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Measuring and improving patient safety in general practice in Ireland

A thesis submitted to the School of Medicine, National University of Ireland Galway in fulfillment of the requirements for the degree of Doctor of Philosophy

By

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Institution:
Discipline of General Practice, School of Medicine, National University of Ireland Galway

November 2019
Volume 1 of 1
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Declaration

This work is submitted to fulfill the requirement of the degree of Doctor of Philosophy, at the National University of Ireland, Galway. No part of this thesis has been previously submitted at this or at any other university. There is a declaration at the beginning of each chapter to specify my contribution to each study. With the exception of Study 3 (Chapter 4), which is part of a group project, I declare that this thesis is entirely my own work.

Signed: Date: 8/11/2019

Ciara Curran
Summary of Thesis

Due to the large volume of primary care consultations and increasing patient complexity, there is substantial potential for unintentional patient harm. Measuring and monitoring of safety is essential to identify the contributory factors to patient harm and to strengthen safety systems to reduce the risk of future harm. Whilst proactive safety assessment methods are emerging in primary care, General Practitioners (GPs) report difficulty in knowing how to improve patient safety. A multi-method approach was taken to examine how patient safety can be measured, monitored and improved in primary care and how GPs can use this information to improve patient safety.

Study 1 is a systematic review of the safety climate (SC) survey instruments that have been utilized in primary care. It considers the reliability and validity of these measures and their suitability for use in primary care settings. Study 2 reports the findings from a survey of perceived SC across primary care practitioners and staff in Ireland and compares the findings to similar SC surveys conducted in primary care in England and Scotland. These findings highlight the negative impact of workload on perceived SC across the three studies. Study 3 describes the feasibility of implementing a patient safety intervention developed to proactively improve safety in primary care. It specifically addresses the impact of the intervention on SC and the acceptability of the intervention to GPs and practice staff. Finally, study 4 identifies contributory factors to patient safety incidents in primary care using the critical incident technique interview approach.

The findings from these four studies highlight the importance of choosing measurement instruments that are valid, reliable, feasible and context-specific. These studies demonstrate that there are a wide range of approaches to support safety improvement in primary care. The challenge is how to encourage and support the use of these techniques in busy GP practices.
Acknowledgements

While this thesis has been a long and arduous journey for me at times, it has been a positive and worthwhile experience overall. There are a few people who have helped and supported me along the way and I would like to acknowledge their support in this section.

First and foremost, thank you to my research supervisor Dr. Paul O’Connor. Thanks you so much Paul for your endless support, guidance and patience with a ‘newbie’ research student. I have learned so much from you - research skills, academic writing, patience and stellar work ethic to name but a few! I consider myself lucky to have had you as a research supervisor. Thank you so much too, for understanding that life does exist outside of PhD when you have four small children and your constant support has been crucial to completion of this PhD.

There are a number of other people who have helped me considerably with my research. Thanks to my co-supervisor Dr. Maureen Kelly, who had an input into translating the learning from this PhD into patient safety workshops for GPs, which aligned with my concurrent teaching role during this fellowship and helped with the dissemination of this research. I will always feel indebted to Dr. Sinead Lydon. Sinead had just completed her PhD when we shared an office and has been a wealth of information and experience, which has been fundamental to completion of this thesis. Her work ethic and academic ability has amazed me across so many different aspects of this research project. Sinead, you are a ‘research machine’ and a role model. Thanks also to the other PhD students and researchers in the office- in particular Caoimhe Madden and Chloe Walsh. Caoimhe, you have been instrumental in guiding me through SPSS, reference managers and MS Word and listening when I voiced frustration. Chloe helped with the data extraction of my systematic review. To all the other research staff in Distillery Road many thanks for the support and guidance through it all.

I also want to thank all the GPs and practice staff, who have participated in all of the research projects. In particular to the GPs who participated in Study 4 (Chapter 5), where they disclosed patient safety
incidents- I imagine that this was not an easy task to do! I would also like to thank Dr. Eamonn O’Shea, who helped with recruitment of GPs and practices and gave me unlimited access to GP CME groups, when asked. On this note, I would also like to thank the practice (Claddagh Medical Centre), where I completed my clinical component of the fellowship, for making me feel so welcome and engaging with any patient safety interventions or improvements that I have gleaned from the literature. I would also like to thank the PDs (Dr. Gennie Mc Guire) and APDs (Pat, Eamonn, John, Anne-Marie and Maureen) of the Western GP Training Programme, who supported me throughout.

Thanks to my GRC members- Professor Andrew Murphy, Professor Liam Glynn, Dr. Denis O’Hora, who provided support, advice and encouragement to pursue a PhD. A special note of thanks to Prof Andrew Murphy, who as my line manager, was a helpful and accommodating ear, when I struggled with workload and managing to balance academic/teaching/clinical components at times.

I owe a debt of gratitude to our wonderful friend and childminder, Catherine, without whom none of this would have been possible. If I didn’t have someone so diligent and caring to mind our children, I would have given up long ago!

I would like to thank my parents for supporting me thus far in my career and who always placed such an importance on education. Also for always being at the end of the phone when I need you- I know that I always feel better after a phonecall home! After a tough year for you both, I hope this puts a smile back on your face.

Lastly to David and to our four wonderful children, I want to say a huge thank you for your support, encouragement and patience through the last four years. David, you once asked if there was a support group for spouses’ of PhD students- I think you should be the founding member! I know it hasn’t been easy, but we have gotten there and for that I am eternally grateful-Yyyyyooouu!! Now to enjoy all the other stuff that we have put on hold until this was over………Mummy’s back kids!!!
Dedication

“Education is the most powerful weapon which you can use to change the world”

Nelson Mandela

I would like to dedicate this to my parents, David and my four beautiful “rebel” girls- Aoibhe, Ailise, Ruth and Una Gallagher.
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<tr>
<td>ACEI</td>
<td>Angiotensin Converting Enzyme inhibitor</td>
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<tr>
<td>AED</td>
<td>Automated External Defibrillator</td>
</tr>
<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>ARB</td>
<td>Angiotensin II receptor blocker</td>
</tr>
<tr>
<td>AUDGPI</td>
<td>Association of University Departments of General Practice</td>
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<tr>
<td>AV</td>
<td>Ambulatory version</td>
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<tr>
<td>CINAHL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
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<tr>
<td>CIT</td>
<td>Critical Incident Technique</td>
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<tr>
<td>CONSORT</td>
<td>Consolidated Standards of Reporting Trials</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
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<tr>
<td>FraSiK</td>
<td>Frankfurt Patient Safety Climate Questionnaire for General Practices</td>
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<tr>
<td>GMS</td>
<td>General Medical Scheme</td>
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<tr>
<td>GP</td>
<td>General Practitioner/ General Practice</td>
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<tr>
<td>HIQA</td>
<td>Health Information Quality Assurance</td>
</tr>
<tr>
<td>HIT</td>
<td>Healthcare Information Technology</td>
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<tr>
<td>HRB</td>
<td>Health Research Board</td>
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<tr>
<td>HSE</td>
<td>Health Service Executive</td>
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<tr>
<td>HSOPSC</td>
<td>Hospital Survey on Patient Safety Culture</td>
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<tr>
<td>ICGP</td>
<td>Irish College of General Practitioners</td>
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<tr>
<td>IHI</td>
<td>Institute for Healthcare Improvement</td>
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<tr>
<td>ISBAR</td>
<td>Identity Situation Background Assessment and Action Response and Rationale</td>
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<tr>
<td>ISI-WoK</td>
<td>Institute for Scientific Information Web of Knowledge</td>
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<td>MeSH</td>
<td>Medical Subject Headings</td>
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<td>MMS</td>
<td>Measuring and Monitoring of Safety framework</td>
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<td>MOSPS</td>
<td>Medical Office Survey on Patient Safety Culture</td>
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Chapter 1

General Introduction
General Introduction: The Importance of Patient Safety

Reducing the incidence of medical error that results in preventable harm to patients receiving healthcare is an ongoing challenge. Studies have found that between 3% and 17% of patients are injured unintentionally. In Ireland, it has been found that 12.2% of hospital patients are estimated to be harmed during their care, and over 70% of this harm is judged to be preventable. Since 2014, in excess of €832 million has been paid to settle medical negligence cases in Ireland. Moreover, the amount paid by the Irish state to settle medical negligence claims has increased by 365%, from €59 million in 2014 to €215 million in 2018.

In order to reduce levels of preventable harm experienced by patients in healthcare, there has been increased focus on research to improve patient safety. Patient safety can be defined as “avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare”. Improving patient safety has become a major concern both nationally, and internationally. The definitive goal of patient safety is to reduce errors of all kinds and pursue high reliability as an essential component of high quality care. However, in order to improve patient safety, it is important that robust mechanisms are in place in order to measure and monitor patient safety.

As compared to secondary care, patient safety in primary care has received much less attention due to a perception that it is relatively low-risk. However, it has been found that 2-3% of primary care consultations may contain a patient safety incident (PSI; defined as “any unintended or unexpected incident that could have led or were judged to have led to patient harm”). This figure is concerning given the high volume of patient contacts that occur in primary care. Approximately 90% of healthcare contacts occur in primary care setting, which equates to 340 million primary care consultations on an annual basis in the UK and 25 million consultations in Ireland. Such PSIs may be potentially preventable in 45-76% of cases, with serious harm (defined as “permanent harm such as disability, death or long-lasting physical or mental consequences”) occurring in approximately 4% of incidents. Furthermore, a systematic
review of primary care malpractice claims, reported that primary care was one of the five most commonly sued specialties in the US and there has been a rise in medical malpractice claims against General Practitioners (GPs) in both the UK and Australia. In addition to the repercussions of patient harm, PSIs have a significant impact on healthcare resources. Most burden on health systems are due to the effect of commonplace PSIs, which are magnified by frequent repetitions and exposure of a large volume of patients as seen in the primary care environment, rather than the effects of a rarer, but more significant PSIs such as wrong site surgery in secondary care.

Chapter Outline

This chapter will firstly outline the basic patient safety terminology commonly used in this thesis. It will then describe healthcare provision in primary and secondary care and utilise a socio-technical model to highlight the major differences that exist between healthcare delivery in primary and secondary care settings. It will then introduce Vincent et al’s Measuring and Monitoring of Safety (MMS) framework and outline how it can be used to consider safety in primary care. Finally, the chapter will outline the aims of the thesis and how these aims are aligned to the MMS framework and contribute to patient safety research in primary care.

Patient Safety Terminology

As patient safety is a relatively new discipline with its own terminology, the same terms often have different definitions and different words are often used interchangeably. For clarification purposes, I will outline some of the main nomenclature used frequently throughout this thesis.

Error is defined as the failure to carry out a planned action as intended or application of an incorrect plan. There are three main types of errors: slips (incorrectly executed plans), lapses (a plan or part of a plan is not executed) and mistakes (choosing or executing the wrong plan). Errors are always unintentional and thus are differentiated from violations, negligence or recklessness. Error is often considered to be a
controversial or punitive term as there is a connotation that blame for the error is attributable to a person-centred approach rather than a systematic approach, where other contributory factors are taken into consideration.\textsuperscript{18}

Harm is defined as the impairment of structure or function of the body and/or any deleterious effect arising there from\textsuperscript{16} or colloquially as anything you would not want to happen to your relatives while receiving care.\textsuperscript{19} While there is a clear association between error and harm, one does not imply the other- only some errors lead to harm and not all harm is as the result of an error.\textsuperscript{18}

Healthcare-associated or medical harm is defined as harm arising from or associated with plans or actions taken during the provision of healthcare rather than the underlying disease or injury.\textsuperscript{16} Within healthcare-associated harm, there are important differences between harm that is preventable and harm as a recognised complication of evidence-based care\textsuperscript{20}. These lines are often blurred due to the lack of a valid and reliable classification system and definition of either concept. Research on preventable harm is further complicated by the interpretation of whether or not an adverse event was actually avoidable (e.g., would the very ill patient have deteriorated regardless of care provided) and retrospective review of patient notes can result in hindsight bias.\textsuperscript{20} For the purpose of this thesis, we have defined preventable harm as harm that is accepted by the community as avoidable in a particular set of circumstances.\textsuperscript{16}

**Definition of Primary and Secondary Care**

The World Health Organisation (WHO) defined primary care as first-contact, accessible, continued, comprehensive and co-ordinated care of patients.\textsuperscript{21} Primary care is an umbrella term, which often includes all of the healthcare professionals working in the community such as dentists, community pharmacists, community occupational therapists, etc. Primary care is often used interchangeably in the literature with other terms such as family medicine, family practice, and general practice. Therefore, for the purpose of this thesis, when the term primary care is used, it refers to the delivery of patient care exclusively within the general practice setting (e.g.,
general practice team consisting of general practitioner, nurse and administrative staff working within a general practice surgery).

Secondary care is defined as medical care provided by a specialist or facility upon referral by a primary care physician and that requires more specialised knowledge, skill, or equipment than the primary care physician can provide. Secondary care is generally conducted in a hospital setting, where the patients are either inpatients (admitted to the hospital for procedure/observation) or outpatients (attending the hospital for consultation with a specialist, but not admitted).

While both primary and secondary care are under the same “healthcare” umbrella term, there are important and relevant contextual differences between healthcare delivery in these two settings. Subsequently, safety concerns in primary care are often very different than in secondary care. This in turn generates difficulties with the extrapolation of secondary care-based patient safety research, methods and interventions directly to primary care setting without careful consideration to the unique primary care environment. It is not valid to simply take research and patient safety initiatives from secondary care, and apply these approaches to primary care. The following paragraphs will highlight key differences between primary and secondary care, using the sociotechnical systems model, in order to further illustrate this important point.

**Sociotechnical Systems Model of Healthcare**

Primary care is a dynamic, multi-dimensional, interdependent and potentially hazardous setting due to a range of risk factors. These risk factors, and the difference from secondary care, can be framed within a sociotechnical systems model of healthcare. This approach to understanding complex organisational work design considers the interaction between people, technology, social and organisational components of the system.

The term complex sociotechnical system refers to a particular set of qualities typical to a workplace, not all of which may be ubiquitous, but might include: a large number of potentially pertinent factors or solutions to
a problem requiring decisions; communication amongst many people within the system; clinical decision-making within the system, which is variable and requires careful consideration to avoid drastic consequences; a potential of misinformation received from the patient or other source and a need to manage unpredictable events in order to maintain system safety and efficacy.\textsuperscript{28} \textit{“The heterogeneity and everyday workload, complexity, uncertainty and adaptability of GP is a testament to this type of complex system”}.\textsuperscript{28(p163)} The next section will outline the unique intricacies of healthcare delivery in the primary care setting within the context of a complex sociotechnical system and how these factors have the potential to impact on patient safety (see Figure 1).

\begin{figure}[h]
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\includegraphics[width=\textwidth]{societal-cultural-regulatory-influences.png}
\caption{Organisational and human factors in sociotechnical systems.\newline Adapted from Moray et al.\textsuperscript{29}}
\end{figure}

\textbf{Patient}  
Patient-centric care is central to the delivery of healthcare. GPs must deliver
high quality, holistic and safe care to all their patients in increasingly challenging circumstances. For example, GPs are caring for an ageing patient population with increasingly complex co-morbidities and poly-pharmacy in the community, while balancing this with managing patient expectations of a good quality of life at home.\textsuperscript{30(p113)} It is widely acknowledged that older patients with multi-morbidity are more likely to experience PSIs in primary care.\textsuperscript{31,32} This older patient population may have multiple complex health problems, and receive care from many healthcare providers at different sites. Unlike secondary care, where hospital physicians will see the patient for review of a single medical condition (e.g., diabetes) within the context of multi-morbidity (simultaneous co-existence of more than one chronic condition within one person), GPs will review the patient from a bio-psychosocial perspective (e.g., within the context of diabetes, GP may review the patient from multiple perspectives such as medication review, ensuring the patient has annual screening of retina and foot to prevent complications from diabetes, driving licence renewal in context of diabetes, application of chronic long term illness card to help with financial implications of diabetes, etc.). GPs have expressed challenges in the management of multi-morbidity in particular, while trying to deliver a safe patient-oriented, shared-care management approach.\textsuperscript{33}

Differences between primary and secondary care are also apparent in the doctor-patient relationship and the potential safety issues. For example, while patients are in hospital they are often prescribed medication by the doctor that is dispensed and administered by nursing staff, while in primary care, patient adherence to medication is often more ad-hoc with a greater reliance on the patient to self-administer the medication. Patient non-adherence can occur because the advice given to them by the doctor has been misunderstood, carried out incorrectly, forgotten, or completely ignored.\textsuperscript{32,34} These types of issues were found to contribute to almost 30% of PSIs in a recent French study of PSIs in primary care.\textsuperscript{35}
Work Environment/Equipment
The work environment refers to the setting in which healthcare is delivered, and the equipment refers to the medical devices used to treat a patient. Infrastructural differences between primary and secondary care have important ramifications for patient safety. As compared to the primary care setting, secondary care is more regulated. Secondary care is generally delivered from purpose-built buildings with accreditation and legislative requirements (e.g., regulation bodies such as Health Information Quality Assurance (HIQA), staff ratios, key performance indicators) and dedicated quality improvement and safety staff within hospitals. However, primary care practices often work as an autonomous and independent business within its own premises and unique organisational working practices. In Ireland, only 44% of GPs operate from purpose-built GP practices, and the majority of GPs are responsible for the provision and upkeep of their own GP surgeries.

The availability and use of equipment also varies across GP practices. For example, a national survey of Irish GPs in 2015 reported that 85% of practices had cryotherapy equipment (equipment for dermatology procedures such as removal of warts). Yet, in the same survey, only 82% of GP practices reported having an automatic external defibrillator (AED; life-saving equipment required to manage a cardiac arrest) in the practice. A five year prospective cross-sectional study of GP management of cardiac arrests in the community noted that 36% of practices had experienced at least one cardiac arrest in that timeframe and in greater than two thirds of arrest cases, the GPs were on the scene before the ambulance. As Irish GPs have the potential to encounter sudden cardiac arrest, the availability of potentially life-saving equipment should be obvious. However, it is often up to the discretion of the practice whether they can afford to have and maintain, an AED onsite.

Individual
Within the socio-technological model, the individual refers to the healthcare provider. Unlike secondary care, where hospital physicians can consult a colleague in another specialty for a second opinion, GPs rely almost exclusively on their own clinical knowledge and skills to evaluate and treat potentially sick patients. There is an onus on GPs to be vigilant to individually monitor and detect rare but serious diagnoses that are frequently encountered in the daily routine practice. GPs must also consider potentially more serious diagnoses over longer time periods for other presentations, while not subjecting the patient to unnecessary investigations and treatment. In 2015, 18% of GPs were working single-handedly (i.e., only one GP per GP practice with no possible inter-referral or discussion of patient cases with another GP within the practice). Additionally, GPs frequently bemoan the lack of timely access to diagnostic tests further hampering their ability to make accurate diagnoses in unusual clinical presentations (e.g., <15% of GPs reported direct access to CT scans for diagnostic purposes). The differences between clinical risk-taking in primary and secondary care can also lead to variability in the types of PSIs in both settings. For example, treatment errors predominate in secondary care settings, whereas diagnostic- (missed, wrong, or delayed diagnosis) errors are the most frequently occurring in primary care. Diagnostic errors are inextricably linked to the nature of risk in primary care and may be attributable, in part, to the reliance on “diagnosis by the test of time”, where diagnosis in primary care typically evolves over time and across several episodes of care. Diagnostic errors are also most likely to result in (severe) patient harm in primary care or a medico-legal claim.

**Team (Group)**

The team refers to the healthcare providers who work together to provide care for a patient. Teamwork is an integral component of the delivery of safe and effective patient care. In secondary care, healthcare delivery is mainly team-based rather than individuals. It usually consists of a consultant-led team, with a number of junior doctors, who may work with
different nurses and administrative staff dispersed throughout the hospital premises. In contrast, teams within primary care tend to be smaller and more cohesive. In Ireland, more than half of GP practices had three or more GPs, and greater than four-fifths of practices include a practice nurse and administrative staff. However, with increasing numbers of GP staff, there is a risk of a breakdown in teamwork and communication, which have been linked to medical error and compromised patient care. While interventions to improve teamwork in secondary care have been developed (e.g., Identity Situation Background Assessment and Action Response and Rationale (ISBAR) handover tool, simulation training), there is a paucity of research in this area in primary care.

Organisational and Management
Organisational and management refers to the administrative, structural, decision-making, practice and policy structures in place in a particular healthcare setting. In Ireland, primary care practices are independent autonomous businesses with different working practices and their own organisational culture, which varies from practice to practice. In an Irish context, general practices are operated independently of the state healthcare system Health Service Executive (HSE). Irish GPs characteristically work in a mixed public-private system, where patients typically pay privately to attend a GP, although almost half of patients with certain circumstances (e.g., unemployment, disability, chronic health conditions) may possess a medical card that allows them to attend their GP without paying a fee (i.e., General Medical Scheme (GMS) patients). GMS patients account for approximately 42% of the Irish population and GPs receive reimbursement from the HSE for the GMS patients in the form of an annual capitation fee.

As GPs are largely independent, they arguably have more autonomy to manage their own working practices than in secondary care (e.g., GPs can determine their own consultation rate averaging 10-15 minute consultation time, decide their own repeat prescribing protocol, choose computer-based
versus paper-based system, opt for different models of out-of-hours cover). However, such heterogeneity in work practices has the potential to present barriers to the universal implementation of national safety initiatives or policies. Furthermore, GPs often lack expertise to address quality and safety issues within their own practices and many organisational and cultural barriers such as increasing workload, lack of dedicated time, lack of financial remuneration and negative attitudes, have been cited by GPs as the main barriers to prevent engagement in quality improvement activities.

**Societal, Cultural and Regulatory Influences**

This last component of the socio-technological model refers to the impact of society, culture, and regulators on the delivery of healthcare. Approximately 90% of healthcare interactions in the developed world occur in the primary care environment, which equates to approximately 340 million primary care consultations in the UK and 25 million consultations in Ireland. A recent study of direct clinical workload of GPs in the UK has warned that current delivery of primary care services may be approaching “saturation point” and elsewhere, excessive workload in primary care has been linked to almost half of adverse events and near misses. In addition, work volume and intensity have also been cited as major contributors to the current GP workforce recruitment and retention crisis in the UK.50

Increasing primary care workload and a looming shortfall in GP workforce is also prevalent in Irish primary care services. By 2025, the HSE has projected that 1,380 additional GPs will be required to meet demand. This is in spite of the current critical shortage of GPs in Ireland required to deliver a safe and high quality primary care service. In 2016, there were 13 vacant general medical service (GMS) panels nationwide and over 10,000 medical card patients did not have access to a permanent GP. This meant that every time these patients visited their local doctor they were seen by a locum doctor or another doctor from a different practice, which contradicts the principle of continuity of care that is the cornerstone of general practice. This deficit of GPs is likely to be further exacerbated by
the 100 GPs retiring on an annual basis from primary care in Ireland.\textsuperscript{52} In addition, Ireland is also facing a pending recruitment crisis in general practice as for the first time ever, 10 GP training places remained unfilled in 2017.\textsuperscript{53} The HSE’s Pre-Consultation draft Patient Safety Strategy Plan (2019-2024) has stated its intention to facilitate and coordinate efforts to assess, plan and manage workforce requirements for implementing improved patient safety practices.\textsuperscript{54} However, if the current workforce shortages are not addressed and resolved by the HSE, the threat of insufficient manpower will undermine any patient safety improvement initiatives.

**Measuring and Monitoring Safety in Healthcare**

Healthcare is an inherently complex environment. While measures of healthcare quality and cost are relatively well established, the measuring and monitoring of safety remains problematic, with no consensus of how this measurement should be achieved.\textsuperscript{5,7} As can be understood from the previous section, this is partially a function of the complexity of the healthcare system. Yet, it is only through safety measurement and monitoring that comparisons can be made between the safety performances of different healthcare organisations, the impact of any safety interventions can be assessed, and there can be a shift to a more proactive systems approach to safety monitoring to the prevention of PSIs.\textsuperscript{5,7}

Safety measurement and monitoring are complex and multi-faceted, yet vitally important if safety is to improve.\textsuperscript{5,7} However, the lack of reliable data on safety hinders improvement efforts at every level of a healthcare system.\textsuperscript{55} The Francis report into the widespread poor patient treatment of patients at the Mid Staffordshire NHS Foundation Trust set the measurement of safety as an absolute priority for healthcare organisations.\textsuperscript{56} However, most healthcare organisations “have little capacity to analyse, monitor, or learn from safety and quality information. This gap is costly and should be closed”.\textsuperscript{57(p9)} Therefore, there is a need to identify practical and useful ways for measuring and assessing safety in healthcare organisations that are grounded in everyday practice, and present the data in such a way
that the information is readily interpreted by regulators, healthcare managers, healthcare providers, and patients.

In 2011, the American Medical Association’s (AMA) ten year report concluded that major gaps exist in our understanding of patient safety in the primary care setting and there was a lack of credible studies on how to improve safety in primary care.\(^5\)\(^8\) Furthermore, the heterogeneity across extant studies (i.e., lack of standardized patient safety terminology,\(^5\)\(^9\) lack of methodological rigour,\(^1\)\(^5\) and the lack of reliable and valid measurement tools\(^6\)\(^0\)\) has resulted in a lack of consensus on preventable harm in primary care and a misconception that patient safety is not an issue for primary care.\(^3\)\(^6\)

To date, primary care patient safety research has largely been exploratory and has focused on efforts, which describe the primary care safety environment, rather than the implementation of interventions to improve safety.\(^1\)\(^5\),\(^6\)\(^1\) As a result, many patient safety interventions in primary care are in the embryonic stages or have been adapted from secondary care\(^6\)\(^2\) and have not undergone rigorous experimental evaluation\(^6\)\(^1\) in the primary care setting, which limits their validity, reliability, acceptability, feasibility and impact.

As with secondary care, the importance of accurately and reliably measuring and monitoring safety is also a burning issue for primary care. Esmail has outlined the challenge posed by lack of organisational and infrastructural capability in primary care, required for implementing patient safety interventions, but has also noted that some aspects of safety and quality improvement (e.g., integration/learning) may be more favourably addressed within primary care.\(^3\)\(^6\)

In response to the pressing need to improve safety in healthcare, Vincent et al\(^5\),\(^7\) developed the measuring and monitoring safety (MMS) framework\(^5\),\(^7\) as an approach to consider safety in healthcare organisations. The MMS framework\(^5\),\(^7\) (see Figure 2) was developed from three scoping reviews concerned with: the measurement of safety in other high risk industries; conceptual approaches and models of systems safety; and the measurement of safety in healthcare.
Figure 2. Measuring and monitoring of patient safety in healthcare (MMS) Framework. Adapted from Vincent et al.\textsuperscript{5,7}

The MMS framework\textsuperscript{5,7} consists of five dimensions:

1. Past harm: has patient care been safe in the past? This dimension is concerned with the rates of past harm to patients and healthcare data have been collated from a wide range of methods and sources.

