Patient involvement in measuring and monitoring patient safety in general practice

A thesis submitted to the School of Medicine, National University of Ireland, Galway in fulfilment of the requirements for the Degree of Doctor of Philosophy in Medicine (Population Health and Health Services Research)

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Summary of the contents

Given their unique viewpoint at the epicentre of the care process, patients can make a unique contribution to improving our understanding of safety in general practice. Despite this, patients remain an underutilised resource in the measurement and monitoring of safety. Therefore, this thesis aimed to: (1) identify an approach to how patients can contribute to the measurement and monitoring of safety climate; and (2) ascertain the value of patient data for identifying and learning from past harm in general practice. These were addressed through the conduct of a systematic review and three empirical studies.

Study One comprised a systematic review of existing patient-report safety climate measures in healthcare and provided an assessment of their psychometric properties and coverage of safety climate domains. Issues were identified with validity, reliability, usability and a lack of agreement on the appropriate safety climate domains.

Study Two described the development and evaluation of a novel, patient-report measure of safety climate for general practice. Five distinctive factors pertaining to safety climate were identified, and the measure was found to be both valid and reliable.

Study Three examined the application of this novel measure, to evaluate the patient perceptions of safety climate in Irish general practice and explore whether these perceptions differ according to patient characteristics. It was found that respondents generally reported positive perceptions of safety- although over two-thirds of free-text responses related to 'poor' SC practices.

Study Four examined the value of utilising a qualitative approach to assess past harm via 'patient stories', resulting in rich descriptions about safety deficiencies in general practice. Findings confirmed that patients provide additional and unique information about safety outcomes often unrecognised by healthcare professionals.

This thesis has established that patients are a valuable source of information about safety in general practice, thus a concerted effort to effectively utilise this evidence in the emerging field of patient involvement in healthcare is recommended.

Declaration

This thesis is submitted to fulfil the requirement of the Degree of Doctor of Philosophy, at the National University of Ireland, Galway. I declare that no part of this thesis has been previously submitted at this or any other university. I declare that this thesis is entirely my own work.

Signed: Caoimhe Madden Date: 29th June 2022

Caoimhe Madden

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Dedication

This thesis is dedicated to the memory of my beloved grandparents, my guardians Bernie and Peggy Higgins, both of whom sadly passed away a few short months before this thesis was submitted.

Although you're not here to see this, you're in every page.

Rest in perfect peace.

List of works

Peer-reviewed publications pertaining to the thesis

Madden C, Lydon S, Murphy AW, O'Connor P. The patient's 'story': An examination of patient-reported safety incidents in general practice. Submitted to Family Practice.

Madden C, Lydon S, O'Dowd E, Murphy AW, O'Connor P. A systematic review of patient-report safety climate measures in health care. J Patient Saf. 2022;18(1):e51-60.

Madden C, Lydon S, Murphy AW, O'Connor P. Development and validation of a patient-report measure of safety climate for general practice. Fam Pract. 2021;38(6):837-44.

Madden C, Lydon S, Murphy AW, O'Connor P. Patients' perception of safety climate in Irish general practice: a cross-sectional study. BMC Fam Pract. 2021;22(1):1-11.

Conference presentations

Madden C, Lydon S, Murphy AW, O'Connor P. Development and validation of a patient-report measure of safety climate for general practice. Paper submitted for presentation at the Association of University Departments of General Practice in Ireland (AUDGPI) conference, March 2022; Dublin, Ireland.

Madden C, Lydon S, Murphy AW, O'Connor P. Patients' perception of safety climate in Irish general practice: a cross-sectional study. Paper submitted for presentation at the Association of University Departments of General Practice in Ireland (AUDGPI) conference, March 2022; Dublin, Ireland.

Madden C, Lydon S, O'Dowd E, Murphy AW, O'Connor P. A Systematic Review of Patient-Report Safety Climate Measures in Healthcare. Paper presented at the National Patient Safety Office Conference, November 2019; Dublin, Ireland.

Madden C, Lydon S, Murphy AW, O'Connor P. Putting the Patient into Patient Safety Measurement in Primary Care. Poster presented at the Limerick Postgraduate Research Conference, May 2019; Limerick, Ireland.

Madden C, Lydon S, Murphy AW, O'Connor P. Putting the Patient into Patient Safety Measurement in Primary Care. Poster presented at NUI Galway Postgraduate Research Day, May 2019; Galway, Ireland.

Additional publications

Below is a list of additional publications produced by the candidate throughout the course of the PhD

O'Connor P, Madden C, O'Dowd E, Byrne D, Lydon S. A meta-review of methods of measuring and monitoring safety in primary care. Int J Qual Health Care. 2021;33(3):mzab117.

Madden C, Lydon S, Cupples ME, Hart ND, Curran C, Murphy AW. et al. Safety in primary care (SAP-C): a randomised, controlled feasibility study in two different healthcare systems. BMC Fam Pract. 2019;20(1),22.

Lydon S, Byrne D, Vellinga A, Walsh C, Madden C, Connolly F, O'Connor P. A mixed-methods exploration of the educational climate and safety climate during the first year of clinical practice in Ireland. Acad Med. 2019;94(11):1800-5.

Curran C, Lydon S,Kelly M, Murphy A, 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.

Madden C, Lydon S, Curran C, Murphy AW, O'Connor P. Potential value of patient record review to assess and improve patient safety in general practice: a systematic review. Eur J Gen Pract. 2018;24(1),192-201.

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List of Abbreviations

AE	Always Events
CIT	Critical Incident Technique
COREQ	Consolidated Criteria for Reporting Qualitative Research
DVC	Doctor Visit Card
ED	Emergency Department
EFA	Exploratory Factor Analysis
FraSiK	Frankfurt Patient Safety Climate Questionnaire
GMS	General Medical Services
GP	General Practitioner
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems
HCP	Healthcare Provider
IOM	Institute of Medicine
KMO	Kaiser-Meyer Olkin
MaPSaF	Manchester Patient Safety Framework
MMS	Measuring and Monitoring Safety
MoRISS	Monitoring Risk and Improving System Safety checklist
NHS	National Health Service
PAF	Principal Axis Factors
PIRT	Patient Incident Reporting Tool
PMOS	Patient Measure of Safety
PPS-GP	Patient Perspective of Safety in General Practice
PRASE	Patient Reporting and Action for a Safe Environment intervention
PREOS-PC	Patient Reported Experiences and Outcomes of Safety in Primary Care
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analysis guidelines
PSI	Patient Safety Incident
SAP-C	Safety in Primary Care study
SC	Safety Climate
SPSS	Statistical Package for the Social Sciences
UK	United Kingdom
US	United States

WAPS World Alliance for Patient Safety

WHO World Health Organisation

"*We need to hear the patient voice at every level even if that voice is just a whisper*."

Don Berwick[1]

Chapter One: Introduction

Patient involvement in measuring and monitoring patient safety in general practice

Patient involvement in measuring and monitoring patient safety in general practice

1.1 Chapter outline

Almost two decades ago, in their seminal paper, Vincent and Coulter[2, p76] suggested:

> "*the most remarkable feature of the many faceted patient safety movement is surely the lack of attention paid to the patient.*"

The current thesis explores potential methods for leveraging the benefits of patient involvement in safety data collection in general practice. This opening chapter will introduce patient safety as a construct and outline the importance of considering, and advancing, patient safety in the general practice setting. The importance, methods, and limitations of existing practices of measuring and monitoring safety in general practice will be described. The rationale, and potential means of, involving patients in measuring and monitoring safety within general practice will be outlined. Finally, important patient safety theories that informed the conceptualisation and design of this thesis, and its component studies, along with the aims and research questions will be presented.

1.2 Definition of patient safety

A variety of definitions of patient safety have been offered by organisations such as the World Health Organisation (WHO)[3] and the Institute of Medicine (IOM).[4] These definitions are centred around avoiding or preventing the occurrence of errors or incidents within healthcare which may lead to harm or negatively impact patient health. Patient safety has been described as:

> "*the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare*"[5, p2]

A range of terminology (e.g. adverse event, adverse outcome, error, injury, medical harm) is used in relation to patient safety and the occurrence of harm to patients receiving healthcare services. This thesis will generally use the term Patient Safety Incident (PSI; defined as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient[6]) to refer to incidents of errors, or near misses, experienced by patients. However, as there can be some variability in

definitions of different terms, the terms used by individual studies or authors (e.g. 'adverse event', 'error' and 'harm') will be used as necessary to communicate or report relevant findings from other studies accurately.

1.3 Patient safety in general practice

Following decades of being under-recognised and under-researched, patient safety became a priority or focus for healthcare services and healthcare researchers in the early 2000s. This was catalysed by alarming findings highlighting the seriousness of harm to patients while receiving hospital care that were published within landmark reports (e.g. "*To Err is Human*"[7] by the IOM in the United States (US), and "*An organisation with a memory*"[8] by the Department of Health in the United Kingdom (UK)). A global rise of the patient safety movement occurred in the subsequent years. In 2004, the World Health Assembly supported the establishment of the WHO World Alliance for Patient Safety,[9] to improve the safety of healthcare delivery across member states. There now exists widespread awareness and acceptance of the problem of avoidable harm and medical error, and a determination to tackle the issue.[10] However, the rationale for focusing on patient safety and reducing patient harm has ultimately been largely conceived, examined, and addressed within the realm of secondary care. This is evident in the substantial body of research which has been conducted to examine the nature and magnitude of PSIs in the hospital setting,[11-13] in addition to strategies to prevent their occurrence.[14, 15] In contrast, in primary care, there has been relatively little research on patient safety.[16, 17] With relatively little known about PSIs in primary care,[16] aside from estimates of prevalence and severity,[18] there remains a paucity of knowledge on how to effectively intervene to improve the safety of primary care delivery.[19]

There is some variability internationally in what constitutes primary healthcare, but the most widely accepted definition describes primary care as:

> "*first-contact, continuous, comprehensive, and coordinated care provided to populations undifferentiated by gender, disease, or organ system*"[20, p1]

In Ireland, primary care includes all of the health or social care services that are found in the community, outside of hospital, such as: General Practitioner (GP) services; community nurse services; occupational therapy services; physiotherapy

services; and social work services.[21] There is a tendency for a range of terms to be used interchangeably when referring to primary care, including: 'family practice', 'general practice' and 'general medicine'.[22] However, for the purpose of this thesis, when the term primary care is used, it is concerned with the delivery of care specifically within the general practice setting. Accordingly, primary care is generally the first point of contact people have with the health system, and in most cases, the first contact people make about a health problem is with a GP (i.e. a family doctor).[23] A vast range of evidence-based services are delivered in modern general practice, including: antenatal care; childhood immunisations; cervical screening; phlebotomy; diagnostic facilities (e.g. laboratory tests and ECGs), travel vaccination services; and chronic disease management.[24] Primary work activities of GPs have been categorised as: direct patient care (in clinic or telephone consultation); clinical paperwork (e.g. reviewing bloods, prescribing); interactions with colleagues (e.g. about patients or processes); internet use (e.g. seeking information for referral) and home visits.[25] An Irish person visits their GP approximately 4.34 times a year, with the average consultation lasting 13.7 minutes.[26] Single-handed GPs see on average 32 patients per day, while GPs in group practices have an average consultation rate of 29 per day.[26] This high volume of usage of these services emphasises the need to ensure they are functioning efficiently and safely.

The lack of empirical investigation of safety in general practice is likely due to the perception that primary care delivery is a lower risk endeavour than care provided in secondary care settings.[16] Indeed, 10% of hospital admissions[27, 28] result in a PSI, as compared to 2-3% of primary care consultations.[29, 30] The lack of attention on safety in primary care is concerning for a number of reasons, however. First, 80-90% of healthcare contacts take place in this domain of healthcare,[16] equivalent to approximately 29 million general practice consultations in Ireland annually.[26] Considering this sheer volume of primary care patients, there exists substantial opportunity for the occurrence of iatrogenic harm.[30] Second, there has been a growing complexity in the delivery of primary care in recent years. People are living longer, resulting in an ageing population with one or more chronic conditions (i.e. multimorbidity). This complexity poses a challenge to the delivery of safe care,[31] given that patient factors such as increasing age, multimorbidity and polypharmacy have all been associated with a greater risk of PSIs.[32] Finally, GPs

face a range of unique systemic challenges within their working environment. The organisational structure is complex as compared to hospital settings; there is no defined leadership at local level, and general practice operates as an independent business with its own organisational culture and dynamic.[16] The physical work environment itself is less regulated than secondary care, with just over half of Irish GPs operating from purpose-built practices.[24] The availability of equipment varies by practice, with the majority of GPs reliant on local hospitals for diagnostics in particular (e.g. ultrasound, the access of which declined from 65% in 1982 to just 25% in 2015[24]). A number of operational failures GPs frequently experience in their work have been identified, most notably interruptions (e.g. other staff entering consultation room, incoming work-related phone calls), missing equipment or supplies needed by a GP to complete a work task, and problems in co-ordinating the care of patients.[25] Further, a significant volume and variety of work is undertaken by Irish GPs, much of which is spent on non-consultation activity.[25, 33] In a study of safety perceptions amongst Irish GPs, of which I am a co-author, respondents perceived workload to impact negatively upon patient safety and practice performance.[34] There is also an under-supply of GPs in Ireland, with the predicted shortage expected to continue to grow.[35] These factors impair experiences of work, imposing burden on an already pressurised system, and may partly explain the substantial increase in perceived stress levels reported by Irish GPs in recent years.[24]

These patient- and practice-related factors culminate in a healthcare setting which is diverse in its challenges and complexities. Consequently, the safety concerns associated with primary care are often different to those in secondary care.[36-38] Therefore, seemingly simplistic attempts at transferring learning from hospital settings to primary care settings are problematic,[19] and the application of research and patient safety initiatives directly from secondary care to primary care is not recommended.[22] The underpinning evidence-base, whether in terms of conceptual frameworks, typologies/taxonomies, epidemiology, risk factors or interventions all therefore potentially need to be developed in their own right in relation to primary care in order to reflect the unique context and challenges of this environment.[19] Similarly, primary care requires its own tapestry of measures to adequately reflect its' unique context and challenges.

1.4 Measuring and monitoring patient safety in general practice

Seminal reports over the last decade (e.g. the Francis Inquiry report[39]) and the Berwick report[1]) have emphasised that the measurement of safety should be an absolute priority for healthcare organisations, including in general practice. Vincent noted that:

> "*in such* [primary care] *contexts we believe that the development of sophisticated monitoring and response strategies may be more important in the overall balance than any of the other broad approaches*."[31, p124]

General practice staff have expressed difficulty in knowing how to improve safety in their practices.[40] However, it has been found that when GPs are provided with data identifying safety issues within their practice, they are able to identify and implement methods to effectively address deficits.[41,42] As a result, there is a need to implement valid, readily available, and easily administered methods of measuring and monitoring safety (MMS) in the primary care setting.[43] The resultant data should provide practice staff with perspective on the state of their safety management systems, facilitate national and international comparisons, and be used for benchmarking purposes and analysing trends.[5]

1.4.1 The MMS framework: Five dimensions of safety monitoring and measuring

In order to guide healthcare organisations in the measurement and monitoring of safety in practice, Vincent et al.[5, 44] proposed the MMS framework of five dimensions and associated questions (see Figure 1). Although initially developed for the secondary care context, the MMS framework could be considered applicable to general practice.[16] To illustrate, the methods employed to-date in general practice within each of the MMS domains are summarised next, as informed by the findings of a meta-review I co-authored that synthesises methods of MMS in primary care.[43]

Figure 1.1 Measuring and monitoring of patient safety in healthcare (MMS) framework, adapted from Vincent et al.[5, 45]

Dimension 1. Past harm

The first MMS dimension is concerned with *Past harm*, or the determination of whether patients have experienced avoidable harm in the organisation previously.[5, 45] Our meta-review found that the most common measure of past harm in primary care was retrospective screening of patient records.[43] Chart review methods included 'trigger tools' to identify the presence of specific clinical prompts that may indicate the occurrence of a PSI,[29, 46, 47] and incident reporting by healthcare providers (HCPs) (e.g. [48-50]). Other methods for assessing past harm were the use of data within comprehensive administrative databases in primary care settings that monitor patient activity, financial and clinical information (e.g. analysing a computerised medical record database to determine the drugs most frequently implicated in severe interactions[51]) and HCPs recalling errors or safety events via interviews or surveys (e.g. [52, 53]).

