure of subjectivity. However, the risk of incorrect assumptions and conclusions were reduced through a combination of reflection, rigorous application of a clearly described and acceptable analysis process and by evaluating the veracity of the results against the international literature. It could also be argued that the subjectivity of analyses is not only a limitation but, if accounted for, has the potential to enrich the data and make the findings more accessible to others.

The potential limitation of bias should not only be considered in relation to the methods of this study, but also to patient safety incidents in a more general manner. Patient safety narratives are '*constructed and re-constructed*' by individuals and health care organisations and in the process their meaning change (381). The narratives of PSIs evolve through each process, starting with their detection, the way in which they are recorded and shared, whether and how further analyses are conducted, in the dissemination of identified learning

points and needs and finally whether they help to inform subsequent improvement actions. Waring described how the narratives of PSIs change through 'washing' of the original experiences of the patients and clinicians until – often unintentionally and unconsciously - their very *form, meaning and content*' have been 'standardised' in a way that is recognisable to organisations (381). It is unclear to what extent the same constructing and re-constructing of PSI narratives currently happen within practices and also in the wider primary care context. While the benefits and potential losses associated with this process are currently unknown, the intuitive implication seems to be that there is a need for a shared understanding of PSIs amongst all health care staff groups. In NPT terms, the recommendation is therefore to increase the work of coherence.

10.3.2. Strengths

In 2013, Schildmeijer et al's focus group study was the first known attempt to explore the strengths and limitations of clinicians working with the Global Trigger Tool (GTT) in secondary care settings (382). A unique strength of *this* study is that it is the first known attempt to investigate how the TRM is experienced and implemented in primary care by exploring the perceptions of clinicians and their general practice teams.

A second strength of this study is that it is informed by a validated theoretical framework, which is recommended for research in the discipline of implementation science (251). As was previously described in Chapter 4, NPT provides a conceptual framework and a socio-technical lens through which factors that hinder or facilitate normalisation of an intervention can be identified, described and understood.

A third strength is the study design, which is longitudinal, incorporated a mix of methods and collected qualitative data at two critical time points. The mixed-methods study design was selected because this approach is considered to be particularly useful for researching implementation processes and complex health care interventions and helped to enhance the reliability of the main findings.

A fourth strength of this study is that the perceptions and experiences of the three different staff groups that were critical to the successful implementation of the TRM were considered. In order to reflect the reality of modern general practice, which is that it is delivered by teams, the qualitative data included 'matched' interviews within each practice, e.g. a practice nurse, GP and practice manager were interviewed, where available, using the same schedules. A further benefit of this approach is that it allowed the work of implementing the TRM to be investigated and understood at the levels of individuals and the practice teams (272). In addition, the interviewer had in-depth knowledge of the TRM and had good working relationships with the study participants. The interviews were candid, detailed and in-depth and it is evident from the transcripts that participants felt no obligation to report 'successes' with the TRM or the implementation process.

From a qualitative data analysis perspective, a key strength of the study is that the analysis were conducted using recognised methods in order to ensure robustness and transparency of the process (283, 285, 288). For example, the reflexivity, rigour and reliability of the findings were increased through data clinics and constant comparison (383). The perceptions of the vast majority of participants were highly congruent and independent of clinical, non-clinical, management or non-management stratification. The observed homogeneity is arguably a success factor in its own right, as it reflects high levels of coherence, which in turn increase the ability of teams to effectively enact interventions. In NPT terms, practice teams were able to successfully perform the necessary work of interactional workability.

The potential limitations of the sampling strategy have already been discussed. By comparison, and in terms of qualitative research, the sample is fairly large, thematic saturation was achieved and more interviews would not have materially strengthened the main findings.

10.3.3. The strengths and limitations of Normalisation Process Theory

Given the proliferation of available theories, each with a unique focus and intent, researchers are strongly advised to explicate their rationale for selecting a specific model, framework or theory (245). In the case of this study, the intervention - e.g. the TRM – had already been developed and tested beforehand. However, NPT was consciously selected to inform the implementation and evaluation of the TRM and incorporated into the study during the planning stage.

The rationale for choosing NPT was provided in Chapter 3, but there were two additional, more personal motivating factors that supported the decision, even if they did not determine the choice. The first factor is that one of my supervisors (COD) had extensive experience of NPT and was therefore able to provide 'expert' support throughout the study period. The second factor is that NPT appealed to me because of its emphasis on 'work' and its focus on the usefulness of interventions. On reflection, it now becomes clear that I was unconsciously performing the work of 'coherence' while deciding on a theory to support the study, asking questions like: how is NPT different to other theories (differentiation); what is the potential value of NPT (communal specification); and how does NPT fit with my previous research and clinical experience (internalization)?

Some researchers have reported struggling to apply the NPT framework because of difficulties in differentiating between its constructs and components (245, 275-277). Initially, differentiation was also challenging in this study, especially during the preliminary coding and before all the exemplar quotes for the framework had been selected. However, coding data to the framework became progressively quicker and easier with experience. My personal experience of using the NPT framework was similar to that of Macfarlane and O'Reilly-de Brun who studies the implementation of a language interpreting service in Irish general practice (384). NPT offers '*an organizing principle to think with*' data and '*orienting principles and concepts*'.

A recent systematic review of the use of NPT found that the meanings researchers attributed to the constructs had high face validity (with a few exceptions) in terms of the reported analyses, interpretations and specific settings (245). But what are the implications if some researchers were to misunderstand the conceptual meanings of the constructs? The review found NPT frameworks were beneficial and helped to identify important issues *irrespective* of subjective judgements about which construct 'fitted best' to the data. The implication is that, while researchers should always aim to perform rigorous analyses of their data, the veracity of their findings is ultimately determined by its practical value (e.g. whether it has explanatory and predictive power).

The other concerns about the application of theoretical frameworks are that researchers may be constrained by theory, miss important findings or alternatively 'shoe horn' data into existing themes (384). NPT is no exception. It focuses on the 'work' study participants do rather than their attitudes or emotional experiences of interventions (245, 273). The concern whether important findings may have been missed in this study is at least partially addressed by having explicitly searched for data outside the framework and describing it. There is also evidence from the international literature that very little data fall outside the NPT framework, and the data that do are typically too generic, diffuse or vague to be meaningful or strictly technical and attitudinal in nature (385). In this study, the vast majority of data relevant to the factors that hindered or facilitated the implementation of the TRM fitted well within the NPT framework. However, the data about participants' perceptions of patient safety did not. NPT, like any other middle range theory, cannot and does not claim to be a 'theory of everything'. It is a heuristic device and not a 'conceptual straitjacket' (245). Data that were outside the NPT framework were therefore analysed thematically.