2. Reliability: are our clinical systems and processes reliable? This dimension is concerned with the reliability of safety-critical processes and the ability of staff to follow these procedures.

3. Sensitivity to operations: is care safe today? This dimension is concerned with whether it is possible to monitor safety on an hourly or daily basis.

4. Anticipation and preparedness: will care be safe in the future? This dimension is concerned with the ability to anticipate, and respond to, future threats to safety. Examples of measure in this dimension
include safety culture assessment, and safety cases. At an organizational level, this dimension is comparatively underdeveloped within healthcare.

5. Integrating and learning: is the healthcare organisation responding and improving? This dimension is concerned with whether the organisation can analyse, learn from and use safety information to improve safety (e.g., aggregate data on complaints, feedback and implementation of safety lessons by clinical teams).

In the next sections, the five dimensions of the MMS framework\textsuperscript{5,7} will be used to consider the measurement and monitoring of safety in primary care.

**Dimension 1: Evaluating Past Harm in Primary Care**

Vincent et al\textsuperscript{5,7} have highlighted the importance of accurate identification and measurement of harm as a core patient safety improvement goal. However, estimates of preventable harm in primary care vary widely. This variation can partially be attributed to methodological differences (e.g., definition, measurement, sampling) and differences in geographical and clinical contexts (e.g., infrastructural differences in primary care delivery between countries\textsuperscript{20}). To date, the main methods used to measure harm in primary care are self-reported incident reporting, patient record review, analyses of databases (e.g., medicolegal databases or prescribing databases) and patient’s or staff’s experience of safety incidents surveys\textsuperscript{20}. These measurement methods will be appraised below.

**Incident reporting.**

Two literature reviews of methods and measures of patient safety in primary care have identified PSI reporting systems as the dominant approach to measuring of harm in primary care\textsuperscript{15,63}. The focus on incident reporting can be attributed to the widespread use in hospital settings. However, due to infrastructural differences between primary and secondary care, incident reporting systems are often difficult to implement in the primary care.
environment and many of the incident reporting systems have been set up by universities specifically for the purpose of patient safety research.\textsuperscript{15}

Incident reporting systems may give a general indication of the types of PSIs identified by healthcare providers. A planned systematic analysis of over 40,000 incident reports collected from a UK primary care incident reporting system intends to identify problem areas for patient safety and inform the development of targeted interventions to provide safer delivery of primary care services.\textsuperscript{64} However, the uptake of incident reporting by GPs in the UK remains low with <1% of incident reports on the National Reporting and Learning System (NRLS) originating in primary care.\textsuperscript{65} With incident reporting systems, there are obvious limitations in terms of under-reporting, selective-reporting, incomplete-reporting and failure of the detection of PSIs,\textsuperscript{64} which makes extraction of meaningful and generalisable data difficult.\textsuperscript{15} A study of adverse event reporting in GP noted that GPs were least likely to report events due to barriers (e.g., time, interruptions, etc.\textsuperscript{65}) and primary care providers rarely reported PSIs that result in serious harm to patients.\textsuperscript{66} Furthermore, incident reporting systems have been criticised for the failure to capture the ‘human factors’ or complexities of the doctor-patient interaction that contribute to preventable patient harm.\textsuperscript{67,68}

**Patient record review.**

Retrospective patient record review has been described as the most effective method for estimating the different types of incidents in primary care and also estimation of patient harm.\textsuperscript{9,15,61} Patient record review (PRR) has also been suggested as the most appropriate method of detecting diagnostic error, which, has been described as the error most frequently associated with severe harm and malpractice claims against GPs.\textsuperscript{9,13} Yet, PRRs are often time consuming and may be influenced by sampling.\textsuperscript{20}

In the hospital setting, PRR has evolved to include the development and implementation of trigger tools (e.g., The Institute for Healthcare Improvement (IHI) Global trigger tool\textsuperscript{19}), which have been used to detect PSIs and improve the understanding of patient safety in this setting.\textsuperscript{61} Targeted chart reviews using “trigger tools” have been shown to detect
adverse events at a similar rate of traditional chart review, but requires less time.\textsuperscript{69} The IHI trigger tool\textsuperscript{19} has been adapted, re-designed and validated in the primary care setting by a group of Scottish primary care patient safety researchers and has been called the Trigger Review Method (TRM).\textsuperscript{70} The TRM is a structured and focused review of a random sample of patient records using a series of validated triggers that alert the reviewers to previously undetected PSIs in the “real-world” practice setting.\textsuperscript{70} In addition to providing key insights into patient safety issues, it also equips practices with a chance to reflect and engage in pro-active quality improvement activities (e.g., significant event analysis, audit) at a practice level to minimise the risk of patient harm in the future.\textsuperscript{70} Analysis of over 500 TRM reports by Scottish primary care providers has generated substantial data for the potential to implement quality improvement processes at practice, regional and national health system levels.\textsuperscript{70}

\textbf{Analysis of databases.}

A number of research studies have used existing databases, registries or datasets to quantify adverse events. For example, a Spanish team analysed patient record database of prescribed medication to look at drug interactions in primary care.\textsuperscript{71} Data from the analysis of medico-legal databases for clinical negligence claims in primary care, have estimated the risk of serious consequences from primary care errors at 20\%,\textsuperscript{72} which is considerably higher than studies of GP-recognised errors in primary care, where severe patient harm accounted for 5-7\% of incidents reported by GPs across six European countries.\textsuperscript{73} While transposing information from medico-legal studies to the generality of care in terms of estimations of frequency and the nature of error in primary care\textsuperscript{56} is limited, it may highlight other safety aspects of care provision in primary care such as prioritising educational strategies and risk management systems.\textsuperscript{13}

\textbf{Patient or staff experiences of safety incidents (surveys and interviews).}
This approach involves either patient or staff recalling errors or events overtime either through a survey or interview format.\textsuperscript{20} To date, this approach has been mainly used in the US and has often been limited by both recall and potential social desirability bias.\textsuperscript{20}

**Summary of the evaluation of past harm in primary care**
Measurement of past harm has dominated extant patient safety research in primary care\textsuperscript{15,20,63} and triangulation of data from these measurement methods (incident reporting, patient record review, medicolegal databases) has been recommended to develop a deeper understanding of the PSIs in primary care.\textsuperscript{15} Furthermore, across healthcare, Vincent et al\textsuperscript{5,7} have called for more “specific and nuanced” measures of harm of direct relevance to the specific clinical setting,\textsuperscript{7} which has prompted research teams to focus on the implementation of “trigger tools”, which also have a learning and quality improvement component embedded within.\textsuperscript{70}

**Dimension 2: Assessing the Reliability of Clinical Systems and Processes in Primary Care**
Vincent et al\textsuperscript{5,7} have described the need to identify all safety critical processes within each clinical setting and specify the levels of reliability expected. In secondary care, reliability is typically assessed by rolling audits (e.g., MRSA screening completed within 24 hours of admission to hospital\textsuperscript{7}). While participation in an annual audit for professional competency purposes in primary care is compulsory in both Ireland and the UK, audit within an Irish GP setting usually focuses on one narrow aspect of care delivery (e.g., was the protocol for B12 injections followed in terms of checking blood levels, patient reminders, attendance for B12 injections on a 3 monthly-basis?). Hence, primary care researchers are investigating alternative methods of assessing reliability in primary care.

Practice assessment lists (e.g., use of a checklist to evaluate specific safety-related indicators such as sharps disposal) are a frequently used proactive safety assessment method.\textsuperscript{74} Never Event (“serious, largely preventable PSI that should not occur is available preventable measures
were implemented by healthcare workers”(p1) lists and Always Event (“a list of events generated by patients which should always happen during an interaction with healthcare professionals”(p2) lists have been generated by GP research teams and may offer a different approach to measuring reliability than the traditional clinical audit, but have yet to undergo rigorous evaluation.

Significant Event Analysis is widely used by GPs in the UK. However, there is considerable variability with its utility in practice in terms of how it is conducted, how it is recorded and the learning that results from its use. Esmail has suggested that if there was further research to ensure consistency in the utility of tools such as Significant Event Analysis then this could account for elements of the “assessment of reliability” and other framework dimensions such as “sensitivity to operations” and “integration and learning”. Similarly, there is a pressing need to ensure that the measurement instruments (e.g., safety climate (SC) surveys, etc.) used are psychometrically sound, in order to produce valid and reliable data that are comparable across studies, different healthcare settings and over time.

Dimension 3: Monitoring Safety in ‘Real Time’ in Primary Care
Vincent et al5,7 have noted the importance of safety walk-arounds, handovers, briefings and debriefings and informal conversations, to the critical monitoring of safety. This dimension of the MMS framework5,7 may pose more challenges for primary care as, unlike secondary care where the handover of information is generally on a face-face basis, information transfer in primary care (in particular the transfer of patient information) is often reliant on medical-record keeping. Furthermore, a qualitative study of GPs has reported that time and resource constraints (e.g., workload, lack of protected time) mean that safety issues are often not prioritised in real-life practice.46

Dimension 4: Anticipating, and Responding to, Future Threats to Safety in Primary Care
There has been a notable shift in the focus of patient safety research in primary care and a move from measuring “lagging” indicators of safety such as adverse events to focus more on measuring and monitoring “leading” indicators of safety, which may be defined as valid and reliable precursors, conditions, events or measures before an incident has occurred. Safety requires anticipation, preparedness and the ability to intervene to reduce risks at ward, department or systems level. Yet, Vincent et al have found this to be the area of greatest weakness for most healthcare organisations. In addressing this aspect of the framework, Vincent et al have outlined the need to address this in their framework under this fourth dimension. For example, assessment of safety culture, which refers to the shared values, attitudes, norms, beliefs practices, policies and behaviours about safety issues in daily practice, is considered to be a leading indicator of safety.

Recently published reviews in the literature have documented that safety culture assessment is one of the most common method of proactive safety assessment in primary care. Safety culture or safety climate (SC) measurement can aid in the identification of areas for improvement, which have the potential to contribute to incidents or errors (e.g., communication, safety systems, work pressure etc.) and repeated measurements can analyse changes in perceived SC over time. Interventions to improve patient safety culture (e.g., the use of questionnaires, educational sessions for clinicians on patient safety issues) have been shown to increase engagement with incident reporting systems and enhance the quality of incident reports in primary care.

**Dimension 5: Using Patient Safety Data to Improve Safety in Primary Care**

The need for co-ordinated care to improve systems safety is becoming increasingly evident. However, there appears to be a disconnect between this evolving evidence base and engagement of the frontline GP staff- many GPs are unaware of the emerging safety research or are prioritising rising clinical workload over safety engagement. Consideration of practical
issues such as protected time for GPs to engage with patient safety programmes, regulatory practices (e.g., professional competency requirements to include an element of patient safety improvement initiatives) and financial incentives, may all need to be considered if frontline staff are to be actively encouraged to engage with patient safety interventions.84

While many of the existing patient safety interventions are considered to be feasible (e.g., freely available online, inexpensive, quick to complete74), many GPs have still reported difficulty in understanding how best to measure and improve safety in their practices.46 Spencer et al62 have criticised the lack of an embedded quality improvement component within many patient safety interventions in primary care, which has resulted in a lack of evidence in their utility in improving, as opposed to only measuring safety issues. Marshall et al85 have noted the importance of a “genuine partnership” between academics and front-line healthcare staff if patient safety research is to be translated into practical and pragmatic quality improvement processes that are useful for staff at the front-line interface. For example, the evaluation of the Scottish patient safety toolkit for primary care resulted in multiple adaptations and contextualisations of the patient safety interventions, when used in “real-life” primary care setting in order to improve applicability for GP staff as the programme evolved84.

**Thesis Focus**

Patient safety research in primary care has grown in the last decade,61 however the measurement of past harm has dominated the literature. Whilst this has been fundamental to understanding the epidemiology of medical error and preventable patient harm, there has been a shift in focus to a more proactive approach to safety measurement and monitoring in recent years.74 Currently it is recognised that research is urgently warranted to further our understanding of “leading indicators” of safety as opposed to limiting research to understanding “lagging factors”.55 Accordingly, although it is recognised that all of the dimension in MMS framework5,7 are important, this thesis will address the dimensions of “Anticipation and Preparedness”
and “Integration and Learning” as critical foci for expanding current knowledge on understanding patient safety in primary care. This rationale for the focus on these two dimensions is due to the limited research in these areas in primary care. While proactive safety assessment methods, are an emerging theme in primary care, further research is required to guide practitioners and researchers on how best to proactively measure safety in this setting.\textsuperscript{74,79}

**Research Aims**

The proposed research project thus aims to further explore these two dimensions of the MMS framework\textsuperscript{5,7} and is centred around the following research questions:

1. Could measures to assess the dimensions of “Anticipation and Preparedness” and “Integration and Learning” of the MMS Framework\textsuperscript{5,7} be used to improve patient safety in primary care?
2. What are the general issues for improving safety in primary care?

The next subsection will outline the aims of this research project and how they are aligned with the two MMS framework\textsuperscript{5,7} dimensions of focus.

**Anticipation and Preparedness**

Vincent has described this dimension as the “area of greatest weakness for most organisations appears to be the capacity to anticipate and prepare for threats to safety” and has highlighted the need for future research into this organisational capacity.\textsuperscript{7(p676)} As a means of assessing a particular aspect of “Anticipation and Preparedness”, this thesis will review, apply, and assess safety climate in primary care. Safety culture is defined as the values, attitudes, norms, beliefs, practices, policies, and behaviours about safety issues in daily practice and SC is considered to be the “mood state” and the measurable component of safety culture.\textsuperscript{86}

The anticipation and preparedness related research aims of this thesis are to:
• conduct a systematic review of SC survey instruments available for use in primary care to guide practitioners and researchers in their selection of the most psychometrically appropriate instrument (Study 1: Chapter 2);

• measure the SC in Irish primary care settings and examine whether perceptions of safety-related domains varied significantly according to respondent characteristics (e.g., job position) (Study 2: Chapter 3); and

• compare the results of perceived Irish SC to published data from primary care samples from Scotland and England (Study 2: Chapter 3).

Integration and Learning

GPs have reported difficulty in understanding how best to measure and improve safety at a practice level\(^{46}\) and have cited several barriers (e.g., competing workload, lack of guidance) to engagement in quality improvement processes, and integrate improvement into practice. The integration and learning related research aims of this thesis are to:

• describe a feasibility study of a primary care patient safety intervention designed to foster improved integration and learning, and consider the potential for the wider implementation of this type of intervention in Irish primary care (Study 3: Chapter 4);

• collect data from the Trigger Review Method (TRM) patient record review in terms of PSIs and the quality improvement action plans (immediate or planned) as a result of its implementation at practice level. (Study 3: Chapter 4), and;

• examine GPs’ perspectives of the factors that contribute to primary care PSIs through their accounts of PSI in which they had been involved (Study 4: Chapter 5).

The final aim is to make recommendations for both research and practice based on the findings from the four published studies described in this thesis (these recommendations are discussed in Chapters 2 to 5, and
then explored more broadly in Chapter 6- the final conclusions and recommendations chapter).

**Conclusion**

Due to the large volume of consultations and the increasing complexity of practice and patient factors in primary care, there is substantial potential for iatrogenic harm.\(^9,8^7\) Proactively measuring and monitoring of safety is critical to identifying the underlying problems with healthcare provision, assessing reliability and strengthening safety systems to reduce the future possibility of further patient harm.\(^7\) In the next chapter, the psychometric properties of SC survey instruments (an example of a measure of the “Anticipation and Preparedness” dimension) designed for use in primary care will be assessed in order to guide practitioners and researchers in the use of these instruments.
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Chapter 2: Study 1
A systematic review of primary care safety climate survey instruments:
their origins, psychometric properties, quality and usage
A systematic review of primary care safety climate survey instruments: their origins, psychometric properties, quality and usage

**Declaration**

Where This Fits in with the Thesis

SC is considered to be a measurable component of safety culture\(^1\) and thus, as a form of proactive safety assessment, addresses the “Anticipation and Preparedness” dimension of the MMS framework.\(^2,3\)

While SC assessment has emerged as the most common theme in primary care patient safety research since 2011,\(^4\) there is no consensus on which survey instrument is the best to use in terms of validity and reliability. Valid and reliable instruments are essential to ensure accurate and meaningful estimates of SC that are comparable across different healthcare settings and to evaluate changes over time.\(^5\) This first study outlines the origins, psychometric properties, quality and SC domains measured by SC survey instruments available for use in primary care. The purpose of the review is to provide guidance to researchers, practitioners and policy makers on the selection of the most appropriate survey instruments for the relevant clinical setting.

**Peer-reviewed Publication**

This study has been accepted and published in a peer-reviewed journal. The citation is: Curran C, Lydon S, Kelly ME, Murphy AW, Walsh C, O’Connor P. A systematic review of primary care safety climate survey instruments: their origins, psychometric properties, quality and usage. J Pat Saf. 2018;14(2):e9-18.

The following chapter is a formatted version of the submitted manuscript to the journal.

**Conference Presentations**

Oral Presentation

Curran C, Lydon S, Kelly ME, Murphy AW, Walsh C, O’Connor P. Systematic Review of Primary Care Safety Climate Survey Instruments: their origins, psychometric properties, quality and

**Poster Presentation**


**Authors’ Contributions**

This study was led by CC. CC and POC were involved in the design and planning of the study. CC, POC, SL and CW carried out data extraction and quality control of studies. CC drafted the initial manuscript. All authors assisted with redrafting the manuscript and reviewed and approved all drafts of the manuscript prior to submission to the journal.

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Abstract

Background
SC measurement is a common and feasible method of proactive safety assessment in primary care. However, there is no consensus on which instrument is “best” to use.

Objectives
The aim of the study was to identify the origins, psychometric properties, quality and SC domains measured by survey instruments used to assess SC in primary care settings.

Data Sources
Systematic searches were conducted using Medline, Embase, CINAHL and PsycInfo in February 2016.

Study Selection
English-language, peer-reviewed studies that reported the development and/or use of a SC survey in a primary care setting were included.

Data Extraction and Synthesis
Two reviewers independently extracted data (survey characteristics, origins and psychometric properties) from studies and applied the Quality Assessment Tool for Studies with Diverse Designs (QATSDD) to assess methodological rigour. SC domains within surveys, were deductively analysed and categorised into common healthcare SC themes.

Results
Seventeen SC surveys were identified, of which sixteen had been adapted from two main US hospital-based surveys. Only one survey was developed de novo for a primary care setting. The quantity and quality of psychometric testing varied considerably across the surveys. Management commitment to safety was the most frequently measured safety climate theme (87.5%). Workload was infrequently measured (25%).
Conclusions and Relevance
Valid and reliable instruments, which are context-specific to the healthcare environment for intentional use, are essential in order to accurately assess SC. Key recommendations include further establishing the construct and criterion-related validity of existing instruments as opposed to developing additional surveys.

Conflict of Interest
The authors declare that they have no conflicting interest.

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Chapter 2

Introduction

Safety climate (SC) measurement as a concept and assessment process emerged from high-risk industries such as aviation.\(^1\) SC is regarded as the measurable component of underlying safety culture at a given point in time\(^2\) and is generally assessed by self-administered survey. Safety culture refers to the values, attitudes, norms, beliefs, practices, policies, and behaviours around safety in an organisation.\(^3\) Hospital-based research has reported that SC scores are positively associated with clinical outcomes and the safety behaviour and attitudes of clinical staff.\(^4,5\) SC measurement has been endorsed as a quality and safety improvement initiative in healthcare,\(^6,7\) resulting in an increase in utility of available SC survey instruments.\(^8\)

In order to accurately measure SC, it is important that the measurement instruments used have sound psychometric properties. Valid and reliable survey instruments are essential if we are to assess the impact of patient safety interventions, to evaluate changes in safety over time, and to make (inter)national comparisons.\(^9\) A systematic review of proactive safety measures in primary care has identified the need to focus on improving the psychometric properties of existing survey instruments.\(^9\) Reviews of SC surveys in secondary care have similarly highlighted the limited psychometric assessment of many SC surveys.\(^8,10\) Another validity issue includes the evaluation of the specific SC domains (e.g., teamwork, organizational factors) within surveys. Firstly, there is a need to establish whether there is consistency of “core” SC domain measurement across all surveys and, secondly, whether these SC domains are context-specific to the healthcare environment they were developed in (e.g., hospital setting) or can be generalised to other healthcare settings (e.g., primary care setting).\(^11,12,13,14\)

Following on from the growth in utility and number of SC measures in secondary care,\(^8\) SC measurement is the most common method of proactive safety assessment in primary care.\(^9\) However, there is no consensus on which instrument is best to use.\(^9\) Some of these surveys have been adapted from SC surveys used in secondary care, and others have been specifically designed for use in primary care. The synthesis of extant research on these primary care measures is necessary to guide researchers,
regulators, and practitioners on their suitability, and make recommendations for how SC can be best measured in primary care. The aims of this systematic review are to:

1. establish the inter-relationship (if any) between extant primary care SC instruments in terms of how they were developed;
2. describe the psychometric properties of these instruments;
3. report the similarities and differences between the SC domains measured by these instruments, and;
4. make recommendations for best practice in measuring SC in primary care settings.

Methods
This systematic review was planned, conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.15

Study Selection
Inclusion and exclusion criteria.
To be eligible for inclusion, studies must have been: 1) written in English; 2) published in a peer-reviewed journal, and; 3) report the development and/or use of a SC survey in a primary care setting (as defined by the World Health Organization16). Studies were excluded if they assessed SC in an ambulatory care setting, in which primary care services were not specifically provided.

Search strategy.
Electronic searches were conducted within the following databases in February 2016: Ovid Medline, Embase, CINAHL and PsychINFO. The search protocol (see Online Supplementary Material 1(Appendix One)) included Medical Subject Headings (MeSH) search terms and keywords and was altered as necessary for databases other than Medline. The reference lists of included articles were also assessed to identify any other eligible articles.
Data Extraction

The following data were extracted from each included study: 1) country of origin; 2) number of items; 3) SC domains measured; 4) psychometric properties; 5) clinical setting; 6) information on study rigour; 7) number of citations, and; 8) the survey’s origins. The psychometric property assessment of the included studies is described below in Table 1 and was undertaken across all 23 included studies. Data extraction was conducted independently by two researchers, and any disagreements were resolved by consensus. Dialogue among co-researchers is considered to be an acceptable method of agreement for data categorisation.17
<table>
<thead>
<tr>
<th>Table 1. Psychometric criteria of safety climate survey instruments</th>
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<tr>
<td><strong>Content Validity</strong></td>
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<td>For the purpose of this review, we rated the assessment of content validity using the following categorisations:</td>
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<tr>
<td>No: 1. No evidence of content validity assessment within instrument</td>
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<tr>
<td>2. No evidence of content validity assessment within instrument, but reference made to prior validation</td>
</tr>
<tr>
<td>Yes: Evidence of content validity assessment within the survey instrument. Content validity was further categorised under the following codes:</td>
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<tr>
<td>A. Expert panel review with documented inter-rater agreement</td>
</tr>
<tr>
<td>C. Literature review to inform the survey development</td>
</tr>
<tr>
<td><strong>Construct Validity</strong></td>
</tr>
<tr>
<td>For the purpose of this review we analysed the assessment of construct validity under the following:</td>
</tr>
<tr>
<td>No: No evidence of factor analysis or inter-dimensional correlations</td>
</tr>
<tr>
<td>Yes: Evidence of factor analysis or correlations. Where construct validity assessment was present it was further categorised under the following headings:</td>
</tr>
<tr>
<td>A. Evidence of Exploratory factor analysis</td>
</tr>
<tr>
<td>C. Evidence of both Exploratory and Confirmatory Factor Analysis</td>
</tr>
<tr>
<td><strong>Criterion-Related Validity</strong></td>
</tr>
<tr>
<td>No: No evidence of criterion-related validity</td>
</tr>
<tr>
<td>Yes: Evidence of criterion-related validity was further categorised under the following:</td>
</tr>
<tr>
<td>A. The number of reported patient safety incidents or incident reports per practice</td>
</tr>
<tr>
<td>C. Stages of healthcare information technology (HIT) implementation (e.g., evaluation post introduction of electronic medical record system)</td>
</tr>
<tr>
<td><strong>Reliability</strong></td>
</tr>
<tr>
<td>No: 1. No evidence of reliability measurement within the instrument</td>
</tr>
</tbody>
</table>
Yes: Evidence of reliability measurement within the instrument and the range of Crohnbach’s alpha was reported

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td>Acceptable Crohnbach’s alpha &gt;0.69 throughout all SC domains. C. Overall reliability of survey provided &gt;0.7</td>
</tr>
<tr>
<td>B.</td>
<td>Crohnbach’s alpha &gt;0.7 for most SC domains, but not all domains. D. Raykov Coefficient also reported in conjunction with Crohnbach’s alpha</td>
</tr>
</tbody>
</table>
Quality Assessment

The methodological rigour of the included studies was assessed by two researchers, utilising the Quality Assessment Tool for Studies with Diverse Designs (QATSDD).\textsuperscript{19} This tool allows standardised evaluation of studies with varying research designs. QATSDD scores range from 0-48, with a higher score indicative of more rigorous methodology and reporting. The rationale for the use of this tool was that it allows an assessment to be made of the quality of research studies across a range of research designs. Two raters concurrently completed the quality assessment and discrepancies were resolved by consensus through discussion.\textsuperscript{17}

The instruments were ranked in terms of the QATSDD score. Where the instruments had the same QATSDD score, the number of citations (used as a proxy of frequency of application of the instrument) was used to order the instruments. These citations were derived from GoogleScholar and the Institute for Scientific Information Web of Knowledge (ISI-WOK) in November 2016.

Evaluation of Safety Climate Domains

Flin et al\textsuperscript{8} identified ten themes as key SC features in a systematic review of healthcare SC instruments: management commitment to safety; safety systems; risk perception; job demands; reporting/speaking up; safety attitudes/behaviours; communication/feedback; teamwork; personal resources (e.g., stress); and organisational factors.