Dimension 2. Reliability

The *Reliability* dimension is focused on assessing agreement and standardisation[5] in the performance of key procedures or processes. In our meta-review,[43] it was found that the most commonly identified methods of assessing reliability included practice checklists (e.g. the Monitoring Risk and Improving System Safety (MoRISS) checklist[54]), direct observations (e.g. simulated medical consultations[55]), and surveys of primary care staff (e.g. to assess the proper storage of medications and vaccines[56]).

Dimension 3. Sensitivity to operations

Sensitivity to Operations refers to healthcare workers' awareness of how the organisation functions, and sensitivity to broader issues that can affect patient care.[5,45] In our meta-review,[43] the predominant methods of measuring *Sensitivity to Operations* included staff surveys (e.g. to explore whether specific characteristics of general practice (e.g. medication, physical infrastructure) were associated with patient safety[53]), interviews (e.g. regarding their perceptions of the safety of the practices that they worked in[57]) and the use of active monitoring systems, whereby physicians completed structured forms after each patient consultation, allowing them to reflect on aspects of the care provided and identify any errors made or potential harm (e.g. [58, 59]).

Dimension 4. Anticipation and preparedness

The *Anticipation and preparedness* dimension is concerned with the ability to intervene to reduce the likelihood of patient harm occurring in the future.[5, 45] Measuring safety climate perceptions of general practice staff via questionnaire is the most frequently adapted method of proactively assessing safety in primary care,[43, 60] with numerous tools developed and implemented for this purpose[61] (e.g. PC SafeQuest[62], The Manchester Patient Safety Framework (MaPSaF)[63], and The Frankfurt Patient Safety Climate Questionnaire (FraSiK)[64]). Other methods of measuring this Dimension include Failure Modes and Effects analysis (Singh et al 2004) to identify practice hazards for prioritisation, and qualitative methodology (e.g. staff interviews and focus groups[63, 65]).

Dimension 5. Integration and learning

Integration and learning highlights the importance of balancing the focus of collecting and integrating safety information with appraising how it is used in a meaningful way in order to deliver feedback, action and improvement.[5, 45] In our meta-review,[43] methods of addressing this Dimension included identifying 'lessons learned' from errors amongst practice staff,[66] the use of safety culture data to inform risk management,[67] and feedback to inform safety improvement (e.g. The Safety in Primary Care (SAP-C) study[41] which I led and evaluated).

Critiquing MMS efforts in primary care

The dimensions within the MMS framework are applicable and relevant to primary care, as evident from the exiting tools which can be used to inform each of the dimensions. There are, however, a number of critiques that warrant consideration. First, although a trigger tool approach to patient record review offers a reliable and usable approach to measuring *Past harm,* this approach required further refinement and investigation.[68, 69] Second, certain dimensions are less developed in the primary care environment than others; for example, methods of measuring and monitoring. *Sensitivity to operations* in the secondary care setting include safety ward rounds, briefings and debriefings,[5, 44] while the methods used in primary care are somewhat unstructured (e.g. focus groups) and time-consuming (e.g. GP staff completing an assessment after a consultation).[43] Third, although a feasible method for assessing *Anticipation and preparedness* in primary care, safety climate surveys typically lack sound psychometric properties,[61] which hinders the collection of meaningful and trustworthy data. Finally, there is a need to integrate safety data from multiple sources in order to inform learning.[43] However, the majority of the tools above are HCP focused, and patients remain an underutilised resource for patient safety.[16, 70] Although patient-centeredness is a key element of primary care delivery,[16] the patient role in safety has not been captured and translated into meaningful patient-centred metrics in primary care. Vincent states:

> "*The full engagement...of patients and carers in the management of risk will be a necessary core of any such approach*"[31, p124]

Future work focused on how to involve patients in safety measurement is needed, which will be the focus of the next section within this chapter.

1.5 Involving the patient in patient safety

The focus on patient involvement in safety initiatives has increased in recent years.[71, 72] A driving force for this emphasis arose from recommendations provided in high-profile inquiries on poor hospital care (e.g. the Francis, Keogh, and Berwick reports[1]), which emphasised the need to develop and support better systems for involving the patient in patient safety in healthcare.[72] Accordingly, the importance of involving patients, their families and carers, and other lay people in improving the safety of healthcare has become a key government and health service concern, as reflected by national-level policies calling for increased patient involvement. Most recently, the 2019-2024 UK National Health Service (NHS) Patient Safety Strategy[73] outlined a Framework[74] for involving patients in their own safety as well as improving patient safety in partnership with staff. In Ireland, the 2019-2024 Health Service Executive (HSE) Patient Safety Strategy[75] identified the empowerment and engagement of patients to improve patient safety as a key strategic commitment. Further, patient involvement in healthcare safety is an international policy priority, with the World Health Organisation's World Alliance for Patient Safety (WHO, WAPS) citing mobilisation and empowerment of patients as a key action area in its 'Patients for Patient Safety Programme'.[76] Such policy has been translated into practice through the establishment of various initiatives which promote understanding and dialogue around patient safety, and the role patients can play (e.g. Patient Safety Champions Network[77] in the UK and Patients for Patient Safety[78] in Ireland).

In spite of international emphasis and repeated calls for greater patient involvement, relatively little progress has been made. Patient involvement comes in many forms, including: educating patients about risk, asking patients to help plan broad service change, collecting of retrospective feedback, encouraging patients to identify risks when they are receiving care and involving patients in monitoring the safety practices of HCPs.[79, 80] Yet, there are too few rigorous studies of patient involvement to provide a reliable evidence base, and therefore a dearth of research on how best to involve patients and whether such involvement leads to improvements in safety.[72, 79] The evidence that does exist suggests that patients have the potential to improve safety and are willing and able to participate, in spite of a

range of barriers.[79] The rationale for including patients in safety efforts, and associated barriers, are described in greater detail in the next section.

1.6 Rationale for, and barriers to, involving the patient in patient safety

The ultimate rationale for including patients in patient safety is that they have the potential to improve safety. As the only people present during every consultation and treatment,[81] patients have a unique position at the epicentre of the treatment process, observing the entire trajectory of care interactions, therefore possessing considerable knowledge about risks, problems and incidents within healthcare systems.[82] Patients have been described as vigilant partners,[83] observers of unsafe practices,[84] privileged witnesses of events,[10] and one of the key protagonists of the patient safety experience.[85] Given their acquisition of contextualised information during the care process,[81] patients can play a pivotal role in patient safety initiatives.[86] Involving the patient in safety can also highlight issues that HCPs may not be aware of.[87] For example, it has consistently been found that patients can identify safety events that have not otherwise been captured by the hospital incident reporting system or documented in the medical record or patient case notes.[79, 88-92] Further, patients can identify hot spots (areas of care where harm or near-misses occur frequently) and blind spots (areas of care that cannot be easily observed by staff in care[93]).

Importantly, patients are willing to be involved in patient safety. As the main protagonist of the safety experience, patients are highly motivated to reduce the risk of harm and ensure good outcomes[94] and have expressed interest in being open about problems in their care[82] and engaging with safety efforts.[95, 96] Patients have been found to welcome the opportunity to partake in safety involvement, as demonstrated by high participation rates,[79] and consider having their queries addressed as a means of providing reassurance and understanding of their care.[97] Finally, they are capable of recognising when things go wrong in their care[98, 99] and able to discuss problematic situations with little prompting.[99]

Patient-related barriers or variables related to inclusion in patient safety include demographic characteristics (e.g. young patients express a greater desire to be involved in safety) and illness-related factors such as severity of illness (e.g. patients with severe disease may prefer a less active role[95, 100, 101]). There is the

potential risk of burdening patients with responsibilities beyond their ability, or inappropriately shifting the responsibility for patient safety from HCPs to the patient.[2, 94, 102] Other patient barriers include factors such as health literacy (e.g. lacking medical knowledge[2]) and lack of access to information about how to report issues[103]), knowledge and confidence (e.g. confidence about grounds for concern[102]), and issues including discrimination, inequality and social exclusion[104] (e.g. educated and employed patients are more likely to be engaged in safety behaviours[101]). Patients have also expressed a reluctance to question or challenge HCPs' actions[100, 101] due to fear of being labelled 'difficult', thus potentially affecting the harmony of the patient-provider relationship and subsequently resulting in compromised care.[97]

From the HCP perspective, staff report welcoming patient engagement, with perceived advantages including improved adherence to treatment, better understanding, and an opportunity to resolve issues before they escalate.[97] However, staff have also expressed concern about feeling challenged, criticised and scrutinised, particularly in light of time and workload demands.[97] Concerns have also been raised over whether patients are a reliable source of information.[94] For example, patients have previously perceived service quality lapses as PSIs,[99, 105] and in some cases, patient-reported outcomes have also shown poor concordance between patients and clinicians.[106]

Taken together, the current evidence suggests that patients hold key information vital for process, systems and policy improvement,[107] as their perceptions of safety could be a good first indicator of deeper system issues that require attention.[99] Therefore, careful observation, measurement, recording, interpretation, and analysis of their subjective experiences can help to delineate what is working well in healthcare, what needs to change, and how to go about making improvements.[108] Tapping into this valuable resource and learning from patients could help to limit the scale of harm for future patients by identifying the need for practical action to reduce future risk.[109] However, more research is needed on how best to involve patients and the associated improvements this leads to.[72, 79]

1.7 Patient involvement in measuring and monitoring safety

As the rationale for involving patients in safety is clear, interest in developing and evaluating specific methods for patient involvement in MMS has grown. Therefore, this thesis will primarily focus on understanding how patients can best be involved in safety measurement and monitoring specifically, given that the development of valid and reliable methods has been slow[110] and primarily conceived through the lens of HCPs[111] and the voices, inputs, evaluations and experiences of patients remain underexplored.[60, 83, 112-114] This is highly problematic, given that evidence from a variety of different sources is required to aid understanding of patient safety in healthcare.[83, 89] Patient concerns are rarely evident in other forms of safety data, indicating a less than complete picture of patient safety and an inability to draw upon a patient's entire care experience which can only be provided by patients themselves.[81] In the preparation of this chapter, simple literature searches were undertaken, along with consideration of data from our meta-review,[43] in order to identify approaches congruent with each of the five domains of Vincent's MMS framework. Methods that have incorporated the patient experience of safety in primary and secondary care settings are outlined below, in accordance with the five dimensions of the MMS.[5, 44]

1.7.1 Dimension 1: Past harm

The patient-focused measures in this dimension tend to use a survey-based approach to assessing whether patients experienced potential patient safety problems, or specific undesirable events during their care. For example, using a survey to estimate the frequency of patient-perceived potentially harmful problems occurring in UK primary care,[115] or administering a survey to patients post-hospitalisation to capture their experiences, including whether they had an adverse event and received honest communication about it.[116] Other methods involve patients reporting safety incidents via a paper form, an online form or by telephone (e.g. gathering medical errors from patients in US family clinics using a web-based error reporting system,[117] or hospital patients disclosing concerns about their safety using the Patient Incident Reporting Tool (PIRT) form[111]), or analysing healthcare complaints systems in primary[93] or secondary[118] care settings. Interviews have also been used to delineate patients' and family members' experiences of safety problems while receiving care (e.g. with rural

general practice in Australia,[119] or with patients with a recent overnight hospital visit in the USA[99]). Finally, online tools or web-based systems have been used less frequently to elicit data from patients regarding adverse events they experienced while receiving primary (e.g. [120]) or hospital (e.g. [121]) care.

1.7.2. Dimension 2: Reliability of safety clinical processes

In terms of how patients have been involved in determining the *Reliability of safety clinical processes*, measures have been relatively few. One example involved examining discrepancies between what doctors prescribe and what patients take in actual practice, by investigating patients' reported use of medications via interviews and comparing these with physicians' records of outpatients in a private practice.[122] 'Open notes' have also been utilised, whereby primary care physicians invite their patients to read their visit notes online through a secure patient internet portal to identify potential errors.[123]

1.7.3 Dimension 3: Sensitivity to operations

As was the case with Dimension 2, measures that incorporate patients in assessing *Sensitivity to operations* are limited. The use of simulated patients is one such example, whereby a range of clinical scenarios were presented to assess primary care physicians' abilities to detect hints of high-risk factors that required consideration for an appropriate, error-free care plan.[55] A user-friendly, self-reporting, bedside tool for patients and families to report harm during their hospital stay has also been developed and tested, allowing patients to report incidents in relation to medication, equipment, and hygiene in real-time.[124]

1.7.4 Dimension 4: Anticipation and preparedness

Regarding the assessment of *Anticipation and preparedness*, patient-report safety climate surveys have been used to examine a range of 'upstream' factors or domains that are known to contribute to safety. For example, a sub-section of the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire examined general perceptions of safety in primary care,[115] while the Patient Measure of Safety (PMOS) questionnaire examined a range of factors or domains known to contribute to hospital safety (e.g. teamwork, communication,

environment).[125, 126] Data gained from these methods have been deemed useful for proactively improving the safety of care (i.e. identifying deficient safety before harm has occurred[60]).

1.7.5 Dimension 5: Integration and learning

Most methodologies involving patients in measuring *Integration and learning* tend to be embedded within incident reporting methodologies (e.g. in a survey of past harm where patients were asked about adverse drug events they experienced during hospitalisation, patients were also provided with an opportunity to offer suggestions for preventing future occurrences[127]). There are, however other examples of examining Integration and learning using a standalone methodology; for example, the Always Events[128, 129] concept involves patients identifying what is so important to them that it should always happen when interacting with healthcare services. This has been demonstrated in the conduct of interviews and surveys with primary care patients in the UK with long-term clinical conditions, to ascertain what they felt should always happen when receiving care in the doctors surgery.[128] A similar approach was taken with emergency department patients in the UK via a questionnaire querying "*what should always happen in the Emergency Department*?"[130] Finally, this Dimension has been assessed from the patient perspective via Citizen Science, which involves non-professionals participating at any phase of scientific research to generate synergies between lay and expert collaboration.[131] For example, one citizen science study implemented in primary care focused on patient responses to "*if you had a magic wand, what would you change in your healthcare*?"[132]

1.7.6 Concluding remarks on patient involvement in measuring and monitoring safety

It is evident that surveys in which patients provide feedback on *Past harm* are commonly implemented, while formal incident reporting systems, interviews and online tools are used to a limited extent.[70, 80] Research involving patients in measuring the *Reliability of safety clinical processes* and *Sensitivity to operations* is limited in comparison. This may be explained by such dimensions requiring an infrastructure of organisational capability that are contextually applicable to a

hospital setting, but not evident in most areas of general practice.[16] As compared to past harm, less work has also considered *Anticipation and preparedness*, which focuses on how patients can report on factors that may contribute to future error (i.e. proactive approaches to safety measurement). In relation to *Integration and learning*, the Always Events (AE)[128, 129] concept and citizen science approach[132] have been useful for leveraging patients' practical knowledge of safety of care received to improve it. Other studies involving patients in the measurement of this Dimension tend to be embedded within incident reporting methodologies. Overall, notably fewer methods appear to have been used to quantify patient safety problems in primary care from the perspective of the patient as compared to secondary care,[80, 133, 134] which is perhaps unsurprising given the paucity of patient safety research conducted in primary care settings generally. It has been acknowledged that further research is needed to identify the optimal method for capturing patient reports, that is relative to different clinical settings in addition to secondary care.[70] Further, it is clear that the majority of work involving patients in safety measurement in primary care has focused on gaining feedback on specific isolated safety incidents, concerns, problems, or adverse events. Although this is valuable data, there is a need to embrace a more expansive view of safety and risk; one where information about the presence of safety may be integrated equally with measures of past harm.[135]

1.8 Theoretical foundation of this thesis

In order to support the comprehensive involvement of patients in measuring and monitoring safety, there is a need for a theoretical foundation in order to guide the approach. Systematic reviews of patient-reported events in healthcare have reported a notable lack of theoretical underpinning in the design or analysis of patient reports, with few included studies referring to theoretical or conceptual standpoints.[85, 98] Recognising the need for a theoretical foundation, this thesis is informed by three theoretical frameworks: (1) patient activation theory; (2) socio-technological systems theory; and (3) safety climate/culture theory.