The close associations between some of the NPT constructs and components were described in Chapter 9. The associations have been conceptualized as a recursive loop by Bamford et al (270). They described how, when an intervention (in this instance, nutritional guidelines) failed to make sense (coherence) or engage staff (cognitive participation), some of them 'acted out' their resistance

(collective action). As a result, the intervention did not produce results, which confirmed their opinion that it had no value (the work of reflexive monitoring).

Recursive loops were also evident in this study. Those clinicians who were concerned about latent safety risks in their systems (the work of coherence) were willing to apply the TRM and share their findings (cognitive participation). When the TRM was applied effectively, PSIs were detected which then, in many instances, led to learning and subsequent improvement actions (the work of collective action). As a result, there was evidence that the TRM was useful, and reviewers were therefore willing to continue using it (the work of reflexive monitoring).

10.3.4. Strengths and limitations of the Trigger Review Method

This study helps to demonstrate three key strengths of the TRM. The first strength of the TRM is the willingness of clinicians to disclose PSIs. This is a crucial finding, as it indicates at least some degree of clinician engagement. It also indicates that the vast majority of clinicians considered the possibility of medical errors and latent risks in their practice systems and proactively searched for them. Only a generation ago, the voluntary participation of clinicians in this kind of study, or a national patient safety programme would have been almost inconceivable. Now that the precedent has been established, i.e. that clinicians are willing to search for and report PSIs in general practice, the next systems issue is whether GPs are prepared to report PSIs originating in secondary care. It is known that some GP's will deal with such interface issues if they identify a significant event but this is neither compulsory nor adequately formalized.

The second strength of the TRM is its flexibility. It was identified as a facilitating factor of its implementation in this study, as was described in Chapter 9. The fact that the trigger review method can be customized for specific environments is one of the important reasons why it is considered valuable by researchers in the international patient safety community (85, 233, 236, 237, 242, 382).

The third strength of the TRM is that clinicians actively identify their own improvement priorities and decide whether and how to enact them. In this way, the TRM works to encourage 'ownership' of PSIs, which was discussed in Chapter 8. The importance of clinical ownership is well-known from the international literature. An example is the study by Sharek et al, who found that clinicians conducting 'internal' reviews in their own hospitals were significantly more likely to detect PSIs compared with a team of experienced external reviewers (386).

The best evidence we currently have suggest that improvement initiatives that are characterised by clinician and patient engagement and 'ownership' are more likely to be successful and become normalised compared with those that are reliant on 'top down' approaches (205). That does not mean that health care managers and leaders do not have important roles in improvement. Strong, visible support by leaders for improvement initiatives are an essential facilitating factor, as was explained on page 261. The most successful initiatives are those that synergistically blend clinician engagement and senior leadership.

In this study, all of the medical records were reviewed manually. The alternative option would have been to automate some or all of the clinical review processes. Whether this decision is considered a strength or limitation depends on the aims of the study and purpose of the researcher. We know from the patient safety literature that automation will detect many more triggers in a much shorter period of time than the manual process and often for a fraction of the cost (387, 388). However, while the results from automated reviews can be insightful, especially when investigating harm rates in larger organisations, they arguably do not confer the unique, personal and specific information about PSIs which prompted the majority of clinicians in this study to take further improvement actions. The findings from this study strongly suggest that it is the very act of searching for triggers in a systematic manner that creates the appropriate 'mindset' required by clinicians to detect PSIs (Chapter 8, page 202).

One of the main limitations of any clinical record review method, including the TRM, is the inherent subjectivity of the reported findings, which is a product of the degree of variation in reviewer characteristics (85, 241, 335, 389, 390). The trigger review findings that were submitted by the participating clinicians in this study were not independently verified. The inter-rater reliability (IRR) between reviewers was also not investigated. Consequently, the reliability of the findings cannot be quantified by, for example, Cohen's kappa statistic (391). The decision not to undertake formal testing of IRR was based on four considerations.

First, work conducted in the hospital setting shows that the IRR was variable despite using more than one reviewer (392, 393). For example, Forster et al estimated that reliable detection and categorisation of PSIs (e.g. a 95% chance that the PSI actually occurred) requires the agreement of at least *three* reviewers (394). The second reason for not conducting IRR testing is therefore that the available resources for this study were insufficient to do so.

Third, the current TRM process has been adapted over the course of several years to be as simple and easy to use as possible (Chapters 1and 3). The original, 2007 version of the TRM had seven steps (40). This version was not perceived as feasible or acceptable beyond the pilot stage, even to the initial group of clinicians that were strongly motivated to use it. In comparison, the perceptions of the vast majority of participants in this study, namely that the TRM is acceptability and feasible, facilitated its implementation and therefore help to justify the omission of IRR testing.

The fourth and final reason is that the study aimed to explore the potential of the TRM as an approach to improve the safety of care in general practice. For this purpose, a measure of the reliability of the numerical data is less important than whether clinicians considered and undertook improvement actions.

Finally, variation can extend beyond the main results of a study to involve the practical aspects of the review process itself. For example, the reported time reviewers required to complete a trigger review varied considerably in this study

(Chapter 7, page 174). Whether it was because of a lack of training, the complexities of the cases being reviewed, or some other factors remain unclear.

10.4. Recommendations

10.4.1. Implementation and improvement initiatives

In this sub-section, three recommendations about implementation and improvement initiatives are made. They are:

I.   Researchers and policy makers should pro-actively identify and address the main factors that are known to facilitate or hinder the implementation of improvement initiatives;

II. The existing knowledge and 'engagement' of clinicians should be recognised and harnessed; and

III. The lessons learnt from PSIs should be widely disseminated.

10.4.1.1. Identify and address the barriers and facilitators to improvement initiatives

The evidence from this study and the wider implementation science literature suggest that a small number of specific factors are instrumental in facilitating or hindering the implementation of most, if not all, complex healthcare interventions. These factors can be identified, described and understood and are amenable to intervention. Researchers should actively consider them from the earliest planning stages, through the implementation and evaluation process and on in an ongoing manner until normalisation eventually occur.

Devlin et al recently identified three key areas for researchers and policy makers to pro-actively consider and address in order to ensure future, large-scale initiatives are successfully implemented and normalised (347). They are: (i) time; (ii) what the authors refer to as 'readiness', which is the product of resources and clinician engagement; and (iii) issues related to information technology (IT).   Although this study was smaller and had a shorter timeline, the equivalent of these three factors (four if the components of 'readiness' are

counted separately) were also identified as the most important determinants of the successful implementation of the TRM.

The first factor is time. To be successful, implementation initially requires adequate time for planning and the necessary work of coherence and activation. Once the project is underway, time remains a critical factor and should be allocated to do the necessary work of implementation. If the aim is to normalise the intervention, then a minimum time of five years, ideally ten, should be commissioned.