For the purposes of this study, five researchers reviewed the SC domains within each instrument, and adopted a deductive content analysis approach to organise and analyse the domains further\textsuperscript{20} under Flin’s categorisation\textsuperscript{8} to examine convergence of SC themes. This analysis approach allowed for the examination of the comprehensiveness of Flin et al’s\textsuperscript{8} SC healthcare theme for surveys designed specifically for use in primary care settings. Should it not be possible to categorise domains under Flin et al’s\textsuperscript{8} themes, these domains were to be coded under “theme not described by Flin et al.”\textsuperscript{8} Any discrepancies were resolved by consensus through group discussion.\textsuperscript{17}
Results

Over 2,800 articles were screened, of which 23 met the inclusion criteria. From these papers, 17 separate SC survey instruments utilised in a primary care setting were identified (see Figure 3). Four survey instruments (PC SafeQuest,21 Dutch Systematic Culture Inquiry on Patient Safety (SCOPE),22 Frankfurt Patient Safety Climate Questionnaire for General Practices (FraSik),23 and Norwegian Safety Attitudes Questionnaire Ambulatory Version (SAQ-AV)24) had been used on more than one occasion, and each of these studies were included for analyses. All included studies were published between 2004 and 2015 and had been conducted in the US6 and Europe.17
**Figure 3.** PRISMA\(^1\) Flowchart: Identification of studies for review

*Note:* Inclusion Criteria: 1) English language only 2) Peer-review publication 3) Report the development and/or use of a safety climate survey instrument in a primary care setting as defined by WHO.\(^6\) Exclusion Criteria: Studies were excluded if they assessed safety climate in an ambulatory care setting, where primary care services were not specifically provided.
Instrument Characteristics and Origins

Table 2 outlines the characteristics of each survey instrument. Online Supplementary Material 2 (Appendix One) provides a more detailed description. The mean number of survey items was 45.1 (range = 14-77, SD = 10.6). The mean number of SC domains was 7.75 (range = 1-15, SD = 4). The mean score on the QATSDP was 26.4 (range = 17-37, SD = 5.85). The mean respondent response rate of each instrument was 63.4% (range = 29-97%, SD = 21.8). Four instruments (Swedish Hospital Survey on Patient Safety Culture (HSOPSC), Gorman et al’s Medical Office Survey on Patient Safety Culture (MOSPS), Schutz et al’s Patient Safety Survey, Martijn et al’s Safety Attitudes Questionnaire-Ambulatory Version (SAQ-AV)), did not report respondent response rates.
### Table 2. Safety climate survey instrument characteristics

<table>
<thead>
<tr>
<th>Tool Name</th>
<th>Country (Year &amp; Author)</th>
<th>N items</th>
<th>N Domains</th>
<th>QATSDD Score</th>
<th>Psychometric Properties Reported</th>
<th>Clinical Setting</th>
<th>n reported studies</th>
<th>Mean Response Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC-SafeQuest(^{21})</td>
<td>Scotland (De Wet et al 2010)</td>
<td>30</td>
<td>5</td>
<td>37</td>
<td>Yes</td>
<td>Yes</td>
<td>No* Described by Bell et al 2015(^{33})</td>
<td>Yes B, D</td>
</tr>
<tr>
<td>Teamwork and Safety Climate Survey(^{11})</td>
<td>England (Hutchinson et al 2006)</td>
<td>22</td>
<td>5</td>
<td>34</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes A</td>
</tr>
<tr>
<td>FraSiK for General Practices(^{23})</td>
<td>Germany (Hoffmann 2011)</td>
<td>44</td>
<td>9</td>
<td>34</td>
<td>Yes</td>
<td>Yes</td>
<td>No* Described by Hoffmann et al 2014(^{26})</td>
<td>Yes B</td>
</tr>
<tr>
<td>SCOPE(^{22})</td>
<td>Netherlands (Zwart et al 2011)</td>
<td>43</td>
<td>8</td>
<td>32</td>
<td>Yes</td>
<td>Yes</td>
<td>No* Described by Verbakel et al 2015(^{37})</td>
<td>Yes B</td>
</tr>
<tr>
<td>Swedish version of HSOPSC(^{13})</td>
<td>Sweden (Hedskold 2013)</td>
<td>48</td>
<td>14</td>
<td>29</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes B</td>
</tr>
<tr>
<td>SCOPE-PC(^{28})</td>
<td>Netherlands (Verbakel et al 2013)</td>
<td>41</td>
<td>7</td>
<td>29</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes A</td>
</tr>
<tr>
<td>Patient Safety Survey(^{29})</td>
<td>Switzerland (Gehring et al 2013)</td>
<td>24</td>
<td>4</td>
<td>28</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes B</td>
</tr>
<tr>
<td>Study Type</td>
<td>Country</td>
<td>Sample Size</td>
<td>Response Rate</td>
<td>Conducted during</td>
<td>Modified</td>
<td>Reported as Mean RR</td>
<td>Setting</td>
<td>Percent Reporting</td>
</tr>
<tr>
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<tr>
<td>Norwegian adapted- SAQ-AV24</td>
<td>Norway (Bondevik et al, 2014)</td>
<td>62</td>
<td>5</td>
<td>28</td>
<td>Yes</td>
<td>Yes</td>
<td>General Practice and OOH</td>
<td>Yes</td>
</tr>
<tr>
<td>MOSPS31</td>
<td>USA (Hagopian et al 2012)</td>
<td>58</td>
<td>12</td>
<td>27</td>
<td>No</td>
<td>Yes</td>
<td>Family &amp; internal medicine offices</td>
<td>Yes</td>
</tr>
<tr>
<td>MOSPS32</td>
<td>USA (Gorman et al 2012)</td>
<td>51</td>
<td>1*</td>
<td>26</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Spanish version of MOSPS33</td>
<td>Spain (Astier-Pena et al 2015)</td>
<td>67</td>
<td>15</td>
<td>24</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No 2</td>
</tr>
<tr>
<td>Turkish version of HSOPSC14</td>
<td>Turkey (Bodur &amp; Filiz 2009)</td>
<td>42</td>
<td>12</td>
<td>22</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes B</td>
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<tr>
<td>SAQ-AV34</td>
<td>USA (Holden et al 2009)</td>
<td>77</td>
<td>6</td>
<td>22</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes C</td>
</tr>
<tr>
<td>PROMISES Project Survey35</td>
<td>USA (Singer et al 2015)</td>
<td>63</td>
<td>11</td>
<td>22</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes B</td>
<td>Yes</td>
</tr>
<tr>
<td>PSCS in Ambulatory Care36</td>
<td>USA (Schutz et al 2007)</td>
<td>21</td>
<td>4</td>
<td>21</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No 1</td>
</tr>
<tr>
<td>SAQ - Modified Version37</td>
<td>USA (Mc Guire et al 2012)</td>
<td>29</td>
<td>6</td>
<td>17</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No 2</td>
</tr>
<tr>
<td>SAQ-AV38</td>
<td>Netherlands (Martijn et al 2012)</td>
<td>14</td>
<td>N/A</td>
<td>17</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No 2</td>
</tr>
</tbody>
</table>

Note: No* described by Bondevik et al 2014.
<table>
<thead>
<tr>
<th>Total</th>
<th>N instrument = 17</th>
<th>736</th>
<th>124</th>
<th>449</th>
<th>11</th>
<th>10</th>
<th>9*</th>
<th>13</th>
<th>N studies = 23</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td></td>
<td>45.1</td>
<td>7.75</td>
<td>26.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>63.4%</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td></td>
<td>10.6</td>
<td>4.0</td>
<td>5.85</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21.8</td>
</tr>
<tr>
<td>Range</td>
<td></td>
<td>14-77</td>
<td>1*-15</td>
<td>17-37</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>29.97%</td>
</tr>
</tbody>
</table>

* Instrument has criterion-related validity reported in another study that also utilises this seminal instrument for this purpose

Note: PC= Primary Care; FraSiK= Frankfurt Patient Safety Climate Questionnaire; SCOPE= Dutch acronym for systematic culture inquiry on patient safety; HSOPSC= Hospital Survey on Patient Safety Culture; SAQ-AV= Safety Attitudes Questionnaire Ambulatory Version; MOSPS= Medical Office Survey on Patient Safety; PROMISES= Proactive Reduction in Outpatient Malpractice Improving Safety Efficiency and Satisfaction Programme; PSCS= Patient Safety Culture Survey
Figure 4 details the origins of each of the seventeen instruments. It is evident that most instruments were adapted from two US hospital-based surveys.\textsuperscript{39,40} Seven surveys (35\%) were derived from the Safety Attitudes Questionnaire\textsuperscript{39} and nine (45\%) from the Hospital Survey on Patient Safety Culture.\textsuperscript{40} Only one survey (PCSafeQuest\textsuperscript{21}) had been developed de novo specifically for primary care setting.
Figure 4. The origins and inter-relationship between safety climate surveys used in a primary care setting
Note: PC= Primary Care; HSOPSC= Hospital Survey on Patient Safety Culture; SCOPE= Dutch acronym for systematic culture inquiry on patient safety; SAQ-AV= Safety Attitudes Questionnaire Ambulatory Version; FraSiK= Frankfurt Patient Safety Climate Questionnaire; MOSPS= Medical Office Survey on Patient Safety; PROMISES= Proactive Reduction in Outpatient Malpractice: Improving Safety Efficiency and Satisfaction Programme, TSC= Teamwork and Safety Climate; PSCS= Patient Safety Culture Survey (For more detailed information on these instruments see Online Supplementary Material 2)
Instrument Content

Psychometric analysis.
The quantity and quality of psychometric assessment of the instruments varied considerably (see Online Supplementary Material 2 and 3 (Appendix One)). Four studies (Astier et al’s Spanish MSOPS, Gorman et al’s MOSPS, Mc Guire et al’s SAQ - modified version, Martijn et al’s SAQ-AV) did not report any psychometric properties, but referred to previous assessment of the psychometric properties of the instruments reported elsewhere. These studies were not included in this review due to both language and setting restriction (i.e., not reported in English language, not primary care).

Eleven instruments (64.7%) described evidence of content validity. Ten instruments (58.8%) reported evidence of construct validity. Criterion-related validity was demonstrated in nine instruments (52.9%). In four of these instruments (PC SafeQuest, FraSik, SCOPE, Norwegian SAQ-AV), criterion-related validity was established in studies separate to the seminal study in which the psychometric development of the instrument were described. Thirteen instruments (76.5%) assessed reliability, with reported Crohnbach’s alpha level ranging from 0.43-0.94 across sub-scales. (See Online Supplementary Material 2 and 3(Appendix One)). Four survey instruments (PC SafeQuest, FraSik, SCOPE, Norwegian SAQ-AV) had evidence of psychometric assessment across all four parameters of content-, construct-, criterion-related validity, and reliability.

Quality.
As evident from Table 2, four (23.5%) instruments (PC SafeQuest, FraSik, Teamwork and Safety Climate Survey, and SCOPE) scored highest on the QATSDD (range = 37-15). Three of these surveys (PC SafeQuest, FraSik, and SCOPE) had undergone psychometric assessment across all four parameters (content-, construct-, criterion-related-validity and reliability) assessed in this study.

56
Evaluation of safety climate domains.

Sixteen surveys (94%) specified 124 SC domains (mean = 7.75, range = 1-15, SD = 4) suitable for analysis and categorisation under Flin et al.’s key SC healthcare themes. Flin et al.’s themes were found to offer a comprehensive assessment of SC in healthcare, and there were no SC domains which could not be assigned to a specific theme.

One survey (Martijn et al.’s SAQ-AV38) was excluded from domain analysis as it consisted of a list of fourteen survey items, which had not been preassigned into specific SC domains either by factor analysis or other groupings.

As evident from Table 3, no instrument in this review included domains mapping to all of the ten SC themes identified by Flin et al.8 Management/supervisor commitment to safety emerged as the most commonly measured domain (87.5%). Other themes such as teamwork (81.2%), organisational factors (75%), safety attitudes/behaviour (75%) and communication/feedback (68.7%) were also frequently evaluated within the SC measures reported in the included studies. Risk perception (18.7%), job demands (25%), and personal resources (25%) were infrequently measured (see Table 3).
Table 3. Convergence of safety climate themes across safety climate domains

<table>
<thead>
<tr>
<th>Tool Name</th>
<th>Country/ Author Year</th>
<th>N domains</th>
<th>Management/ Supervisors Commitment to Safety</th>
<th>Safety Systems</th>
<th>Risk Perception</th>
<th>Job Demands</th>
<th>Reporting/ Speaking Up</th>
<th>Safety Attitudes/ Behaviours</th>
<th>Communication/ Feedback</th>
<th>Teamwork</th>
<th>Personal Resources (e.g. stress)</th>
<th>Organisational Factors</th>
<th>No of themes per survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>PC-SafeQuest(^{21}) (PC= Primary Care)</td>
<td>Scotland (De Wet et al 2010)</td>
<td>5</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>5</td>
</tr>
<tr>
<td>Teamwork and Safety Climate Survey(^{11})</td>
<td>England (Hutchinson et al 2006)</td>
<td>5</td>
<td>✓</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>4</td>
</tr>
<tr>
<td>Frankfurt Patient Safety Questionnaire for General Practices(^{23}) (FraSiK)</td>
<td>Germany (Hoffmann et al 2011)</td>
<td>9</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>9</td>
</tr>
<tr>
<td>SCOPE(^{22}) (Dutch acronym for systematic culture inquiry on patient safety)</td>
<td>Netherlands (Zwart et al 2011)</td>
<td>8</td>
<td>✓</td>
<td></td>
<td></td>
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<td>6</td>
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<tr>
<td>Survey Description</td>
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<td>✓</td>
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</tr>
<tr>
<td>Swedish version of Hospital Survey on Patient Safety Culture^{13} (HSOPSC)</td>
<td>Sweden</td>
<td>2013</td>
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<td>✓</td>
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</tr>
<tr>
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<td>2013</td>
<td>✓</td>
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<tr>
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<td>Switzerland</td>
<td>2013</td>
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<tr>
<td>Norwegian- adapted Safety Attitudes Questionnaire Ambulatory Version^{24}</td>
<td>Norway</td>
<td>2014</td>
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<tr>
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<tr>
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<td>2012</td>
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<tr>
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<td>2015</td>
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<tr>
<td>Safety Attitudes Questionnaire Ambulatory Version (SAQ-AV)(^34)</td>
<td>USA (Holden et al 2009)</td>
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<td>PROMISES Survey(^35) <em>(Proactive Reduction in Outpatient Malpractice: Improving Safety, Efficiency and Satisfaction Programme)</em></td>
<td>USA (Singer et al 2015)</td>
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<td>✓</td>
<td>✓</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Survey of Patient Safety Culture in Ambulatory Care(^36)</td>
<td>USA (Schutz et al 2007)</td>
<td>4</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety Attitudes Questionnaire Ambulatory Version (SAQ-AV)(^37)</td>
<td>USA (Mc Guire et al 2012)</td>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong> Number of domains</td>
<td>124</td>
<td>16</td>
<td>11</td>
<td>4</td>
<td>4</td>
<td>13</td>
<td>13</td>
<td>16</td>
<td>17</td>
<td>6</td>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Percentage of surveys including the domain | 87.5% (14) | 43.7% (7) | 18.7% (3) | 25% (4) | 50% (8) | 75% (12) | 68.7% (11) | 81.2% (13) | 25% (4) | 75% (12) |

*Note:* The ‘ticks’ correspond to safety climate domains represented in the included surveys. Where there are multiple ‘ticks’ in one column, the safety climate domains were considered to represent the same Flin et al.’s\(^3\) Safety Climate theme following deductive analysis by the research group. *Gorman et al\(^12\) reported only one of the twelve safety climate domains within its survey (Overall perceptions of patient safety and quality). The other 11 domains were not described in the seminal paper. \(^1\)One SC survey instrument (Martijn et al\(^18\) 2012- Safety Attitudes Questionnaire Ambulatory Version\(^39\)) had a variable list of items (14), which was not categorised into a specific safety climate domain and hence was unsuitable for analysis of safety climate domain commonalities.
Discussion

SC assessment has the potential to support a proactive approach to safety measurement and monitoring and has been linked to positive staff and patient outcomes in secondary care. This review identified 17 instruments that had been employed to measure SC in primary care settings across 23 studies. These instruments demonstrated considerable diversity with regard to general characteristics, their origin and quality, the strength of their psychometric properties, and the SC domains measured.

The majority of instruments identified were derived from two main US hospital-based surveys. This approach of adapting a survey designed for use in one healthcare domain and applying it within a different domain leads to two key concerns. If a survey is to be conducted in a different healthcare domain (either different country or clinical setting) from which it was developed, it cannot be assumed that the instrument is valid and appropriate to be used in the new domain. To illustrate, the structure of SC domains for US hospital-based HSOPSC was not found to be valid when the survey was carried out with UK hospital personnel. Furthermore, the reliability of SC domains was unacceptable following psychometric assessment after applying a US hospital-based survey in a primary care setting.

A thorough psychometric evaluation is essential for making valid and reliable inferences about SC in UK primary care based on US hospital-based surveys. However, this review has highlighted the limited psychometric assessment of many of the SC instruments used in primary care settings. Vincent et al. have described how the “lack of reliable data on safety, and indeed quality, hinders improvements at every level.” Reliability refers to consistent measurement of the concept and validity refers to accurate measurement of a concept. Both validity (accuracy) and reliability (consistency) are essential to extract meaningful and trustworthy results. Researchers and practitioners must give consideration to choosing high-quality instruments that are demonstrated to be valid and reliable for the specific healthcare domain. This review has reported on the quality and psychometric properties of SC survey instruments used in a primary care
setting, which should help guide future decision-making when selecting an instrument.

Moreover, when adapting SC instruments designed for use in secondary care, it is important to consider that domain-specific areas of primary care SC may not be addressed. Primary care is not a microcosm of the hospital environment; it is the setting where continuous and comprehensive patient-centred care is delivered by leaders of a small to medium business enterprise. This frontline role carries a major workload burden. Workload has previously been described as a “core” SC dimension shared between industry and healthcare, yet it was only explicitly addressed within four instruments (25%) in this review.

Interestingly, both studies of SC in English and Scottish primary care, which have utilised PC-SafeQuest survey, reported lowest SC scores across the workload domain compared to all other SC domains (communication, leadership, teamwork, and safety systems) within the instrument.

Since 2010, the number of primary care consultations has increased from 300 million to 340 million in the UK. Subsequently, many general practitioners feel that their workload is no longer manageable and have been linked to high levels of burnout. Workload and burnout are inextricably linked and have been shown to increase the risk for medical errors and influence quality of care. Burnout and other issues such as work-life balance are not included in this review because the focus is on SC, but may be critical domains for survey respondents. Sexton et al have reported that higher work-life balance scores are associated with both higher teamwork and SC scores in a recent study of hospital healthcare workers in the US. Future research ideas could include correlations between SC measurement in primary care with other measures of burnout or work-life balance.

Increasing workload may also impact on the willingness of primary care respondents to engage with SC survey participation. General practitioners have identified high workload as a reason for not responding to surveys. In this review, there was considerable variability with both response rates (mean = 63.4, range = 29-97, SD = 21.8) and number of survey items (mean number of items = 45.1, range = 14-77, SD =10.6), which may be considered a proxy for ease of use. Consideration must be
given to incentivising SC survey participation such as financial or accreditation processes\textsuperscript{54,55} in the face of increasing workload, if widespread engagement in SC measurement in primary care is desired.

Deductive analysis of SC domains in this review\textsuperscript{20} has demonstrated convergence of SC themes across five main areas (see Table 3). These five themes are addressed in over two-thirds of surveys. While there may be some universal factors that measure SC across all healthcare domains, particular care must be given to ensure measurement of contemporaneous context-specific SC domains relevant to primary care, such as workload or burnout.

Additionally, establishing criterion-related validity of an instrument is essential to be able to differentiate between practices or staff roles (e.g., general practitioner, nurse, administration) with differing levels of safety performance.\textsuperscript{2,8} SC healthcare survey reviews have highlighted the need to correlate SC scores with appropriate criteria that are related to patient safety outcomes as part of this process.\textsuperscript{10} Of the nine\textsuperscript{14,25,26,27,30,31,32,37,38} (52.9\%) studies included in this review that attempted to establish criterion-related validity, eight studies\textsuperscript{14,25,26,27,30,31,32,38} attempted to correlate SC scores with emerging patient safety indicators and quality outcome measures. Two studies\textsuperscript{32,37} used the SC scores themselves as a measure of safety following Healthcare Information Technology (HIT) implementation. Following the initiation of incentives such as the Quality and Outcomes Framework in the UK\textsuperscript{56} (clinical quality indicators) and patient safety incident reporting scheme in the Netherlands,\textsuperscript{57} there are more available measures of quality and safety-related behaviours (such as significant event analyses, near misses, root cause analyses). These measures can be used as criterion-variables, and future research should aim to further establish criterion-related validity by linking SC measurement with these outcomes.

**Strengths and Limitations**

This review has numerous strengths. Firstly, search terms were comprehensive and were not restricted by year of publication or geographical location. Two researchers independently extracted data using a structured form to ensure accurate representation of the studies and resolved
discrepancies systematically. A group of five multi-disciplinary researchers (psychologists and general practitioners) categorised the SC dimensions into safety management themes during the construct validity assessment process. Two researchers critically appraised the methodological rigour of the instruments in accordance with the QATSDD score and the instruments were ranked in descending order.

This review has several limitations. Firstly, the inclusion criteria stipulates that English language only studies are reported, which leads to a theoretical introduction of a language bias and a potential limitation of our study. However, in confining the search to English language publications, other systematic reviews have demonstrated little evidence of a systematic bias from the use of a language restriction.\textsuperscript{58} Secondly, this review is also limited by the fact that it did not include grey literature, that is, unpublished research such as conference proceedings and theses or research that has been published in its non-commercial form such as government reports or policy statements.\textsuperscript{59} For example, some of the medical indemnity providers offer their own SC tools (e.g., Medical Protection Society SC Survey\textsuperscript{60}), but these are not captured within the current review. A further limitation is in the analysis of SC survey domains under Flin et al’s\textsuperscript{8} common healthcare SC themes, rather than individual survey item analysis. Firstly, one instrument (Martijn et al’s SAQ-A V\textsuperscript{38}) was excluded from domain analysis as there was no pre-defined SC domains. Secondly, only a limited number of instruments performed factor analysis to ensure that the items within the domains were correctly assigned to the specific domains. For the instruments that have not been subjected to factor analysis, item rather than domain analysis may have offered a more accurate insight into common SC themes in these surveys.

**Recommendations**

SC survey measurement is a potentially feasible and valuable instrument for researchers,\textsuperscript{9} regulators, and general practitioners to assess the prevailing SC of primary care practices. Choosing an appropriate instrument is essential for facilitating effective, accurate, and useful measurement of
safety. The following recommendations may be made for improving SC assessment in primary care based upon our review:

1. If a survey is adapted from another healthcare setting or country, outside of that which it was developed, thorough psychometric assessment of the survey in the new environment, is fundamental to ensure the validity and reliability of the findings.

2. Careful consideration should be given to selecting an instrument that has context-specific SC domains that are ubiquitous to the primary care environment in order to strengthen construct validity.

3. Consideration should be given to other contemporary issues such as burnout or work-life balance, which may have a direct influence on the primary care working environment and an indirect influence on the SC.

4. Rather than constructing more SC surveys, researchers should focus on further establishing the criterion-related validity of existing surveys by correlating SC with other metrics of safety performance (quality- or safety-related indicators) in order to discriminate between practices of different levels of safety performances. In secondary care, the availability of important safety data (e.g., morbidity and mortality rates) can be correlated with SC measurements in this setting. However, the lack of such available safety data in primary care has limited the usefulness of SC survey measurement as a predictor of safety performance.

5. Three instruments were found to have more evidence of validity than the other instruments reviewed. These instruments were the PC-SafeQuest,21 FraSiK,23 and SCOPE.22 However, that is not to say that these instruments are necessarily appropriate across all primary care settings, and considerations should be made to the appropriateness of the measures within the context of each specific setting. This review should help in providing information to allow researchers and primary care practitioners to make an informed decision as to which measure is most appropriate.

Conclusion
Primary care SC measurement has been promoted as a quality and safety initiative by government institutions\textsuperscript{6,7} following positive patient and staff outcomes associated with SC assessment in secondary care.\textsuperscript{4,5} A recent systematic review of proactive safety measures in primary care has reported that SC surveys are the most frequent method of safety assessment in primary care and are easily implemented.\textsuperscript{9} However, it also notes the lack of consensus on the most suitable survey to use in primary care settings.\textsuperscript{9} This review aims to provide a useful overview of SC surveys in terms of development and origins, psychometric properties, quality assessment, and utility. This should help guide primary care practitioners and researchers with their decision-making, when choosing an instrument.

Valid and reliable instruments are fundamental to extracting reliable data on safety and quality.\textsuperscript{4,3} However, this review has highlighted the limited psychometric assessment of many of these primary care SC surveys. Rather than continuing to develop novel or modified survey instruments, key recommendations include further establishing the construct and criterion-related validity of existing instruments. These recommendations for future research will help ensure that SC measurement is optimal, effective and yields data that is both actionable and accurate.
References


2006;6(1):44.


58. Morrison A, Polisena P, Husereau D, Moulton K, Clark M, Fiander M,


Chapter 3: Study 2
Perceived safety climate in Irish primary care settings-a comparison
with Scotland and England
Perceived safety climate in Irish primary care settings—a comparison with Scotland and England

Declaration

Where This Study Fits in with the Thesis

SC measurement is a common method of proactive safety assessment in the primary care setting[^1][^2] and thus addresses the “Anticipation and Preparedness” dimension of the MMS framework[^3][^4]. Following on from Study 1 (Chapter 2), this second study utilised a survey instrument developed for SC measurement in primary care. The measure used was identified as having high levels of validity and reliability in the systematic review reported in chapter two. The purpose of this second study was to measure SC in Irish primary care and examine whether perceptions of SC varied according to respondent characteristics. Furthermore, as this SC survey instrument has been utilized to measure perceived SC of primary care staff across Scotland and England, it allowed for an international comparison of SC scores across samples from these three primary care settings.

Peer-reviewed Publication

This study has been accepted and published in a peer-reviewed journal. The citation is: Curran C, Lydon S, Kelly ME, Murphy AW, Madden C, O'Connor P. Perceived safety climate in Irish primary care settings—a comparison with Scotland and England. Eur J Gen Pract. 2018;24(1):252-7. The following chapter is the final version of the manuscript accepted by the journal.
Conference Presentations

Oral Presentations


Curran C, Lydon S, Kelly ME, Murphy AW, Madden C, O’Connor P. Safety climate measurement in primary care in Ireland- a comparison with England and Scotland. Association of University Departments of General Practice Ireland (AUDGPI)/ Irish College of General Practitioners (ICGP) Annual Scientific Meeting; 2018 Mar 9th; Galway (Ireland).


Authors’ Contributions

This study was led by CC. CC and POC were designed and planned the study. CC, POC and CM carried out data analysis. CC drafted the initial manuscript. All authors assisted with redrafting the manuscript and reviewed and approved all drafts of the manuscript prior to submission to the journal.

References


Abstract

Background
Safety climate (SC) measurement is a key component of quality and safety initiatives in primary healthcare.

Objectives
To: (1) measure perceived SC in Irish primary care; (2) examine whether perceptions of safety varied according to respondent characteristics, and; (3) compare responses from our Irish sample to data from England and Scotland.