1.8.1 Patient activation theory

Despite the growing awareness of the benefits of involving patients in health research, theory-driven approaches are lacking. This may, in part, be explained by the considerable confusion regarding the use of terminology in this area, with various terms used synonymously with involvement (e.g. engagement, participation, consultation, partnership[104, 136]). As a result, various potentially relevant theories were considered in the development of this thesis; namely, patient activation theory, and program theory and guidance for managing active patient involvement.

Patient activation theory is based on the premise that patients have a key role in influencing health care.[137] The concept of patient activation involves four stages, the first two of which are relevant to this thesis: (1) believing the patient role is important, and (2) having the knowledge and confidence to take action. The current thesis has previously detailed evidence for these assertations, as discussed in section 1.6.

Further building on patient activation theory, Boivin et al.[138] outline theoretical constructs that have been proposed to explain effective public involvement, two of which include: (1) public members' credibility and ability to contribute to knowledge that is considered valid and relevant, and (2) their legitimacy to speak on behalf of people affected by health care services. In the literature, technocratic theories of public involvement stress the importance of the public's ability to demonstrate 'credible expertise'. From these theoretical perspectives, access to the best available evidence through training and preparation is critical to ensure the delineation of valid and relevant participation from competent participants.[139, 140] Therefore, discussions about public expertise largely focus on the notion of technical competence, assuming that 'lay' members of the public do not always understand 'scientifically valid' evidence. However, this suggestion has been refuted by suggestions that members of the public are 'experience-based experts' whose knowledge is based mainly on their personal experiences rather than their degrees or professional qualifications.[141] Boivin et al.[138] describe how recruitment of patients and caregivers with direct personal experience, provided with the opportunity to broaden their knowledge base by interacting with other community members, is sufficient in developing a specific public expertise. Second, criteria to support or question the public's legitimacy have been suggested

(e.g. statistical representativeness of a group). However, Boivin et al.[138] acknowledge that statistical representativeness is only one aspect of public members' legitimacy and is most applicable to public consultation strategies in which large groups of participants can be recruited and suggest adapting a balanced recruitment strategy and the use of a preparation meeting to support participants' ability to legitimately represent their community. In line with these suggestions, the current thesis will adopt these recruitment strategies within the individual studies.

Finally, the conduct of a realist synthesis identified three inter-dependent theories to guide the involvement of patients in improving healthcare: tailoring, interaction and partnership, and behavioural change.[142] Together, these theories form a programme theory and guidance for managing active patient involvement in relation to improvement efforts; active patient involvement can be a tool (resource), if tailored for interaction and partnership (reasoning), that leads to behaviour change (outcome) within healthcare improvement efforts.

1.8.2 Socio-technological systems theory

It has been suggested that when investigating patient-reported information, taking a human factors approach is the most appropriate foundation for research, due to its focus on the multi-factorial nature of PSI causation, and increasing adoption by service providers in safety improvements.[85] Developing a method for capturing patient-reported information without recognising human factors may lead to a superficial interpretation of PSIs, and one which may inappropriately focus on the role of individuals in causation.[85] Indeed, safety theories have shifted from focusing on the individual to understanding organisational conditions that result in human error (e.g. The Organisational Accident Model[143, 144]), followed by an awareness to understand not only organisational culture but also a range of human factors (i.e. managerial, team and individual characteristics that influence the behaviour of healthcare staff in relation to safe patient care[145]; e.g. The London Protocol[146-148]).

Such factors can be framed within a sociotechnical systems model of healthcare. Taking a systems approach to safer primary care involves examining how different components relate to one another and considering various factors which could influence safety.[149] This approach recognises that organisational change requires the consideration of factors interacting at different levels, including the

patient, healthcare providers, teams, organisations, and the economic and political context.[145] These are organised within Moray's model of the organisational and human factors in sociotechnical systems[150] (see Figure 1.2). This theory shaped the current thesis by highlighting the contextual differences that exist in the delivery of primary and secondary care,[22] thus making a case for the design of measures that specifically address the unique challenges of primary care. Further, this theory postulates that patients can comment on factors within levels of the organisation other than patient level.

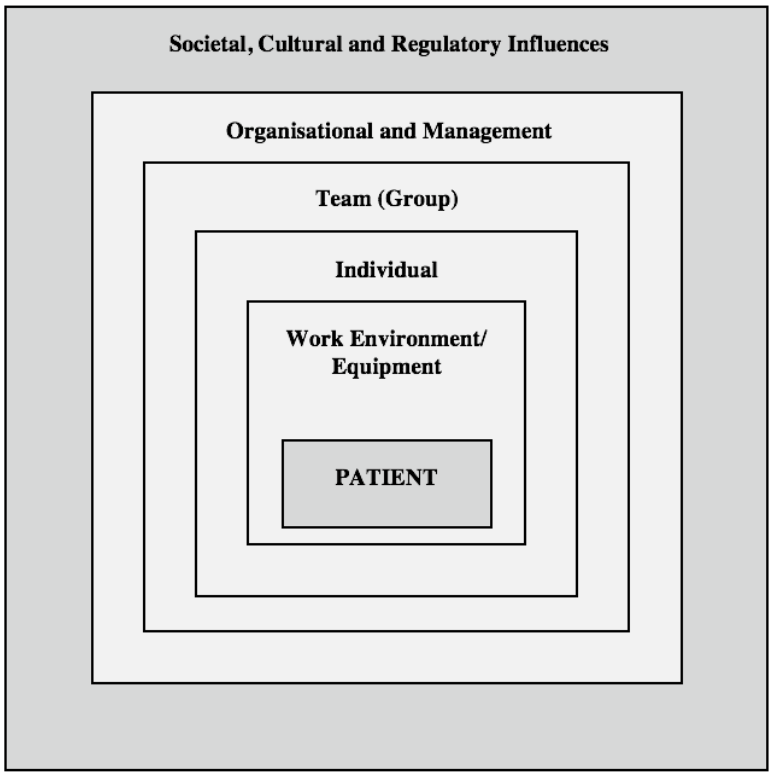

Figure 1.2 Organisational and human factors in sociotechnical systems, as adapted by Curran[22] from Moray et al.[150]

1.8.3 Safety climate/culture theory

A number of key human factors topics have been identified as most relevant for patient safety[145]; one of which is safety culture. Analysing the safety culture or safety climate of an organisation is a proactive method of measuring *Anticipation and preparedness*. Much debate has surrounded the definitions of safety climate and

safety culture, and the relationship between both concepts,[151] with both terms used interchangeably in the literature, despite a clear distinction between them.[152] The term 'safety culture' entered occupational safety discourse in response to disastrous events in industries such as nuclear power, offshore oil, and commercial aviation[152] and has been described as individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine an organisation's commitment to safety.[153]

Safety climate is considered a reflection[154] or the measurable component[155] of the underlying safety culture in an organisation at a particular point in time. Safety climate has been associated with a number of favourable outcomes including lower relative incidence of PSIs in aviation,[156] reduced hospital medication errors,[157, 158] and improved hospital HCP and patient satisfaction.[157] Measuring safety climate is the most frequently adapted method of proactively assessing safety in the primary care setting,[60] and has led to greater insight into various factors that can influence HCPs perceptions of safety climate in primary care (e.g. years of experience, professional roles[41, 159]). A number of core safety climate domains have been suggested to exist in healthcare, including: safety systems; risk perceptions; job demands; reporting/speaking up; safety attitudes/behaviours; communication/feedback; teamwork; personal resources; and organisational factors.[160] As discussed in section 1.4, instruments that assess safety climate tend to focus on the perceptions and attitudes of organisation members[161, 162] (i.e. in the context of healthcare professionals, managerial or staff members). Safety climate theory was used to support the current thesis, as its' measurement is considered valuable for allowing organizations to monitor and evaluate changes in perceived safety of a service over time,[62] enabling deficiencies in safety to be identified and targeted for improvement.

1.9 Statement of research aims and research questions

There are a multitude of approaches to MMS in primary care. For the purpose of this thesis, the focus will be on the MMS domains of *Past harm* and *Anticipation and preparedness* (more specifically, safety climate). Although *Past harm* is the most commonly measured domain within the MMS framework, it is infrequently assessed from the patient perspective. This is problematic, as the examination of past harm is

often a key method of informing *Integration and learning*. Further, patients are well-placed 'observers' of unsafe practices,[84] and capable of providing information on issues that may not be visible to HCPs.[113] Similarly, safety climate is commonly assessed from a healthcare professional perspective[61] but the patient insight into safety climate has been considered less frequently. Examination of these dimensions from a patients' perspective will support triangulation of safety data as has been recommended,[163] and will address the need to examine the value of adding the patient perspective to the '*tapestry of measures*' that provide an overview of safety.[124] Accordingly, the two overarching aims of this thesis are to:

(1) *identify an approach to how patients can contribute to the measurement and monitoring of safety climate*; and

(2) *ascertain the value of patient data for identifying and learning from past harm in primary care*.

These two aims are addressed through the completion of four studies- each addressing a specific research question. The first study will use a systematic review methodology in order to critically appraise existing patient-report safety climate measures. Little research has specifically considered the extant patient-report safety climate measures for healthcare settings. The first research question is:

1. *What patient-report safety climate measures have been described in the literature, and what are the psychometric properties of, and coverage of safety climate domains, within these measures?*

Based upon the findings from the systematic review, a suitable patient-reported measure of safety climate will either be identified, or developed, and used to collect data from general practice patients in Ireland. The psychometric properties of the applied tool will be established amongst this population specifically, which is imperative given that validity, reliability, and useability are essential to the collection of meaningful and trustworthy data.[61] Therefore, the second research question is:

2. *What are the validity, reliability, and usability of a patient-report measure of safety climate among a sample of Irish general practice patients?*

In order to identify potential areas of suboptimal safety requiring improvement in Irish general practice, it is necessary to consider patient perceptions of safety climate. Therefore, the third research question is:

3. *What are patients' perceptions of, and insights on, safety in general practice, and do these differ according to patient characteristics?*

The final research question will examine the value of utilising a qualitative approach to assessing *Past harm* via 'patient stories' (i.e. first-hand accounts of experiences by patients) to better understand safety and identify deficiencies. Such an approach has been taken to understand patient safety incidents from the perspective of GPs. However, is suggested that there may be value in also considering incidents from the perspective of patients. Therefore, the final research question is:

4. *What can we learn from patient accounts of patient safety incidents in general practice, and do patients and GPs differ in their perceptions of the likelihood, severity and preventability of the patient safety incidents described?*

Recommendations for research and practice will be made based on the findings from the research questions addressed in the published studies described in this thesis (such recommendations are discussed in Chapters 2 to 5, then explored at a broader level in Chapter 6- the final discussion chapter).

1.10 Conclusion

Considering the large volume of consultations, combined with the increasing complexity of practice and patient factors in general practice, there is substantial potential for the occurrence of PSIs in this setting. Therefore, the 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. No one method can serve the purpose of determining whether a clinical area is safe; this thesis is therefore based on the premise that patients can make a unique contribution to our understanding of safety, over and above the safety intelligence already gathered using other methods[111] and

could effectively supplement other measuring and monitoring methodologies such as incident reporting, and staff surveys.[164] In the next chapter, the psychometric properties (i.e. reliability, validity, and useability) of safety climate patient-report survey instruments designed for use in healthcare will be assessed.

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Chapter Two: Study One

A systematic review of patient-report safety climate measures in healthcare

A systematic review of patient-report safety climate measures in healthcare

2.1 Declaration

Alignment with the thesis

Safety climate (SC) is considered to be a reflection[1] or the measurable component[2] of the underlying safety culture of an organisation at a particular point in time. Analysing the safety climate of an organisation is a proactive method of measuring the *Anticipation and preparedness* domain of the Measuring and Monitoring Safety (MMS) framework.[3,4] Safety climate is commonly assessed from a healthcare provider perspective,[5] while the patient insight into safety climate has been considered less frequently. This first study of the thesis used a systematic review methodology in order to critically appraise existing patient-report safety climate measures that have been developed for use in healthcare settings.

Peer-reviewed publication

This study has been published in a peer-reviewed journal; the Journal of Patient Safety, the citation of which is:

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Authors' contributions

The contributions of the individual authors are as follows:

- CM: Conceptualization, Investigation, Data Curation, Formal Analysis, Methodology, Writing- Original Draft Preparation, Writing- Reviewing and Editing.

- SL: Conceptualization, Data Curation, Formal Analysis, Writing- Reviewing and Editing.
- EOD: Methodology, Data Curation, Formal Analysis, Writing- Reviewing and Editing.
- AM: Conceptualization, Writing- Reviewing and Editing.
- POC: Conceptualization, Data Curation, Formal Analyses, Writing- Reviewing and Editing.

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2.2 Abstract

Objectives

Patients are a valuable, yet underutilized source of information for safety measurement and improvement in healthcare. The aim of this review was to: identify patient-report SC measures described in the literature; analyse the included items in order to consider their alignment with previously established SC domains; evaluate their validity and reliability; and, make recommendations for best practice in utilising patient-report measures of SC in healthcare.

Methods

Searches were conducted, with no limit on publication year, using Medline, Embase, CINAHL, PsycINFO, and Academic Search Complete in November 2019. Reference lists of included studies and existing reviews were also screened. English-language, peer-reviewed studies that described the development or use of a patient-report measure to assess SC in healthcare were included. Two researchers independently extracted data from studies and applied a quality appraisal tool.

Results

A total of 5,060 studies were screened, with 44 included. Included studies described 31 different SC measures. There was much variability in the coverage of SC domains across included measures. Poor measure quality was marked by inadequacies in the testing and reporting of validity and reliability. There was also a lack of usability testing among measures.

Conclusion

This review identified the extant patient-reported SC measures in healthcare and demonstrated significant variance in their coverage of SC domains, validity and reliability, and usability. Findings suggest a pressing need for a standalone measure that has a high validity and reliability, and assesses core SC domains from the patient perspective, particularly in primary care.

Keywords

Patient safety; safety climate; safety climate measurement; patient perspective

2.3 Introduction

Estimates of harm across primary[1] and secondary[2] care settings highlight the necessity of proactive measurement and monitoring of patient safety.[3] Patient safety can be assessed using a variety of measures[4,5]; however, many of these (e.g. incident reporting systems) comprise lagging indicators of safety,[6] which are 'reactive' in nature, requiring an adverse event to occur for data to be collected. It has been suggested that a focus on valid, reliable, feasible, and acceptable methodologies that proactively identify deficient safety before harm has occurred may be more palatable to physicians,[3] and contribute more effectively to safety improvement.[7,8] One proactive, 'leading'[6] measure of safety commonly used is the evaluation of the 'safety climate' (SC) of healthcare organizations.