The second factor is 'readiness'. The findings from this study add to the large body of evidence (366, 369) of the essential role provision of adequate resources have as a facilitator of improvement interventions. This issue was also described in Chapter 9 and section 10.2.3, page 263. The other component of 'readiness' is clinician engagement. For an improvement intervention to be successfully implemented, it is recommended that researchers and policy makers ensure local staff and clinicians understand and are prepared for the proposed change(s). In NPT terms, there is need for the work of coherence and cognitive participation, e.g. the intended users of the intervention need to understand what is required of them and be willing and able to do this.

This recommendation is strongly supported by evidence that coherence is an essential precursor to successful implementation (268, 376). Franx et al recommended, based on their research about the management of depression in primary care, that the problems of general practice teams should be addressed first and 'sensitising strategies' should be considered at local levels before any attempts are made to implement further improvement initiatives (276). Bamford et al and, more recently, Jeffries et al made a similar recommendation, namely that researchers and policy makers should ensure all potential stakeholders and users understand the rationale for and benefits of an intervention before attempting to implement it (270, 395). This study provides a further, practical example of the need for initial coherence work by researchers, policymakers, clinicians and staff.

The third factor is information technology (IT), which includes the related issues of information governance and the interoperability of systems. In NPT terms the work of reflexive monitoring, e.g. evaluating the effectiveness of an intervention, typically requires IT support and systems. It also requires the researchers and participants to agree outcome measures and processes for collecting the necessary data to evaluate the intervention. In this study, the implementation of the TRM was facilitated by the fact that practice teams already had adequate IT systems and were therefore able to quickly generate random patient lists for sampling. Because clinicians worked in the practice they were able to access electronic medical records without additional concerns which have to be addressed when external reviewers are involved. However, despite all patient identifiers intentionally being removed, a small minority of clinicians were still concerned how the findings may be used at regional or national levels (Chapter 9). Finally, implementation was facilitated because reviewers were able to enter data into simple trigger review Summary Sheets that were compatible with their existing software.

10.4.1.2. Harness existing knowledge and clinician engagement

The practice teams in this study participated voluntarily. They were able to provide many examples of improvement work they were already doing and demonstrated knowledge of a range of improvement methods. In addition, many participants clearly identified priority areas for interventions and described what they would require to undertake this work (Chapter 6). These findings seem at odds with the common perception that clinician engagement is challenging (346). The implication may be that the sentiment about clinician engagement should be further qualified, e.g. clinician engagement is challenging *when* they are expected to contribute to initiatives that do not seem to have value for them or their patients *and* they are not adequately supported to perform the work.

The second recommendation in relation to improvement initiatives is therefore to harness the existing knowledge of clinicians and staff and support and enable them to implement the changes they perceive as priorities by allowing some

flexibility at local levels. From a regional and national perspective it is desirable – and necessary - to standardise processes and agree overarching objectives and outcomes. However, these requirements should not necessarily preclude frontline staff and clinicians to also plan, prioritise, design and test their own potential solutions (366).

This approach (local flexibility) is in stark contrast to the three common approaches taken by some initiatives. The first approach is to raise awareness of a problem, with the expectation that this will lead to improvement. A practical example would be to inform general practices that some investigation results of their patients are not appropriately managed, and as a result PSIs occurred. The second approach is to raise awareness of a problem and propose a solution. In the example of investigation management, a potential solution might be for practices to keep a log of all investigation requests and reports and regularly audit their performance. The third approach is to raise awareness of a problem, propose a solution and partly incentivise or mandate its application. In the investigation management example, a Health Board may offer a local enhanced service to help practices implement an investigation management system, with the expectation that the practice will absorb the recurrent costs and increase in workload.

While this example is simplistic, it helps to explain why some initiatives are not normalised. In many instances clinicians are already aware of problems but, for one reason or the other are unable to implement a solution. Alternatively, clinicians may be aware of solutions, but lack the resources or influence to implement them. The challenge is therefore to select the 'right' approach in each instance, in order to appropriately harness existing knowledge and ensure clinician engagement. In this context 'right' may mean raising awareness of problems, proposing potential solutions, offering additional resources or a combination of all three approaches.

10.4.1.3. The lessons learnt from PSIs should be shared

The importance of learning from mistakes has been recognised for many years. Almost 30 years ago now Wu et al considered whether house officers learn from their mistakes (336). They concluded that doctors *do* learn from mistakes, and categorised the subsequent changes that clinicians make as a result of their learning in two main groups: constructive ('increased information seeking' and 'increased vigilance') and defensive ('keeping mistakes to self' and 'avoid similar patients'). These findings have been replicated many times since, including in this study. Chapter 8 summarised the wide range of learning needs and learning points reported by participants in this study as a result of conducting trigger reviews. It also described the great potential PSIs have for individual clinicians to learn and reflect on their own professional practice.

The answer to the question of whether (some) clinicians can learn from PSIs is therefore an indisputable 'yes'. However, a more appropriate question may be who should learn from PSIs, and more specifically, whether health care organisations learn from them (396)? Influential reports such as '*An organisation with a memory*' (27) clearly described the organisational imperative to learn from PSIs. The rationale is that when organisations fail to learn from mistakes, patients inevitably suffer the same preventable harm. However, detecting, reporting and even analysing PSIs do not automatically generate collective learning within practice teams or organisations. Only if the learning points from analyses are effectively shared, stored and can be retrieved as required, can the behaviour of teams and organisations change (337, 397). The implication is therefore that the findings from improvement initiatives should be disseminated to all relevant stakeholders, from the individual practice through to the national level to enable and maximize collective learning (21).

10.4.2. Recommendations relating to the TRM

This sub-section describes five specific recommendations in relation to the TRM. They are contingent on the assumption that eventual normalisation of the TRM is desirable. Many of the issues the recommendations relate to have been discussed already. However, it is worthwhile to consider them again, as they

helped determine the successful implementation of the TRM and may be equally applicable to other improvement methods.

10.4.2.1. Incorporate the TRM into existing general practice contexts

This issue was previously discussed (Chapters 9 and Chapter 10). The main points are that the TRM will continue to feature in GP specialty training and as quality improvement method for appraisal and revalidation on a voluntary basis, but it needs to be incentivised locally or nationally for wider sustained implementation coverage. At deanery level in Scotland, the next steps will be to further refine TRM as a tool together with the associated training process and educational supporting materials. Exploring the potential need for e-learning and other interactive technology will also be necessary.

10.4.2.2. Provide training to clinicians before they apply the TRM

Training is an essential factor for successful implementation as, without it, participants are much less likely to have the necessary understanding and knowledge to complete trigger reviews. This finding is consistent with the international literature (398), which considers training to be of 'vital importance' for QI initiatives (227).

TRM training needs to be clear about the intended aims, benefits and practical application of the method. Specifically, the importance of the TRM as an approach to improve the safety of care needs to be emphasized. Reviewers need to understand that searching for triggers, detecting PSIs and 'ticking boxes' are intermediate outcomes to support the main purpose of the TRM, which is ultimately to improve the safety of care. The training should explicitly acknowledge that a small proportion of reviews may not detect PSIs and the potential reasons for this. Finally, training should emphasize the importance of identifying preventable system-causes of PSIs rather than a preoccupation with the perceived severity of PSIs or how many are detected.