Methods
PC-SafeQuest Survey was administered to all practice staff in Irish general practices between March-May 2016. This survey consists of 30 items across five safety domains (workload, communication, leadership, teamwork, and safety systems). Multiple regression analysis was used to identify predictor variables of perceived safety. The effect size of the difference between the Irish sample’s scores and published English and Scottish data were calculated.

Results
A total of 231 questionnaires (38.5%) were returned. Generally positive perceptions of perceived safety were identified among Irish respondents, but workload had the lowest overall mean score ($M = 4.3$, $SD = 1.2$) of the five domains. Comparisons across the Irish, English and Scottish samples identified a medium size effect difference in workload; Scottish respondents perceived workload to have less of a negative impact on safety than Irish or English counterparts (Cohen’s $d = 0.60$, 0.67 respectively). Analyses indicated that Irish GP Principals perceived a more negative impact of workload on safety than administrative staff ($\beta = 0.28$, $p = 0.03$).

Conclusions
Irish SC data are largely similar to those of England and Scotland. The perceived potential for workload to negatively impact upon safety emerged within each country, and Irish GP principals perceive this as a greater threat than practice administrators.

**Conflicts of Interest**
None declared

**Funding**
This project was supported by funding obtained from the Health Service Executive, Irish College of General Practitioners, Association of University Departments of General Practice in Ireland and the Irish Health Research Board.

**Acknowledgements**
We would like to thank the WestREN network and practice staff of participating GP surgeries for consenting to take part in this study.
Introduction
Safety climate (SC) has been recommended as a useful component of quality and safety improvement initiatives in healthcare.\textsuperscript{1,2} SC is regarded as the measurable component of safety culture,\textsuperscript{3} which is defined as the values, attitudes, norms, beliefs, practices, policies, and behaviours about safety issues in daily practice.\textsuperscript{4} Positive perceptions of SC are associated with an open culture and willingness to learn from mistakes and errors.\textsuperscript{5} Hospital-based research has indicated that perceived SC is positively associated with clinical outcomes and the safety behaviours and attitudes of staff.\textsuperscript{6}

In secondary care, SC data have been used to benchmark safety cultures internationally.\textsuperscript{7} This process has resulted in the identification of systematic differences in perceived SC within and between hospitals, allowing for the identification of specific areas of safety that may be targeted for improvement.\textsuperscript{7} A recent systematic review\textsuperscript{8} found that in primary care, SC instruments are rarely used beyond the initial development study, suggesting that there is a need to investigate SC across primary care organisations internationally.

The comparison of SC perceptions across employees within organisations can also yield useful data. In primary care settings, differences in SC perception by gender and job position (clinical versus non-clinical) have been inconsistent across studies.\textsuperscript{9-13} However, it has been repeatedly found that respondents in management roles (e.g., general practitioner (GP) principals/practice managers) report significantly more positive SC perceptions than those performing non-management roles\textsuperscript{9,10,13} (e.g., GP assistants, nurses, administrators). The explanation for this finding is that managers may be detached from front-line operations, resulting in more favourable perceptions of staff and system safety performance.\textsuperscript{9}

The purpose of this study is to assess perceived SC in Irish primary care and to examine whether perceptions of safety-related domains varied significantly according to respondent characteristics. Furthermore, perceived SC within Irish primary care practices will be compared to SC data from English\textsuperscript{13} and Scottish\textsuperscript{9} samples. An international comparison of perceived SC across Ireland, Scotland and England is possible, as both the studies from Scotland\textsuperscript{9} and England\textsuperscript{13} are the only known published studies
to utilise the same SC survey instrument that will be used to measure SC in this study.

Methods

Setting and Sample Size
Staff in 187 practices in the Western Research and Education Network (WestREN) were surveyed as part of the study. WestREN is a university-affiliated general practice research network in the West of Ireland that has been shown to be broadly representative of the national general practice profile in Ireland.\(^\text{14}\)

Data Collection
Ethical approval for this study was obtained from the Irish College of General Practitioners (1\(^{\text{st}}\) May 2015). Following approval, general practices affiliated with the WestREN network were invited by letter or email to participate in the “NUI Galway WestREN Safety Climate Survey” from April 2016. GP principals or practice managers distributed the surveys to clinical and administrative staff. Practice staff completed the surveys anonymously. Surveys were returned either in a prepaid envelope or electronically to the research team. Reminders were sent two and four weeks after initial contact.

Survey Instrument
Perceived SC was measured using the PC-SafeQuest (Primary Care-SafeQuest). This instrument was developed specifically for SC assessment in primary care\(^\text{15}\) and has good reliability and validity.\(^\text{8}\) PC-SafeQuest has 30 items which measure five specific SC domains:

1. “Workload” - perception of the effects of working conditions on patient safety.
2. “Communication” - perceived importance of open and honest discussion between practice team members.
3. “Leadership” - perception of management’s commitment to safety within the practice.
4. “Teamwork”- perception of the importance of collaboration between practice team members to deliver efficient and effective patient care.


Responses are measured on a seven point scale from 1 ("not at all") to 3 ("to a limited extent") through to 7 ("to a very great extent"). Higher scores on each of the domains are indicative of a perception that the factor contributes positively to safety in the practice while lower scores on a domain are indicative of a perception that the factor is perceived to detract from safety within the practice to an extent.

A demographic questionnaire was used to collect information on the following respondent characteristics: gender, job role, work pattern, the number of years of experience in the practice and total number of years’ experience in general practice.

**Statistical Analysis**

All data were entered into SPSS (version 22) for analysis. Negatively worded items were reversed scored for analysis purposes. Preliminary analyses were conducted to ensure the assumptions of normality, linearity, multicollinearity and homoscedasticity were within acceptable limits. Missing data (1.92%) were managed by excluding cases pairwise. Following this initial screening, a series of six multiple linear regressions were conducted to examine whether demographic variables were predictive of “favourable” SC domain scores and/or the overall SC score. These multiple regressions, using a forced entry method, were carried out with the following predictor variables: gender (male, female); role within the practice (GP principal, GP other, nurse, administration); years of professional experience (<10 years, >10 years); years of experience within this practice (<10 years, >10 years); work pattern (full-time, part-time); and practice staff characteristics (management, non-management). Both “role within the practice” and “practice staff characteristics” were included within the regressions in order to assess whether differences in perceptions of safety existed according to professional role, and to facilitate the
comparison of our data with international data suggesting differences in perceptions of safety between managerial and non-managerial staff.\textsuperscript{9,10,12,13}

Cohen’s $d$ was used to measure the effect size of the standardised mean difference\textsuperscript{16} between the Irish sample, a sample of 563 primary care respondents from Scotland,\textsuperscript{9} and 335 respondents from England.\textsuperscript{13} Effect sizes are generally classified as small (Cohen’s $d = 0.2$), medium (Cohen’s $d = 0.5$) and large (Cohen’s $d = 0.8$), where greater than a medium effect size is generally of practical significance.\textsuperscript{16} Both the Scottish\textsuperscript{9} and English\textsuperscript{13} studies utilised the PC-SafeQuest questionnaire and were reported in the literature in 2012 and 2015 respectively.

**Results**

**Response Rate and Demographics**
Participating practices of the WestREN network requested 600 surveys of which 231 were returned (38.5% response rate). The majority of respondents were female (71.2%), and worked full-time (63.5%). Other respondent characteristics and reported demographics of participants from the English\textsuperscript{13} and Scottish\textsuperscript{9} data samples are provided in Table 4.
Table 4. Respondent characteristics across all three data samples

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Ireland n (%)</th>
<th>Scotland n (%)</th>
<th>England n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Professional Role</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Managerial</td>
<td>98 (45.2%)</td>
<td>208 (36.9%)</td>
<td>102 (30.4%)</td>
</tr>
<tr>
<td>Non-managerial</td>
<td>119 (54.8%)</td>
<td>343 (60.9%)</td>
<td>233 (69.6%)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>62 (28.6%)</td>
<td>92 (16.4%)</td>
<td>56 (16.7%)</td>
</tr>
<tr>
<td>Female</td>
<td>155 (71.4%)</td>
<td>467 (83.5%)</td>
<td>279 (83.3%)</td>
</tr>
<tr>
<td><strong>Work Pattern</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Full-time</td>
<td>138 (63.5%)</td>
<td>280 (49.7%)</td>
<td>195 (41.4%)</td>
</tr>
<tr>
<td>Part-time</td>
<td>77 (35.6%)</td>
<td>281 (49.9%)</td>
<td>138 (58.6%)</td>
</tr>
<tr>
<td>Locum</td>
<td>2 (0.9%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Years in current practice</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤10 years</td>
<td>109 (50%)</td>
<td>331 (59.2%)</td>
<td>213 (63.6%)</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>111 (50%)</td>
<td>228 (40.8%)</td>
<td>122 (36.4%)</td>
</tr>
<tr>
<td><strong>Years of experience in primary care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤10 years</td>
<td>88 (40.6%)</td>
<td></td>
<td>171 (51%)</td>
</tr>
<tr>
<td>&gt;10 years</td>
<td>129 (59.4%)</td>
<td></td>
<td>164 (49%)</td>
</tr>
</tbody>
</table>

*Note: *Missing data has been accounted for in this column.*
Reliability of the Survey Instrument

The Cronbach’s alpha co-efficient of scale reliability was 0.82 for the overall SC score, which is considered to be acceptable.\textsuperscript{17} Cronbach’s alpha scores for each of the subscales were also favourable (for workload = 0.69; communication = 0.89; leadership = 0.71; teamwork = 0.93; safety systems = 0.90).

Perceptions of Safety Climate in Ireland

Table 5 shows the means and standard deviations for each survey domain. The “leadership” domain had the highest mean score, and “workload” had the lowest. Closer examination of responses to individual items in the workload domain showed that two items with particularly negative responses were “team members always have enough time to complete work tasks safely” (modal response is 3 “agree to a limited extent”), and “when pressure builds up, team members are expected to work faster even if it means taking shortcuts” (modal response is 7 “to a very great extent”).
Table 5. Safety climate scores from Ireland, Scotland and England, and comparison of scores across the countries using effect sizes.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Ireland Mean(^a)</th>
<th>Ireland SD</th>
<th>Scotland Mean(^a)</th>
<th>Scotland SD</th>
<th>England Mean(^a)</th>
<th>England SD</th>
<th>Ireland-Scotland Comparison Cohen’s (d)(^b)</th>
<th>Ireland-England Comparison Cohen’s (d)(^b)</th>
<th>Scotland-England Comparison Cohen’s (d)(^b)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workload</td>
<td>4.3</td>
<td>6.0</td>
<td>5.0</td>
<td>1.2</td>
<td>4.2</td>
<td>1.2</td>
<td>-0.6</td>
<td>0.1</td>
<td>0.7</td>
</tr>
<tr>
<td>Communication</td>
<td>1.2</td>
<td>1.0</td>
<td>5.1</td>
<td>1.1</td>
<td>4.7</td>
<td>1.4</td>
<td>0.3</td>
<td>0.5</td>
<td>0.3</td>
</tr>
<tr>
<td>Leadership</td>
<td>5.4</td>
<td>5.5</td>
<td>6.1</td>
<td>0.9</td>
<td>5.5</td>
<td>1.3</td>
<td>0</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Teamwork</td>
<td>1.3</td>
<td>1.1</td>
<td>5.7</td>
<td>0.9</td>
<td>5.3</td>
<td>1.2</td>
<td>0.3</td>
<td>0.6</td>
<td>0.4</td>
</tr>
<tr>
<td>Safety Systems</td>
<td>6.1</td>
<td>5.4</td>
<td>5.6</td>
<td>1.07</td>
<td>5.5</td>
<td>1.2</td>
<td>-0.1</td>
<td>0</td>
<td>0.1</td>
</tr>
<tr>
<td>Overall</td>
<td>0.9</td>
<td>0.8</td>
<td>5.5</td>
<td>0.8</td>
<td>5.1</td>
<td>1.0</td>
<td>-0.1</td>
<td>0.3</td>
<td>0.4</td>
</tr>
</tbody>
</table>

Note: \(^a\)Higher scores with each of the domains are indicative of a perception that the factor contributes positively to safety in the practice while lower scores on a domain are indicative of a perception that the factor detracts from safety within the practice. \(^b\)Cohen’s \(d\) represents an effect size. An effect size quantifies the size of the difference between two groups and may be considered to be a true measure of the significance of the difference. Cohen’s \(d\) effect sizes are generally classified as small (\(d = 0.2\)), medium (\(d = 0.5\)) and large (\(d = 0.8\)), where greater than a medium effect size is generally of practical significance.
Perceptions of Safety Climate According to Respondent Characteristics

Only the workload domain resulted in a significant regression model \((F(8, 206) = 2.38, p = 0.02, R^2 = 0.085)\). Workload scores were significantly higher among administrative staff (receptionist/practice managers) as compared to GP Principals \((\beta = 0.28, p = 0.03)\). As higher scores are indicative of a more positive disposition to the domain, this finding suggests that GP Principals perceived a significantly more negative impact of workload on safety and performance within the practice than administrative staff.

Comparisons of Safety Climate between Ireland, Scotland, and England

There was little difference between the overall SC scores for comparisons of Irish, Scottish and English samples (see Table 5). However, Scottish respondents perceived less of a negative impact of workload on safety than both Irish (Cohen’s \(d = -0.6\)) and English (Cohen’s \(d = 0.7\)) respondents (see Table 5). For the leadership domain, the Irish and Scottish perception of the impact of leadership on work performance and safety was more positive than the English sample (both Cohen’s \(d = 0.5\); see Table 5). A medium sized difference (Cohen’s \(d = 0.6\)) was also reported between Irish and English samples across the teamwork domain, indicating that teamwork was perceived as less likely to compromise practice and patient safety by Irish respondents.

Discussion

Main Findings

Overall, SC was perceived to be largely positive within Irish primary care and was found to be broadly comparable to England and Scotland. Across all three samples, workload was perceived to have the potential to negatively impact patient safety and received the lowest mean SC domain scores. In the Irish sample, GP Principals perceived a significantly more negative impact of workload on safety and performance within the practice than perceived by administrative staff.
Strengths and Limitations
The internal reliability was found to be acceptable for the overall questionnaire score and domain scores. Responses were obtained from GPs and other practice staff with a broad range of experiences allowing for comparisons in attitudes to SC to be compared based upon a range of respondent characteristics.

However, recruiting respondents through the university-affiliated network could also be considered a limitation as it may have introduced a voluntary response bias. Practices within the university network may theoretically be more likely to be responsive to the survey invitation, or practices that did respond to the survey may be more interested in patient safety than non-responders. As we anonymised the results to encourage responses in a confidential manner, we had no data available to allow comparison of responders to non-responders. Next, the response rate (38.5%) may affect the external validity of our results. However, this was higher than the 29% respondent rate of the similar English study. In addition, the delay in publication of the data, collected in 2016, may also be considered a limitation. However, there has been no notable shift in the context or nature of primary healthcare in Ireland, Scotland or England, and there is no reason to think that perceived SC would have changed during this period. Lastly, SC is often referred to as the “snapshot” and measurable component of the underlying of safety culture, but there have been considerable problems with validity and reliability of SC measurement across primary care. More recently, patient safety culture is being viewed as a multi-layered construct and a multi-method approach to explicate the encompassing layers has been recommended. Thus, in order to further explore the intricacies of safety culture within the health care setting, a more qualitative approach to safety culture assessment may be a more appropriate approach.

Comparison with Existing Literature

Workload.
There has been a substantial, and unaddressed, increase in workload in primary care.\textsuperscript{19} All three data samples (Ireland, England,\textsuperscript{13} and Scotland\textsuperscript{9}) within this paper reported the lowest mean domain score for workload, suggesting a perception that it was likely to negatively impact on safety. A perceived negative impact of workload on SC and patient safety has been reported in other European countries\textsuperscript{10} and the US.\textsuperscript{20} A recent survey of GPs in the UK reported that more than nine out of ten GPs believe that their workload has negatively impacted on quality of care.\textsuperscript{21,22} Further, research has suggested that excessive workload in primary care is linked to almost half of adverse events and near misses.\textsuperscript{23} Across our three samples, Scottish respondents\textsuperscript{9} perceived workload as less of a threat to patient safety than Irish or English respondents. It has been found previously that, within the UK, GPs in Scotland were least likely to say their workload was both “unmanageable” and that it had “significantly negatively impacted on the quality of care that patients had received”.\textsuperscript{22} Further reflection on Scottish and other European primary care practices, where GPs have a better perception of the impact of workload on their daily practice, may be worthwhile if we are to develop interventions to tackle the workload issue internationally and improve safety.

**Differences in safety climate perception based on professional roles.**

In contrast to previous European studies,\textsuperscript{9,10,12,13} we did not find any significant difference between the perception of SC on the basis of management/non-management staff roles. The more positive managerial SC perceptions reported previously\textsuperscript{9,10,12,13} had been attributed to several reasons. On the one hand, detachment from frontline operations, could potentially lead to a lack of awareness of the day-to-day potential safety issues in the practice. On the other hand, the more positive perception of SC from a managerial position when compared to a non-managerial position, could be informed by a more holistic understanding of the pressing safety issues across the practice, rather than focusing on one area of the practice (e.g., the frontline). One possible reason for our finding may be the smaller team size in Ireland than in the UK- the average number of GPs per practice
in the WestREN network is 2.4 GPs\textsuperscript{14} compared to 6 or 7 in England,\textsuperscript{24} and more than 90% of practices in the UK are considered as group practices.\textsuperscript{24} With smaller practice teams, staff are likely to work more closely and cohesively with each other\textsuperscript{12} and it is arguable that detachment from the front-line interface is less likely to occur.

**International comparison of safety climate.**

Perceptions of SC in primary care in other European countries has also been found to be generally positive.\textsuperscript{10-12} However, when benchmarking SC results across primary care settings, it is important to take into account contextual differences in primary healthcare delivery.\textsuperscript{8,25} Irish GPs typically work in a mixed public-private system, as opposed to state-led universal healthcare system such as the National Health Service (NHS) which operates in in Scotland and England.\textsuperscript{24,26} There was also a notable positive perception of the impact of leadership and teamwork on work performance and safety noted by Irish respondents. It is arguable that greater independence and autonomy associated with private practice in Ireland\textsuperscript{26} may positively influence perceptions of SC. However, new government-led healthcare delivery models in Ireland involve the development of large primary care centres,\textsuperscript{27} which will likely result in an increase in the average size of practices in Ireland. Therefore, it will be important to foster shared cultural perceptions about SC and the delivery of safe high quality care in these larger practices so that staff members continue in close alignment with one another.

**Implications for Future Research and Clinical Practice**

Based on our findings, we offer the following recommendations for future research and practice:

- Participation in SC measurement may increase awareness of safety at an individual team member level.\textsuperscript{9} At a practice level, SC measurement can be used as an educational tool to identify relative strengths and weaknesses, which may in turn be targeted by initiatives to build a stronger safety culture.\textsuperscript{9} SC measures have been
widely used in primary care in the Scottish Patient Safety Programme in Primary Care,\textsuperscript{9} where a high usage of the intervention has resulted in an improved quality of, and safer, patient care.\textsuperscript{24}

- There is a need for more detailed assessment of the contributors to workload in primary care and how these factors can be addressed and alleviated, in order to develop interventions to improve the delivery of safe and efficient patient care.

- SC measures have been benchmarked across healthcare systems in different geographical areas, and countries, in secondary care\textsuperscript{7} with aggregation of data informing safety and educational opportunities.\textsuperscript{6,7} There is a need to consider benchmarking SC measures at a primary care level, as in the current study, to inform and target safety improvements. SC measurement in practices that are not affiliated to the university network, or in practices in other geographical settings across Ireland with different patient populations (e.g., older vs. younger patients; rural vs urban location), is also recommended. Patient safety programmes must deal with specific characteristics of primary care,\textsuperscript{25,27} and careful consideration should be given to contextual primary healthcare settings when interpreting results of SC surveys.\textsuperscript{8}

**Conclusion**

SC measurement is a key element of quality and safety initiatives in healthcare settings. In Irish primary care, perceived SC was generally positive and broadly similar to published data from England and Scotland. All three studies highlighted the negative impact of workload on perceived SC. In Ireland, GP principals perceive this as a greater threat than practice administrators do.
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Chapter 4: Study 3
Safety in primary care (SAP-C): a randomised, controlled feasibility study in two different healthcare systems
Chapter 4

Safety in primary care (SAP-C): a randomised, controlled feasibility study in two different healthcare systems.

Declaration

Where This Fits in with the Thesis

The aim of this study was to assess the feasibility of a primary care patient safety intervention designed to foster improved integration and learning at a practice level and thus addresses the “Integration and Learning” dimension of the MMS framework.\(^1\)^\(^2\) It was a practical application of tools designed to proactively improve safety in primary care.\(^3\)^\(^4\) The purpose was to assess whether these tools were acceptable to those working in primary care, and if they positively impact on SC.

Peer-review Publication


The following chapter is the final submitted manuscript accepted by the journal.

Conference Presentations

Oral Presentations


**Authors’ Contributions**

POC, SL, MC, AWM, and CC designed and planned the study. CM, SL, MC, NH, CC and POC contributed to intervention delivery and data collection. CM, POC, and SL carried out the data analysis and drafted the initial manuscript. All other authors assisted with redrafting the manuscript and all authors reviewed and approved the manuscript prior to submission. The specific contributions made by CC to this study were: recruitment of practices in the Republic of Ireland, training of GPs to carry out the trigger tool chart review, advising and responding to queries from GPs carrying out the chart review, collection and initial analysis of the chart review data.

**References**


Abstract

Background
Patient safety research is conducted predominantly in hospital settings, and there is a dearth of knowledge on patient safety in primary care, despite suggestions that 2.2% of primary care consultations result in a patient safety incident. This study aimed to assess the feasibility of an intervention intended to improve patient safety in general practice.

Methods
A randomised controlled feasibility study was conducted with general practices in the Republic of Ireland \((n = 9)\) and Northern Ireland \((n = 2)\), randomly assigned to the intervention \((n = 5)\) or control \((n = 6)\) group. The nine-month intervention consisted of: 1) repeated safety climate (SC) measurement (using GP-SafeQuest questionnaire) and feedback (comparative anonymised practice-level SC data), and 2) patient record reviews using a specialised trigger tool to identify instances of undetected patient harm. For control practices, SC was measured at baseline and study end only. The intervention’s perceived usefulness and feasibility were explored via an end-of-study questionnaire and semi-structured interviews.

Results
Thirteen practices were invited; 11 participated; 10 completed the study. At baseline, 84.8% of intervention practice staff \((39/46)\) and 77.8% \((42/54)\) of control practice staff completed the SC questionnaire; at the study terminus, 78.3% \((36/46)\) of intervention practice staff and 68.5% \((37/54)\) of control practice staff did so. Changes in SC scores, indicating improvement, were observed among the intervention practices but not in the control group. The trigger tool was applied to 188 patient records; patient safety incidents of varying severity were detected in 19.1% \((36/188)\). Overall, 59% of intervention practice team members completed the end-of-study questionnaire, with the majority in both healthcare systems responding positively about the intervention. Interviews \((n = 9)\) identified the intervention’s usefulness in informing practice management and patient
safety issues, time as a barrier to its use, and the value of group discussion of feedback.

**Conclusion**
This feasibility study suggests that a definitive randomised controlled trial of the intervention is warranted. Our findings suggest that the intervention is feasible, useful, and sustainable. Practices were willing to be recruited into the study, response and retention rates were acceptable, and there is possible evidence of a positive effect of the intervention.

**Trial Registration**
The trial registration number is: ISRCTN11426121 (retrospectively registered 2th June 2018).

**Protocol Reference**

**Conflicts of Interests**
The authors declare that they have no competing interests.

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**Acknowledgements**
We gratefully acknowledge the contributions of primary care teams in all participating practices and the support of the Western Research Network (WestREN) and the Northern Ireland Clinical Research Network Primary Care Group in recruitment.
Introduction

The importance of an increasing focus on patient safety in healthcare has been recognised.\(^1\) However, whilst the majority of patient contacts occur in primary care,\(^2\) there has been a far greater focus on patient safety in hospital settings,\(^2-5\) arguably due to a perception of primary care as a relatively lower-risk endeavour.\(^2\) However, both patient\(^6\) and practice factors\(^7\) have contributed to a growing complexity of clinical practice for general practitioners (GPs) which, combined with the sheer volume of patient contact, increases the potential for patient safety incidents (PSIs) in primary care. This is particularly concerning as GPs have reported several barriers to monitoring patient safety, such as limited and unreliable data on serious incidents, time to review practice-level data, and lack of examples of serious harm or ‘never’ events that are applicable to primary care settings.\(^8\)

Recognising the limited data on patient safety in primary care, the World Health Organisation has noted the pressing need to study and address patient safety in this setting.\(^9\) In secondary care settings, targeted strategies have been implemented,\(^10\) with varying degrees of supporting evidence. However, a systematic review\(^3\) of interventions to improve safety culture in primary care identified only two published interventional studies. Although both studies reported positive outcomes, methodological issues precluded the derivation of conclusive recommendations.\(^3\)

The Scottish Patient Safety Programme in Primary Care (SPSP-PC)\(^4\) is one of the first comprehensive and coordinated attempts to improve patient safety in primary care. This programme has been implemented in 90% of Scottish general practices, with 83% reporting that it enabled them to make changes within their practice, potentially resulting in safer, higher quality patient care.\(^4\) GP feedback on the programme’s acceptability, feasibility, and utility has been predominantly positive.\(^11\) However, its impact has not yet been evaluated independently of its developers, or assessed using a strong experimental design. Given the dearth of information on safety interventions in primary care, we therefore aimed to inform the design of a definitive randomised controlled trial of a primary care patient safety intervention.
We report the feasibility of conducting a randomised controlled trial of an intervention, developed previously by SPSP-PC, within primary care settings in two different healthcare systems; the Republic of Ireland (RoI) and Northern Ireland (NI). Following recommendations for good practice when designing pilot and feasibility studies,\textsuperscript{12} we aimed to evaluate rates of recruitment and retention of practices, response rates to questionnaires, completion of outcome measures, and participants’ perceptions of the intervention and effects of the intervention on safety climate (SC).

**Methods**
Our study protocol was published previously and provides a detailed overview of the study’s methodology\textsuperscript{13} in accordance with CONSORT guidelines for pilot studies.\textsuperscript{14}

**Design**
A randomised controlled design was used, whereby participating practices were assigned to either the intervention or control group by an external researcher using online randomisation software. Given the nature of the intervention, blinding of practice assignment among the researchers was not feasible.

**Ethical Approval**
Ethical approval for the study was received from the Irish College of General Practitioners’ Research Ethics Committee (no reference number, approved January 2016) and the Office for Research Ethics Committees of Northern Ireland (16/NI/0008, approved February 2016).