SC is defined as the measurable component of underlying safety culture at a point in time.[9] Safety culture is described as the shared values, attitudes, and behavior of staff with regards to safety.[10] SC measurement was first used in high-risk industries such as aviation[11] and predicts better safety performance[12] and quality outcomes[13] in healthcare. Measuring SC is therefore valuable as it allows for organizations to monitor and evaluate changes in perceived safety of a service over time,[14] allowing for deficiencies in safety to be identified and targeted for improvement. Although a qualitative approach to exploring SC can be taken, available instruments are typically quantitative in design, and examine the perspective of frontline healthcare providers (HCPs) via self-report measures.[14]

However, HCPs only have a partial view of the patient journey,[15] and the recognition of the patient role in safety measurement and improvement has grown.[16] As 'observers' of unsafe practices,[17] patients are an important source of knowledge for reducing avoidable harm and improving healthcare.[18] Patients can provide additional information of which HCPs may be unaware, such as breakdowns in the continuity of care, medication incidents, and communication inefficiencies.[19] Measuring patients' subjective experiences can therefore aid understanding of what is working well in healthcare, what needs to be addressed, and how to facilitate improvements.[20] Further, patients have expressed interest in being involved in their care,[21] and are highly motivated to decrease the risk of harm and ensure good outcomes.[22] The potential for patients to act as a source of data for improving safety is recognized by policymakers; a recent review of the National Health Service

(NHS) in the UK includes empowering patients as a key action for achieving high-quality care.[23] Further, the 'patients for patient safety' movement has gained global traction in highlighting patients' role in achieving patient safety.[24]

To-date, the solicitation of patient feedback has tended to focus on after-event reporting and incident disclosure.[25] Although information from the perspective of the patient who has suffered harm are undoubtedly relevant, patients may still provide useful data for quality and safety improvement even when a safety incident has not resulted in harm.[26] Accordingly, appropriate instruments to capture this data are required. It has been recommended that such measures should be selected based upon comprehensive evidence[27] of validity (the degree to which an instrument accurately measures the concept it is intended to measure[28,29]), and reliability (the ability of an instrument to measure an attribute consistently[28,29]). Further, it is necessary that instruments are 'useable' (i.e. short, readable, easy to complete) to reduce the occurrence of potential errors that may lead to measurement, or nonresponse, errors.[30]

Little research has specifically considered the extant patient-report SC measures for healthcare settings with regards to these factors. One review[26] examining patient-report safety measures focused only on primary care, and included studies with a specific focus on lagging indicators, as opposed to patients' general experience of SC. The aims of the current systematic review were therefore to: 1) identify patient-report SC measures described in the literature; 2) analyse the included items in order to consider their alignment with previously established SC domains; 3) evaluate the validity, reliability, and usability of these measures; and, 4) make recommendations for best practice in utilising patient-report measures of SC in healthcare.

2.4 Methods

This systematic review was planned, conducted, and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[31] A protocol for this systematic review has been published on Prospero, an international prospective register of systematic reviews, in May 2019 (registration identification: CRD42019131913; see Appendix A).

2.4.1 Search strategy

Systematic searches were conducted across five electronic databases: Medline, Embase, CINAHL, PsycINFO, and Academic Search Complete. Searches were carried out in May 2019, and updated in November 2019. The search strategy (see Appendix B for MEDLINE search strategy) included Medical Subject Headings (MeSH) search terms along with other keywords related to clinical settings (e.g. 'Primary Health Care'; 'Secondary Care'), measurement tools (e.g. 'instrument'; 'scale'), and quality and safety (e.g. 'patient harm'; 'adverse event'). The search strategy was altered as necessary for databases other than Medline. Language was restricted to English, with no limits placed on publication year.

Additional search methods were also utilised. First, the reference lists of all studies identified as suitable for inclusion through the electronic searches were manually screened so as to locate any additional, relevant papers. Second, the bibliographies of the first and last author of each study identified for inclusion were also examined to identify potentially relevant studies. Finally, the reference lists of recent systematic reviews pertaining to safety measurement[3,26,32,33] were also screened.

2.4.2 Study selection

Inclusion and exclusion criteria

To be included in this review, studies had to: (a) be published in an English language, peer-reviewed journal; (b) report original research, and; (c) describe the development and/or use of a patient-report measure designed to assess the perceived safety, or SC, of primary or secondary healthcare services. Measures that were specifically framed, or described, as a 'safety measure' were included along with broader patient-report measures that contained at least one subscale or domain pertaining to perceptions of safety.

Studies were excluded for a number of reasons, including: (a) development or use of a measure which was focused on the occurrence of one specific adverse event rather than examining a more general perception of safety; (b) development or use of a measure that focused solely on the safety of a healthcare facility's physical environment rather than the safety of healthcare delivery; and (c) development or use of a measure for which individual items were not presented within the paper and

were not obtained following contact with the paper's corresponding author (in all such cases, two emails were sent to the corresponding author- an initial request email and a reminder email two weeks subsequent).

Screening

The titles and abstracts of all papers identified during the search process were screened by the first author (CM) in order to assess suitability for inclusion. If these provided insufficient information so as to determine inclusion or exclusion, then the full-text of the paper was examined. A second author (SL) reviewed any articles for which there was uncertainty surrounding suitability for inclusion.

2.4.3 Data extraction

Two authors (CM and EOD) conducted data extraction independently and disagreements were resolved through discussion until consensus was achieved.[34] Across studies, agreement was calculated at 95.5% (range: 77.8%-100% for individual studies). A structured tool was used to extract data from individual articles, including: country in which the study was conducted; healthcare setting; number of respondents; how the measure was used; and features of the measure including number of items pertaining to safety; item content; and rating scale used.

Beyond this, additional coding was undertaken in relation to the type of usage of the measure reported in the paper and its coverage of core SC domains. With regards the type of measure usage that was described within the paper, this was coded as either: 1) development (i.e. describes the development process of a SC measure), 2) validation (i.e. psychometric validation of the SC measure conducted), or 3) application to sample (i.e. cross-sectional application of the measure and focus on resulting data).

The coverage of core SC domains was assessed through a comparison with the ten core domains of SC, as explicated by Flin et al.[27] These core domains were derived from a review of healthcare SC questionnaires, and included: safety systems; risk perceptions; job demands; reporting/speaking up; safety attitudes/behaviours; communication/feedback; teamwork; personal resources; and organisational factors. For the purposes of this review, four patient safety researchers reviewed the individual items within each questionnaire and used a deductive content analysis

approach[35] to code the items using Flin et al's[27] domains. Discrepancies in the categorisation of items to specific domains were resolved by group discussion until consensus was achieved.

2.4.4 Quality appraisal

As the primary focus of this review was on the measures described and used within studies, the quality assessment process undertaken consisted of an evaluation of the validity and reliability of included measures, in addition to factors that indicated patient usability. No existing appraisal tool was found that examined validity, reliability, and usability factors. Therefore, a checklist of appraisal criteria was developed by the research team, based on recommendations and assessment methods described in a number of previously conducted reviews of measurement tools relating to quality and safety of care,[36,37] and constituted a comprehensive evaluation of all three properties (for complete detail regarding the criteria used, see Table 2.1). A score was awarded for each appraisal element deemed present, resulting in a possible total appraisal score from zero to nine. For measures used in multiple studies, the tool was applied across the studies (see Appendix C). Two authors (CM and EOD) carried out this systematic critical appraisal using the checklist and considered the properties of each tool that was identified.

Table 2.1 Psychometric quality appraisal criteria as adapted from Curran et al.[36] and Eigenmann et al.[37]

	Yes (✓)	No (X)
Reliability testing		
• Internal consistency: Measure of consistency of internal factor structure.	-Acceptable Cronbach's alpha of greater than >0.69 throughout all domains/for most SC domains. -Cronbach's alpha for entire SC measure provided (not applicable to measures containing SC subscale). -Other acceptable indices of reliability within conventional cut-offs.	No evidence of reliability measurement within measure. No evidence of reliability measurement within measure but reference made before consideration or assessment.
• Test-retest reliability: Extent to which the survey elicits the same scores each time it is used under the same conditions.	Pearson/Kappa/Spearman rho rank order correlation coefficient of >0.7 for group comparison.	No evidence of test-retest reliability provided.
Validation methods		
• Content validity: The degree to which the survey items are representative of a defined factor, which they are intended to measure.	Evidence of content validity (e.g. expert panel review, literature review to inform survey development, pilot test of survey, or pre-test panel where survey was reviewed by a focus group of experts before being further revised or retested).	No evidence of content validity assessment within instrument. No evidence of content validity within instrument, but reference made to previous validation.
• Construct validity: The extent to which the survey measures what it is intended to measure.	Evidence of factor analysis (i.e. exploratory factor analysis, confirmatory factor analysis) or interdimensional correlation assessment.	No evidence of factor analysis or interdimensional correlations.
• Criterion-related validity: Assessed by correlating the SC scores with another outcome or criterion variable.	Correlations with other quality or safety indicators.	No evidence of criterion-related validity.
Usability		
• Interpretability Ability to assign easily understood meaning to a tool's quantitative scores.	All of the following provided: response scales used, values assigned to responses, negatively worded items and how total scores were obtained.	One or some aspects provided, but not all.

• Burden Completion requires minimal time and effort.	Should take no longer than 10 minutes to complete. Minimal effort for scoring and data collection required.	Burden not addressed or burden addressed but survey considered lengthy and/or time consuming.
• Acceptability Tool is considered acceptable by respondents.	Measure assessed for readability (e.g. formal testing carried out). Interviews/pilot testing carried out with respondents to examine acceptability.	Acceptability of the measure not assessed.
• Availability No fees attached, easy to access.	Survey provided in the appendix, in supplementary materials, presented in a table in-text, or obtainable via Google search.	Survey only obtainable via authors or pay-per-view.

2.5 Results

As shown in Figure 2.1, over 5,000 papers were returned from the electronic database searches, with 14 additional studies identified via reference list and bibliography screening. Of these, 44 studies[19,25,38-79] met the inclusion criteria, describing 31 separate measures. Included studies were published between 2003 and 2019. As shown in Table 2.2, studies were predominantly conducted in Europe (61.4%), followed by North America (22.7%).

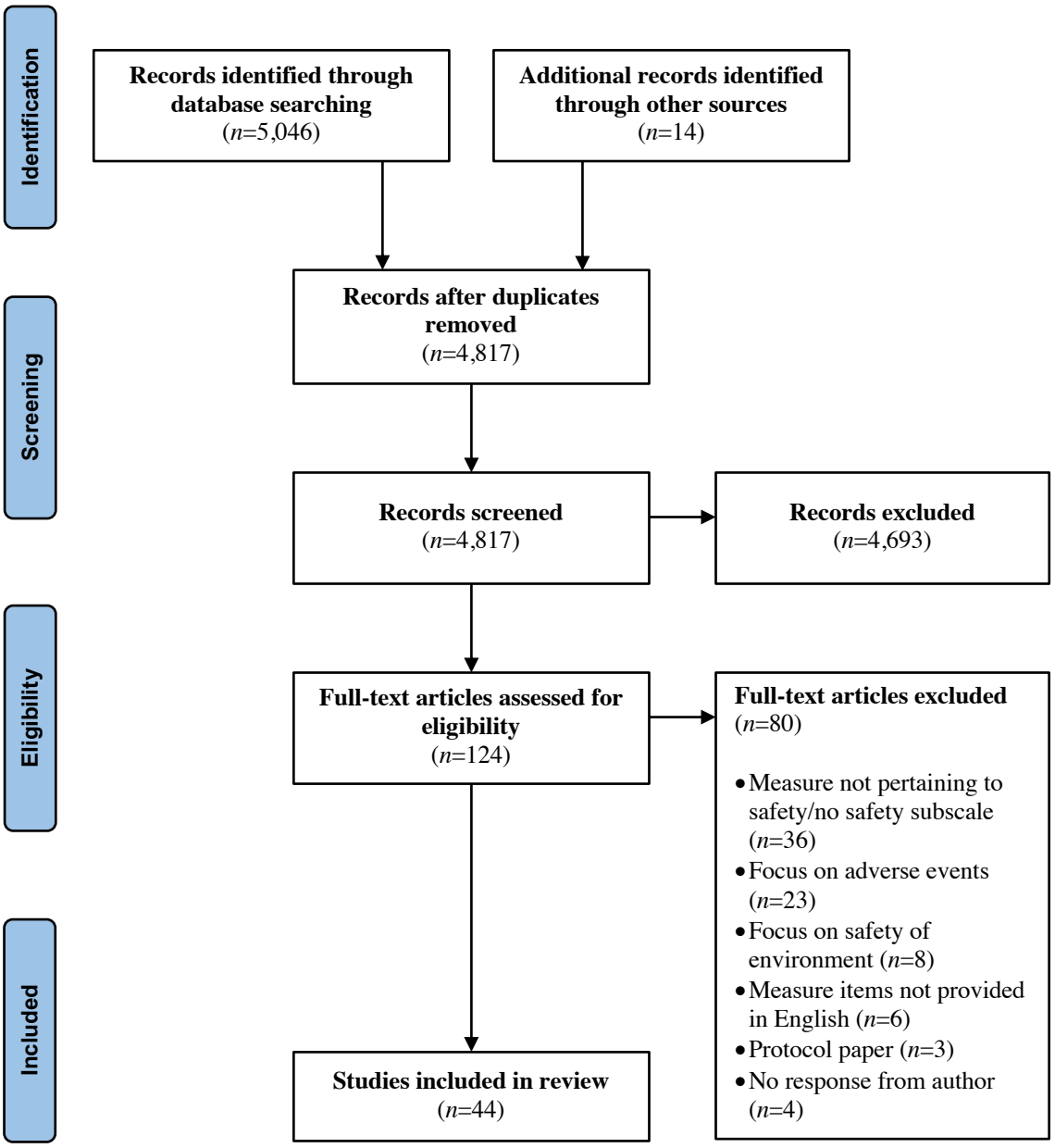

Figure 2.1 PRISMA[31] flowchart depicting identified studies for review.

Table 2.2 Characteristics of included studies (*n*=44)

Characteristic	*n* (%)
Continent*	
Europe	27 (61.4%)
North America	10 (22.7%)
Asia	4 (9.1%)
Australia/New Zealand	4 (9.1%)
Healthcare setting	
Primary care	10 (22.7%)
Secondary care	31 (70.5%)
Transitional care	3 (6.8%)
Usage	
Application to population	12 (27.3%)
Development and validation	12 (27.3%)
Development and application to population	10 (22.7%)
Validation	5 (11.4%)
Development	5 (11.4%)
Sample	
Patients	36 (81.8%)
Parents of paediatric patient	5 (11.4%)
No sample recruited	3 (6.8%)

*Figures do not total to 44 as some studies fit within more than one of the categories.

2.5.1 Samples and setting

Detailed information regarding the included studies can be found in Appendix C. As shown in Table 2.2, the majority (70.5%) of studies were conducted within secondary care. Studies recruited a mean of 2817 participants (*SD*=5462.9), the majority of which were healthcare patients (81.8%); fewer had parents of pediatric patients complete the measure (11.4%). Three studies[25,56,77] did not recruit a sample, all of which were which focused on developing a measure.

2.5.2 Measure usage

The majority of studies applied the measure to a sample or described both the development and validation of a measure (both 27.3%, respectively). Other studies described the development process and used it to collect data from a sample of participants (22.7%). Fewer studies described the validation of the measure only (11.4%), or the development process only (11.4%).

2.5.3 Measure content

Of the measures described (*n*=31), twelve (38.7%) were specifically framed as a 'safety measure', whilst 19 (61.3%) were measures pertaining to other constructs (e.g. patient experience[42] or quality of care[46]) that contained at least one subscale or domain pertaining to patients' perceptions of safety. Safety measures contained a mean of 26.5 (*SD*=12.9) items, while the subscales consisted of a mean of 4.6 (*SD*=2.1) items pertaining to safety. Responses were predominantly (96.6%) collected using Likert scales.