The group teaching format was judged acceptable by GP trainees in this study, which increases the potential feasibility of delivering teaching to larger numbers of clinicians in comparison to one-to-one teaching (by another clinician) for specific aspects of the training curriculum. This is in keeping with other QI techniques such as criterion audit and SEA which can be taught by both clinicians and non-clinicians in large group settings but applied at the individual and practice-based levels.

10.4.2.3. Select reviewers with the knowledge and influence to enact change

The TRM should be applied by trained clinicians who have *sufficient influence* to ensure the findings are shared with their practice teams and who are capable to improve care for patients as well as at systems-level.

10.4.2.4. Allocate adequate resources and time to the TRM

This issue has previously been discussed. Of particular relevance to the TRM, is that reviewers should be allocated sufficient and protected time to allow them to conduct their trigger reviews, which include the completion of a trigger review summary sheet, in one session.

10.4.2.5. Disseminate the trigger review findings and learning points

The findings from trigger reviews should be disseminated to all relevant stakeholders, from the practice through to the national level to enable collective learning. This recommendation was justified and discussed in more detail on page 283.

10.4.3. Recommendations about future research and research priorities

This sub-section includes four recommendations in relation to future patient safety research, and potential research priorities in this discipline:

I.   Patient safety research has practical value and should remain a priority area in general practice;

II.   One of the main research priorities is to develop and validate a range of effective and cost-effective improvement methods;

III.   Research is necessary to understand how a strong and positive safety culture can be built in diverse health care settings;

IV.   If the value of 'hidden contributions' to patient safety are to be harnessed, more research will be necessary;

10.4.3.1. Patient safety research is a priority with practical value for general practice

The first, general recommendation is that patient safety should remain a priority research area (399, 400). There are many potential benefits, ranging from the philosophical pursuit of knowledge through to the practical aspects of helping to ameliorate or prevent patient harm. Three benefits in particular help to support this recommendation (47). The first benefit is that patient safety research increases our understanding of the nature and scale of PSIs as well as the associated safety threats. Being able to present reliable evidence of significant and systemic shortfalls in delivered care provides justification for policy makers and managers to allocate additional resources to help address deficiencies and allow them to distribute the resources in the most efficient manner.

The second benefit of patient safety research is that it helps to bridge the gap between 'what might work' which is based on intuition and expectation and what actually works in complex, dynamic and unique health care settings. Research methods are imminently suitable for developing, testing and rigorously evaluating complex health care interventions. Importantly, ineffective, unacceptable and unfeasible interventions can be identified before they are widely implemented.

The third benefit is the potential to measure health care performance. Reliable measures help staff set specific improvement targets, monitor their progress and identify when their aims have been achieved. Research can also help to identify and understand the factors that hinder or facilitate improvement processes.

10.4.3.2. Develop and validate a range of effective and cost-effective improvement methods

A systematic review and meta-analysis in 2006 found no evidence for the effectiveness of any intervention to reduce preventable drug-related PSIs and admissions, with the possible exception of pharmacist-led medication reviews (91). The need for a range of complementary methods to reliably improve care standards have previously been described on page 255. This recommendation is also supported by the wider patient safety research community (399, 401).

10.4.3.3. Understand how to build a strong and positive safety culture in health care

Different aspects of safety culture were considered in Chapters 2, 6 and 9. From a practical perspective though, the most important implication is that the prevailing safety culture (or conversely the lack of a safety culture) influences clinicians and staff to choose behaviours that enhance - or compromise - safety practices and thinking (171). This poses an important question: can a primary care organisation build a strong and positive safety culture that is capable of both predicting and avoiding patient safety incidents? The answer is a cautious and provisional 'yes', but will likely require many steps, considerable effort and research.

The very basic first steps and key requirements are to actually become aware of, measure and discuss the concept of a 'practice safety culture'. Perhaps more importantly, even if safety culture can be adequately measured, can we associate these metrics to clinical and organisational outcomes such as reductions in healthcare errors and avoidable patient harm, or improvements in the safety attitudes, knowledge and behaviours of the primary care workforce? The answers at this stage are unknown, but largely because the necessary depth of research and evaluation has yet to take place, hence the recommendation to prioritise safety culture as a research priority (350, 367, 402).

10.4.3.4. Harness *the value of 'hidden contributions' to patient safety*

Chapter 2 described a number of large-scale patient safety improvement programmes and initiatives. All of the programmes were endorsed by government or health care institutions, had clearly defined aims and interventions and were evaluated to some extent. However, there are many other patient safety-related activities in health care apart from these programmes. They often are unrecognised, unreported and unappreciated despite their considerable value.

One of the main mechanisms through which 'hidden contributions' are made to patient safety is through mitigation. Mitigating factors are defined as actions or circumstances that prevent or moderate the progression of an incident towards harming a patient (3). It has been estimated that mitigation may help to prevent from 8% (2) to as much as a quarter of health care errors in primary care (403). Practice staff are the most common mitigators, but patients and their families and other health care professionals such as pharmacists also make important contributions (404). Two exemplars are the recent ethnographic studies by Swinglehurst et al and Grant et al who found receptionists and administrative staff made important "hidden" and informal contributions to the safety of repeat prescribing in UK general practice (309, 369). Such hidden contributions warrant better identification and, potentially, utilisation in everyday practice.

Conclusion

In the last few decades there have been extraordinary advances in medical research and technology that have enabled clinicians to better diagnose, investigate and treat an ever-expanding list of pathological conditions, thereby further improving the overall health of individual patients and populations. At the same time, there has also been a growing acknowledgement that patient safety incidents (PSIs) commonly occur and that a substantial minority result in preventable, iatrogenic harm to patients.

This study is the first known attempt to investigate how the TRM is implemented and perceived in primary care from the perspective of general practice clinicians and staff. All of the study aims were achieved:

- The perceptions and understanding of general practice clinicians and staff of 'patient safety' were described in Chapter 6.
- The usefulness of the TRM was evaluated and the main outcomes from its implementation were described in Chapter 7.
- An explanation of how the TRM worked was provided in Chapter 8.
- The main factors that facilitated or hindered the implementation of the TRM in general practice were identified and described in Chapter 9.

In addition, four specific questions in relation to this study were considered in Chapter 10, and the potential answers as well as their implications for patient safety, implementation and improvement initiatives were described.