**Recruitment**
Our sample size was pragmatic, aiming to include practices of diverse size and location, and from two different healthcare systems, in order to test the intervention’s feasibility in a range of settings. A purposeful sample of RoI practices was recruited through the Western Research Network (WestREN),\textsuperscript{15} an Irish GP research network. Practices were stratified according to size (large (>2 GP principals) or small (≤2 GP principals) and
location (urban or rural). In the RoI, 13 practices were invited to participate, with 11 practices agreeing: two declined, due to the required time commitment. In NI, two practices of similar size and location (large; urban) were invited through the NI Clinical Research Network Primary Care Group\textsuperscript{16}: both agreed to participate.

Invitation letters were sent to the principal GP(s) in the selected practices (see Figure 5) and, with their consent, other staff were then invited to participate. In the RoI, GPs provide services for private patients who pay for each consultation, and for patients with medical cards, whose healthcare is publicly funded. In NI, GP services are provided free-of-charge through the National Health Service.

**Setting and Participants**

Of the 11 practices who initially joined the study, 10 completed (8 RoI, 2 NI; 7 urban, 3 rural). A total of six of the practices were “large”. The mean number of managerial staff (GP principals, practice managers) was 4.8 ($SD = 1.5$; range = 3-7), and of non-managerial staff (non-principals, practice nurses, administrators) was 7.5 ($SD = 2.9$; range = 4-11). Practices ($n = 4$) categorised as “small” had a mean of 2 managerial staff ($SD = 0$), and 4.3 ($SD = 1.7$; range = 2-6) non-managerial. In each practice, all staff provided personal written consent regarding their participation and all data were recorded anonymously.

**Procedure**

*Intervention practices.*

The intervention consisted of two components: (1) SC measurement and feedback and (2) patient record review using a specialised trigger tool to identify instances of harm (i.e., the trigger review method (TRM)\textsuperscript{17}).

SC was assessed using the GP-SafeQuest for primary care.\textsuperscript{18} SC is described as a measurable snapshot of an underlying safety culture at a particular period of time.\textsuperscript{3,10,19} The GP-SafeQuest is a valid and reliable\textsuperscript{20} survey instrument, designed specifically to measure SC perception, in primary care settings, across five subscales (leadership, teamwork, communication, workload, and safety systems), using Likert scales. Paper
copies and stamped addressed envelopes were delivered to practices at three time points (baseline, study midpoint, and study terminus; see Figure 5).
Figure 5. Flow diagram of the SAP-C feasibility study
Each intervention practice received individualised practice-level feedback (a written report) on their baseline and study midpoint SC surveys, within a month of survey completion. Simple descriptive statistics and illustrative diagrams allowed comparison of SC scores with other practices’ anonymised data. Additionally, a research team member presented and led discussion of the findings at a practice meeting where the primary care team also discussed PSIs identified through reviews of their patients’ records, as described below.

One GP from each practice was asked to conduct a patient record review using the TRM at 3 and 7 months (see Figure 5).\textsuperscript{17} The GP who conducted the review attended a two-hour training workshop delivered one-to-one by a facilitator (CC) using previously developed materials.\textsuperscript{11} It is important to indicate that the TRM was an intervention component and not an outcome measure: its purpose was to facilitate the identification of specific patient safety issues within each practice.

At each time-point, the reviewer was requested to apply the TRM\textsuperscript{17,21} to a minimum of 20 and maximum of 30 records from a high-risk group (aged $>75$ years), randomly selected from patients who had attended the practice during the previous three months. Records were first reviewed in order to detect whether they contained a “trigger”, defined as flags, occurrences or prompts that alert reviewers to potential errors and previously undetected adverse events (e.g., more than three consultations in seven days, hospital admission, repeat medication stopped).\textsuperscript{17} If a trigger was found, the record was reviewed in greater detail to determine whether the patient experienced any harm. Based on the definition used by De Wet and Bowie,\textsuperscript{17} harm was defined as “anything that happens as a result of interaction with health services that you would not want to happen to you or your relatives”. If no harm was detected, or the reviewer was unsure whether harm had occurred, they were advised not to record the incident. If harm was detected, the reviewer classified its perceived severity, and whether it was preventable and originated in secondary or primary care, using previously developed rating scales.\textsuperscript{11}

Participants completed a Trigger Review Summary Report (TRSR),\textsuperscript{11} a standardised form containing a summary of anonymised data on
the number of detected triggers, details of PSIs, and actions that were or should be taken as a result of the review.

Each intervention practice received 1,000 Euro for participating. All participants from control and intervention practices were entered into a draw for a 100 Euro voucher at study baseline and terminus.

Control practices.
All staff in control group practices were invited to complete the GP-SafeQuest\(^{18}\) at baseline and at the study’s terminus (see Figure 5). Feedback on their SC was provided at the conclusion of the study, with access to the intervention materials.

Outcome Measures

Safety climate.
The GP-SafeQuest was used to evaluate the impact of the intervention, with SC measured at the beginning and end of the study in all practices (see Figure 5).

Process evaluation.
Process outcomes of interest were: willingness of practices to participate; response rates to questionnaires; retention of control and intervention practices; and the intervention group’s views on the feasibility, usefulness, and sustainability of the intervention. Semi-structured interviews were conducted (see supplementary material for interview schedule (Appendix Two)) with between one and three members of each intervention practice team regarding their perceptions of the intervention and an end-of-study questionnaire was circulated to all members of the intervention practices. Purposive sampling was used to select interview candidates, in order to obtain perspectives from a range of healthcare professionals and practices. We aimed to interview at least one GP in each practice and, where feasible, others with nursing or administrative responsibilities.

Interviews were conducted by a human factors psychologist (POC) and General Practitioner (CC). The interviews were either carried out by phone or face-to-face, digitally recorded and then transcribed.
Final feedback questionnaire.
A feedback questionnaire was distributed for completion at the end of the study (see online supplementary material 2 (Appendix 2)).

Data Analysis

Safety climate questionnaire.
Descriptive statistics were used\textsuperscript{12} to report means and standard deviations of the five subscale scores and total scores on the GP-SafeQuest for each group at baseline and the study terminus. The effect size, regarding differences in pre-test and post-test subscale and total GP-SafeQuest scores, was computed.

Patient record review using TRM.
Descriptive analysis was carried out on the number of records reviewed, triggers identified, number and type of PSIs recorded, PSI severity, preventability and origin, and changes made following the review.

Feedback questionnaire.
Descriptive analysis was used to examine feedback questionnaire responses.

Interviews.
Interview transcripts were analysed using the Framework Method\textsuperscript{22} of thematic analysis which provided a structured process to summarise and explain the data. After two researchers independently coded three of the transcripts, a set of codes was agreed upon and grouped into clearly defined categories to form a working analytical framework which was then applied to all interviews by one researcher.

Results
Thirteen practices were invited to participate, eleven accepted (85%), and one (intervention group) withdrew at month 4 (after first chart review) when
the lead GP left the practice. Data from that practice were excluded from the analysis. The study ran from November 2016 to July 2017.

**Safety Climate Questionnaire**

The SC questionnaire staff response rate was 84.8% (39/46) for intervention practices and 77.8% (42/54) for controls at baseline and 78.3% (36/46) for intervention practices and 68.5% (37/54) for controls at the study terminus. Overall, the questionnaire was completed by 81% (range 42.9%-100%) and 73% (range 57.1%-100%) of practice staff at baseline and study terminus respectively.

At baseline, 35.8% (29/81) of respondents were in managerial roles (GP principal, practice manager), and 61.7% (50/81) had non-managerial positions (GP assistant/ locum/ trainee/ intern, practice nurse, administrator, pharmacist). At the study terminus, 32.9% (24/73) of respondents were in managerial positions; 63% (46/73) were in non-managerial positions.

Table 6 shows means, standard deviations, and differences in subscale and total SC scores, before and after the intervention. Across the two time-points, total SC scores increased for the intervention group, suggesting an improved safety climate (negative Cohen’s $d$), but fell slightly in the control group. Effect sizes for the intervention group were generally small to moderate, with the strongest differences (Cohen’s $d >0.6$) observed in the teamwork, safety systems and total SC scores of managerial staff.
Table 6. Means, standard deviations, and effect sizes of Safety Climate (SC) subscale and total scores calculated for control and intervention practices.

<table>
<thead>
<tr>
<th>Safety Climate scores: Control practices</th>
<th>Safety Climate scores: Intervention practices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1 Mean (SD)</td>
</tr>
<tr>
<td>Workload</td>
<td></td>
</tr>
<tr>
<td>Managerial</td>
<td>3.48 (0.93)</td>
</tr>
<tr>
<td>Non-managerial</td>
<td></td>
</tr>
<tr>
<td>Leadership</td>
<td>6.24 (0.86)</td>
</tr>
<tr>
<td>Teamwork</td>
<td>5.62 (0.93)</td>
</tr>
<tr>
<td>Safety systems</td>
<td>5.79 (0.65)</td>
</tr>
<tr>
<td>Total SC</td>
<td>5.52 (0.63)</td>
</tr>
</tbody>
</table>

Note: T1= pre-test (baseline), T2=post-test (end of study), d=Cohen’s d. *d represents the effect size of the difference between the scores at T1 and T2.
**Patient Record Review Using the TRM**

Overall, 188 records were reviewed across the two chart reviews; triggers were identified in 150 (79.8%). In total, 36 PSIs were identified: 19.1% (36/188) of records reviewed contained a PSI.

Table 7 shows the severity and preventability of PSIs identified: 13.9% resulted in prolonged, substantial or permanent harm, including hospitalisation, and 27.8% were deemed to have been less severe, with the potential to cause harm. A total of 19.4% of PSIs were judged to be preventable and originated in primary care.
### Table 7. Severity and preventability of patient safety incidents (n=36) as identified by trigger tool.

<table>
<thead>
<tr>
<th>Rating scale</th>
<th>Description</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Severity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Any incident with the potential to cause harm.</td>
<td>10 (27.8)</td>
</tr>
<tr>
<td>2</td>
<td>Mild harm, inconvenience, further follow-up or investigation to ensure no harm occurred.</td>
<td>13 (36.1)</td>
</tr>
<tr>
<td>3</td>
<td>Moderate harm: required intervention or duration for longer than a day.</td>
<td>8 (22.2)</td>
</tr>
<tr>
<td>4</td>
<td>Prolonged, substantial or permanent harm, including hospitalisation.</td>
<td>5 (13.9)</td>
</tr>
<tr>
<td><strong>Preventability</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Not preventable and originated in secondary care.</td>
<td>2 (5.6)</td>
</tr>
<tr>
<td>2</td>
<td>Preventable and originated in secondary care OR not preventable and originated in primary care.</td>
<td>10 (27.8)</td>
</tr>
<tr>
<td>3</td>
<td>Potentially preventable and originated in primary care.</td>
<td>17 (47.2)</td>
</tr>
<tr>
<td>4</td>
<td>Preventable and originated in primary care.</td>
<td>7 (19.4)</td>
</tr>
</tbody>
</table>
Table 8 details the most commonly identified types of PSIs, the most frequent being related to medication and monitoring.
Table 8. Frequency and details of main types of patient safety incidents \((n = 36)\) and the most common medications \((n = 21)\) implicated.

| PSI Characteristics | \( n \) (%)
|--------------------|---
| **Types of PSIs\(^a\)** |  |
| Medication | 21 (58.3%) |
| Monitoring | 15 (41.7%) |
| Diagnosis and diagnosing | 9 (25%) |
| Coding/record keeping | 7 (19.4%) |
| Investigations | 7 (19.4%) |
| Communication | 6 (16.6%) |
| Unclear/insufficient info to classify | 3 (8.3%) |
| **Medications most commonly implicated in PSIs\(^b\)** |  |
| Diuretics | 8 (38.1%) |
| ACEI/ARBs | 3 (14.3%) |
| Opiates | 3 (14.3%) |
| Antibiotics | 2 (9.5%) |
| Warfarin | 2 (9.5%) |
| Other hypoglycaemic agents | 1 (4.8%) |
| NSAIDs including aspirin | 1 (4.8%) |
| Not specified | 3 (14.3%) |

*Note:* \(^a\)Figures do not total to 36 as some PSIs fall within more than one of the categories. \(^b\)Figures do not total to 21 as more than one medication was implicated in the instance of some PSIs. ACEI= angiotensin-converting enzyme inhibitors, ARB= angiotensin II receptor blockers, NSAID= nonsteroidal anti-inflammatory drug.
Various actions were taken immediately or planned by the intervention practices, based upon their TRM findings. Immediate actions related predominantly to improvements in coding/record keeping (e.g., adverse drug event code added), prescribing (e.g., repeat blood tests for patients with repeat prescription), communication (e.g., community level referral pathway clarified for diabetic patients), and investigations (e.g., recall for overdue血液). The most common actions planned included feedback to colleagues (e.g., discussion of NSAID prescribing in renal impairment), management (e.g., more intensive monitoring of patients on repeat prescriptions), and updating or developing a protocol (e.g., updating warfarin prescribing protocol following ICGP guidelines).

**End-of-study Questionnaire**

Overall, we evaluated end-of-study questionnaires for 59% (27/46) of the intervention practice staff; the true response rate was probably higher as, due to an administrative error, some participants did not receive a questionnaire. Most respondents either agreed or strongly agreed that feedback on the SC survey and trigger tool chart audit was useful for improving patient safety (Table 9). Almost all (92.6%) agreed/strongly agreed that completing the survey helped them reflect on how patient safety was managed in practice.

Approximately half of respondents (55.5%) agreed/strongly agreed that changes were made based upon information obtained from the intervention. Two thirds of respondents (66.6%) agreed/strongly agreed that it had a positive effect on patient safety, while 74% agreed/strongly agreed that it was worth evaluating as a randomised controlled trial.
Table 9. Intervention practice responses \((n = 27)\) to statements in end-of study questionnaire

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback on the safety climate survey was useful for improving patient safety.</td>
<td>1 (3.7%)</td>
<td>2 (7.4%)</td>
<td>1 (3.7%)</td>
<td>15 (55.6%)</td>
<td>8 (29.6%)</td>
</tr>
<tr>
<td>Completing the survey helped me reflect on how we manage patient safety in this practice.</td>
<td>1 (3.7%)</td>
<td>-</td>
<td>1 (3.7%)</td>
<td>16 (59.3%)</td>
<td>9 (33.3%)</td>
</tr>
<tr>
<td>Feedback from the trigger tool chart audit was useful for improving patient safety.</td>
<td>1 (3.7%)</td>
<td>-</td>
<td>6 (22.2%)</td>
<td>12 (44.4%)</td>
<td>8 (29.6%)</td>
</tr>
<tr>
<td>Changes were made at this practice based upon the information obtained from this intervention.</td>
<td>1 (3.7%)</td>
<td>6 (22.2%)</td>
<td>5 (18.5%)</td>
<td>10 (37%)</td>
<td>5 (18.5%)</td>
</tr>
<tr>
<td>Overall, I believe that this intervention had a positive effect on patient safety at this practice.</td>
<td>2 (7.4%)</td>
<td>3 (11.1%)</td>
<td>4 (14.8%)</td>
<td>11 (40.7%)</td>
<td>7 (25.9%)</td>
</tr>
<tr>
<td>The effect of this intervention is worth evaluating as a randomised controlled trial.</td>
<td>2 (7.4%)</td>
<td>-</td>
<td>5 (18.5%)</td>
<td>13 (48.1%)</td>
<td>7 (25.9%)</td>
</tr>
</tbody>
</table>
Open-ended responses confirmed individuals’ Likert scale responses. A total of 19 of the respondents (70.4%) provided open ended responses. Written comments that the intervention allowed “reflection on current practice” and “prompted consideration of factors which put patients at higher risk”, suggested that respondents had considered the questions in relation to their personal work situation. Concerns included whether “it may engender negative feelings in practice whereby staff are not receptive to honesty”, and that “the volume of records [reviewed] were insufficient to make viable recommendations”. In order to improve the intervention, participants suggested that practices should “assign more time to partake in the study”.

Interviews
Nine members of the practice teams were interviewed across the four intervention practices, including: three principal GPs, three non-principal GPs, one practice nurse, and two administrators. Two interviews were carried out by telephone, and seven were conducted face-to-face. No invitees declined to be interviewed but not all who agreed were available at times convenient to the researcher and recruitment ceased when data saturation was considered to have been achieved. Interviews lasted approximately ten minutes. Three themes emerged from the analysis of interview data, with supporting quotes anonymised by the interviewee’s role (managerial/ non-managerial: M/NM) and participant number.

Benefits from the intervention.
Several interviewees considered that the intervention was helpful in raising awareness of safety issues, promoting learning and “beneficial for your own practice...and for your own patients” (NM1). One commented that the intervention “would cover areas that I suppose we mightn’t, you know, be aware of” (M1), and noted that it “highlighted things to us that we mightn’t have realised at all were issues”.

The SC survey was beneficial in providing a “voice” for more junior and non-managerial staff. Interviewees recognised that “it’s hard to raise concerns on a personal basis...it’s good to do this sort of thing
anonymously” (NM6) and commented on the tailored practice-level feedback: “it was good to see how you compared to other practices as well to use it as a benchmark” (NM3). Group discussions identified different approaches within practices, of primary care team members, to decision-making and patient management, that were previously unrecognised. Revelations of “where unnecessary work was being done and where gaps were being left” (NM4) were beneficial to organisational planning.

Changes and improvements in practice.

One interviewee reported how the intervention had indicated that “changes should be made……but that takes effort and time” (NM4). However, this perception of inaction was a deviant view: other interviewees, including others from the same practice, reported changes in practices’ processes and management. For example, “note taking got a bit better after house calls” (NM1), changes were made to protocols; “we were all actually using different protocols kind of to change the Warfarin dosage…we standardised that and we have it in now in our system” (NM3), “the prophylactic antibiotics given for UTI… are now changed to nitrofurantoin – because guidelines had changed” (NM6). The intervention encouraged clinical meetings in one practice and in another, there was a plan to “try to make discussions at those more inclusive” (NM5).

Acceptability and recommendations.

Most interviewees welcomed the intervention; one noted “I definitely think it’s worth it” (NM2), although a commonly perceived barrier was lack of time; “It was time intensive- with current workloads and demands on time it couldn’t be given a priority” (NM5), and that “many practices do not have the resources” (M3).

The general consensus was that the intervention was worth investigating in a larger trial and that evidence of its effectiveness would promote its use in routine practice. Comments revealed perceptions that the SC questionnaire “asked same basic questions in different ways” (NM4) but this was welcomed as it allowed opportunity to consider different situations within their responses. Also, comments indicated some uncertainty in
identifying PSIs: group discussion was valued in developing an agreed definition. Interviewees offered recommendations, such as, “... the [TRM] tool needs a few tweaks- it’s a good way of assessing how things go but thought should be given to giving it more rigour” (NM6) and, regarding the time required, “obviously that has to be reimbursed” (NM3).

Discussion
This novel study investigated the feasibility of determining the impact of an intervention, derived from the SPSP-PC, on the SC of primary care practices in two different health care systems, one with a mixed public/private economy and the other funded publicly. Within both these systems our findings regarding rates of recruitment, retention and completion, and evidence of potential positive impact suggest that a definitive trial is feasible. Only two practices declined to participate; one practice withdrew from the study, after the doctor leading participation left the practice, demonstrating the importance of a local “champion” to drive the intervention. The overall response rates to the SC (over 70%) and end-of-study questionnaires (59%) were encouraging: obtaining good response rates from GPs is challenging.

Our intervention group’s perceptions that the TRM was useful in improving patient safety concurred with previous reports. The number of PSIs, their severity, and the proportions considered preventable and originating in primary care were within the range of previous studies reporting TRM use in primary care; a recent systematic review reported an overall mean of 12.6 safety incidents (range: 2.3 to 26.5) per 100 records. However, caution should be taken in comparing numbers of PSIs between studies as differences may be attributable to different methodologies. The chart review in our study was used to identify areas for improvement: its reliability in assessing PSIs as a measure of patient safety cannot be determined as it was conducted by only one GP, with limited training, in each practice.

The intervention was generally well received but time was the main barrier to its use. Therefore, as previously suggested, there would be a need to incentivise participation and compensate practices for the time
required to participate in a definitive trial of the intervention. Such incentives could be financial, or alternatives may be identified by prospective trial participants. Particularly if the intervention is to be translated into routine practice, the issue of time allocation for its use must be considered.

In the control practices, changes in subscale and overall SC scores were either in the undesired direction or minimal but in intervention practices, all the changes in SC scores were in the desired direction, although the size of change varied across subscales. The mean scores we observed on the five SC subscales are broadly comparable to other studies which have used the GP-SafeQuest survey. Concurring with previous reports, managerial groups tended to have a more positive view of SC than had the non-managerial groups. Of note, amongst the intervention managerial group, the workload subscale had the lowest mean score. High workload is of particular concern given that it has been found to have a negative effect on patient care, doctor well-being, and is considered to be a major contributor to the recruitment and retention crisis facing UK general practice. There is a need for improved understanding of the contributors to workload in primary care and of its implications for patient safety.

Although it is widely agreed that a good SC is associated with safety, and that there is a relationship between safety culture and PSIs, the nature of the causal relationship between these variables is not well understood. Therefore, whilst we have identified a potential positive effect on SC from our intervention, which may be used to inform a sample size calculation for a definitive trial, other appropriate primary outcome measures of patient safety should also be considered. One such measure may be the change in the number of PSIs identified in an independent and blinded review of high-risk patient charts using the TRM. However, this outcome was not explicitly assessed in the current study and has limitations, particularly in terms of the required resources and recent European data protection regulations. These regulations require consent from patients for review of their records, or the records must be anonymised prior to review. Another interventional technique developed by the SPSP-PC, the safety
checklist for general practice,\textsuperscript{29} which offers a practical approach to the identification of potential hazards in the practice,\textsuperscript{37} may also be considered for use in further work.

**Limitations and strengths**
Consistent with recommendations that analysis of feasibility studies should be mainly descriptive, we did not conduct inferential statistics or hypothesis testing.\textsuperscript{11,38,39} Our sample size was pragmatic, aiming to include practices of diverse size and location, and from two different healthcare systems. There was a potential for selection bias to occur, as practices in which there is a greater focus on patient safety, and consequently an increased motivation to implement interventions to improve patient safety, may be more likely to choose to partake in the proposed study and this may impact upon intervention outcomes. Whilst there was a reliance on self-report (i.e., of SC and PSIs) rather than objective data, a strength of our study was that we preserved anonymity of all data, both within and between participating practices in order to minimise reporting bias.

**Conclusion**
We believe our feasibility study suggests that a novel definitive randomised controlled trial of an intervention to improve patient safety in primary care is warranted. Our findings suggest that the intervention we have tested is feasible, useful, and sustainable in two different healthcare systems but requires recognition of time required, particularly for reviewing records. There is evidence of a possible positive effect, practices were willing to be recruited, response rates were acceptable, and almost all participants remained for the duration of the trial. However, further consideration is required regarding the clinical significance of changes in SC scores and choice of an appropriate primary outcome measure.
References


36. European Parliament. Protection of natural persons with regard to the processing of personal data and on the free movement of such data, and


Chapter 5: Study 4
An analysis of General Practitioners’ perspectives on patient safety incidents using critical incident technique interviews
An analysis of General Practitioners’ perspectives on patient safety incidents using critical incident technique interviews

Declaration

Where This Fits in with the Thesis
While application of the TRM to patient records identified PSIs in primary care practices in the third study, the purpose of this fourth study was to analyse GPs’ perspectives of the contributory factors to PSIs in primary care through their accounts of lived experiences of PSIs in this setting. PSIs are common in primary care, occurring at a rate of 2-3% of consultations and thus, there is a pressing need to develop a better understanding of the contributing factors to PSIs in primary care. While incident reporting is considered to be the main method of investigating PSIs in primary care, it is limited by under-reporting and a failure to capture the human factors that contribute to the PSI. Furthermore, this study explored the use of the critical incident technique (CIT) interview approach in conjunction with the Yorkshire Contributory Factors Framework (YCFF) as a means of investigating PSIs in primary care and informs the ‘Integration and Learning’ dimension of the MMS framework.

Peer-reviewed Publication
This study has been accepted and published in a peer-reviewed journal. The citation is: Curran C, Lydon S, Kelly ME, Murphy AW, O’Connor P. An analysis of general practitioners’ perspectives on patient safety incidents using critical incident technique interviews. Fam Pract. 2019. https://doi.org/10.1093/fampra/cmz012
The following chapter is a formatted version of the submitted manuscript to the journal.
Conference Presentations

Oral Presentation

Curran C, Lydon S, Kelly ME, Murphy AW, O’Connor P. An analysis of general practitioners’ perspectives on patient safety using critical incident technique interviews. Association of University Departments of General Practice Ireland (AUDGPI)/ Irish College of General Practitioners (ICGP) Annual Scientific Meeting; 2018 Mar 9th, Galway (Ireland).

Authors’ Contributions

This study was led by CC. POC and CC designed and planned the study. CC recruited participants and carried out data collection. CC and POC carried out the data analysis. CC drafted the initial manuscript. All authors assisted with redrafting the manuscript and all authors reviewed and approved the manuscript prior to submission.

References


Abstract

Background
General Practitioners report difficulty in knowing how to improve patient safety.

Objectives
To analyse General Practitioners’ perspectives of contributing factors to patient safety incidents by collecting accounts of incidents, identifying the contributory factors to these incidents, assessing the impact and likelihood of occurrence of these incidents, and examining whether certain categories of contributory factors were associated with the occurrence of high-risk incidents.

Methods
Critical incident technique interviews were carried out with 30 General Practitioners in Ireland about a patient safety incident they had experienced. The Yorkshire Contributory Factors Framework was used to classify the contributory factors to incidents. Seven subject matter experts rated the impact and likelihood of occurrence of each incident.

Results
A total of 26 interviews were analysed. Almost two thirds of the patient safety incidents were rated as having a major to extreme impact on the patient, and over a third were judged as having at least a bimonthly likelihood of occurrence. The most commonly described active failures were “Medication Error” (34.6%) and “Diagnostic Error” (30.8%). “Situational Domain” was identified as a contributory domain in all patient safety incidents. “Communication” breakdown at both practice and other healthcare-provider interfaces (69.2%) was also a commonly cited contributory factor. There were no significant differences in the levels of risk associated with the contributory factors.

Conclusions
Critical incident technique interviews support the identification of contributory factors to patient safety incidents. There is a need to explore the use of the resulting data for quality and safety improvement in general practice.

Keywords
Critical incident technique; doctor-patient relationship; family practice; interviews; patient safety incidents; primary care.

Conflict of interest
The authors report no conflict of interest.

Acknowledgements
I would like to thank all the GPs who consented to participate in this interview process.