Safety Climate domains

Across the twelve safety measures and 19 safety subscales, there were a total of 405 items. A number of these items (*n*=48; 11.9%) pertained to issues such as patient-centered care (e.g. 'healthcare workers let me participate in my own care') healthcare costs (e.g. 'the cost of seeing a doctor, nurse or other health professional at the practice prevented me from seeking care when I needed it'), and comfort (e.g. 'it was quiet in the unit so that I could rest'). Although such issues are undoubtedly relevant to the patient experience, the researchers did not consider them to

encompass the issues of patient safety, and they were therefore excluded from subsequent analysis.

With respect to Flin et al's[27] SC domains, 'job demands' and 'personal resources' were combined for the purpose of our analysis, as items often encapsulated both domains (e.g. 'staff were under stress'). All other domains were retained with the exception of 'organisational factors', as none of the included items pertained to this. Five additional themes not covered by Flin et al's[27] SC domains emerged during the deductive content analysis process; 'co-ordination of care', 'staff competence', 'access and timeliness', 'facilities and equipment', and 'dignity and respect'. The number of items coded within each of the SC domains, along with exemplar items, and details of which measures included related items, are provided in Table 2.3. Items were most commonly related to 'communication/feedback' (*n*=78; 21.8%), 'co-ordination of care' (*n*=39; 10.9%), and 'safety attitudes/behaviours' and 'facilities and equipment' (both *n*=34; 9.5%). Items less frequently related to 'job demands/personal resources' (*n*=6; 1.7%), 'dignity and respect' (*n*=12; 3.4%), and 'reporting and speaking up' (*n*=15; 4.2%).

Table 2.3 Safety Climate domains assessed by items included in the measures reviewed

Safety Climate domain and sample item (*n*= measures including related items; % = of total numbers of items)	**Measures assessing related Safety Climate domains**		
Safety systems (*n*=29; 8.1%) *'On the day of surgery, I felt safe when I was asked several times by the surgical team to repeat my name'*	Child HCAHPS (*n*=1) PEPS (*n*=1) PC PMOS (*n*=2) PMOS (*n*=5) PMOS-30 (*n*=2)	PREOS-PC (*n*=1) CQI IHC (1) (*n*=2) CQI IHC (2) (*n*=2) PC PMOS-28 (*n*=2) PMOs-10 (*n*=1)	FPS (*n*=1) Cox et al. (*n*=2) Dixon et al. (*n*=4) PMOS-A (*n*=3)
Teamwork (*n*=16; 4.5%) *'Staff worked together as a team here'*	NAPinICU (*n*=1) PC PMOS (*n*=1) PMOS-A (*n*=4)	PMOS (*n*=3) PREOS-PC (*n*=1) PMOS-30 (*n*=2)	TRIQ (*n*=2) An et al. (*n*=1) PMOS-10 (*n*=1)
Co-ordination (*n*=39; 10.9%) *'Was your GP aware of changes in your treatment plan made in hospital?'*	PC PMOS (*n*=4) PMOS (*n*=4) PC PMOS-28 (*n*=2) PMOS-10 (*n*=1)	PREOS-PC (*n*=2) TRIQ (*n*=16) PMOS-A (*n*=4)	Cox et al. (2013) (*n*=3) Desmedt et al. (*n*=1) PMOS-30 (*n*=2)
Communication/Feedback (*n*=78; 21.8%) *'Healthcare workers always gave me the information that I needed'*	Child HCAHPS (*n*=3) CPEQ (*n*=2) FPS (*n*=1) PaPeR (*n*=3) PC PMOS (*n*=9) PC PMOS-28 (*n*=5) PMOS-10 (*n*=2)	PEPS (*n*=12) PMOS (*n*=6) PREOS-PC (*n*=4) TRIQ (*n*=3) Bandurska et al. (*n*=1) PMOS-A (*n*=6)	Dixon et al. (*n*=5) Scott et al. (*n*=6) Bruyneel et al. (*n*=2) Robinson et al. (*n*=2) Malik et al. (*n*=1) PMOS-30 (*n*=5)

Staff competence (*n*=23; 6.4%) *'Did you have the impression that the staff had good professional skills?'*	CQI IHC (1) (*n*=1) FPS (*n*=1) HEALTHQUAL (*n*=2) PC PMOS (*n*=4) PMOS-30 (*n*=2)	PMOS (*n*=2) PREOS-PC (*n*=1) TRIQ (*n*=2) PC PMOS-28 (*n*=2) PMOS-10 (*n*=1)	Bruyneel et al. (*n*=1) Robinson et al. (*n*=1) Schwappach et al. (*n*=1) PMOS-A (*n*=2)
Access & timeliness (*n*=27; 7.6%) *'Did you feel that your GP(s) was available when you needed to see or talk to them?'*	Malik et al. (*n*=1) PC PMOS (*n*=5) PMOS (*n*=3) PMOS-30 (*n*=3)	PREOS-PC (*n*=2) Robinson et al. (*n*=2) PC PMOS-28 (*n*=3) PMOS-10 (*n*=1)	Schmidt et al. (*n*=1) Scott et al. (*n*=3) PMOS-A (*n*=3)
Facilities & equipment (*n*=34; 9.5%) *'Cleanliness of this practice'*	HEALTHQUAL (*n*=1) MPS (*n*=1) NAPinICU (*n*=1) PC PMOS-28 (*n*=2)	PMOS (*n*=7) PC PMOS (*n*=2) Duggirala et al. (*n*=1) PMOS-A (*n*=9)	Malik et al. (*n*=1) Padma et al. (*n*=2) Scott et al. (*n*=3) PMOS-30 (*n*=4)
Safety attitudes/behaviours (*n*=34; 9.5%) *'Adequacy of hygienic care and procedures (e.g. wearing gloves) followed by the hospital personnel'*	Child HCAHPS (*n*=1) CQI IHC (1) (*n*=2) CQI IHC (2) (*n*=1) MPS (*n*=1) NAPinICU (*n*=2) PaPeR (*n*=1) PMOS-30 (*n*=1)	PC PMOS (*n*=3) PEPS (*n*=1) PMOS (*n*=2) PREOS-PC (*n*=1) Bandurska et al. (*n*=1) PC PMOS 28 (*n*=2) PMOS-10 (*n*=1)	Dixon et al. (*n*=7) Robinson et al. (*n*=2) Duggira et al. (*n*=2) Padma et al. (2010) (*n*=1) Schwappach et al. (*n*=1) PMOS-A (*n*=1)
Management (*n*=19; 5.3%) *'It was clear who was in charge of staff'*	PC PMOS (*n*=1) PMOS-A (n=5)	PMOS (*n*=7) PMOS-30 (*n*=4)	TRIQ (*n*=1) PMOS-10 (*n*=1)

Risk perceptions (*n*=25; 7%) *'Felt safe on the ward'*	CPEQ (*n*=1) HEALTHQUAL (*n*=1) MPS (*n*=1) PaPeR (*n*=1) PMOS (*n*=1)	PREOS-PC (*n*=1) An et al. (2017) (*n*=2) Bruyneel et al. (*n*=1) Cox et al. (*n*=2) Desmedt et al. (*n*=1)	Dixon et al. (2015) (*n*=3) Malik et al. (2016) (*n*=1) Schmidt et al. (2013) (*n*=1) Scott et al. (2016) (*n*=7) Schwappach et al. (*n*=1)
Reporting/speaking up (*n*=15; 4.2%) *'I will freely speak up if I see something that may negatively affect my child's care'*	Child HCAHPS (*n*=1) PC PMOS (*n*=1)	PEPS (*n*=1) PREOS-PC (*n*=2)	An et al. (2017) (*n*=4) Cox et al. (2013) (*n*=6)
Job demands/personal resources (*n*=6; 1.7%) *'Staff were under stress'*	Cox et al. (2013) (*n*=1) PaPeR (*n*=1)	PC PMOS (*n*=1) PEPS (*n*=1)	Robinson et al. (*n*=1) PC PMOS-28 (*n*=1)
Dignity & respect (*n*=12; 3.4%) *'I was always treated with dignity and respect'*	PMOS (*n*=3) PMOS-A (*n*=2) PMOS-30 (*n*=2)	PC PMOS (1) (*n*=1) PC PMOS (2) (*n*=1) PMOS-10 (*n*=1)	PaPeR (*n*=1) MPS (*n*=1)

Quality appraisal

Variance in the validity, reliability, and usability of the measures was evident (see Table 2.4); between 0-77.7% of appraisal criteria were fulfilled. Three measures (Patient Measure of Safety; PMOS, PMOS-10, and Child Hospital Consumer Assessment of Healthcare Providers and Systems; Child HCAHPS) attained 77.7% of criteria and one measure achieved none of the criteria ([68]; untitled measure). Although 21 of the measures (67.7%) were tested for internal consistency, acceptable values were reached for only 14 (45.2%). Further, only four measures assessed test-retest reliability, all of which failed to meet acceptable values. In terms of validity, content validity was the most commonly reported, evident in the majority of measures (*n*=24; 77.4%), followed by construct validity (*n*=18; 58.1%). Fewer measures provided evidence of criterion validity (*n*=14; 45.2%), which was assessed by correlating scores with other quality and safety measures as staff ratings of safety[59], and measures of patient experience (e.g. [19,45]), and satisfaction (e.g. [72,79]).

Regarding measure usability, interpretability was addressed by 13 measures (41.9%). Although burden was discussed in the case of 11 measures, only three fulfilled the criteria of being quick to complete. Four measures[47-49,50,51,69] were classed as burdensome, as they were considered to be too long and onerous for respondents, and three[62,63,69,78] were considered resource intensive for data collectors. Burden of the original PMOS was regarded as inconclusive due to the contradicting remarks provided by studies reporting its' use. Few studies (*n*=7; 22.6%) addressed respondent acceptability of the survey, using formal assessments (e.g. Flesch Reading Ease, Flesch-Kincaid Grade level), cognitive interviews, or evaluation forms from respondents. Most of the measures (*n*=28; 90.3%) were publicly available. Further detail is provided in Appendix D.

Table 2.4 Reliability, validity, and usability of included measures

	Reliability		Validity			Usability				% of criteria met
Measure title	**IC**	**TRR**	**Content**	**Construct**	**Criterion**	**Interpretability**	**Burden**	**Acceptability**	**Availability**	
Child HCAHPS	✓	X	✓	✓	✓	✓	X	✓	✓	77.7%
CPEQ	-	-	✓	✓	✓	✓	X	X	✓	55.5%
CQI (1)	✓	X	X	X	X	✓	X	X	✓	33.3%
CQI (2)	-	X	X	✓	X	✓	X	X	✓	33.3%
FPS	X	X	✓	✓	✓	X	X	X	✓	44.4%
HEALTHQUAL	✓	X	✓	✓	X	X	X	X	X	33.3%
MPS	✓	X	X	✓	✓	X	-	X	✓	44.4%
NAPinICU	✓	X	✓	X	X	X	-	X	✓	33.3%
PaPeR	-	X	✓	✓	X	X	-	X	✓	33.3%
PC PMOS	X	X	✓	X	X	X	X	✓	✓	33.3%
PC PMOS-28	-	-	X	✓	✓	✓	✓	X	X	44.4%
PEPS	✓	X	✓	X	X	X	X	X	✓	33.3%
PMOS	✓	-	✓	✓	✓	✓	*	✓	✓	77.7%
PMOS-A	-	X	✓	✓	✓	✓	-	X	✓	55.5%
PMOS-30	✓	X	✓	X	X	✓	✓	✓	✓	66.6%
PMOS-10	✓	X	✓	X	✓	✓	✓	✓	✓	77.7%
PREOS-PC	✓	-	✓	✓	✓	X	X	X	✓	55.5%
TRIQ	✓	X	✓	✓	X	X	-	X	✓	44.4%

Untitled measures										
An et al.	✓	X	✓	✓	X	✓	X	X	✓	55.5%
Bandurska et al.	X	X	X	X	X	X	X	X	X	0%
Bruyneel et al.	X	X	✓	✓	✓	X	-	X	✓	44.4%
Cox et al.	X	X	✓	✓	X	✓	X	X	✓	44.4%
Desmedt et al.	X	X	X	X	✓	X	X	X	✓	22.2%
Dixon et al.	X	X	✓	X	X	X	X	X	✓	22.2%
Duggirala et al.	-	X	✓	✓	✓	X	X	X	✓	44.4%
Malik et al.	✓	X	✓	✓	X	✓	X	X	✓	55.5%
Robinson et al.	✓	X	✓	X	X	X	X	X	✓	33.3%
Schmidt et al.	X	X	✓	X	✓	✓	X	X	✓	44.4%
Schwappach et al.	X	X	X	X	X	X	X	X	✓	11.1%
Scott et al.	X	X	✓	X	X	X	-	✓	✓	33.3%
Padma et al.	-	X	✓	✓	✓	X	X	✓	✓	55.5%
% of measures meeting the criterion	45.2%	0%	77.4%	58.1%	45.2%	41.9%	9.7%	22.6%	90.3%	

Note. IC = Internal Consistency, TRR = Test-retest Reliability, ✓= criteria fulfilled, X= criteria not fulfilled, - = assessed, but criteria not fulfilled, * = inconclusive

2.6 Discussion

Although patients have a key role to play in ensuring the safety of healthcare,[80] the patient perspective is not typically considered within healthcare SC measurement.[26] The aims of this review were to: identify patient-report SC measures, evaluate the extent to which the core domains of SC are covered in these measures, and assess the validity, reliability, and usability of these measures. This information allows for a number of recommendations for best practice in utilising patient-report measures of SC to be made.

None of the measures included in our review assessed all of the SC domains identified by Flin et al.[27] 'Communication and feedback' was the most commonly assessed domain, which is unsurprising given that ineffective communication has been consistently identified by patients[81-83] as a key contributor to patient safety incidents. It would be expected that patients could provide useful information on domains such as 'staff competence' and 'risk perceptions'. SC domains, that are important, but were also infrequently assessed included 'job demands/personal resources', and 'dignity and respect.'

It has been suggested that a lack of clarity surrounding the dimensionality of SC has resulted in the development of measures of disparate length and thematic focus[84] which are sensitive to different aspects of SC, making findings difficult to compare, and of limited value when attempting to develop cumulative knowledge.[85] It is likely that there is even less certainty regarding the SC domains that are assessable by patients, considering the literature has a tendency to focus on SC measurement from the HCP perspective.[26] This assertion is supported by the extra themes that emerged during the coding process, which should be considered during measurement of SC among patients going forward. A greater focus on patient input at the development stage could also be a useful approach to gain further insight into what SC domains should be assessed. Although the majority of included measures established content validity with patients in the form of a pre-test panel or pilot test, only seven (22.6%) involved patients (e.g. by conducting interviews, or focus groups) in designing and selecting SC domains and items for inclusion in the measure.

There was considerable variability in the extent to which the validity and reliability of the included measures were assessed. Moreover, none of the measures

fulfilled all five requirements of validity and reliability- essential to the collection of meaningful and trustworthy data.[36] Previous reviews of SC measures designed for HCWs have identified similar limitations.[36,86] There was also an overall lack of consideration of the burden and acceptability of measures for respondents (i.e. usability). Use of complex and lengthy SC measures has been shown to negatively impact the validity of the findings[87]; increased response rates and reduced non-response bias are more likely if a measure is quick and easy to complete.[88] Further, patients from vulnerable groups (e.g. the elderly, socially disadvantaged) may have difficulty completing measures, which is problematic considering such groups are at a greater risk for patient safety incidents (PSIs).[89,90] However, there are examples of measures included in our review in which researchers have attempted to improve the usability of a measure (by decreasing the number of items) without negatively impacting the validity and reliability.

The original 44-item PMOS measure was reduced to 30, and ten-item versions, without having a large negative impact on reliability and validity. A similar approach was taken with the 50-item PMOS-PC, which was reduced to 28 items. However, in this case, despite a significant improvement in measure acceptability, the reliability metrics failed to reach acceptable values. It is challenging to optimise the validity, reliability, and usability of a measure. It is suggested that, particularly in primary care, more refinement of the measures is required, and measures should be designed with end-users in mind. The provision of additional resources to ease participation (e.g. external facilitation[25] in the form of volunteers of patient peers, or more accessible versions of measures and response scales[62]) may be recommended.