The findings from this study reaffirm the potential of the TRM to identify avoidable PSIs with potential educational and improvement value, particularly when it is applied to high risk groups of patients. In addition, most participants experienced the method as acceptable and feasible and perceived it as potentially useful. It is clear that the TRM is uncovering important patient safety concerns and also driving improvements in related care systems and processed at the individual practice level. The implication is that this is making a significant and demonstrable difference to patient care while impacting positively on local

safety culture. On the evidence presented, normalisation of the TRM in general practice can therefore be recommended.

However, while the usefulness of an intervention is an important factor in determining whether it is normalised or not, the study findings also clearly indicate – consistent with the international literature – that there are other factors that are at least equally important. They are: that clinicians have the prerequisite knowledge to apply the method; practice and senior organisational leadership support; contextual integration; and allocation of adequate resources. At the time of writing, some of these requirements have been met. The vast majority of clinicians seem to have adequate knowledge to apply the TRM, and it has been included in the RCGP Patient Safety Toolkit. However, there is currently no formal mandate or financial incentives for general practice teams to perform regular trigger reviews. It therefore seems likely that the normalisation of the TRM in UK general practice will be gradual and piecemeal, if it happens at all. Nevertheless, the lessons learnt from this study can be incorporated in the ongoing efforts to further improve the safety of care in general medical practice.

Appendix 1. Ethical approval letter

University of Glasgow | College of Medical, Veterinary & Life Sciences

20 June 2012

Dear Carl De Wet

MVLS College Ethics Committee

Project Title: A mixed-methods study to explore the safety of health care delivered in general medical practice
Project No: 2012054

The College Ethics Committee has reviewed your application and has agreed that there is no objection on ethical grounds to the proposed study. They are happy therefore to approve the project, subject to the following conditions

- The research should be carried out only on the sites, and/or with the groups defined in the application.

- Any proposed changes in the protocol should be submitted for reassessment, except when it is necessary to change the protocol to eliminate hazard to the subjects or where the change involves only the administrative aspects of the project. The Ethics Committee should be informed of any such changes.

- If the study does not start within three years of the date of this letter, the project should be resubmitted.

- You should submit a short end of study report to the Ethics Committee within 3 months of completion.

Yours sincerely

Dr Dorothy McKeegan
College Ethics Officer

Dr Dorothy McKeegan

Senior Lecturer

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Glasgow G61 1QH Tel: 0141 330 5712
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Appendix 2. Invitation letter to general practices.

NHS
Education
for
Scotland

Date

Dear Practice Manager

**Invitation to Practices to Participate in a Pilot Research Project:
Trigger Review of Electronic Patient Records and Making General Practice Safer**

Why is the research important?
- It is now widely accepted that patients can suffer unintentional but preventable harm as a result of their health care. As a result, the Scottish Government has made improving patient safety a priority. The Scottish Patient Safety Programme (SPSP) initially focused on hospital care but is now being extended into primary care and will roll out on a national basis in March 2013.
- Improving and assuring the safety of patients is clearly desirable. However, very little is known about the extent of the safety threat or how this aim can be achieved in general practice. This pilot will help us to examine patient safety in our setting and allow practical improvement tools to be further developed and tested in partnership with frontline staff. The pilot will involve up to 10 general practices in NHS Greater Glasgow and Clyde and last between nine and 12-months

How will your practice be expected to contribute?
- At least one GP and a practice nurse will be nominated to receive a short training session (around 2-hours) in the 'trigger review method'. The session will help to prepare him/her to review your own medical records in a rapid, structured and focused manner to detect potential safety-critical issues. Training will be delivered in the practice by a fellow GP (who is the lead researcher) and any number of additional team members can attend.
- A nominated GP or practice nurse will conduct two 'trigger reviews' of a small random sample of medical records (n=25) over the course of the study. The patient population will be those taking high risk medications. Each review should take around two hours. The reviewer will summarise the main findings, share these with practice colleagues and jointly consider how they may inform specific improvements in the practice. The GP researcher will liaise with the practice team at periodic intervals to discuss progress and issues with the implementation of improvements.
- During the course of the study, the practice manager, a practice nurse and one GP will participate separately in two semi-structured interviews at a time and venue convenient to them. Interviews will last no more than 60 minutes. Their purpose is to explore in confidence participants' experiences and perceptions of the key threats to patient safety in primary care.

What are the benefits of participating?
- You will uncover important opportunities to improve the quality and safety of the patient care you provide.
- You will be in a better position to engage with SPSP once it spreads into primary care in the near future.
- GPs may submit the 'trigger review findings' as supporting audit evidence for appraisal and revalidation
- Practice nurses and Practice Managers can use participation to inform their CPD obligations
- Once trained, you will be able to demonstrate to others in the practice how to conduct trigger reviews of records
- You will receive practical training and support and in your own practice by a small, dedicated and experienced research team. Training will include access to a range of patient safety improvement resources.
- Your overall contribution will help to inform the evolving patient safety agenda in primary care.

Financial reimbursement

- We are able to provide each practice with a backfill participation fee of **£813.03** (equivalent to three GP and Practice Nurse NES sessions each and a single Practice Manager session) **immediately payable** on agreement to participate. We appreciate that this contribution is more of a gesture of thanks and will not necessarily cover the full resource implications of participation.

Research Ethics

- The study was submitted to the West of Scotland Research Ethics Service. They considered the protocol and confirmed that it did not require to be submitted to an Ethics Committee. The study has been approved by the Research Ethics Committee, College of Medical, Veterinary and Life Sciences, University of Glasgow.

Participation and Further Information

- If your practice would like to participate in this study or you would like further clarity or information before making a decision, please contact Dr Carl de Wet direct on 0141 223 1450 or email him on carl.dewet@nes.scot.nhs.uk

Thank you in anticipation for your assistance with this study.

Kind regards

Dr. Carl de Wet
GP/Research

Dr. Paul Bowie
Associate Adviser

c.c. Linda Davidson, NHS GG&C

Appendix 3. Invitation letter to GP Specialist Trainees

NHS
Education
for
Scotland

Date

Dear Doctor...

Invitation to Practices to Participate in a Pilot Research Project:
Trigger Review of Electronic Patient Records and Making General Practice Safer

Why is the research important?

- It is now widely accepted that patients can suffer unintentional but preventable harm as a result of their health care. As a result, the Scottish Government has made improving patient safety a priority. The Scottish Patient Safety Programme (SPSP) initially focused on hospital care but is now being extended into primary care and will roll out on a national basis in March 2013.

- Improving and assuring the safety of patients is clearly desirable. However, very little is known about the extent of the safety threat or how this aim can be achieved in general practice. This pilot will help us to examine patient safety in our setting and allow practical improvement tools to be further developed and tested in partnership with frontline staff. The pilot will involve up to 40 GPSTs in NHS Greater Glasgow and Clyde and last between three and four months.

How will you be expected to contribute?

- You will have to attend a short training session (around three hours) in the 'trigger review method'. The session will help to prepare you to review your own medical records in a rapid, structured and focused manner to detect potential safety-critical issues. Training will be delivered in a venue in Glasgow by two GP Associate Advisors from NHS Education for Scotland.