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Chapter 5

Introduction

It is estimated that 2-3% of all primary care consultations contain a patient safety incident (PSI)- defined as any unintended or unexpected incident(s) that could have or were judged to have led to patient harm.\(^1\) Given that approximately 90% of all healthcare contacts occur in primary care,\(^2\) there is a large potential for iatrogenic harm. Thus, there is a need to examine the contributory factors to PSIs in primary care, in order to improve the quality and safety of primary healthcare delivery.

PSI research in primary care has been dominated by the analysis of data from reporting systems.\(^3\) These systems provide valuable data on threats to patient safety.\(^4\) However, they have limitations including under-reporting of incidents,\(^5\) a failure to adequately capture the factors that contribute to PSIs,\(^6\) the resources required for operation, and reluctance among many healthcare providers to report PSIs.\(^7\)

Although the data from reporting systems provides a broad overview of the factors that contribute to PSIs, it does not support providers to improve the specific safety issues they have within their own practices. Moreover, given that primary care providers have reported difficulty in understanding how best to improve patient safety in their practices,\(^8\) there is a need to consider how providers can be supported to reflect and learn from PSIs that have occurred within their own practice, and explore how latent factors (e.g., safety systems, policies) may have contributed.\(^9\)

The purpose of this paper is to systematically explore and analyse general practitioners’ (GPs) perspectives of the factors that contribute to PSIs in general practice, using critical incident technique (CIT) interviews. The specific objectives of this study were to: i) collect accounts of PSIs experienced by GPs; ii) identify the contributory factors to these PSIs; iii) assess the impact and likelihood of occurrence of these PSIs, and; iv) examine whether certain categories of contributory factors were associated with the occurrence of high-risk incidents.

Methods

This qualitative narrative research study was conducted and reported in accordance with the Standards for Reporting Qualitative Research.\(^11\)
Setting and Ethical Approval
Ethical approval was obtained from the Irish College of General Practitioners’ Research and Ethics Committee. Participants were GPs practicing in Ireland.

Participants and recruitment
Sampling was carried out using judgement (participants were sought on the basis of their professional clinical experience in general practice\textsuperscript{12}) and snowballing (i.e., participants disseminated information on the study via word of mouth to colleagues who they considered would be able to participate\textsuperscript{13}) methodologies to ensure adequate representation of the diversity of practicing Irish GPs in terms of age, position, gender and experience. Recruitment efforts were focused within the Western Research and Education Network (WestREN), which is broadly representative of the national profile of GPs in Ireland.\textsuperscript{14} Information on the study was also shared with GPs at continuing education events. The use of a snowball sampling approach also allowed information on the study to be disseminated to GPs outside of the network. Participation required informed consent, and was not incentivized.

Interview Design and Procedure
CIT interviews were used to elicit a detailed and rich description of GPs’ lived experiences of PSIs, and to explore potential contributory factors. The CIT interview is a type of cognitive interview used to identify tacit knowledge about specific events in a high-risk work environment.\textsuperscript{15} The CIT interview has been widely used in studies of human error and safety.\textsuperscript{15}

The CIT interview technique utilises a process rather than an interview schedule. The focus is on a participant’s description of one specific incident and the interviewer works to enrich the initial summary provided by soliciting further information and pertinent detail. There are four stages to a CIT interview: (i) selecting an appropriate incident; (ii) developing a detailed description of specific events using probing questions to understand the rationale; (iii) exploring cues and reasoning for the actions
taken by team members; and (iv) identifying the root causes of the incident using a series of probing questions.15

The probing questions were derived from the Yorkshire Contributory Factor Framework (YCFF), an evidence-based system for classifying the underlying contributory factors to PSIs occurring in healthcare.16 A contributory factor may be understood as any “influencing and causal factors” that contributed to a PSI. The YCFF was specifically developed based on evidence collected from healthcare settings.16 It includes 20 factors divided across six domains (active failures, situational factors, local working conditions, latent/organisational factors, latent/external factors, and general factors). There are two general factors comprising of communication systems and safety culture which can potentially interact with the other five domains.16 Examples of probing questions used included: “was there any features of this task (e.g., difficult, unfamiliar, monotonous) that made this incident more likely to happen?” and “on the day of the incident, how were you feeling prior to the incident (e.g., stressed, distracted)?”

Data Collection
Interviews were completed between September and December 2017. The interviewer was a female GP (CC). A GP interviewer may have facilitated participants to feel comfortable disclosing PSIs given the shared understanding that existed. However, this may also have influenced the reflexivity of the interviewer who had her own prior experiences of PSIs and an interest in this area.

The interviews were conducted either in person (n = 10) or via telephone (n = 20) and were recorded using a digital audio recorder. The participant information sheet read: “prior to the interview you will be asked to think about a specific incident which you were involved with as a general practitioner, where you felt patient safety was, or had the potential to be compromised”. These instructions were repeated prior to the interview in order to guide participants in their selection of an appropriate incident for discussion. Participants were also cautioned that they should anonymise the PSI described, and that they should not describe dangerous or negligent
practices as interviewer confidentiality could not be guaranteed in such instances. Finally, participants were offered two examples of PSIs, comprising a medication error and a failure to follow up on a blood test that resulted in a near miss.

Throughout each interview, the interviewer generated field notes relating to the PSI, and these notes were relayed to the participants for further clarification or correction during the interview. This process allowed the events to be put into chronological order and repetitions omitted. These field notes also offered a useful platform for generating effective probing questions.

The mean duration of interviews was 24.5 minutes ($SD = 8.7$). Interviewing continued until new categories, themes or explanations stopped emerging and it was judged that data saturation had been reached.

**Data Analysis**

Of the thirty interviews collected, four were discarded from further analysis because the PSI did not originate in primary care ($n = 3$) or the interviewee was not directly involved in the PSI ($n = 1$). The unit of analysis was each of the remaining 26 PSI descriptions.

The recording and field notes were used to develop a single, rich description of the PSI, essentially the “story” of the PSI. The interviews descriptions were “edited” into a standard format that was concise, clear and comparable across the interviews for content analysis. The transcript was not verbatim but instead comprised a chronological account of the incident and included mention of any contributory factors that had arisen. This approach is typical of how CIT interviews are transcribed.15

**Content Analysis**

To ensure rigour and trustworthiness of the data, content analysis was performed equally by two researchers from different professional backgrounds: CC (a qualified GP with an interest in patient safety) and POC (a human factors psychologist). No software was used to support the analysis. The researchers annotated printed copies of each PSI description as they worked through the content analysis process. The healthcare-based
YCFF\textsuperscript{16} was used as the initial framework for classifying the factors that contributed to the PSIs. Although a protocol was published in 2015 describing an approach to adapting the YCFF specifically for the primary care setting, the primary care-adapted version of the YCFF\textsuperscript{17} has yet to be published. Therefore, a deductive content analysis approach\textsuperscript{18} was taken to analyse the interview data in order to make adaptions to the published YCFF\textsuperscript{16}.

It was found that the YCFF was appropriate for analysing the data, with only two adaptions required to classify the factors from identified in the CIT interviews: (i) “scheduling and bed management” was changed to “scheduling”; and (ii) “support from other departments” was changed to “support from other service providers”.

In order to ensure the classifications were adequately internally homogenous and externally heterogenous, the factors and definitions were exemplified with sample behaviours extracted from the interview data. For each PSI description, the two coders discussed each incident and consensus was reached on the categorisation of the contributory factors.

**Ratings of Impact and Likelihood**

Seven subject matter experts (SMEs) rated the risk to patients associated with each of the 26 PSIs and the likelihood of other GPs encountering a similar incident. SMEs were selected on the basis of substantial clinical experience in general practice and an expressed interest in quality and safety in primary care. The SMEs were all qualified GPs practicing in Ireland ($n = 4$ male; $n = 3$ female) with a mean of 14 years working as a GP ($SD = 9.18$). Four of the SMEs served as GP principals (57.1%), two as GP Assistants (28.6%), and one as a Lecturer in General Practice (14.3%).

Each PSI description was summarised for distribution to the SMEs. The PSI descriptions were presented to the SMEs in a random order. For each PSI, the SMEs rated the potential impact of the incident on patient safety on a five point scale from 1 ("negligible") to 5 ("extreme"), and the likelihood of other GPs encountering a similar incident from 1 ("rare/remote") to 5 ("almost certain").
The “impact” and “likelihood of occurrence” ratings from each PSI description were multiplied together to give an overall risk score. A risk rating of less than 5 was considered “low risk”, between 5 and 12 “medium risk” and greater than 12 “high risk”. The modal risk score of the seven SMEs was calculated for each PSI description. Fisher’s exact test was utilized to compare the frequency with which the categories of contributing factors (i.e., latent organizational factors, local working conditions etc.) were identified based upon level of risk.

Results

Participants
PSI descriptions contributed by 26 participants were included. Of these participants, 13 were female (50%) and 13 were male (50%). Twelve participants served as a principal GP (46.2%), 10 served as an Assistant GP (38.5%), three served as Locum GPs (11.5%), and one as a GP trainee (3.8%). Mean years since qualification as a GP was 12.6 (SD = 10.2). Twenty-two (84.6%) of the participants were based in WestREN practices, whereas four (15.4%) worked at practices elsewhere in Ireland.

Content Analysis
The findings from the content analysis are described using the six contributory factor domains of the YCFF (active failures, situational factors, local working conditions, latent/organisational factors, and latent/external factors, and general factors).

Active failures.
Table 10 outlines the initial active failure that led to the PSI in all of the included scenarios. Of the 26 PSI descriptions, the most common failures identified included medication errors (n = 9; 34.6%) and diagnostic errors (n = 8; 30.77%).
Table 10. Active failures ($n = 26$) data from critical incident technique interviews collected September to December 2017.

<table>
<thead>
<tr>
<th>Types of Error</th>
<th>Definitions</th>
<th>$n = 26$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication Error</td>
<td>Any error that occurred in the medication management system in primary care</td>
<td>9 (34.6%)</td>
</tr>
<tr>
<td>Prescribing</td>
<td>Errors in prescription or prescribing</td>
<td>3 (11.5%)</td>
</tr>
<tr>
<td>Dispensing</td>
<td>Dispensing error identified by GP or pharmacist prior to patient receipt of medication</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td>Administration</td>
<td>Any deviation between medication as prescribed and that administered or potential adverse drug event due to patient errors during medication use</td>
<td>3 (11.5%)</td>
</tr>
<tr>
<td>Monitoring</td>
<td>Medication not monitored in way that would be considered to be routine general practice</td>
<td>1 (3.8%)</td>
</tr>
<tr>
<td>Diagnostic Error</td>
<td>Error made in diagnosis</td>
<td>8 (30.8%)</td>
</tr>
<tr>
<td>Missed</td>
<td>No diagnosis ever made</td>
<td>3 (11.5%)</td>
</tr>
<tr>
<td>Delayed</td>
<td>Diagnosis was unintentionally delayed</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td>Wrong</td>
<td>Another diagnosis was made before a correct one</td>
<td>3 (11.5%)</td>
</tr>
<tr>
<td>Failure to follow up on result</td>
<td>Failure to follow up on result of investigation (e.g. blood, histology, urine etc.)</td>
<td>6 (23.1%)</td>
</tr>
<tr>
<td>Patient non-compliance</td>
<td>Patient not following prescribed course of medication or treatment</td>
<td>2 (7.7%)</td>
</tr>
<tr>
<td>Failure to monitor patient</td>
<td>Failure to check on a patient’s condition</td>
<td>1 (3.8%)</td>
</tr>
</tbody>
</table>
Table 11 provides definitions, and identified examples, of each the remaining five contributory factor domains of the YCFF. Specific examples for each factor, and illustrative quotes from the interviews, are provided in Supplementary Material 1(Appendix 3).
Table 11. Contributing factors to patient safety incidents with identified examples.

<table>
<thead>
<tr>
<th>Factors and definitions</th>
<th>Identified examples</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Situational Factors (n = 26, 100%)</strong></td>
<td></td>
</tr>
<tr>
<td>Service user factors (n = 22, 84.6%)</td>
<td>Difficult historian; frequent attender; ‘Doctor- Shopper”; “Door-stepper”; complex medical history; polypharmacy; recently discharged from hospital; paediatric patient; infrequent attender; new or unfamiliar patient; upset patient; language barrier; poor access to GP</td>
</tr>
<tr>
<td>Task characteristics (n = 22, 84.6%)</td>
<td>Monotonous task; difficult task; unfamiliar task</td>
</tr>
<tr>
<td>Individual staff factors (n = 17, 65.4%)</td>
<td>Stressed; rushed; distracted; inexperienced; isolated; overconfident; gatekeeper; managing patient expectations</td>
</tr>
<tr>
<td>Team factors (n = 9, 34.6%)</td>
<td>Delegation to inappropriate staff; conflicting team goals</td>
</tr>
<tr>
<td><strong>Local Working Conditions (n = 14, 53.8%)</strong></td>
<td></td>
</tr>
<tr>
<td>Workload &amp; staffing Issues (n = 11, 42.3%)</td>
<td>High unit workload; insufficient staff; staff sickness</td>
</tr>
<tr>
<td>Leadership, supervision &amp; role (n = 9, 34.6%)</td>
<td>Remote supervision; inappropriate delegation; unclear responsibilities</td>
</tr>
<tr>
<td>Drug, equipment &amp; supplies (n = 5, 19.2%)</td>
<td>Inadequate maintenance of drugs; unavailable drugs; equipment not working or available; inappropriate storage of drugs or equipment</td>
</tr>
<tr>
<td><strong>Latent Organisational Factors (n=21, 80.8%)</strong></td>
<td></td>
</tr>
<tr>
<td>Support from other service providers (n =11, 42.3%)</td>
<td>Lack of support from laboratory; lack of support from secondary care team (e.g. psychiatry, medical or surgical departments); lack of support from pharmacy; lack of support from primary care provider.</td>
</tr>
<tr>
<td>Scheduling (n = 10, 38.5%)</td>
<td>“Walk-ins”; house-call request; emergency department referrals; lack of access to secondary care teams</td>
</tr>
<tr>
<td>Local Policies or Protocols (n = 10, 38.5%)</td>
<td>No protocol existed; protocol was too complicated</td>
</tr>
<tr>
<td>Physical Environment (n = 6, 23.1%)</td>
<td>Unfamiliar practice set-up; out-of-hours; practice location; poor set-up</td>
</tr>
<tr>
<td>Staff Training or Education (n = 1, 3.8%)</td>
<td>Staff were not trained to perform the task</td>
</tr>
<tr>
<td><strong>Latent/external factors (n=9, 34.6%)</strong></td>
<td></td>
</tr>
<tr>
<td>Design of Equipment, Supplies &amp; Drugs (n=6, 23.1%)</td>
<td>Similar drug names, but different dosages per volume; ambiguous labelling and packaging; results from laboratory which were abnormal, but were not flagged in red</td>
</tr>
<tr>
<td>Physical Environment (n = 6, 23.1%)</td>
<td>National Guideline Protocol; Irish Government Drug Reimbursement Scheme (Government-funded incentive to prescribe generically)</td>
</tr>
<tr>
<td><strong>General factors (n=19, 73%)</strong></td>
<td></td>
</tr>
<tr>
<td>Communication (n = 18, 69.2%)</td>
<td>Poor communication between practice staff; poor communication between practice/pharmacy; poor communication between practice/patient; lack of information in patient notes; poor communication between primary-secondary care</td>
</tr>
<tr>
<td>Safety culture (n = 5, 19.2%)</td>
<td>Poor attitude to risk management</td>
</tr>
</tbody>
</table>
Organisational values, beliefs, and practices
surrounding the management of safety and learning
from error.
Chapter 5

Situational factors.
The “situational factors” domain was identified as a contributory factor in all scenarios ($n = 26, 100\%$; see Table 11). Within this domain, there were two commonly identified factors: “service user factors” and “task characteristics” (see Table 11). There were thirteen identified examples of “Service User Factors”. These included both “frequent attender”,
“patient was a frequent attender of Out-of-Hours Services and medical outpatients, which resulted in a lot of correspondence and prescriptions” (GP6),
and “infrequent attender”,
“this patient was a frequent non-attender despite needing increased medical input because of his co-morbidities.” (GP27).

For the “task characteristic” factor, monotonous tasks were the most frequently identified factor,
“There are lots of minor abnormalities in blood tests. It is a monotonous task” (GP2).

Latent/organisational domain.
This domain was also a commonly identified contributory factor and within this domain “support from other providers’ was the most frequently identified contributory factor (see Table 11). Examples of providers from which lack of support was noted include the laboratory, secondary care, community pharmacies and primary care. To illustrate,
“I was disappointed the pharmacy hadn’t picked up on it” (GP14).

Latent external factors.
The “latent external factors” domain was the least frequently identified and encompasses external factors such as “national policies” or the “design of equipment, supplies or drugs” (see Table 11). To illustrate,
“the containers themselves are in similar looking and similar sized plastic bottles. Only from the front can the containers be identified as different” (GP13).

Local working conditions.
The “local working conditions” domain was identified in approximately half of the interviews (see Table 11). Within this domain, “workload and staffing issues” was the most prevalent contributory factor. For example, “(I) see more than 40 patients per day…strong tradition of house calls at lunch…lunch consisted of a sandwich in the car” (GP9).

**General factors.**

Within the “general factors” domain, “communication” was a commonly identified factor (see Table 11). Examples of poor communication were identified both within the practice and with other organisations (e.g., pharmacy), among practice staff, practice and pharmacy, practice and patient, practice and secondary care and also written communication in terms of medical records. To demonstrate, “notes were variable. It was difficult to see when the drugs were started and stopped and the reasons why” (GP29).

**Ratings of Impact and Likelihood**

The majority (62.6%) of PSIs were rated by subject matter experts as having a major to extreme impact on the patient (see Table 12). Almost a third of PSIs (30.8%) were rated as having a bimonthly or 75% probability of likelihood of occurrence (see Table 12).

The modal risk score was “high” for eight of the scenarios, and “medium” for 18 of the PSIs. No PSIs were judged to be “low” risk. The frequency with which different categories of contributory factors were identified for high and medium-risk PSIs were compared via Fisher’s exact test\(^\text{19}\) to ascertain if there were any differences. No differences emerged.
Table 12. Distribution of subject matter expert ratings relating to the impact of incidents on patient safety and likelihood of occurrence in general practice.

<table>
<thead>
<tr>
<th>Impact</th>
<th>Percentage (proportion of ratings)</th>
<th>Likelihood</th>
<th>Percentage (proportion of ratings)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Negligible</strong></td>
<td>0.1% (12/182)</td>
<td>Rare/Remote</td>
<td>0.01% (2/182)</td>
</tr>
<tr>
<td>(Adverse event leading to minor injury not requiring medical intervention; No impaired psychosocial functioning)</td>
<td></td>
<td>(Occurs &gt;5 years or more; 1% probability)</td>
<td></td>
</tr>
<tr>
<td><strong>Minor</strong></td>
<td>12.1% (22/182)</td>
<td>Unlikely</td>
<td>0.1% (18/182)</td>
</tr>
<tr>
<td>(Minor injury or illness, medical intervention required; impaired psychosocial functioning &lt;1 month)</td>
<td></td>
<td>(Occurs every 2-5 years; 10% probability)</td>
<td></td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>18.7% (34/182)</td>
<td>Possible</td>
<td>51.6% (94/182)</td>
</tr>
<tr>
<td>(Significant injury requiring medical intervention or hospital stay or impaired psychosocial functioning &gt;1 month; Impaired psychosocial functioning capacity &gt; 6 months)</td>
<td></td>
<td>(Occurs every 1-2 years; 50% probability)</td>
<td></td>
</tr>
<tr>
<td><strong>Major</strong></td>
<td>39.0% (71/182)</td>
<td>Likely</td>
<td>30.8% (56/182)</td>
</tr>
<tr>
<td>(Major injuries or long term incapacity requiring medical treatment and or counseling; Permanent psychosocial functioning incapacity)</td>
<td></td>
<td>(Bimonthly; 75% probability)</td>
<td></td>
</tr>
</tbody>
</table>
Extreme (Incident leading to death or major permanent incapacity) 23.6% (43/182)  
Almost Certain (At least monthly, 99% probability) 0.1% (12/182)  

Note: “The denominator is derived from the 7 subject matter expert ratings for each of the 26 scenarios (total n for analysis= 182)
Discussion
This paper systematically explored and analysed GPs’ perspectives of the factors that contribute to PSIs in general practice using CIT interviews. The resulting data elucidate the nature of PSIs occurring in primary care, indicate the factors that appear to commonly contribute to the occurrence of PSIs, and suggest that CIT interviews used in this manner may be of use in informing safer care in general practice.

Key Findings and Comparison with Existing Research
Consistent with previous research, the most commonly identified active failures identified from the interviews were medication and diagnostic errors.\(^{20}\) It has been recommended these types of errors should be addressed.\(^{1,20}\) However, there is a lack of awareness of the causes.\(^5\) Our study has identified many contributory factors to PSIs in primary care, which may offer educational opportunities and targets for the design and implementation of patient safety strategies to reduce avoidable patient harm. It is suggested this could be done at the level of a practice, or group/cluster of practices, by sharing the accounts, and analysis of these types of PSIs.

Primary care has become increasingly vulnerable to error due to the increasing complexity of patients.\(^{20}\) The most challenging patient factors identified in our study included treating “new or unfamiliar patients”. Although an ongoing therapeutic relationship between patient and a specific GP has been shown to improve patient care,\(^{21}\) increasingly patients visit multiple GPs either within the same practice or across different practices.\(^{21,22}\) Future research should explore the impact of continuity of care on patient safety.

Communication failures were a commonly described contributory factor to PSIs in our study. Communication between healthcare providers relies on accurate medical record-keeping or “informational continuity”. However, accurate medical record is often given a low priority.\(^{22}\) Barriers to “informational continuity” include GPs not recording information shared by patients in the medical records, which is often due to time pressures and patients not disclosing important details due to a lack of knowledge about what GPs perceive as important.\(^{23}\) Future research should focus on the
quality and methods of maintaining informational continuity from GPs’ and patients’ perspective in order to maximise consistent, coherent and safer patient care.

Scheduling of appointments was another commonly identified organisational contributory factor. Managing requests for “same-day” appointments has been shown to be a significant cause of stress for GPs.\textsuperscript{24} Despite doctor fatigue increasing the potential for error,\textsuperscript{25} there is a paucity of research around “safe” levels of working.\textsuperscript{26} In Ireland, most GPs see 30 or more patients a day. There is an urgent need to balance patient expectations with research required to identify a realistic safe limit to individual GP workload in order to ensure delivery of high quality and safe patient care.

**Using Critical Incident Technique Interviews to Study Safety in General Practice**

The data collected in this study suggests that CIT interviews- used in conjunction with a structure such as the YCFF- provide an approach for capturing, and understanding the less visible social processes of inquiry, investigation and improvement that unfold around PSIs.\textsuperscript{27} Our study has demonstrated that, with minor adaptations, the YCFF can be adapted to identify the factors contributing to PSIs in primary care. It could provide a structured approach for primary care practices, and regulators, to investigate and learn from PSIs, as well as drawing comparisons between primary and secondary care. Future research exploring its use in the analysis of PSIs occurring in general practice is warranted.

This study has provided useful data to support an improved understanding of the nature and causes of PSIs in general practice. Future research might usefully establish whether this data is valuable in informing quality and safety improvement efforts. The next stage is to evaluate whether the information could be used by GPs to then identify strategies to improve patient safety.\textsuperscript{7} Prior research suggests that this is something that GPs are competently able to do once the issues have been identified.\textsuperscript{28,29} It is suggested that the approach to collecting and analysing CIT used in this paper could be used by GPs in a particular practice, or group of practices, to
identify areas for improving safety. It is recognised that this study was conducted as a research project. There is a need to consider how our approach could be used as a quality improvement method within a specific GP practice, or group of practices. Some training and guidance would be required on how to conduct and analyse the CIT interviews. However, there is not a clearly identified model for how to train practice members carry out and analyse the CIT interviews (e.g., who should conduct the CIT, what triggers the need for a CIT, the willingness to share the findings from the CIT interviews). Therefore, there is a need to consider how to train GPs to use this approach, and evaluate whether the data led to improvements in patient safety in the practice.

**Strengths and Limitations**

The primary strength of this study is the use of qualitative approach to allow for the elaboration of contextual contributing factors, rather than merely how often they occur - as is typically reported in incident monitoring systems commonly used in General Practice settings internationally. However, a number of limitations should also be noted. The CIT interview could be criticized due to the potentially biased nature, of participants’ reports. However, Macrae argues that although such biases are a weakness in terms of epidemiological measurement, they can be strengths in terms of safety management by allowing specific issues to be subjected to increased scrutiny. There is also the potential for subjectivity in the reporting and analysis of the data. In order to address these potential issues, a rigorous approach was taken to both the data collection, and analysis. Since the CIT interviews were based on specific incidents as recalled by the GPs who participated, it is possible that they may not be representative of typical PSIs. However, the ratings of the likelihood of the PSIs by the SMEs would suggest that these are not atypical or uncommon occurrences.

**Conclusion**

Due to the large volume of primary care consultations, there is considerable potential for iatrogenic harm. Our data emphasise that contributory factors to PSIs in general practice can be readily identified. Knowledge of these
contributory factors is useful for creating awareness surrounding types of patients or circumstances that appear more frequently associated with errors, so that greater care can be taken in these instances. The approach described in the paper to identifying contributory factors to PSIs also has the potential to provide GPs with the information they need to address the most common and most serious errors occurring in their practice in order to maximise learning from these incidents and improve patient safety.
References


Chapter 6
General Discussion
Introduction
This thesis addresses how patient safety can be measured, monitored, and improved in primary care. The purpose of this thesis was to consider what are the general issues for improving patient safety in primary care and to determine if measures to assess the dimensions of “Anticipation and Preparedness” and “Integration and Learning” of the MMS Framework\textsuperscript{1,2} can be used to improve patient safety in primary care. “Anticipation and Preparedness” refers to the ability of healthcare staff to anticipate and assess potential hazards, which may threaten patient safety and take action to reduce the risk of future patient harm. “Integration and Learning” refers to the ability of a healthcare organisation to analyse and learn from safety and quality information at a practice level. The rationale for focusing on these two dimensions was the limited research in both of these dimensions in primary care currently.\textsuperscript{3–5} Furthermore, there is a growing appreciation of the importance of developing our understanding of “leading indicators” of safety, defined as valid and reliable precursors, conditions, events or measures before an incident has occurred.\textsuperscript{6} Proactive safety assessment methods are becoming increasingly commonplace in primary care.\textsuperscript{3} However, in order to improve safety there is a need to guide researchers and practitioners on the most effective methods to proactively measure safety in this setting.\textsuperscript{3–5} Scholars in the field have asserted that little is actually known about how to improve quality and safety across healthcare settings.\textsuperscript{7,8} One of the principal methodological weaknesses is the use of poorly validated measurement instruments, and the use of subjective measures of QI success.\textsuperscript{8}

This final chapter of the thesis will summarise the results of the four studies reported in this thesis. These studies will then be considered using the Moray et al\textsuperscript{9} healthcare socio-technical model to frame the assessment, and implications for improving the application of patient safety initiatives in primary care, derived from this thesis.
Overview of Studies

Study 1 (Chapter 2): A systematic review of primary care safety climate survey instruments: their origins, psychometric properties, quality and usage.