2.6.1 Future research

The majority of measures were designed for use by patients in secondary care, with far fewer designed for measuring the attitudes of primary care patients. This finding is perhaps unsurprising as there is a far greater focus on patient safety in hospital settings as compared to primary care.[91-93] Therefore, the measurement of patient-report SC in primary care specifically warrants a greater focus, which could be achieved by adapting instruments designed for use in secondary care.[85] However, caution should be taken in the case of altering existing instruments originally

designed for use in other settings, due to the unique context of primary care and the domain-specific issues related to it.[94]

The extent to which the evaluation of SC by patients and HCPs are related is unknown. It is suggested that there is a need to examine SC in the same organisation, and at the same time, from both the patient and HCP perspective.[32] This comparison could be facilitated through the development of patient and HCP versions of the same measure within future research, which would determine whether patients identify issues not observed by HCPs.

SC measures have been described as a 'quick and dirty' method of assessing an organization's state of safety[95]; although a large amount of data can be collected with relatively minimal effort, only a broad indication of SC is provided. It has been suggested that a triangulation of quantitative and qualitative assessment methods could be used for comprehensive SC evaluation.[96] The value of utilising a mixed-methods approach when measuring patient safety has been emphasised.[3,8,97] Future research therefore may wish to further explore issues emerging from SC via interview or through other qualitative engagement with patients.

2.6.2 Limitations

There are two key limitations to this review. First, restricting the searches to English language, peer-reviewed papers may have resulted in the omission of SC measures. However, limited guidance exists regarding the reproducibility of grey literature searches.[98] Second, the quality of SC measures were assessed as opposed to the quality of included studies. However, considering the aim was to inform and appraise existing measures of SC from a patient perspective, a quality assessment at an individual study level was considered beyond the scope of the current review.

2.6.3 Conclusion

Previous research has demonstrated that patients are highly motivated to contribute to reducing the risk of harm and ensuring good outcomes. This review has demonstrated variance in the coverage of SC domains amongst the extant measures. Few measures reported satisfactory levels of validity and reliability, particularly regarding criterion validity, and test-retest reliability. Further, inadequacies in usability testing amongst the extant measures was observed. In order to minimise

respondent burden, and ensure maximum response rates, a greater focus on enhancing acceptability (e.g. by reducing measure length) is recommended. The shorter variations of the original PMOS (PMOS-30 and PMOS-10) appear to be the most suitable valid, reliable, and acceptable measures of patient safety in secondary care. However, as yet, it is not yet possible to recommend a valid, reliable, and acceptable measure for use in primary care settings.

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Chapter Three: Study Two

Development and validation of a patient-report measure of safety climate for general practice

Development and validation of a patient-report measure of safety climate for general practice

3.1 Declaration

Alignment with the thesis

Based upon the findings from Study One, a suitable patient-reported measure of safety climate was developed and used to collect data from general practice patients in Ireland. Given that validity, reliability, and useability are essential to the collection of meaningful and trustworthy data,[1] the psychometric properties of the novel tool were evaluated.

Peer-reviewed publication

This study has been published in a peer-reviewed journal; Family Practice, the citation of which is:

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This chapter is a formatted version of the published manuscript in the journal.

Conference presentation

This study has been submitted for presentation at the Association of University Departments of General Practice in Ireland (AUDGPI) conference. 4th-5th March 2022: Dublin, Ireland.

Authors' contributions

The contributions of the individual authors are as follows:

- CM: Conceptualization, Investigation, Data Curation, Formal Analysis, Methodology, Writing- Original Draft Preparation, Writing- Reviewing and Editing.
- SL: Conceptualization, Methodology, Data Curation, Formal Analysis, Writing- Reviewing and Editing.
- AM: Conceptualization, Methodology, Writing- Reviewing and Editing.

- POC: Conceptualization, Methodology, Data Curation, Formal Analyses, Writing- Reviewing and Editing.

Ethical approval

Ethical approval was granted by the National University of Ireland, Galway Research Ethics Committee (REF: 19-Oct-15).

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3.2 Abstract

Background

Patients remain an under-utilised source of information on patient safety, as reflected by the dearth of patient-report measures of safety climate, particularly for use in general practice settings. Extant measures are marked by poor coverage of safety climate domains, inadequate psychometric properties, and/or lack of consideration of usability.

Objective

To develop a novel patient-report measure of safety climate specifically for completion by general practice patients, and to establish the validity, reliability and usability of this measure.

Methods

An iterative process was used to develop the safety climate measure, with patient and general practitioner input. A cross-sectional design was employed to examine the validity (content, construct, and convergent), reliability (internal consistency), and usability (readability and burden) of the measure.

Results

A total of 584 general practice patients completed the measure. The exploratory factor analysis identified five factors pertaining to safety climate in general practice: Feeling of Safety with GP; Practice Staff Efficiency and Teamwork; Staff Stress and Workload; Patient Knowledge and Accountability, and; Safety Systems and Behaviours. These factors strongly correlated with two global safety measures, demonstrating convergent validity. The measure showed strong internal consistency, and was considered usable for patients as indicated by readability and duration of completion.

Conclusion

Our novel measure of safety climate for use in general practice demonstrates favourable markers of validity, reliability, and usability. This measure will provide a

mechanism for the patient voice to be heard in patient safety measurement, and to be used to improve patient safety in general practice.

Keywords

Delivery of Health Care; Family Practice; General Practice; Patient Safety; Primary Healthcare; Surveys and Questionnaires.

3.3 Introduction

The measurement and monitoring of safety is fundamental to patient safety improvement.[1, 2] Although a range of patient safety measures exist,[3, 4] many (e.g. incident reporting systems) constitute 'lagging' indicators of safety,[5] requiring an adverse event to occur before safety can be improved. The use of 'leading' measures of safety (e.g. safety audits) has been recommended to support the proactive identification of areas for improvement.[1, 2] Evaluating the 'safety climate' (SC) of healthcare organisations, defined as the measurable component of safety culture[6] (i.e. the shared values, attitudes, and behaviour of staff with regards to safety[7]) at a point in time, is considered one such proactive, 'leading' approach to safety measurement and monitoring.

SC is typically assessed from the perspective of frontline healthcare providers (HCPs).[8] However, in recent years, the inclusion of the patient perspective of safety has been gaining traction.[9] Patients are well-placed 'observers' of unsafe practices,[10] and capable of providing information on issues that may not be visible to HCWs, including but not limited to medication incidents, communication breakdowns, and poor continuity of care.[11] Patients are interested in being involved in their care,[12] and motivated to decrease the risk of harm and promote good outcomes.[13]

Our recent systematic review of patient-report SC measures in healthcare identified that extant measures had limited psychometric properties, usability, and/or did not sufficiently address different domains of SC.[14] Such deficits impede the collection of meaningful and trustworthy data.[15] Further, the majority of the SC measures were designed for use in secondary care (i.e. hospital) settings. This finding is perhaps unsurprising as the study of safety in primary care is less extensive as compared to secondary care.[16] However, multiple patient and practice factors contribute to a growing complexity of clinical practice for general practitioners (GPs).[17] This, combined with the sheer volume[18] of patient contacts within general practice, increases the potential for patient safety incidents (PSIs). The World Health Organisation (WHO) has identified patient engagement as a key strategy for patient safety improvement in this sector.[19]

Accordingly, the aim of this study was to develop a novel patient-report measure of SC specifically for completion by general practice patients, and to establish the validity, reliability, and usability of this measure.

3.4 Methods

3.4.1 Questionnaire development process

Systematic literature review

A systematic literature review of extant patient-report SC measures was conducted, whereby domains addressed within the measures were identified. As described in detail elsewhere,[14] the safety-related items (n=405) across each of the 31 measures identified were coded according to the core domains of SC explicated by Flin et al[20] (safety systems; risk perceptions; job demands/personal resources; reporting/speaking up; safety attitudes/behaviours; communication/feedback; teamwork; management; and organisational factors). As part of the classification process for the systematic review, an additional five safety domains were explicated (co-ordination of care; staff competence; access and timeliness; facilities and equipment; and dignity and respect). These 14 SC domains guided the process of item construction.

Item construction

An iterative method was used to construct the questionnaire items. This method consisted of three face-to-face consensus-building meetings with the research team (two research psychologists, a patient safety researcher, and a GP, all with experience in questionnaire development) over a two-month period in 2019. The specific items from existing questionnaires were deliberately not reviewed as part of this process as the team wished to start from the 14 SC domains identified in the systematic review described above.[14] However, it is acknowledged that similarities with items from existing measures may arise through convergence as part of the development process as there are only a finite number of ways of asking about attitudes towards these SC domains. In the first consensus-building meeting, questionnaire items (total n = 169) were constructed to cover all 14 SC domains. During the two subsequent consensus-building meetings, these items were reviewed,

refined and condensed to 68 items, and eventually reduced to 48 items that the research team felt were most representative of the 14 domains of SC. Any disagreements amongst the research team were resolved via discussion.

Cognitive interviewing

Cognitive interviewing[21] in the form of a 'think-aloud'[22] methodology was used to examine the face validity of the 48-item measure. Academic GPs (*n*=5) and patient representatives with no prior research experience (*n*=5) verbalised their thoughts to a researcher while completing the measure. Based on the reviewer feedback, the definition of 'safety' was refined, a number of items were rephrased, and the order of items was changed (see Appendix E).

Piloting

The revised measure was piloted with a small sample of patients (*n*=3). No issues were identified, and so no further changes to the items were made.

3.4.2 Measure content

The SC measure was presented within a larger survey consisting of three sections. The first section contained the 48-item SC measure which used a 5-point Likert response scale, ranging from 1 ('strongly disagree') to 5 ('strongly agree').

The second section contained two spaces for free-text entry (any additional comments, and the opportunity to list areas where improvements in safety could be made), and two additional items concerned with the participant's overall safety rating of the practice (scored from 1-10) and the likelihood of their recommending the practice to friends and family (with five response options, ranging from 'extremely unlikely' to 'extremely likely').

Finally, demographic information was collected in the third section including gender, nationality, ethnicity, and whether the respondent was entitled to free general GP care. In the Republic of Ireland, patients typically pay privately to attend a GP but some patients with special circumstances (e.g. lower income, advanced age) may attend their GP without paying a fee. Six additional questions were included as 'proxies' for identifying high-risk patient status[23, 24] (e.g. age, presence of chronic/long-term conditions, and number of repeat medications). The total length of

the survey that patients completed (including the Safety Climate items, global measures of safety, open-ended and demographic questions) consisted of 68 items (see Appendix F for measure administered to respondents).

3.4.3 Sample and data collection

Data were collected between February and June 2020. A combination of convenience and purposive sampling was used to recruit participants who were over 18 years old, English-speaking, and had visited a GP in Ireland within the previous 24 months. The study was advertised on social media (Twitter, Facebook), patient advocacy groups, in local newspapers and via interviews with local radio stations. In order to ensure inclusion of 'high-risk' patients and members of the public, specific organisations and groups (e.g. community retirement groups, chronic illness support groups) were contacted (n=176) and asked to share information on the study and/or distribute a copy of the measure. Participants were provided with the choice of either paper or online measure completion via SurveyMonkey, which was compatible with numerous devices (e.g. mobile phone, laptop, tablet, desktop computer). Participation was voluntary, and a prize draw for 50 euro gift vouchers was used as an incentive.

3.4.4 Data analysis

Data were analysed using SPSS version 26. Given the sample size, missing data were excluded listwise, as per recommendations by Field.[25]

Assessment of construct validity

In accordance with best practice, an exploratory factor analysis (EFA) was conducted to establish the construct validity of the SC measure.[26, 27] First, the suitability of the data for EFA was assessed. Inter-item correlations were investigated to determine whether items were sufficiently related (r>.3), whilst ensuring there was no issue with multicollinearity (r<.8). The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy and Bartlett's test of sphericity were calculated to determine the appropriateness of conducting factor analysis. Principal Axis Factors (PAF) was used to explore the underlying structure of the questionnaire items, using an oblique rotation (direct oblimin) with delta set to zero and number of

iterations set to 25. Given the ambiguity associated with using a sole criteria to determine the number of factors to retain,[26] three different factor retention methods were consulted; Kaiser's criterion, Cattell's scree test, and parallel analysis. Items were retained if they revealed factor loadings greater than 0.4.

Assessment of convergent validity

In order to assess convergent validity, total scores for each factor were correlated with the two global outcome measures of SC; (1) overall safety rating of the practice, and; (2) likelihood of recommending the practice.

Assessment of reliability

After reverse scoring negatively worded items, internal consistency for the scale as a whole, and for individual factors, was assessed using Cronbach's alpha, with a value of above .7 considered 'acceptable'.[28]

Assessment of usability

The measure was assessed for readability using Flesch-Kincaid reading ease and grade level tests.[29] Timing data was gathered from the online survey host, to determine whether the measure could be completed within a target timeframe of 10-15 minutes.[30]

3.5 Results

3.5.1 Sample

A total of 584 participants completed the measure, with 336 (57.5%) completing the online version and 248 (42.5%) completing the paper version. The response rate for the paper version was 49.6%. A Mann Whitney U test found that age of the paper respondents was significantly higher than age of the online respondents (U=32941.5, p<.001). There were no sex differences in the respondents who completed online versus paper versions, as demonstrated by a non-significant Chi-square test (X^2=.14, p=.71).

The majority of respondents (427; 75.6%) were female, and 138 (24.4%) were male. The mean age was 42.6 years (SD=16.1; range:18-91 years). Most (414;

72.6%) were private patients, and the remainder were medical card (122; 21.4%) or GP visit card holders (34; 6%).

3.5.2 Assessment of construct validity

Preliminary analysis

Inspection of the correlation matrix revealed that three of the 48 items did not correlate sufficiently ($r<.3$) with other items ('*I see safety issues that could be improved in the practice*'; '*Safety is better here than at other practices*', and; '*There is a delay when I am referred to other services*') and were removed from further analyses. Two items ('*The GP tells me about potential side effects of my treatment*', and; '*The GP tells me about any risks related to my care*') were highly correlated ($r>.8$), so the former was also removed from the analyses. Factor analysis was then conducted on the remaining 44 items, with 537 responses included after data were excluded listwise.[25] The KMO measure of sample adequacy was .96 ('superb'[25]), and Bartlett's test of sphericity was significant ($p=<.001$), indicating that the data were suitable for EFA.

Extracting factors

An initial analysis revealed the presence of six factors with eigenvalues over Kaiser's criteria of 1.0. However, given the tendency of Kaiser's criteria to overestimate factors, and considering one of these factors contained only two items, the scree plot was also examined.[27] As seen in Appendix G, this was ambiguous, showing two inflexions which justified retaining either four or five factors. For further clarity, a parallel analysis was performed, which suggested the retention of four factors. Two follow-up analyses were therefore conducted with forced entry of four and five factors respectively. It was ultimately decided that the five-factor model had the best theoretical 'fit' with the established SC domains.[14, 20] Therefore, five factors were extracted in the final analysis, cumulatively explaining 58.94% of the variance.

Factor loadings

Table 3.1 shows the factor loadings after rotation. The clustering of items suggested that they represented the following: (1) Feeling of Safety with GP (7 items); (2)

Practice Staff Efficiency and Teamwork (12 items); (3) Staff Stress and Workload (7 items); (4) Patient Knowledge and Accountability (6 items); and (5) Safety Systems and Behaviours (5 items). Seven items had a factor loading of below 4.0, and so failed to meet the criteria for loading sufficiently onto any factor. The intercorrelations between the five factors ranged from -.31 to .52 (see Table 2), supporting the assumption that the factors are not independent from each other. However, multicollinearity was not found to be an issue given the value of correlation coefficients (r<.8; see Table 3.2), which also suggests adequate discriminant validity, given that the factors are not highly correlated with each other.[31] The resultant 37-item instrument was named the Patient Perspective of Safety in General Practice (PPS-GP). Of the SC domains initially used to guide the construction of questionnaire items, ten were encompassed by the five final factors (see Figure 3.1).