- After the training you will be expected to conduct one 'trigger review' of a small random sample of medical records (n=25) and summarize the main findings on the 'Trigger Review Summary Report'. The patient population that we recommend is those >75 years of age with COPD. The complete review process should take a maximum of four hours. We recommend that you consider sharing the findings with practice colleagues like your educational supervisor (if relevant) and jointly consider how they may inform your personal and professional learning needs and specific improvements in the practice.

- During the course of the study, we aim to hold a number of focus groups at convenient times and venues to discuss your experiences with the trigger review method.

- At the end of the study we will ask every participant to anonymously complete a survey which should last no more than ten minutes. The purpose of the survey is to explore in confidence participants' experiences and perceptions of the patient safety in primary care in general and the trigger review method in particular.

What are the benefits of participating?

- You may uncover important opportunities to improve the quality and safety of the patient care you provide.
- You will be in a better position to engage with SPSP once it spreads into primary care in the near future.
- GPs may submit the 'trigger review findings' as supporting audit evidence for appraisal and revalidation
- Once trained, you will be able to demonstrate to others in the practice how to conduct trigger reviews of records
- Your overall contribution will help to inform the evolving patient safety agenda in primary care.

Research Ethics

- The study was submitted to the West of Scotland Research Ethics Service. They considered the protocol and confirmed that it did not require to be submitted to an Ethics Committee. The study has been approved by the Research Ethics Committee, College of Medical, Veterinary and Life Sciences, University of Glasgow.

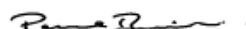**Participation and Further Information**

- If you would like to participate in this study or you would like further clarity or information before making a decision, please contact Dr Carl de Wet direct on 0141 223 1450 or email him on carl.dewet@nes.scot.nhs.uk

Thank you in anticipation for your assistance with this study.

Kind regards

Dr. Carl de Wet
GP/Research

Dr. Paul Bowie
Associate Adviser

Appendix 4. Consent form for general practices

NHS
Education
for
Scotland

Research project: A mixed-methods study to explore the safety of health care delivered in general medical practice

Consent form for GP practices

PLEASE READ THIS FORM CAREFULLY:

- The purpose of this study has been explained to me and the practice team, I have received and read a research information sheet and have had an opportunity to ask any questions and/or discuss any further concerns.

- I understand that all information collected during the study will be confidential and that all information, including the practice name, will be anonymised.

- The practice team agrees to participate and to allow the researchers supervised access of the premises, medical records and safety-related meetings at arranged times.

- The practice agrees to nominate a named general practitioner (GP), practice manager (PM) and practice nurse (PN) to:

- Receive a short training session (around 2-hours) in the 'trigger review method'.

- Conduct two 'trigger reviews' of a small random sample of medical records (n=25) over the course of the study

- Participate separately in two semi-structured interviews at a time and venue convenient to them during the study period.

- The estimated duration of participation in the study will be from 1st June 2012 to 31st May 2013

- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

☐   PLEASE TICK THE BOX, SIGN AND DATE THE FORM TO INDICATE THAT YOU AGREE WITH EACH STATEMENT AND THAT THE PRACTICE IS WILLING TO TAKE PART IN THE STUDY.

Name   _____ (Please print)

Signature   _____
              On behalf of practice
Date   _____

Practice name: _____

Appendix 5. Consent form for individual study participants

NHS
Education
for
Scotland

Research project: A mixed-methods study to explore the safety of health care delivered in general medical practice

Consent form for individual participants

PLEASE READ THIS FORM CAREFULLY

■ The purpose of this study has been explained to me and I have received and read a research information sheet.

■ I understand that all the information I give is confidential and that all information I give will be anonymised.

■ I agree that the interview can be audio-recorded.

■ I understand that I am not obliged to answer all the research questions asked during the interview.

■ I understand that the audio-recordings will be stored securely and only those working on the study will have access to these.

■ I understand that the audio-recordings will be destroyed when the project has been completed.

■ I understand that the interview transcripts will be stored securely and that only those working on the study will have access to them.

■ I understand that the information I give in the interview will be used for research purposes only.

■ I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.

☐ PLEASE TICK THE BOX, SIGN AND DATE THE FORM TO INDICATE THAT YOU AGREE WITH EACH STATEMENT AND IS WILLING TO TAKE PART IN THE STUDY.

Name _____ (Please print)

Signature _____

Date _____

Appendix 6. Schedule for interview one: general practitioners, practice managers and practice nurses

Introduction

- Hello...
- Thank you for agreeing to meet with me today. Please take a few minutes to read through the consent form. Feel free to discuss any concerns or ask for clarification before signing.
- The aim of this interview is to discuss your awareness, perceptions and personal experiences of patient safety in general practice.

General

Main question	Additional question	Clarifying question
What is your role in this practice?	How long have you been in this practice? How long have you worked in any primary care role?	

Patient safety and general practice

Main question	Additional question	Clarifying question
What does the term 'patient safety' mean to you?	What do the terms 'harm', 'error' and 'patient safety incident' mean to you?	
What do you think are the main patient safety threats in general practice?	Do you think any of the following are threats? • Diagnostic errors • Prescribing errors • Primary-secondary care interface issues	Why do you think patient safety is a problem in general practice?

Personal experiences with patient safety

Main question	Additional question	Clarifying question
Why did you or your practice agree to participate in this project?	Do you have any previous patient safety experience?	
Have you or your family ever been involved in a patient safety incident in primary care?	Would you mind telling me a little about what happened?	
Are you aware of any recent patient safety incident in this practice?	...or any incident you may have been involved in? If yes – would you mind telling me a little about what happened? If no – how would you have known or detected an incident if one had happened?	'Recent' could be interpreted as anytime in the last three months.

Thank you for your time and participation.

Appendix 7. Schedule for interview two: general practitioners, practice managers and practice nurses

Introduction
- Hello...
- Thank you for agreeing to meet with me today. Please take a few minutes to read through the consent form. Feel free to discuss any concerns or ask for clarification before signing.
- The aim of this interview is to discuss your experience with the trigger review method (TRM).

General
This section will only be used for those respondents that did not participate in interview one.

Main question	Additional question	Clarifying question
What is your role in your practice?	How long have you been in this practice? How long have you worked in any primary care role?	

1. Coherence (i.e. 'meaning and sense making' by interviewees)

Main question	Additional question	Clarifying question
What are the benefits of the trigger review method (TRM)?	Who are likely to benefit? Is it clearly distinct from other interventions?	Patients? Staff? Are they likely to value the benefits?
Which findings or aspects of the TRM were unexpected?		

2. Cognitive participation (i.e. 'commitment and engagement')

Main question	Additional question	Clarifying question
What changes did you make as a result of the review findings?	If none, why?	It may be helpful to consider different levels, i.e. patient, practitioner, practice, primary care.
Who else could use the TRM?	Will they understand the rationale for the method? Will they be prepared to invest time and work in it?	