SC measurement is the most common method of proactively assessing safety in primary care. A systematic review of primary care SC survey instruments was conducted to establish the validity and reliability of these instruments and to provide guidance to researchers and practitioners on the selection of the most accurate, reliable and useful SC survey instruments for the primary care setting.

Of the 17 survey instruments identified, only one instrument had been developed de-novo by researchers for use in primary care. The other 16 instruments included in the review, were derived from two main US hospital-based surveys (SAQ and HSOPS). Adapting instruments which were specifically developed for use in secondary care, for use in primary care, was found to lead to issues with validity and reliability. Firstly, there was limited psychometric assessment of many of the SC instruments used in the primary care setting, which had been initially developed for assessment of SC in secondary care and this generated issues with reliability. Secondly, more relevant and context-specific SC domains to primary care (e.g., workload in primary care) were excluded from many survey instruments, which were originally secondary care-based and this had implications for the validity of results. However, this review has reported that some SC surveys have demonstrated more evidence of validity and reliability than others and therefore, can provide useful information to primary care practitioners to guide proactive safety improvement.

Study 2 (Chapter 3): Perceived safety climate in Irish primary care settings- a comparison with Scotland and England.

The second study in this thesis compared perceptions of SC in Irish primary care with those in England and Scotland using the PC-SafeQuest-a SC measurement instrument specifically designed for primary care.
In the Irish sample, there was generally a positive perception of perceived SC among respondents. When comparing SC across professional roles, Irish GP principals perceived a more negative impact of workload on safety than administrative staff, which may be a reflection of burnout. Overall, perceived SC in Irish primary care was found to be broadly comparable to England\textsuperscript{13} and Scotland\textsuperscript{14}. Across all three samples, workload received the lowest SC domain scores and thus, was perceived to have the potential to negatively affect patient safety. In summary, this project has highlighted the adverse impact of workload on patient and doctor safety and further research is recommended to further explore and address the contributors to workload in primary care. This study also demonstrated that the PC-SafeQuest can be used to compare attitudes towards SC across professional roles, and between different healthcare systems.

**Study 3 (Chapter 4): Safety in primary care (SAP-C): A randomised, controlled feasibility study in two different healthcare systems.**

The third study described a feasibility study of a randomised controlled trial of a primary care patient safety intervention, which was developed previously by Scottish Patient Safety Programme in Primary Care (SPSP-PC\textsuperscript{15}). The intervention involved the use of proactive safety assessment methods—serial SC measurement and use of Trigger Review Method (TRM). For the purpose of this thesis, the main area of interest was the use of the SC questionnaire and TRM and to inform learning.

A GP in each of the five participating practices was trained to carry out the TRM. Of the 188 patient record reviewed, 39 PSIs (13.9\%) were deemed to have caused severe patient harm (prolonged, substantial or permanent harm including hospitalization) and 36 (19.4\%) of the harm were considered to be preventable and originated in primary care. Based on the findings of the TRM, quality improvement actions were undertaken by GP practices either immediately, while conducting the record review (e.g., adverse drug event coded) or were planned (e.g., updating or developing a protocol). Serial SC measurements for both control and intervention practices reported the lowest mean SC domain score for workload. As part
of the evaluative process of the intervention, semi-structured interviews and end-of-study questionnaires were conducted with members of staff from the intervention group. At the end of the study, staff from the intervention practices were generally positive in their post-intervention evaluation and staff reported that SC survey participation had increased their awareness of patient safety. However, it was TRM participation that had resulted in most benefit in terms of quality improvement and the implementation of changes at practice level. Therefore, the participants were positive about the feasible and acceptability of the intervention (particularly the TRM). However, the challenges of evaluating and improving safety in a busy primary care practice were also very clearly stated.

**Study 4 (Chapter 5): An Analysis of General Practitioners’ perspectives on patient safety incidents (PSIs) using critical incident technique (CIT) interviews.**

PSIs are common in primary care and given the sheer volume of healthcare interactions in this setting, there is substantial potential for patient harm. While much information has been gathered from analysis of incident reporting of PSIs, it has a number of limitations (e.g., under-reporting). Moreover, GPs have reported difficulty in understanding how best to improve patient safety at a practice level. Thus, there is a need to consider how GPs can be supported to reflect and learn from PSIs that have occurred within their own practice.

This final study systematically explored and analysed GPs’ perspectives of contributory factors to primary care PSIs, using CIT interviews. CIT interviews, when used in conjunction with a structured approach such as the Yorkshire Contributory Factors Framework (YCFF), identified common contributory factors to primary care PSIs, which may offer educational opportunities and targets for the organizational improvement (e.g., scheduling appointments) to improve patient safety. Therefore, the CIT interview method could also potentially provide GPs with a structured approach to investigate and learn from PSIs at a practice level in order to improve patient safety.
Overall Implications and Recommendations

The findings from the four studies reported in this thesis demonstrated that the safety assessment methods evaluated (i.e., SC measurement, TRM, and CIT interviews) can support the identification, measurement, and improvement of patient safety in primary care setting. However, although these methods have the potential to inform the improvement of patient safety in primary care, barriers to the implementation of the patient safety interventions, were also identified. To summarise and organise the issues with measuring and improving safety within primary care, the implications and further recommendations from the research reported in this thesis will be discussed using Moray et al’s socio-technological systems model (see Figure 1; chapter 1 for a more detailed discussion of this model).

Societal, Cultural and Regulatory Influences

From a societal viewpoint, there is a workforce crisis in primary care in both the UK and Ireland. In the UK, 71% of GPs cited workload as the main factor that negatively impacted on their personal commitment to a career in general practice. GP, as a career choice, is perceived as a stressful, work-pressured, low status job with excessive administration and this has resulted in difficulty with the recruitment and retention of GPs. Ireland is facing a shortage of up to 1,400 GPs over the next 10 years and the Royal College of General Practitioners in the UK has estimated that more than 8000 more full-time equivalent GPs will be needed by 2020 in order to fulfil working requirements the NHS. Lack of GPs has led to short-staffing, higher workload, burnout and subsequently, protected time to engage with patient safety interventions is difficult.

From a cultural perspective, while most GPs consider patient safety to be an important issue, it has yet to become a priority at either a practice or healthcare policy level. While the HSE have published their Pre-Consultation draft Patient Safety Strategy Plan (2019-2024), the focus has been on the hospital setting and there is no reference to primary care. In contrast, in the UK, the new GP contract of April 2019 introduced a new
domain focusing on quality improvement into the Quality and Outcomes Framework (QOF), where GPs were both incentivised and contractualised to engage in quality improvement activities within their practices. The ICGP, which is the professional body for GPs in Ireland and responsible for their training and CME needs, has a small-scale quality in practice and safety initiative, but no formal training for GPs on how to measure, address and improve safety in their practices.

From a regulatory point of view, in other safety critical industries (e.g., aviation, nuclear energy), there is often a governing body, which regulates safety-critical processes. The regulatory body for GPs in Ireland is the Medical Council. Irish GPs must submit evidence of engagement in professional competency activities to the postgraduate training body (ICGP), in order to comply with requirements for satisfactory completion of professional competency as set out by the medical council (e.g., annual audit, external educational activities, internal practice activities such as clinical staff meetings etc.). However, there is no stipulation that any of these activities have to have evidence of a “patient safety” component (e.g., QI project in practice, SC survey). This is in spite of the fact that “patient safety and quality patient care” are core domains of good professional practice identified by the medical council.

There is a lack of prioritization of patient safety interventions within the primary care setting at a policy, regulatory and national level. Therefore, it may not be unsurprising that patient safety is not prioritised at a practice level. However, if engagement with patient safety intervention was to become a core regulatory requirement, there is a danger that it may become a tick-box exercise by GPs. Further research should explore how best to cultivate and facilitate a shift towards engagement with GPs with patient safety interventions at local and national levels. Further considerations should be made as to how patient safety can be prioritised and incentivised in practices.

Organisational and Management
Primary care practices have their own unique working environment and organisational culture, which has the potential to pose challenges with widespread implementation of patient safety initiatives. In the evaluation of the implementation of the Safety and Improvement in Primary Care (SIPC) in Scotland, a number of technical challenges (e.g., information technology support, data interpretation) were identified with the implementation of the SC survey, which improved with the explanation of the survey findings within the context of individual practices. In Study 3 (Chapter 4), GPs were most enthusiastic with the tailored feedback to the practice, which identified local issues and resulted in quality improvements at practice level. Similarly in the Netherlands the move from central to localised incident reporting in a Dutch OOH primary care setting, resulted in increased reporting and quality improvement initiatives at a local level.

If there is to be large-scale implementation of patient safety interventions in primary care, bespoke feedback to GP practices with the potential to result in the implementation of local changes is an important motivator for practice engagement.

In Study 2 (Chapter 3), a cross-sectional survey of perceived SC of practice staff had a response rate of <30%. In contrast, where there was incentivisation and “buy-in” from participating practices in Study 3 (Chapter 4) the response rate of perceived SC of participating practice staff in intervention practices, was 84.8% and 78.3% respectively. While Study 3 (Chapter 4) and the evaluative study of the SIPC-PC programme had both used financial incentives to compensate practices for the time required to participate in a definitive trial of the patient safety intervention, both studies reported problems with the allocation of protected time to engage with the safety intervention. In Study 3 (Chapter 4), time was cited as the major barrier to participation and although certain GP practices had been financially compensated for the anticipated time to participate in the intervention, they had struggled to protect and prioritise that time for safety meetings.

If GPs are to truly engage with patient safety interventions, there needs to be appropriate use of incentivisation (e.g., financial or alternative)
and a cultural shift where patient safety engagement is prioritized at a practice level. Further exploration of what is appropriate incentivisation for GPs and of the potential barriers and facilitators to wider engagement with safety interventions in primary care is required. From a practical perspective, protected time for team members appears to be critical for team engagement. Hence, consideration of how best to facilitate and prioritise protected time within the practice (e.g., is it mandatory or does it require the practice to shut for the afternoon) is paramount to successful implementation of patient safety interventions. There is also a need to consider how to involve the practice team more (e.g., can the administrative staff identify charts from high-risk cohorts?, can the nurse identify the “triggered” charts for the doctor to review or can there be a technological solution where the Information technology system can identify the “triggers” automatically). Furthermore, as GPs and practice staff are under so much time pressure, there is potential for the introduction of a “safety officer”, who is employed on a part-time basis by the practice. Their role as a “safety officer” would be to support the practice with patient safety initiatives (e.g., TRM record review, incident reporting, learning from PSIs) at a practice level to reduce the risk of preventable harm to patients and improve the quality of healthcare delivery. Increasingly, medical indemnity organisations provide on-site risk management assessments within a GP practice looking at several aspects of clinical care such as management of medication and test ordering/follow-up. These risk management assessments are arranged at the behest of the GP practice, which would imply that GPs may be willing to engage with onsite safety experts in their practices. However, further research is recommended to explore the feasibility and acceptability of a “safety officer” onsite in primary care.

**Team (Group)**

Effective teamwork between the members of the practice team is crucial for patient safety. In Study 4 (Chapter 5), feedback from the SC survey and TRM PRR was found to be useful to identifying where teamwork could be improved. The SC survey was perceived as providing a “voice” for more
junior and non-managerial staff, as theoretically results are anonymous, and participants felt they could voice their concerns (e.g., communication problem). However, within smaller practices (e.g., single-handed GPs, one nurse, one administrator) it was recognised that it may be more difficult to be ‘open’ if there is a problem (e.g., failures in communication) identified within the practice due to the ability of the participant to be recognised by default.

The findings from the SC survey and TRM chart review were presented at practice meetings as part of the intervention in Study 3 (Chapter 4). This information allowed the practice staff to be informed involved, and generally resulted in improved teamwork (e.g., more cohesive decision-making and patient management approaches among practice team members). However, it was often very difficult to arrange the structured practice meeting to discuss survey and TRM reports with all team members present. The lack of protected time to participate, competing workload and a failure to prioritise the patient safety intervention within the practice, were barriers to the implementation of the intervention. Another issue with these practice meetings was that sometimes results of the SC survey and TRM generated difficult conversations (e.g., communication problems within the practice), which required moderation and facilitation by a lead GP. This lead GP or “local champion” was often instrumental in the discussion meetings and in implementing changes after the intervention. In addition, Study 3 (Chapter 4) highlighted the importance of a “local champion” to drive the patient safety intervention at practice level after the withdrawal of a GP practice from the study following the departure of the doctor leading the safety intervention. Similar challenges of wider engagement of GP teams beyond core programme participants and difficulties encountered during feedback meetings were identified in the SIPC-PC study,\textsuperscript{30} which stresses the importance of having a lead GP and a culture of willingness to change within the practice.

From a practical perspective, “buy-in” is required from the practice leadership to promote widespread practice engagement (e.g., allocating protected time to facilitate a meeting), but how this is facilitated (e.g.,
financial incentive, regulation or otherwise) would require further exploration. This thesis has also identified that hierarchical structures in the GP setting can impede open and honest discussion at practice meetings by more junior staff members. While this issue has been recognised in the secondary care setting, further exploration of the perceived issues by staff members to speaking up in the primary care setting should be considered, if there is to be an open and safe culture at a practice level.

**Individual**

Within this socio-technological model, the individual refers to the general practitioner. GPs in the UK have reported a difficulty in how best to measure and improve patient safety in their own practices and have highlighted the lack of external support and guidance as barriers to tackling patient safety in their own practices. Likewise in Ireland, “patient safety” has been identified as one of the top five learning priorities for Irish GPs as part of their continuous medical education (CME). However, there is a lack of awareness amongst Irish GPs on the existence and accessibility of suitable and relevant patient safety interventions in primary care. A recent systematic review has demonstrated that proactive assessment of safety in practice is feasible, inexpensive and readily accessible. Furthermore, training GPs in safety assessment and quality improvement techniques is also possible, as evidenced by the application of the TRM and other interventions in this research project and other international project. Implementation of patient safety interventions are more likely to be successful where clinicians can readily acknowledge their value. In Study 3 (Chapter 4), GPs were particularly enthusiastic about the local quality improvement actions as a result of the TRM in this research project.

While it is becoming increasingly commonplace for hospital doctors to receive training in quality and safety improvement, there is less emphasis on driving quality improvement techniques across primary care in Ireland. Future recommendations include the provision of formal training initiatives in patient safety and quality improvement, specifically aimed at GPs, either at policy (HSE) or postgraduate training level (ICGP). For example in the
UK, the Royal College of General Practitioners (RCGP) in the UK consider quality improvement to be fundamental to general practice\textsuperscript{39} and have launched an online quality improvement e-learning platform for their GP members, which includes basic training in quality improvement methodologies and how to involve your practice in quality improvement programmes.\textsuperscript{40} In Scotland a network of GP clusters has been established to encourage GPs to participate in quality improvement activity with their peers.\textsuperscript{41} Increasing awareness and accessibility to patient safety interventions for GPs would be an important adjunct to equipping GPs with the necessary skills to engage with patient safety and quality improvement.

**Work Environment**

The work environment refers to the setting in which the patient safety intervention is delivered. Primary care is a high-pressure, dynamic work environment, which is increasing in complexity and intensity across patient- (e.g., ageing population, multimorbidity), practice- (e.g., substantial and unaddressed increase in workload\textsuperscript{17}) and systems factors (e.g., recruitment and retention of GPs leading to understaffing,\textsuperscript{20-23,42} under-resourced setting, lack of investment in services). Across all four studies in described in this thesis, the negative impact of workload on patient safety was evident.

Excessive workload also has implications for doctor safety.\textsuperscript{43} In Study 2 (Chapter 3), GP Principals perceived a more negative impact of workload on perceived SC than administrative staff. Interestingly, recent surveys of Irish and UK GPs noted that GP Principals were significantly more likely to report higher stress than non-principals\textsuperscript{20,21} and chronic work-related stress is a well-known precursor to burnout.\textsuperscript{45} Internationally, GPs also reported a higher incidence of burnout than doctors in other secondary care-based specialties such as oncology, surgeons, paediatricians etc.\textsuperscript{33,46} In a European study, 12\% of GPs scored highly across the burnout scale\textsuperscript{47} and nationally, almost 7\% of Irish GPs fulfilled the criteria for burnout in 2014.\textsuperscript{48}  

Burnout, stress and high workload are large the factors contributing to the willingness and motivation of GP’s to engage in safety interventions.
Unsurprisingly, clinical workload is prioritized and time designated for patient safety engagement is often not protected. Further exploration of these contributing factors to workload and how these factors may be alleviated in practice is required if the threat posed by workload across all parameters in primary care is to be reduced. Furthermore, Study 1 (Chapter 2) and other studies\(^4\) have suggested correlating measures of SC in primary care with workload, burnout and job satisfaction due to their direct influence on the primary care working environment and indirect influence on SC. From a practical perspective, GPs in the UK have adopted measures such as increasing use of telephone in an attempt to tackle workload,\(^1\) but further exploration of how to alleviate the non-clinical workload burden by delegation of tasks to administrative staff is recommended.\(^5\)

**Patient**

There is growing recognition of the contribution that patients can make to improving safety in healthcare.\(^5\) Berwick\(^5\) and Vincent\(^1\) have argued that the patient voice is an important mitigator of potential PSIs in the safety system. Despite this, a recent systematic review of proactive safety assessment methods in primary care has noted the lack of patient input into the assessment of safety in this setting.\(^3\) The patients’ perspective of safety in primary care was not explicitly addressed as part of this thesis. However, patients are potential sources of safety information. Patients and their carers process a large amount of data, observing and evaluating all healthcare interactions.\(^5\) They have privileged access to information on continuity of care, communication failures, and dignity issues.\(^5\) Furthermore, patients and their carers experience important elements of healthcare that are not observable by GPs. As patients and their carers are outside the given healthcare organisation they provide an independent assessment of an organisation that is grounded in the changing norms and expectations of society. Therefore, research should consider the value of patient input for informing safety improvements.

In the US, the Agency for Health Research and Quality (AHRQ) has reviewed the literature on patient involvement in primary care. Gaps in the
research have been identified with a lack of patient measures of safety and limited patient involvement with the design of patient safety interventions in primary care. Future research recommendations include the development of an instrument, which could correlate both patients’ and staff’s perspective of safety within a GP practice (e.g., staff SC survey and contemporaneous patient SC survey). From a practical perspective, patient feedback in the primary care setting has demonstrated better communication and improved medical performance. While each primary care practice has a procedure in place to deal with complaints from patients, there is less focus on exploring other aspects of patient feedback (e.g., scheduling of appointments, miscommunication of results), which may be more relevant and may actually avoid a complaint in the future. Future recommendations for practice would be for GPs to embrace, reflect on and learn from patient feedback.

**Strengths and Limitations**

The strengths and limitations for each of the four studies have already been discussed in Chapters 2 to 5. This section discusses some of the broader strengths and limitations of this body of research as a whole, which have implications for the interpretation of its findings.

The greatest strength of this thesis was the use of a multi-method approach to measuring patient safety in practice, which is recommended in order to obtain a comprehensive overview of patient safety. Using both quantitative (e.g., SC survey, TRM data) and qualitative (e.g., CIT interview, post-intervention interviews) methods allowed for a thorough exploration and richer understanding of the issues relating to measuring and improving patient safety in Irish primary care.

Furthermore, this thesis was grounded on the theoretical exploration of two dimensions of the MMS framework. The MMS framework was developed specifically for the measuring and monitoring of safety in healthcare and was derived from three scoping reviews of safety across high-risk industries, models of systems safety and safety in healthcare. It
has been applied across multiple healthcare settings and specialties both in the UK and internationally.\textsuperscript{58-60}

Selection of appropriate healthcare-based instruments and where possible, instruments derived specifically for primary care, is another strength of the research reported in this thesis. The validated survey instrument (PC-SafeQuest) used in Studies 3 and 4 (Chapters 4 and 5 respectively) was selected because it was developed de novo for the primary care setting and had demonstrated more evidence of validity and reliability than other SC survey instruments considered in the systematic review reported in Study 1 (Chapter 2). Also, Study 4 (Chapter 5) utilised the healthcare-specific evidence-based YCFF framework\textsuperscript{19} to classify the underlying contributory factors to PSIs described by GPs in a healthcare setting.

However in spite of these considerable strengths, this research project had a number of important limitations that must be considered when interpreting the broader findings from the research. As discussed above in the outline of the sociotechnical model, the major limitation of this research project is the lack of the patient perspective of safety within primary care. It is widely recognized that patients are important mitigators in their own care and sources of potential quality and safety information\textsuperscript{54,55}. Future research should consider patient input in the development of safety and quality improvements at both research and practice levels.

Despite the utility of the MMS framework\textsuperscript{1,2} to measure and monitor safety across different healthcare settings,\textsuperscript{58-60} there are several limitations with the application of this hospital-based framework in the primary care setting. Esmail has already outlined the difficulties with the application of the third dimension (“Sensitivity to operations- Is care safe today”) within the organisational structural constraints of primary care\textsuperscript{61}. Furthermore, application of the third (“Sensitivity to operations- Is care safe today”) and fourth (“Anticipation and Preparedness”) dimensions of the MMS framework\textsuperscript{1,2} have the potential to be challenging when considering the safety concept within the complex healthcare system. “\textit{Safety is concerned with the myriad ways in which a system can fail to function}”,\textsuperscript{(p670)} which in the complex healthcare system, includes doctors and nurses reacting in
unpredictable ways to avert system malfunction. Often these rapid reactions or other ways in which the system compensates to keep things on track are almost impossible to measure or monitor.\(^1\) Vincent et al\(^6\) have also described safety in healthcare as a “constantly moving target”,\(^6\)\(^{p539}\) as the perimeter of patient safety science in healthcare is constantly evolving. For example more types of harm (e.g., pressure ulcers, venous thromboembolism) have come to be regarded as preventable with rising standards of care.\(^6\) Thus if safety in healthcare is considered to be such a dynamic concept, it could be argued that the predictability of future safety issues, on which the third and fourth dimensions are based on, has the potential to be problematic. Furthermore, the measurement and monitoring of safety or quality improvement in healthcare overtime becomes more arduous due its constantly evolving safety perimeter.\(^6\)

From another conceptual perspective, this research project may be limited by its focus on the assessment of safety culture and/or SC as part of the “Anticipation and Preparedness” dimension. Over the past twenty years safety culture has been described extensively in the literature, yet, there is still neither a universally accepted model nor a fixed number of variables or content to describe and measure it.\(^6\)\(^3\) Thus, this generates an important caveat with the measurement of either safety culture and SC- if it is not a construct is it truly measurable? In spite of these conceptual and theoretical concerns, measuring the SC or culture of healthcare workers has become a key component of patient safety initiatives across all healthcare settings\(^3\)-\(^5\) and is seen as an integral component to the “Anticipation and Preparedness” dimension of the MMS framework.\(^1\),\(^2\) In acknowledgement of these concerns, we were meticulous with our instrument selection for SC measurement in order to measure SC in primary care as accurately as possible.

Another potential limitation is that this research project was largely confined to an Irish context. However, Study 3 compared results from the measurement of SC in Ireland to data from English\(^13\) and Scottish\(^14\) samples, which identified universal issues such as workload that may adversely affect SC across all three countries. Similarly, Study 4 involved a randomised controlled feasibility study of a patient safety intervention in practices.
cross Ireland and Northern Ireland, which is part of the NHS in the UK. Other limitations (e.g., sample sizes) have been discussed as per relevant studies.

**Conclusion**

In recent years there has been a shift in focus towards proactively measuring and monitoring safety in primary care.\(^3,4\) There are a range of valid and reliable tools and approaches to proactively monitor and provide feedback on safety in primary care\(^3\). However, these measures still tend to be confined to research, with few actual examples of the use of these approaches as practical methods to inform safety improvement in primary care. This thesis demonstrates that measures to assess the dimensions of “Anticipation and Preparedness” and “Integration and Learning” of the MMS Framework\(^1,2\) such as reliable and valid SC measurement instruments, application of the TRM in PRR and CIT interviews, can be used to improve patient safety in primary care.