Table 3.1 Pattern matrix for Principal Axis Factors with oblique (oblimin) rotation of five factor solution of safety climate items completed by 584 general practice patients between February and June 2020.

Item	Pattern coefficients					Cronbach's a
	1	2	3	4	5	
Factor 1: Feeling of Safety with GP						.93
The GP listens to me	**.577**	.127	-.024	.202	.096	
The GP treats me with dignity and respect	**.537**	.242	-.002	.048	.198	
The GP is good at their job	**.485**	.247	.022	-.012	.360	
I trust the GP	**.475**	.183	-.010	.138	.255	
The GP gives me time to ask questions	**.473**	-.011	-.192	.123	.228	
The GP speaks to me in a way I can understand	**.412**	.074	-.049	.209	.225	
The GP takes time to understand my medical history	**.409**	.010	-.090	.212	.302	
Factor 2: Practice Staff Efficiency and Teamwork						.94
Staff in the practice help each other	-.167	**.781**	-.005	.023	.072	
There is good communication between the staff in the practice	-.081	**.776**	-.057	.081	-.011	
Staff in the practice work well together	-.018	**.758**	-.081	.059	-.019	
Staff work together to ensure safety	-.094	**.756**	.028	.039	.159	
The atmosphere in the practice always seems pleasant	.093	**.723**	-.095	.092	-.166	
Staff deliver effective care	.217	**.714**	.005	-.012	.000	
All staff in the practice are good at their jobs	.091	**.631**	-.045	.050	.054	
The attitude of staff towards me is good	.222	**.585**	-.059	.074	-.050	
Patient safety is a priority in the practice	.064	**.567**	.043	.029	.199	
I feel safe being treated as a patient in the practice	.258	**.542**	.021	-.005	.211	
When I am really sick, the practice staff make sure I get an appointment	.025	**.520**	-.066	.020	.053	
Staff communicate clearly with patients	.181	**.431**	-.127	.101	.034	

Factor 3: Staff Stress and Workload						.84
Staff are stressed in the practice	.083	-.107	**.733**	.070	.048	
The GP is usually stressed	-.041	.119	**.697**	-.056	-.096	
Patient safety is affected by workload in the practice	.108	-.038	**.663**	.008	-.036	
The GP is usually rushed	-.250	.031	**.618**	-.153	.120	
The GP is usually distracted	-.219	.050	**.555**	-.015	-.168	
Serious mistakes could happen here	.060	-.258	**.425**	.038	-.110	
The GP has enough time to spend on my care	.380	.048	**-.404**	.170	.039	
Factor 4: Patient Knowledge and Accountability						.84
I know how to report issues with my care	-.084	-.097	.003	**.664**	.076	
I can contact the practice if I have any questions about my care	.076	.161	-.005	**.663**	-.041	
I am comfortable raising concerns about my care	.138	-.003	.039	**.649**	.093	
The practice answers questions about my care outside of appointments	.020	.082	-.014	**.636**	-.032	
The practice is responsive to concerns about my care	.087	.291	.065	**.610**	-.013	
I know how to access the GP after-hours service	-.035	.011	-.081	**.565**	-.055	
Factor 5: Safety Systems and Behaviours						.85
I am always given clear instructions on how to take medications	.047	.039	-.085	.020	**.694**	
The instructions I am given about my care are clear	.132	.054	-.095	.034	**.647**	
The GP washes their hands	-.048	.087	-.035	.020	**.554**	
The GP tells me about any risks related to my care	.096	-.077	-.080	.174	**.527**	
I feel safe receiving care from the GP	.318	.256	-.028	-.047	**.453**	

Note: Major loadings for each item are bolded

Table 3.2 Intercorrelation matrix of five factors, and correlation of five factors with two global safety outcome measures from the safety climate measure completed by 584 general practice patients between February and June 2020.

Factor	1.	2.	3.	4.	5.	Safety rating	Recommendation
1. Feeling of safety with GP	1.00					.62**	.60**
2. Practice staff efficiency	.36	1.00				.59**	.56**
3. Staff stress & workload	-.31	-.43	1.00			-.53**	-.46**
4. Patient knowledge & accountability	.36	.52	-.43	1.00		.50**	.51**
5. Safety systems/behaviours	.48	.52	-.36	.50	1.00	.57**	.50**

**Correlation is significant at the 0.01 level (2-tailed)

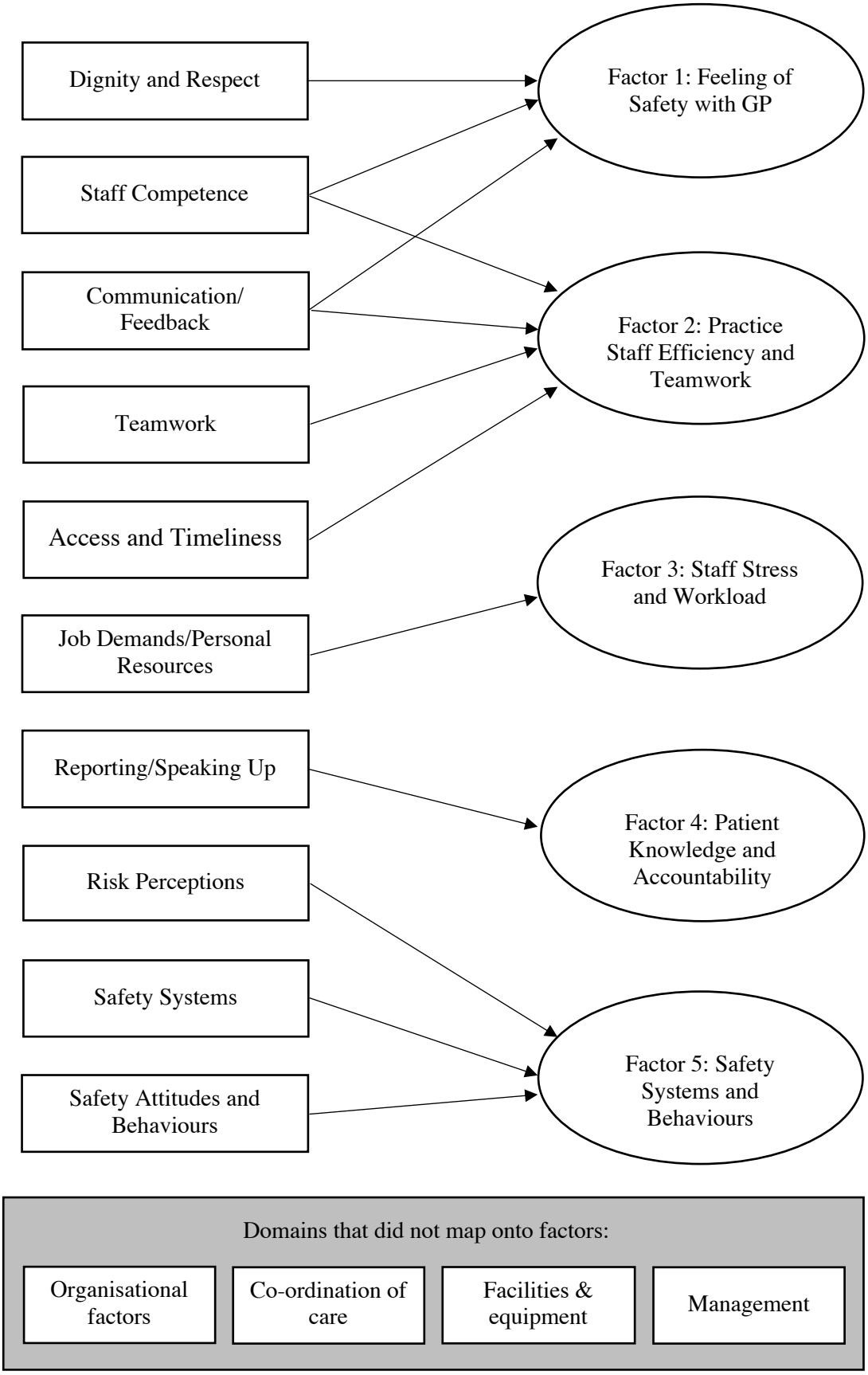

Figure 3.1 Mapping of safety climate domains onto the five factors resultant from the exploratory factor analysis of safety climate items

3.5.3 Assessment of convergent validity

The relationships between the factors and the two outcome measures are shown in Table 3.2. For 'Safety Rating', intercorrelations with all five factors were statistically significant (r =.50 to .62). Similarly, for 'Likelihood to Recommend', intercorrelations with all five factors were statistically significant (r =-.46 to .60).

3.5.4 Assessment of reliability

The complete measure had a Cronbach's a of .96. As shown in Table 3.1, Cronbach's a coefficients for the five individual factors ranged from .84 to .94, suggesting that all had strong reliability.[28]

3.5.5 Assessment of usability

The readability assessments resulted in a Flesch Reading Ease score of 80.3%, and Flesch-Kincaid Grade level of 6, indicating that the text should easily be understood by 11-12 year olds.[29] Timing data gathered from the completed online responses (n=336; 57.5% of included responses) found that the mean time to complete the measure was 9 minutes, 47 seconds.

3.6 Discussion

SC is typically assessed from the perspective of the healthcare worker; however, patients also have a perspective on safety that is important to take into consideration. The novel Patient Perspective of Safety in General Practice (PPS-GP) reported in this paper was developed to address a range of shortcomings in research on measuring patient safety in primary care.[14] It is suggested that this measure should be used alongside staff measures of SC, or other data collection approaches (e.g. qualitative interviews) in order to obtain a broad understanding of SC.

The final 37-item measure (see Appendix H) demonstrated adequate psychometric properties; specifically, good reliability and content, construct, and convergent validity. The methods involved in developing the measure also showed content and face validity. The resulting measure therefore appears psychometrically sound and user-friendly (i.e. low reading grade, short completion time). The measure constitutes an important step in furthering the potential to capitalise on patient

insights[13] for improving patient safety in general practice settings. Given existing measures have been criticised for inadequate attainment of such psychometric properties,[14] these findings are positive. However, further validity work is recommended to determine whether our factor structure retains amongst different participant samples.[32] In addition, establishing of criterion validity, whereby the measure is correlated with a 'gold standard' measure that has been established as valid, might be considered and could be achieved through the triangulation of this survey and a staff SC survey administered within practices.

The PPS-GP was designed specifically for use in general practice, a unique setting where there is a recognised paucity of patient safety research.[16] This is significant, as the adaptation of measures intended for assessing hospital care to general practice has been criticised previously,[15] leading to issues with reliability and validity and the exclusion of SC domains that were relevant and context-specific to general practice specifically. Considering the lack of established safety interventions for general practice,[33] future research using this measure may support quality improvement efforts and the development of novel interventions.

The PPS-GP builds on previous recommendations that a range of relevant domains should be considered when measuring SC among patients.[14] Items in the measure assess domains which have been infrequently considered by previous measures- despite their importance and relevance to safety[14] (e.g. 'dignity and respect' and 'staff competence'). After conducting the factor analysis, there was coverage of the majority of the core SC domains.[14, 20] However, four SC domains were no longer covered after item reduction, including: 'co-ordination of care', 'management', and 'facilities and equipment'. This is likely because although these domains are undoubtedly relevant to SC, they are not necessarily visible to patients and/or patients may not understand how these factors manifest within their care (i.e. what co-ordination of care 'looks' like in general practice). Qualitative engagement with patients may elucidate means of understanding and eliciting patient's insights into these issues. Alternatively, triangulation of patient-report and staff-report measures may be necessary to ensure coverage of all SC domains.

6.1 Future research

Previously, clinician-focused SC measures have been used to inform safety interventions in general practice.[34] The current patient-focused measure could be used in conjunction with a clinician-focused SC measure (e.g. PC SafeQuest[8]) to identify where improvements should be made. Triangulating data from both of these measures would produce a comprehensive assessment of safety, and allow concordance and discordance to be identified and addressed. It would also support an understanding of the 'value added' by the use of multiple measures and facilitate GPs consideration of the most effective use of resources when seeking to understand safety.

Factors such as patient age[35, 36] and multimorbidity[37] are known to impact patient safety. Therefore, it may be useful to explore how our measure can be used to identify patient or practice characteristics that predict perceptions of safety. This information would help pinpoint areas with potential for improvement for specific high-risk patient populations.

Finally, a quantitative survey is only one method of assessing SC, and it has been suggested that such survey measures may be best viewed as a trusted 'wet finger' to find out which way the wind blows.[38] Other approaches such as qualitative interviews or focus groups may provide additional information on safety to guide improvement efforts. Previous research[39] has utilised staff 'stories' of safety incidents as a means of understanding safety and identifying deficiencies. As interest in involving patients in safety improvement grows, the use of patient 'stories' in this way may also be insightful.

6.2 Limitations

This study had a number of limitations. First, due to singular administration of the measure, test-retest reliability was not assessed. This type of reliability has been infrequently assessed in patient- or practitioner-reported SC measures in healthcare.[14, 15] Future research should examine consistency in responses to the measure over time. Further, when internal consistency was assessed, the Cronbach's alpha score for the measure as a whole was high; some researchers suggest that an exceptionally high Cronbach's alpha may indicate redundant items[40] or failure to demonstrate adequate discriminant validity. However, we are satisfied that despite

the high Cronbach's alpha scores, subscales are adequately measuring different constructs, given the value of correlations between subscales (r<.8), which indicate adequate discriminant/divergent validity amongst them.[31]

Second, although we obtained a response rate for the paper-administered version of the measure, we were unable to calculate a response rate for the online version, as it was not possible to collect data on how many patients were invited to complete the online measure due to recruitment using social media and through community groups. Given that low response rates can be an indicator of poor receptivity of the instrument by patients,[41] this information would be useful in future studies for identifying and addressing reasons for non-response.

Third, although questionnaire items were developed from our previous systematic review,[14] rather than from reviewing the items in other existing SC questionnaires, there are some similarities between our questionnaire and other existing questionnaires (e.g. '*I always felt that patient safety was a top priority*'[42] and '*Patient safety is a priority in this practice*'; current study). This convergence in items is arguably not unexpected as the measures are addressing similar domains of SC and there are only a finite number of ways in which to ask about attitudes towards these domains.

Finally, participant recruitment partly took place during the COVID-19 pandemic. Although there is no known research to date specifically on patient-reported perceptions of safety in primary care during COVID-19, some studies have reported on patient satisfaction with specific aspects of care delivery (e.g. the use of telemedicine[43, 44]). Considering patient satisfaction has been found to be higher in the COVID-19 period than in the period immediately before,[43] there is a possibility of an artefact from the pandemic (e.g. skewness of item responses), given the links between patient safety perceptions and patient satisfaction.[45]

6.3 Conclusion

Patients see safety issues that clinicians do not, and are motivated to contribute to quality and safety improvement efforts. We have developed a novel patient-report measure of SC specifically for completion by general practice patients, that is valid, reliable, and useable. The PPS-GP provides a mechanism for including patients in

safety improvement initiatives in general practice going forward, and should be used in conjunction with clinician measures of SC.

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Chapter Four: Study Three

Patients' perception of safety climate in Irish general practice: a cross-sectional study

Patients' perception of safety climate in Irish general practice: a cross-sectional study

4.1 Declaration

Alignment with the thesis

Safety climate (SC) is typically assessed from the perspective of healthcare providers[1], while patients' insight into SC has been considered less frequently. In order to identify potential areas of suboptimal safety requiring improvement in Irish general practice, it is necessary to consider patient perceptions of, and insights on, safety in general practice. Therefore, the study reported in this chapter reports the analysis of patients' perceptions of safety climate.