3. Collective action (i.e. 'work participants do' to make TRM 'function'

Main question	Additional question	Clarifying question
What did you think of the training session?	Was the training adequate? How could the training be improved?	What was your experience of the provided learning resources, venue, presenter and presenting style?
How compatible is the TRM with your existing work?	What (if any) impact does it have on different professional groups?	Consider: division of labour, resources, power, responsibility.
How does the TRM fit with the overall ethos of general practice?		How does it fit the wider organisational goals?
Who did you share the findings with?	If no one, why?	

4. Reflexive monitoring ('reflect on and appraise' the TRM)

Main question	Additional question	Clarifying question
How can the TRM be adapted or improved?		
What would help ensure that you continue using it?	Does the TRM have a role in appraisal, revalidation, education and training?	

Thank you for your time and participation.

Appendix 8. Trigger Review Summary Sheet

Step One: Planning and Preparation

Please complete:

Name of Reviewer:		**Name of Practice**	
Date of Review		**Profession** (please circle)	GP Principal – GPST - Sessional GP - Salaried GP - Practice Nurse
No. of Records Reviewed		**Review Period** (e.g. 3-months)	
What Patient Group did you select records from?			

Step Two: Review of Records

Please aim to review 25 records from the chosen patient group. Tick one box (✓) next to each trigger each time you find it in one of the records.

Trigger (A 'prompt' that may indicate a safety incident)		**Total**
≥3 consultations in 7 days		
New 'high' priority read code added		
New allergy read code added		
'Repeat' medication item discontinued		
Out of Hours/A&E attendance		
Hospital admission		
Hb <10.0		
eGFR reduction ≥5		

REVIEW FINDINGS:
Please briefly describe the patient safety incidents that you detected. Next, judge the severity and preventability of each incident using the scales below and then add the two scores in the 'priority' column.

Description of Detected Patient Safety Incidents	Severity	Preventability	PRIORITY
	☐ +	☐ =	☐
	☐ +	☐ =	☐
	☐ +	☐ =	☐
	☐ +	☐ =	☐
	☐ +	☐ =	☐

Severity Scale:		**Preventability Scale:**	
1	Any incident with the potential to cause harm	1	Not preventable and originated in secondary care
2	Mild harm: inconvenience, further follow-up or investigation to ensure no harm occurred.	2	Preventable and originated in secondary care OR not preventable and originated in primary care
3	Moderate harm: required intervention or duration for longer than a day	3	Potentially preventable and originated in primary care
4	Prolonged, substantial or permanent harm, including hospitalization	4	Preventable and originated in primary care

Patient Safety Incident:
"Any incident that caused harm, or could have caused harm to a patient as a result of their interaction with health care"
(The definition encompasses error, harm, adverse event, significant event and near miss)

Step Three: Reflection, Action & Improvement

A. Please describe any Actions/Improvements made DURING the review (e.g. updated coding or prescribing)

B. What do you plan to do NEXT as a result of the trigger review findings?
(Use PRIORIITY scores to guide you - tick as appropriate)

Specific actions	✓	✓	✓	✓	✓	Please describe:
Significant event analysis						
Audit						
PDSA Cycle						
Feed back to colleagues						
Make a specific improvement(s)						
Add to Appraisal documentation						
Discuss with Educational Supervisor						
Update or develop a protocol						

C. Please describe identified Personal, Professional or Practice Team Learning Needs:

Personal:

Professional:

Practice Team:

Please add any comments about the trigger review process:

Finally, approximately what length of time (in minutes) did it take you to review all records?   mins.

Appendix 9. The NPT Framework and exemplar TRM quotes from this study

NPT constructs and components	Exemplar quotes
Coherence: The work participants have to do to understand the TRM	
Differentiation	Mistakes usually are only picked up when they've blown up, rather than going looking for them... This [the TRM] was better because actually I was fishing for things (GP06)
Communal specification	I think it's useful as a learning tool to learn about your own systems and a way of trying to improve those systems and a way of learning as a team with the results (GP05)
Individual specification	I was able, I felt empowered by looking at it, that I could look at the system, pick out errors that we hadn't really seen, bring it to somewhere to discuss, reflect on my own practice, and make some changes within that (GP06)
Internalization	I like nothing more than going back over notes, and reviewing and researching what we have or haven't done (GP06)
Cognitive participation: The work of building a TRM 'community of practice'	
Initiation	I've been trying to start the ground level approach of saying 'this is how it should be used', you know, used formatively and using it to look at your systems as well, and things like that (GP05)
Enrolment	One of my partners has said to me: 'Do you mind if I do the next trigger tools? Cause I'm looking for something to do for an audit (GP05)
Activation	That made us then do that as an SEA which made us decide 'well, ok, we all need whatever we do, we all need to do the same'...and it also made us do a search really for anyone with an HbA1c of over 6.5 who didn't have a diagnosis of diabetes (GP05)
Legitimation	I'm not sure if I'd have gone back to [the TRM] if it had disappeared off the horizon. If it was out of QOF, but part of what we do, or it's made an RCGP approved tool or it was something that trainees do, then I could see why people would become lured to the idea that it is a good thing and it would've developed...

cause it gives it fruits. There are fruits for your labour. Well, you have to justify the time in order to make it happen (GP06)

Collective action: Enactment of the TRM, e.g. how the work gets done

Interactional workability	I did it electronically from the outset because that's just much easier to store and save it (GP06)
Relational integration	GPs hopefully see it as a tool to help them - and the second thing that'll help with that, is what's done with the results that come from it at trust level. And I think that needs to be made clear to GPs at the beginning [pause] so they don't feel that this is going to be something to punish them and just another tick box exercise but see it as something positive (GP05)
Skill-set workability	I would hope, I would have to say I would think, most GPs would be able to do that' [reflect on TRM findings] (GP05)
Contextual integration	So even having the lunchtime meeting, when we went over the trigger tool, that's done slightly on a squash and a squeeze - it's not easily done. Protected learning time helps for that kind of process...if you're trying to make it part of the structure (GP06)

Reflexive monitoring: The work of appraising the TRM

Systematisation	That paper copy I don't think can be found at this time, which is a bit disappointing cause I have seen it, it was done and we thought we'd sent it, or she'd sent it, but it hasn't transpired, I gather (GP06)
Individual appraisal	I think it's been very useful for us...generates plenty of SEAs, has helped us refine some of our protocols and like for the diabetes thing we changed that. I think it does pick up [pause] incidents directly related to one patient (GP05)
Communal appraisal	I think it can be a fantastic tool for appraisal (GP05)
Reconfiguration	I'm just trying to think if this would take away from it in any way, but is there a way to identify the triggers using some computer based template and then come up with x number of patients to review? (GP05)

Appendix 10. Publications related to this study

P1.   Bowie P, Halley L, Gillies J, Houston N, **de Wet C**. *Searching primary care records for predefined triggers may expose latent risks and adverse events*. Clinical Risk. 2012;18(1).