This thesis also identified several important issues for improving safety in primary care. Despite the importance placed on patient safety by GPs,\(^6,4\) there is a reluctance to engage with formal safety and quality improvement processes in primary care.\(^5\) This reluctance to engage can at least partially be attributed to a lack of resources, burnout, and the high workload of GPs and practice staff. Therefore, if safety is to be proactively measured, monitored, and improved in primary care there is a need to consider how GPs can be supported to do so. Researchers need to shift from the development of additional monitoring tools, to studying how to more effectively implement the existing tools in primary care. Regulators need to consider how to support, encourage and incentivise GPs to proactive monitor safety. GPs must consider how to make time for safety, and their patients need to demand an increased safety focus. Furthermore, we need to consider how we can involve patients in the safety of their own care. The proactive monitoring and improvement of safety is challenged at every level of the healthcare system. We arguably already have the tools and knowledge
to improve safety in primary care. We just need to identify the most effective way to implement these methods of improving safety.
References


40. Royal College of General Practitioners. QI Ready. RCGP [Internet]. Rcgp.org.uk. 2020 [cited 11 February 2020]. Available from:
https://www.rcgp.org.uk/qi-ready


Chapter 6


64. Dowling S, Last J, Finnegan H, O’Connor K, Cullen W. Does locally delivered small group continuing medical education (CME) meet the

Appendices


Appendix One

1.1 Online Supplementary Material 1: Summary of Medline OVID Search Strategy

*Note:* Exp= explode, ti=title, ab=abstract,

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<td>exp Medical Error/</td>
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<td>7 and 20</td>
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<td>22</td>
<td>limit 19 to (english language and humans and (addresses or autobiography or bibliography or biography or comment or congresses or dictionary or directory or duplicate publication or editorial or festschrift or in vitro or interactive tutorial or interview or lectures or legal cases or legislation or letter or news or newspaper article or overall or patient education handout or periodical index or portraits or twin study or video-audio media or webcasts))times.</td>
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### Online Supplementary Material 2: Safety Climate Survey Detailed Descriptions

**Table: Safety Climate Survey Detailed Descriptions**

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<th>Tool Name</th>
<th>Country (Year &amp; Author)</th>
<th>N Items</th>
<th>Safety Climate Factors/ Domains</th>
<th>Psychometric Properties Reported</th>
<th>Clinical Setting</th>
<th>QATSDD Score</th>
<th>Number of Citations</th>
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<td>PC-SafeQuest</td>
<td>Scotland (De Wet et al 2010)</td>
<td>30</td>
<td>5 domains: Workload, Communication, Leadership, Teamwork, Safety Systems</td>
<td>Content Validity: Yes (Steering group, literature review, semistructured interviews with primary care team members, modified Delphi, CVI by experts)</td>
<td>Primary care</td>
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<td>19</td>
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<td>Construct Validity: Yes (Exploratory Factor Analysis Confirmatory Factor Analysis)</td>
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<td>Criterion-Related Validity: No* (established in Bell et al study)</td>
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<td>Reliability: Yes (Cronbach’s alpha 0.6-0.94)</td>
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</tbody>
</table>

*QATSDD = Quality Assessment Tool for Surveys of Doctoral Dissertations*  
*ISI WoK = Institute for Scientific Information, Web of Knowledge*  
*GS = Google Scholar*
<p>| Teamwork and Safety Climate Survey(^\text{11}) | England (Hutchinson et al 2006) | 22 | 5 domains: | Yes (Focus groups of hospital and primary care professionals/Pilot sample) | Yes (Exploratory and confirmatory factor analysis) | No | Yes (Cronbach's alpha &gt;0.69 for all 5 factors) | Primary care setting (&amp; also hospital setting) | 34 | 30 | 75 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | • Teamwork 1 - Input into decisions and collaboration with other staff | | | | | | | | | |
| | | | • Teamwork 2 – Information Handover | | | | | | | | |
| | | | • Safety Climate Factor 1 - Attitudes to safety within own team; capacity to learn from errors | | | | | | | | |
| | | | • Safety Climate Factor 2 – Overall confidence in safety of organization | | | | | | | | |
| | | | • Safety Climate Factor 3 – Perceptions of management’s attitudes to safety | | | | | | | |</p>
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<tr>
<th>Source</th>
<th>Country</th>
<th>Domain Count</th>
<th>Domains</th>
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<th>Validation Method 2</th>
<th>Cronbach's Alpha</th>
<th>Practice</th>
<th>Sample Size</th>
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<tbody>
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<td>Frankfurt Patient Safety Questionnaire for General Practices (FraSiK)</td>
<td>Germany</td>
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<td>Teamwork, Error Management, Safety of clinical processes, Perception of causes of errors, Job Satisfaction, Safety of Practice Structure, Receptiveness to healthcare assistants and patients, Staff Perception of Management (non-doctors only), Quality and Safety of Medical Care (doctors only)</td>
<td>Yes (expert interviews, pilot testing)</td>
<td>Yes (Exploratory Factor Analysis)</td>
<td>0.55 - 0.90</td>
<td>General Practice</td>
<td>34</td>
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<tr>
<td>SCOPE</td>
<td>Netherlands (Zwart et al 2011)</td>
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<td>Handover and Teamwork, Support and Fellowship, Communication openness, Feedback about and learning from error, Intention to report events, Adequate procedures and adequate staffing, Overall perceptions of safety, Supervisor/manager expectations/actions</td>
<td>Yes (Expert review, Pre-test panel)</td>
<td>Yes (Exploratory Factor Analysis Pearson’s Correlations)</td>
<td>No* (established in Verbakel et al 2015)</td>
<td>General Practice</td>
<td>32</td>
</tr>
</tbody>
</table>
| Swedish version of US AHRQ “Hospital Survey on Patient Safety Culture (HSOPSC)” | Sweden (Hedskold 2013) | 48 | 14 domains:  
  - Communication  
  - Openness  
  - Feedback and communication about error  
  - 3. Frequency of error reporting  
  - Hands-off and transitions between units and shifts  
  - Executive management support for patient safety  
  - Non-punitive response to error  
  - Organizational learning-continuous improvement  
  - Overall perceptions of safety  
  - Staffing  
  - Supervisor/manager expectations and actions promoting safety  
  - Teamwork across units  
  - Teamwork within units  
  - Information and support to patients and family who have suffered an adverse event  
  - Information and support to staff who have been involved in an adverse event | Yes (Expert panel of health care and patient safety experts; pilot testing with 2 focus groups) | Yes (Confirmatory Factor Analysis Exploratory Factor Analysis) | No | Yes (Cronbach’s Alpha 0.64-0.88) | Primary Care Centre Staff & Hospital staff | 29 | 7 | 19 |
<table>
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<tr>
<th>Study Name</th>
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<th>Year</th>
<th>Sample Size</th>
<th>Confirmatory Factor Analysis</th>
<th>Description</th>
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<td>SCOPE-PC[^29]</td>
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<td>41</td>
<td>Yes (Research team and expert review)</td>
<td>7 domains:</td>
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<td></td>
<td></td>
<td>• Open Communication and learning from error</td>
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<td>• Handover and Teamwork</td>
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<td>• Adequate procedures and working conditions</td>
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<td>• Patient Safety management</td>
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<td>• Support and Fellowship</td>
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<td>• Intention to report events</td>
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<td>• Organizational Learning</td>
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<tr>
<td>Patient Safety Survey[^29]</td>
<td>Switzerland</td>
<td>2013</td>
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<td>Yes (Iterative testing with practitioners and adapted accordingly)</td>
<td>4 domains:</td>
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<td>• Team-based error prevention</td>
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<td>• Assignment of responsibilities</td>
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<td>Norwegian adapted Safety Attitudes Questionnaire-Ambulatory Version[^24]</td>
<td>Norway</td>
<td>2014</td>
<td>62</td>
<td>Yes (Confirmatory Factor Analysis, Correlations)</td>
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<td>• Perceptions of Management</td>
</tr>
</tbody>
</table>

[^29]: Verbakel et al. 2013
[^24]: Bondevik et al., 2014

Yes (Crohnbach's alpha 0.7-0.9)
Yes (Confirmatory Factor Analysis and Pearson’s inter dimensional correlations)
Yes (Crohnbach's Alpha 0.85 overall with 0.51-0.82 variability)
Yes (Crohnbach's alpha 0.67-0.83)
Yes (established by Bondevik et al 2014[^29])
Yes (Crohnbach's alpha 0.67-0.83)
Yes (Crohnbach's alpha 0.67-0.83)
Yes (Crohnbach's alpha 0.67-0.83)
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<td>58</td>
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<td>Yes (Cronbach's alpha 0.874)</td>
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<td>- Work pressure and pace</td>
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<td>No (Not reported in this article/Reported in Spanish Journal 2012)</td>
<td>No (Not reported in this article/Reported in Spanish Journal 2012)</td>
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<td>12 primary health care centres</td>
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<td>Safety Attitudes Questionnaire Ambulatory Version (Holden et al 2009)</td>
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| | | | | | | | | |

191
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<th>Study Title</th>
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<td>PROMISES Project Survey&lt;sup&gt;35&lt;/sup&gt;</td>
<td>USA</td>
<td>63</td>
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<td>Medication Management, Test ordering and result management, Follow-up and referral management, Patient-focused care, Access to service and care, Malpractice concerns, Quality and Risk Management, Practice Communication, Work pressure, Teamwork, Practice Leadership</td>
<td>Yes (Expert review, pretest panel)</td>
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<td>Patient Safety Culture Survey in Ambulatory Care&lt;sup&gt;36&lt;/sup&gt;</td>
<td>USA</td>
<td>21</td>
<td>4 domains</td>
<td>Teamwork, Leadership, Communication, Tendency to report errors</td>
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<td>Safety Attitudes Questionnaire-Modified Version&lt;sup&gt;37&lt;/sup&gt;</td>
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<sup>35</sup> Singer et al (2015)  
<sup>36</sup> Schutz et al (2007)  
<sup>37</sup> Mc Guire et al (2012)
| Safety Attitudes Questionnaire Ambulatory Version (SAQ-AV)³⁸ | Netherlands (Martijn et al 2012) | 14 | 14 statements relating to patient safety. No pre-defined sub-domains | No (Reference to previous validation, but not specifically for Dutch primary care) | No (Reference to previous validation, but not specifically for Dutch primary care) | Yes (Number of Patient Safety Incidents identified through audit) | No (Reference to previous validation, but not specifically for Dutch primary care) | Primary Care Practices | 17 | 0 | 4 |

*Instrument has criterion-related validity reported in another study that also utilises this seminal instrument for this purpose.

¹ Note: PC= Primary Care; SCOPE= Dutch acronym for systematic culture inquiry on patient safety; PROMISES= Proactive Reduction in Outpatient
1.3 Online Supplementary Material 3: Psychometric assessment of included studies

<table>
<thead>
<tr>
<th>Tool Name</th>
<th>Study</th>
<th>QATSD D score</th>
<th>Psychometric Properties (Criteria outlined in Table 1: Psychometric Criteria)</th>
<th>Content Validity</th>
<th>Construct Validity</th>
<th>Criterion-related Validity</th>
<th>Reliability</th>
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<td>Survey&lt;sup&gt;11&lt;/sup&gt;</td>
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<td>Authors</td>
<td>Year</td>
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<td>Hedskold et al. (2013)</td>
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<th>SAQ-AV&lt;sup&gt;38&lt;/sup&gt;</th>
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Yes: 11 (64.7%)
Yes: 10 (58.8%)
Yes: 9 (52.9%)
Yes: 13 (76.5%)
Appendix Two

2.1 Online Supplementary Material 1: SAP-C Interview Schedule

1. What did you think about the usefulness of the feedback on the safety climate survey for improving patient safety?
2. What did you think about the usefulness of the feedback from the trigger tool chart audit?
3. Were any changes made at the practice based upon the feedback from the intervention, and if any were made what were they?
4. How do you think the intervention impacted patient safety at this practice?
5. What, if any, were the challenges to implementing this intervention?
6. What do you think of the intervention as a method for improving patient safety in primary care?
2.2 Online Supplementary Material 2: SAP-C Feedback Questionnaire

Safety in Primary Care (SAP-C) Feedback

We would like to collect some final reactions on your thoughts about the usefulness of the SAP-C intervention. We would be grateful if you would answer the questions below.

1. Please circle the appropriate response.

<table>
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<tr>
<th>Feedback on the safety climate survey was useful for improving patient safety.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
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<td>3</td>
<td>4</td>
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<thead>
<tr>
<th>Completing the survey helped me reflect on how we manage patient safety in this practice</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
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<table>
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<tr>
<th>Feedback from the trigger tool chart audit was useful for improving patient safety.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
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<td>4</td>
<td>5</td>
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</table>

<table>
<thead>
<tr>
<th>Changes were made at this practice based upon the information obtained from this intervention.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
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<td>4</td>
<td>5</td>
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<table>
<thead>
<tr>
<th>Overall, I believe that this intervention had a positive effect on patient safety at this practice.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
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<tbody>
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<td>4</td>
<td>5</td>
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<table>
<thead>
<tr>
<th>The effect of this intervention is worth evaluating as a randomized-controlled trial.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree</th>
<th>Strongly agree</th>
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<td>3</td>
<td>4</td>
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</table>

2. What did you think was most useful about this intervention?

3. What did you think was least useful about this intervention?

4. What could be done to improve the intervention?
Supplementary Table 1. Contributing Factors to PSIs, Identified Examples & Exemplar Quotes for the contributing factors to patient safety incidents. Data from critical incident technique interviews collected September to December 2017.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Identified Examples</th>
<th>Exemplar Quotes</th>
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<tr>
<td><strong>SITUATIONAL FACTORS (N=26, 100%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service User Factors (n=22, 84.6%)</td>
<td>• Difficult Historian</td>
<td>“Always a difficult historian…it was difficult to pin down what was wrong with him” (GP2)</td>
</tr>
<tr>
<td></td>
<td>• Frequent Attender</td>
<td>“I would be assigned a double appointment twice per week to review this patient…Patient was a frequent attender of Out-of-Hours Services and medical outpatients, which resulted in a lot of correspondence and prescriptions”. (GP6)</td>
</tr>
<tr>
<td></td>
<td>• ‘Doctor-Shopper’</td>
<td>“Patient was a frequent attender to other doctors in the community. When her level of anxiety became intractable she often would have visited five different doctors in one week.” (GP7)</td>
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<tr>
<td></td>
<td>• “Door-stepper”</td>
<td>“Despite being informed of the appointment system, patient would continue to turn up unexpected without appointment… …Often did not have time for him in the way that you did with others because he presented the way he did”. (GP2)</td>
</tr>
<tr>
<td></td>
<td>• Complex Medical History</td>
<td>“As GPs we are trying to do the impossible. We are trying to see these complicated people and turn them around in fifteen minutes and this is increasingly difficult”. (GP15)</td>
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<tr>
<td></td>
<td>• Polypharmacy</td>
<td>“Patient was on approximately 30 types of medication equating to 90 tablets per day”. (GP6)</td>
</tr>
<tr>
<td></td>
<td>• Recently Discharged from hospital</td>
<td>“Patient was recently discharged from hospital, where the medication had been changed. We had no correspondence to inform us of this”. (GP29)</td>
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<tr>
<td></td>
<td>• Paediatric Patient</td>
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### Appendix Three

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<th>Task Characteristics $(n=22, 84.6%)$</th>
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<td><strong>Task Characteristics</strong> $(n=22, 84.6%)$</td>
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<tr>
<td><strong>Infrequent Attender</strong></td>
<td>“With a child you have to weigh them and do a math’s calculation…Prescribing for infants wouldn’t be an all-day everyday task”. (GP14)</td>
</tr>
<tr>
<td><strong>New or unfamiliar Patient</strong></td>
<td>“This patient was a frequent non-attender despite needing increased medical input because of his co-morbidities. There was definitely a lack of responsibility for his own medical conditions”. (GP27)</td>
</tr>
<tr>
<td><strong>Upset Patient</strong></td>
<td>“When meeting a patient for the first time, it is very difficult to gauge the patient”. (GP20)</td>
</tr>
<tr>
<td><strong>Language Barrier</strong></td>
<td>“I was disproportionately influenced by the fact that the patient came into the room and started crying…It blinded me to the fact that there may be an underlying cause for her symptoms”. (GP12)</td>
</tr>
<tr>
<td><strong>Poor Access to GP</strong></td>
<td>“The mother had really poor English…I tried my best to explain that I was using an off-license medication, but there was a language barrier”. (GP16)</td>
</tr>
<tr>
<td><strong>Monotonous Task</strong></td>
<td>“This patient had a medical card but had difficulty getting to the GP with the hours she was working, so her main attendances were to the OOH setting either late in the evening or at weekends.” (GP20)</td>
</tr>
<tr>
<td><strong>Difficult Task</strong></td>
<td>“This patient relied on public transport to come and see us. I’m not sure if this affected her presenting to us”. (GP26)</td>
</tr>
<tr>
<td><strong>Unfamiliar Task</strong></td>
<td>“There are lots of minor abnormalities in blood tests. It is a monotonous task, but yet this case has taught me that if they are not followed up appropriately, it can be catastrophic”. (GP2)</td>
</tr>
<tr>
<td><strong>Logistical Task</strong></td>
<td>“Repeat prescribing can be a monotonous task— it is something where people fall into the trap of just signing the script and not looking more at the chart.” (GP29)</td>
</tr>
<tr>
<td><strong>Unfamiliar Task</strong></td>
<td>“Logistically the task was difficult as you couldn’t get a blood sample same day”. (GP12)</td>
</tr>
<tr>
<td><strong>Unfamiliar Task</strong></td>
<td>“There was difficulty getting the urine sample from the child” (GP3)</td>
</tr>
<tr>
<td><strong>Unfamiliar Task</strong></td>
<td>“There was so much to cram into the consultation”. (GP17)</td>
</tr>
<tr>
<td><strong>Unfamiliar Task</strong></td>
<td>“As the GP I had done too much of the work that the pharmacy would normally do, which led to the error”. (GP14)</td>
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</table>
"Since working in hospitals I wouldn’t have had to deal with a medication that I have to draw up, dilute and then give." (GP11)

<table>
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<tr>
<th>Individual Staff Factors</th>
<th>Delegation to inappropriate staff</th>
<th>Team Factors</th>
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<tr>
<td>(n=17, 65.4%)</td>
<td>“Combination of rushed and fatigue led to baseline carelessness”. (GP15)</td>
<td>(n=9, 34.6%)</td>
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<tr>
<td>• Stressed</td>
<td>“It was a busy, busy practice. It was definitely more rushed than I would like to be in general”. (GP11)</td>
<td>• Delegation to inappropriate staff</td>
</tr>
<tr>
<td>• Rushed</td>
<td>“The patient left the room to see if they could get a urine specimen…so the usual flow of the consultation was disrupted”. (GP3)</td>
<td>“One person ticks the box and expects the other team members to follow suit…you are relying on them to follow suit…there is no failsafe mechanism to ensure that if you have ticked “discuss with patient” that this is done by other team members”. (GP4)</td>
</tr>
<tr>
<td>• Distracted</td>
<td>“I was so new to general practice, so I definitely wasn’t within my comfort level”. (GP23)</td>
<td>• Conflicting Team Goals</td>
</tr>
<tr>
<td>• Inexperienced</td>
<td>“Single-handed practice is isolating and you are residing in your own head. Sometimes you feel you should be residing in the heads of others”. (GP7)</td>
<td></td>
</tr>
<tr>
<td>• Isolated</td>
<td>“Receptionist did not alert the doctor or the nurse at the time…this was contrary to what an experienced medical receptionist would do with a patient presenting with chest pain” (GP8).</td>
<td></td>
</tr>
<tr>
<td>• Overconfident</td>
<td>“Some patients burst into tears when you tell them they may have to go into the emergency department (ED). There is a sense of guilt and failure that you feel when you make a referral to ED. This likely influenced my decision. I was jumping through hoops backwards trying not to send the patient in”. (GP12)</td>
<td></td>
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<tr>
<td>• Gatekeeper</td>
<td>“When you are trying to keep your referral rate down, dealing with persistent complaints from this kind of patient can be difficult. Patients like this really want to be referred where you don’t think it is indicated. Managing expectations can be difficult.” (GP13)</td>
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</tbody>
</table>
“I felt LMP would have been relevant to illicit here in the nursing triage of this patient. This is where a team effort is needed. You are under so much time pressure (in an Out-of-hours setting)—often the consultations are shorter and you might not have the time to illicit all information. Had that question been asked, it might have highlighted things earlier”. (GP20)

**LOCAL WORKING CONDITIONS (N=14, 53.8%)**

| Workload & Staffing Issues (n=11, 42.3%) | • High unit workload  
• Insufficient Staff  
• Staff Sickness | “See more than 40 patients per day…strong tradition of house calls at lunch…lunch consisted of a sandwich in the car”. (GP9)  
“In an Out-of-hours setting you can be really busy. Patients are often booked for 5 minute slots; interruptions; house calls.” (GP20)  
“Needed at least one more doctor there full-time.” (GP14)  
“As a part-time GP, I am not present on all days. I asked the nurse to follow-up on the blood results… but the nurse was on sick leave on the day the test was supposed to be followed up on”. (GP24) |
| Leadership, Supervision & Role (n=9, 34.6%) | • Remote Supervision  
• Inappropriate delegation  
• Unclear responsibilities | “Because I only work part-time I feel more vulnerable with patient supervision” (GP26)  
“The administrative staff took all the requests for prescriptions and the GP just came out to the desk and signed them” (GP29)  
“There wasn’t clarity around the roles…It wasn’t clear who was going to action it”. (GP18) |
| Drug, Equipment & Supplies (n=5, 19.2%) | • Inadequate maintenance of drugs  
• Unavailable drugs  
• Equipment not working or available  
• Inappropriate storage of drugs or equipment | “Having vaccines in the fridge that were a month out of date was inadequate”. (GP23)  
“I recognised that my doctor’s bag was unequipped for rural practice”. (GP9)  
“Near point INR machine was not available at the time. Hence, there was no instant blood result and the blood sample had to be sent to the lab.” (GP24)  
“In the treatment room all the similar looking boxes with containers that contain water, sodium chloride, lidocaine and adrenaline were all
in a row. There was no readily identifiable flag to say which was which”. (GP11)

<table>
<thead>
<tr>
<th>LATENT ORGANISATIONAL FACTORS (N=21, 80.8%)</th>
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<tbody>
<tr>
<td><strong>Support from other service providers</strong></td>
<td><strong>(n=11, 42.3%)</strong></td>
</tr>
<tr>
<td><strong>• Lack of support from laboratory department</strong></td>
<td>“Access to bloods is dependent on drivers bringing lab specimens to the lab. This particular assay has to be analysed within 4 hours so I couldn’t take the sample there and then”. (GP12)</td>
</tr>
<tr>
<td><strong>• Lack of support from secondary care team (e.g., psychiatry, medical or surgical departments)</strong></td>
<td>“The INR results are returned as a Word document. Hence abnormalities are not marked in red.” (GP24)</td>
</tr>
<tr>
<td><strong>• Lack of support from pharmacy</strong></td>
<td>“Primary-secondary care gap is a big issue. There is no collaboration, no correspondence when you are asking for help”. (GP10)</td>
</tr>
<tr>
<td><strong>• Lack of support from primary care giver</strong></td>
<td>“In GP we deal with an awful lot of psychiatry that doesn’t make it to their door. So I think when we do send someone in it would be nice to have more of an open door policy- that psychiatry pick up the phone and let us know. It could work both ways- we could pick up the phone and ask for advice instead of sending someone in”. (GP28)</td>
</tr>
<tr>
<td><strong>• House-call request</strong></td>
<td>“Disappointed that the pharmacy hadn’t picked up on it”. (GP14)</td>
</tr>
<tr>
<td><strong>• Emergency Department referrals</strong></td>
<td>“It had turned out the mother had given twice the dose that I had written down to give”. (GP16)</td>
</tr>
<tr>
<td><strong>• Lack of access to secondary care teams</strong></td>
<td>“This patient continued to turn up unexpected without appointment...made it a rushed interaction on top of your normal day’s work...” (GP2)</td>
</tr>
<tr>
<td><strong>Scheduling</strong></td>
<td><strong>(n=10, 38.5%)</strong></td>
</tr>
<tr>
<td><strong>• “Walk-ins”</strong></td>
<td>“There was no appointment system. Everyday was a walk-in clinic in both the morning and evening surgery, hence you had no idea how many patients you would see that day”. (GP9)</td>
</tr>
<tr>
<td><strong>• House-call request</strong></td>
<td>“Request for a house call where the mother of the child had transport and it was a child with an sore throat was an unusual request”. (GP9)</td>
</tr>
<tr>
<td><strong>• Emergency Department referrals</strong></td>
<td>“Referring to ED inappropriately is always in your head. There are many times when the patient has been looking to be referred in and I have managed to tweak the situation and avoid a referral”. (GP13)</td>
</tr>
<tr>
<td><strong>• Lack of access to secondary care teams</strong></td>
<td></td>
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</tbody>
</table>
“The patient wanted and needed the test and someone had to make a
decision for that to happen. Access to secondary care as a public
patient can be difficult…The fact that the patient procedure had been
cancelled and there was a considerable waiting list already meant the
decision to stop the medication was more urgent”. (GP10)

**Local Policies or Protocols**

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<thead>
<tr>
<th>Number (n)</th>
<th>Percentage</th>
<th>Issues</th>
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</thead>
</table>
| 10         | 38.5%      | - No protocol existed  
- Protocol was too complicated |

“There was no protocol in place for travel vaccines”. (GP17)

“[With the blood result tracking system in place] There was often a
lag period between when the bloods were reviewed initially and
when they were actually actioned as it required both the doctor and
nurse being on site to go through them together”. (GP18)

**Physical Environment**

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<tr>
<th>Number (n)</th>
<th>Percentage</th>
<th>Issues</th>
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</thead>
</table>
| 6          | 23.1%      | - Unfamiliar practice set-up  
- Out-of-hours setting  
- Practice Location  
- Poor Set-up |

“I didn’t know the patients. I didn’t know how the practice worked”. (GP9)

“If it had been one GP seeing that patient on multiple consultations I
have no doubt they would have pieced the puzzle together. But in an
Out-of-hours setting you see a patient as a one-off and you may not
have all the information or the time to get all the information”. (GP20)

“House calls were difficult as the geography of the area involved a
vast hinterland, windy roads and mobile phone coverage was poor at
best of times…House was 30 miles from nearest hospital over poor
quality roads…patient was too unwell to wait for the ambulance”. (GP9)

“The injections were up high on a shelf- I couldn’t see them. I had to
put my hand up to get them”. (GP25)

**Staff Training or Education**

<table>
<thead>
<tr>
<th>Number (n)</th>
<th>Percentage</th>
<th>Issues</th>
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<tbody>
<tr>
<td>1</td>
<td>3.8%</td>
<td>- Staff were not trained to perform the task</td>
</tr>
</tbody>
</table>

“Admin Staff inadequately trained to be taking on all repeat
prescriptions.” (GP29)

**LATENT/EXTERNAL FACTORS (N=9, 34.6%)**

**Design of equipment, supplies & drugs**

<table>
<thead>
<tr>
<th>Number (n)</th>
<th>Percentage</th>
<th>Issues</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>23.1%</td>
<td>- Similar drug names, but different dosages per volume</td>
</tr>
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“As regular practice I would never prescribe anything other than
diamicron MR30mg tabs…this is my usual practice…I hadn’t been
used to using the same drug at a higher dose”. (GP15)
<table>
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<tr>
<th>Appendix Three</th>
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<tbody>
<tr>
<td><strong>Ambiguous labeling and packaging</strong></td>
</tr>
<tr>
<td><strong>Results from laboratory which were abnormal, but were not flagged in red</strong></td>
</tr>
<tr>
<td><strong>National Policies</strong></td>
</tr>
<tr>
<td><strong>(n=4, 15.4%)</strong></td>
</tr>
<tr>
<td><strong>Drug Reimbursement Scheme- (government funded incentive to prescribe generically)</strong></td>
</tr>
</tbody>
</table>

| **GENERAL FACTORS (N=19, 73%)** |
| **Communication** | **Poor communication between practice staff** |
| **(n=18, 69.2%)** | “Communication worked in terms of repeating the test, but didn’t work in terms of appropriate follow-up of tests not done or tests that didn’t come back”. (GP2) |
| **Poor communication between practice/pharmacy** | “I was disappointed that I didn’t get a phone call from the pharmacist”. (GP14) |
| **Poor communication between practice/patient** | “Difficult patient in terms of coming to a shared agreement- often was a unilateral conversation, where the patient got his way…Sometimes it is hard to get through to some patients; to communicate risk effectively”. (GP27) |
| **Lack of information in patient notes** | “Notes were variable. It was difficult to see when the drugs were started and stopped and the reasons why”. (GP29) |
| **Poor communication between primary-secondary care** | “Lack of communication between hospital and GP regarding lithium monitoring” (GP6) |

| **Safety Culture** | **Poor attitude to risk management** |
| **(n=5, 19.2%)** | “We were all very busy and probably felt we couldn’t speak up to the senior that we were all too busy and something needed to be done. You know not to be seen to complain and just get on with” |
things…We each had a significant event in our time there…Going into work was like ‘I hope nothing happens today’…The principal wasn’t aware how much we were struggling around him and how difficult the environment was”. (GP14)