P2.   **de Wet C**, Johnson P, O'Donnell C, Bowie P. *Can we quantify harm in general practice records? An assessment of precision and power using computer simulation*. BMC Med Res Methodol. 2013;13:39.

P3.   McKay J, **de Wet C**, Kelly M, Bowie P. *Applying the Trigger Review Method after a brief educational intervention: potential for teaching and improving safety in GP specialty training?* BMC Med Educ. 2013;13:117.

P4.   **de Wet C**, Bowie P. *Patient safety and general practice: traversing the tightrope*. Br J Gen Pract. 2014;64(621):164-5.

P5.   **de Wet C**, Kelly M, McKay J, Bowie P. The *Trigger Review Method*. In: Bowie P, de Wet C, editors. Safety and Improvement in Primary Care: The Essential Guide. London: Radcliffe Publishing Ltd; 2014.

P6.   **de Wet C**. *The KM Seedat Lecture: Why patient safety incidents predictably occur in Family Medicine*. Transactions. 2015;59(2):4.

P7.   **de Wet C**, Black C, Luty S, McKay J, O'Donnell CA, Bowie P. *Implementation of the trigger review method in Scottish general practices: patient safety outcomes and potential for quality improvement*. BMJ Qual Saf. 2016.

P8.   Bowie P, McKay J, McNab D, **de Wet C**. *The past, present and future of patient safety education and research in primary care*. Educ Prim Care. 2016;27(1):3-9.

P9.   **de Wet C**. *How primary care research contributes to improving the quality and safety of healthcare*. In: Goodyear-Smith F, Mash R, editors. International perspectives on primary care research. London: CRC Press; 2016. p. 8.

P10.   de Wet C, Bowie P, O'Donnell C. *Implementation of the trigger review method in Scottish general practices: a qualitative study to identify barriers and facilitators using Normalisation Process Theory*. Submitted for peer review.

P11.   de Wet C, Bowie P, O'Donnell C. *'The big buzz': A qualitative study of how safe care is perceived, understood and improved in general practice*. Submitted for peer review.

Appendix 11. Presentations related to this study

Date	Event or Organisation	Venue	Delegates	Presentation
26/10/17	GP17 – RACGP Annual Conference	Sydney	N/A	'The Big Buzz': How safe care is perceived, understood and improved in GP
11/04/17	Communication Hour Symposium	Griffith University	Medical students (years 3 and 4)	Normalisation Process Theory
15/09/16	'Subject Matter Experts' workshop	Gold Coast University Hospital; Australia	Managers and clinicians from the Specialist Outpatient Services (±20)	The value of NPT in planning and implementing change
05/08/15	Lunch-time lecture	Medical School; Durban; South Africa	Students, faculty (±20)	Perspectives of contributing factors to PSIs
01/08/15	Annual conference of the South African Academy of Family Physicians	Empangeni Hotel; Durban; South Africa	Family practitioners; medical superintendents; academic staff (±200)	The KM Seedat lecture: Perspectives of the contributing factors to PSIs
31/10/14	Workshop to plan the 'Harm in New Zealand general practice' study	Dunedin; New Zealand	Academic staff (±15)	TRM and general practice
13/06/14	SPSP-PC national Learning Event	Training centre; Glasgow; Scotland	Programme leads and participants (±90)	The TRM and QOF: Findings and recommendations
21/05/14	The Patient Safety Congress	Conference Centre; Liverpool; England	National and international delegates with an interest in safety	Improving patient safety in primary care in Scotland
09/05/14	SPSP-PC national	Crowne Plaza;	Programme leads	Qualitative findings

Date	Learning Event	Location	Audience	Content
	Learning Event	Glasgow; Scotland	and participants (±90)	from this study
26/03/14	Quality Improvement workshop for GPSTs	NES office; Edinburgh	GPST (±40)	The potential of the NPT framework for QI projects
31/10/13	NES GP Educational Supervisor conference	Grand Central Hotel; Glasgow; Scotland	GP educational supervisors (±150)	Interactive workshops: the potential of TRM for GPST
16/10/14	ISQUA conference	Conference Centre; Edinburgh; Scotland	Delegates (±50)	The TRM and GPST
11/09/13	NES GP Appraiser conference	Grand Central Hotel; Glasgow; Scotland	GP appraisers (±150)	How to successfully incorporate the TRM in GP appraisal
28/08/13	AMEE	Prague; Czech republic		Workshop: The TRM and self-directed learning Presentation: Potential of TRM for teaching and improving safety in GP
19/06/13	NHS Lanarkshire PLT event	Hamilton Race Course; Scotland	All Lanarkshire GPs and staff	The Trigger Review Method
12/06/13	NHS Dumfries and Galloway educational event	Dumfries; Scotland	GPs, PMs, PNs (±180)	Patient safety and the TRM
22/05/13	Patient Safety Conference	Conference Centre; Birmingham; England	Delegates	Two posters: Monte Carlo simulation and the potential of the TRM for GPST
30/04/13	SPSP-PC Learning Event	AA football club; Scotland	A range of GP staff and clinicians (±250)	The TRM

15/03/13	SPSP-PC National Launch	Herriot Watt; Edinburgh; Scotland	A range of GP staff and clinicians (±250)	The TRM: Presentations, workshops
25/01/13	NADEGS conference	Stirling; Scotland	Staff from Scottish Medical schools	'There is safe and then there is safe': A qualitative exploration of patient safety in GP using NPT
24/09/12	Lothian Local Enhanced Patient safety workshop	Murrayfield; Edinburgh; Scotland	A range of GP staff and clinicians (±200)	The TRM
27/06/12	GGC Local Enhanced Patient safety Service workshop	Glasgow; Scotland	A range of GP staff and clinicians (±100)	Patient safety and general practice
31/05/12	The Scottish Practice Management Development Conference	Crieff Hydro; Scotland	GP Practice Managers	The Trigger Review Method, safety culture and patient safety
29/03/12	SIPC national learning event	Glasgow; Scotland	SIPC participants and board support staff	The Trigger Review Method
28/03/12	Lanarkshire PLT event	Lanark; Scotland	A range of GP staff and clinicians (±150)	The Trigger Review Method, safety culture and patient safety
01/03/12	MDDUS conference	Fairmont hotel; Scotland	A range of GP staff and clinicians	The Trigger Review Method, safety culture, never events and patient safety
20/01/12	NADEGS conference	Dundee; Scotland	Staff from Scottish Medical schools	The Trigger Review Method
05/2011	Patient safety congress	Birmingham; England	Conference delegates	Poster presentation of the TRM

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