Peer-reviewed publication

This study has been published in a peer-reviewed journal; BMC Family Practice, the citation of which is:

> Madden C, Lydon S, Murphy AW, O'Connor P. Patients' perception of safety climate in Irish general practice: a cross-sectional study. BMC Fam Pract. 2021;22(1):1-11.

This chapter is a formatted version of the published manuscript in the journal.

Conference presentation

This study has been submitted for presentation at the Association of University Departments of General practice in Ireland (AUDGPI). 4th-5th March 2022: Dublin, Ireland.

Authors' contributions

The contributions of the individual authors are as follows:

- CM: Conceptualization, Investigation, Data Curation, Formal Analyses, Methodology, Writing- Original Draft Preparation, Writing- Reviewing and Editing.
- SL: Conceptualization, Methodology, Formal Analyses, Writing- Reviewing and Editing.
- AM: Conceptualization, Methodology, Writing- Reviewing and Editing.

- POC: Conceptualization, Methodology, Formal Analyses, Writing-Reviewing and Editing.

Ethics approval

Ethical approval was granted by the National University of Ireland Galway's Research Ethics Committee (Ref: 19-Oct-15).

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4.2 Abstract

Introduction

Although patients have the potential to provide important information on patient safety, considerably fewer patient-report measures of SC have been applied in the primary care setting as compared to secondary care. Our aim was to examine the application of a patient-report measure of safety climate in an Irish population to understand patient perceptions of safety in general practice and identify potential areas for improvement. Specifically, our research questions were:

1. What are patients' perceptions of SC in Irish general practice?
2. Do patient risk factors impact perceptions of SC?
3. Do patient responses to an open-ended question about safety enhance our understanding of patient safety beyond that obtained from a quantitative measure of SC?

Methods

The Patient Perspective of Safety in General Practice (PPS-GP) survey was distributed to primary care patients in Ireland. The survey consisted of both Likert-response items, and free-text entry questions in relation to the safety of care. A series of five separate hierarchical regressions were used to examine the relationship between a range of patient-related variables and each of the survey subscales. A deductive content analysis approach was used to code the free-text responses.

Results

A total of 584 completed online and paper surveys were received. Respondents generally had positive perceptions of safety across all five SC subscales of the PPS-GP. Regarding patient risk factors, younger age and being of non-Irish nationality were consistently associated with more negative SC perceptions. Analysis of the free-text responses revealed considerably poorer patient perceptions (n=85, 65.4%) of the safety experience in primary care.

Conclusion

Our findings indicate that despite being under-utilised, patients' perceptions are a valuable source of information for measuring SC, with promising implications for

safety improvement in general practice. Further consideration should be given to how best to utilise this data in order to improve safety in primary care.

Keywords

Primary Care; General Practice; Patient Safety; Safety Climate; Patient Involvement.

4.3 Introduction

Approximately 21.4 million consultations are conducted by General Practitioners (GPs) in Ireland annually.[1] Given that 2-3% of primary care consultations are associated with the occurrence of a Patient Safety Incident[2] (PSI; an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient[3]), there is ample opportunity for PSIs to occur considering the volume of patient contacts in Irish general practice. Further, there is a growing complexity of primary health care delivery, with the interaction of multiple patient factors including age, multimorbidity, and polypharmacy posing significant and ongoing challenges for GPs,[4] having been associated with a higher risk of PSIs in primary care.[5-7]

Such data highlight the need for the consistent measurement and monitoring of safety in general practice. The measurement of safety climate (SC), defined as the perceived state of safety in an organisation at a given time and place,[8] is recognised as a 'leading',[9] or proactive, method of safety measurement in healthcare.[10, 11] SC measures are typically quantitative in design, and examine the perspectives of HCPs.[12] However, it has been suggested that the patient perspective may also constitute a valuable source of information on patient safety.[7, 13] Further, patients have expressed interest in being involved in the safety of their care to improve outcomes.[14]

A recent systematic review of patient-report SC measurement in healthcare found that considerably fewer measures have been developed for use in the primary care setting as compared to secondary care.[15] Further, extant patient-report SC measures were found to have limited psychometric properties, usability, and/or did not sufficiently address all of the domains of SC.[15] Such findings culminated in the subsequent development of a novel patient-report measure of SC; the Patient Perspective of Safety in General Practice (PPS-GP), which has demonstrated favourable validity, reliability, and usability.[16] This tool creates the potential to capitalise on patient insights and experiences to improve the safety of primary care delivery.

Considering GPs have cited difficulties in understanding how best to measure and improve patient safety in their practices,[17] it may be useful to explore how the PPS-GP can be used to identify patient or practice characteristics that predict

perceptions of safety or to consider the areas in which patients may perceive safety to be suboptimal. Further, a focus on high risk patients may improve the safety of care by helping to pinpoint areas requiring improvement.[18] Therefore, the aim of this study was to examine the application of a patient-report measure of SC with primary care patients in the Republic of Ireland to understand patient perceptions of safety in general practice and identify potential areas for improvement. Our specific research questions were:

1. What are patients' perceptions of SC in Irish general practice?
2. Do patient risk factors impact perceptions of SC?
3. Do patient responses to an open-ended question about safety enhance our understanding of patient safety beyond that obtained from a quantitative measure of SC?

4.4 Methods

4.4.1 Design

The study used a cross-sectional survey design. The study is reported in accordance with the 'Strengthening the Reporting of Observational Studies in Epidemiology' (STROBE) Statement.[19]

4.4.2 Measure administered

The first section of the survey presented the PPS-GP[16] which contained 37-items pertaining to SC across five subscales: (1) Feeling of safety with the GP (e.g. '*I trust the GP*'; 7 items); (2) Practice staff efficiency and teamwork (e.g. '*Staff in the practice help each other*'; 12 items); (3) Staff stress and workload (e.g. '*The GP is usually rushed*'; 7 items); (4) Patient knowledge and accountability (e.g. '*I know how to report issues with my care*'; 6 items), and; (5) Safety systems and behaviours (e.g. '*The instructions I am given about my care are clear*'; 5 items). Items were rated on a 5-point Likert response scale, ranging from '1' ('strongly disagree') to '5' ('strongly agree'). Additionally, there were two free-text entry questions (any additional comments in relation to the safety of care received while visiting the practice, and the opportunity to list areas where changes could be made to GP care[20]), and two global safety items concerned with the participant's overall safety

rating of the practice (scored from 1-10) and the likelihood of their recommending the practice to friends and family[21] (five response options, ranging from 'extremely unlikely' to 'extremely likely'). The PPS-GP has demonstrated good internal reliability and content, construct, and convergent validity, and favourable markers of participant usability (e.g. readability and duration of completion). Psychometric properties of the PPS-GP are comprehensively detailed in a previous publication by the research team.[16]

The second section of the survey presented questions seeking demographic information including gender, nationality, and whether the respondent was private or publicly funded. In the Republic of Ireland, the General Medical Services (GMS) scheme entitles patients with incomes below a threshold on a means tested basis or with specified illnesses to obtain a medical card, which provides free health care in the form of prescriptions and GP visits, while a GP visit card, or doctor visit card (DVC; typically held by individuals over the age of 70 regardless of income and children under the age of six) entitles a patient to free GP access only.[22] Additional questions included 'proxies' for identifying high-risk patient factors[23, 24] and included: age; hospital admission within the last 12 months; fall within the last 12 months; frequency of GP attendance within the last 12 months; presence of chronic diseases (e.g. chronic obstructive pulmonary disease, cardiovascular disease, heart failure), and the number of repeat medication items.

4.4.3 Participant recruitment and data collection

A combination of convenience and purposive sampling were used to recruit participants as part of a previous study; data from the same participant sample were used in the current study.[16] Data were collected between February and June 2020. Inclusion criteria specified that participants were required to be over 18 years old, English-speaking, and to have visited a GP in the Republic of Ireland within the previous 24 months. The study was advertised on social media (e.g. Twitter), to patient advocacy groups, in local newspapers and via interviews with local radio stations. In order to ensure inclusion of 'high-risk' patients and members of the public within the sample of respondents, 176 relevant organisations and groups (e.g. community retirement groups, chronic illness support groups) were contacted and

asked to share information on the study and/or distribute a copy of the measure to their members.[16]

Participants were provided with the choice of completing the survey via paper copy, which was posted to participants alongside a stamped, addressed return envelope, or accessed online via SurveyMonkey, by distributing a survey link to participants' email addresses. Participation was voluntary, and a prize draw for 50-euro gift vouchers was used to incentivise participation.

4.4.4 Data analysis

Data were analysed using SPSS (version 26). The items within each of the five subscales were summed to give total subscale scores. Higher scores represented greater perceived SC for each of the subscales, with the exception of *Staff stress and workload*; as six out of seven of these items were negatively worded, the positively worded item was reverse scored such that higher scale scores represented greater perceived stress.[16]

Patient's perceptions of safety climate in Irish general practice

Descriptive statistics were used to summarise patients' perceptions of SC in Irish general practice in relation to each of the five SC subscales, and the two global safety items. As the Kolmogorov-Smirnov test revealed a non-normal distribution of data ($p<.001$), the median for each subscale is reported and the interquartile range as an indicator of dispersion.[25]

Impact of patient risk factors on safety climate perceptions

A series of five separate hierarchical regressions were used to examine the relationship between a range of patient-related variables and each of the SC subscales, which were treated as the criterion variable in each case. In the regression model, predictors included demographic variables (gender, age, nationality, and GMS status) which were entered in Step 1 of the analyses, and high-risk patient indicators which were entered in Step 2 (number of GP visits in the past 12 months, recent fall, recent hospitalisation) and Step 3 (polypharmacy, multimorbidity). Missing data were managed by excluding cases listwise. For analysis purposes, nationality was coded as 'Irish' or 'non-Irish', and 'GMS' was collapsed into

'private patient' or 'public patient'. A participant met the criteria for polypharmacy (coded as 'yes'/'no') if they reported being on five or more repeat medications, and were considered multimorbid ('yes'/'no') if they listed the presence of at least two chronic conditions.

Open-ended responses of patients

A deductive content analysis approach[26] was used to code the free-text responses to 'additional comments in relation to safety of care'. These responses were coded according to SC domains explicated by Flin et al.[27] and Madden et al.,[15] which included: safety systems; risk perceptions; job demands/personal resources; reporting/speaking up; safety attitudes/behaviours; communication/feedback; teamwork; management; organisational factors; co-ordination of care; staff competence; access and timeliness; facilities and equipment; and dignity and respect. Further, we coded whether each assertation constituted a positive (i.e. good practice) or negative (i.e. poor practice) exemplar.[28] Comments were excluded if they were not considered to convey information about a specific safety domain (e.g. *'I'm satisfied with my GP'*). Responses were initially coded by the first author (CM), and reviewed by a second author (POC) to enhance trustworthiness. Disagreements were resolved via discussion[29] until consensus was achieved.

4.5 Results

4.5.1 Participant characteristics

A total of 584 participants completed the survey (57.5% online, 42.5% paper version). There were 500 paper copies administered, yielding a response rate of 49.6% (248/500). We were unable to calculate a response rate for the online version of the survey, as it was not possible to determine the number of contacts each of the support/community groups invited to partake.

Participant demographic characteristics and risk factors are shown in Table 4.1. Respondents were predominantly female (75.6%), most were Irish (91.3%), and the majority were private patients (72.6%). The mean age was 42.6 years (*SD*=16.1; range:18-91 years). Participants had attended a mean of 3.60 (*SD*=3.24; range= 0-30)

appointments with a GP in the previous 12 months. The breakdown of additional patient risk factors are detailed in Table 4.1.

Table 4.1 Participant characteristics

Variable	Frequency* (%)
Gender	
Male	138 (24.4)
Female	427 (75.6)
Nationality	
Irish	533 (91.3)
Non-Irish	36 (6.3)
GMS status	
Medical card	122 (21.4)
GP visit card	34 (6)
Private patient	414 (72.6)
Recent fall	
Yes	45 (7.9)
No	526 (92.1)
Recent hospital admission	
Yes	109 (19.0)
No	464 (81.0)
Polypharmacy	
Yes	69 (12.3)
No	490 (87.7)
Multimorbidity	
Yes	77 (13.4)
No	498 (86.6)

* Numbers do not add to 584 (total *N*), as demographic data were missing for some participants. The valid percent is reported.

4.5.2 Patients' perceptions of safety climate in Irish general practice

Safety Climate subscales

Patients reported that they felt safe under the care of their GP, with more than four-fifths of the patients reporting that they either 'agreed' or 'strongly agreed' with each of the seven items that assessed the 'Feeling of safety with GP' subscale. Participants had a median score of 24.0 (*IQR*=7.0) out of a possible 28 for this subscale.

With a median subscale score of 37.5 (*IQR*=11.0) out of a possible 48, patients also had favourable perceptions of 'Practice staff efficiency and teamwork', with 71.5%-90.4% of participants consistently selecting the most positive response options ('agree'/'strongly agree') for each of the 12 items.

In relation to 'Staff stress and workload', although over 40% of participants responded that they 'neither agreed nor disagreed' that *'Patient safety is affected by workload in the practice'*, and approximately 30% reported that they were uncertain as to whether '*Serious mistakes could happen here'*, participant perceptions remained positive; most 'strongly disagreed/disagreed' that the GP was usually stressed, rushed, or distracted (72.7%, 56%, and 84.9% respectively). Three quarters (75%) of the participants either 'agreed'/'strongly agreed' that the GP had enough time to spend on their care. Participants scored a median of 9.0 (*IQR*=6.3) out of a possible 28.

In general, participants reported notably positive levels of 'Patient knowledge and accountability' (most items >70%), with the exceptions of *'The practice answers questions about my care outside of appointments'* and *'I know how to report issues with my care'*, for which 55.6% and 59% provided positive answers respectively. The mean subscale score was 17.0 (*IQR*=5.0) out of a possible 24.

Finally, participants had predominantly favourable responses to 'Safety systems and behaviours', with over 75-94% consistently agreeing or strongly agreeing to each of the five items, and a median score of 16.0 (*IQR*=5.0) out of a possible 20.

Global safety items

The majority of participants (84.9%) stated that they were either 'likely' or 'extremely likely' to recommend the practice to friends and family if they needed

similar care or treatment. Participants had a median response of 9.0 (*IQR*=2.0) to 'on a scale of 0-10, how safe is the care in your practice?'.

4.5.3 Influence of patient risk factors on safety climate perceptions

In the first hierarchical regression, the model was found to account for 3% of the variance in 'Feeling of safety with the GP', $F(9,506) = 2.75$, $p = .004$. As shown in Table 4.2, gender ($p = .04$, $\beta = -.09$), age ($p = .002$, $\beta = .14$) and nationality ($p = .02$, $\beta = .11$) were significant predictors, such that being male, of older age, and being Irish were associated with higher subscale scores (i.e. better perceptions of safety).

In the second regression, the model accounted for 4.4% of the variance in 'Practice staff efficiency and teamwork', $F(9,504) = 3.59$, $p < .001$. Age and nationality were significant predictors, whereby older age, and being Irish were associated with higher subscale scores.

The third regression accounted for 3% of the variance in 'Staff stress and workload', $F(9,508) = 2.80$, $p = .003$. Age ($p < .001$, $\beta = -.18$) and nationality ($p = .04$, $\beta = -.08$) were significant predictors, such that older age and being Irish was associated with lower perceived staff stress and workload.

Within the fourth regression, the model accounted for 10.1% of the variance in 'Patient knowledge and accountability', $F(9,503) = 7.40$, $p = <.001$. Older age ($p < .001$, $\beta = .34$) was the only predictor in the model.

Finally, the fifth regression accounted for 3% of the variance in 'Safety systems and behaviours', $F(9,513) = 2.80$, $p = .003$. Age ($p = .02$, $\beta = -.10$) and nationality ($p = .02$, $\beta = .10$) were significant predictors, whereby being male, of older age, and being Irish were associated with higher subscale scores.

Table 4.2 Hierarchical multiple regressions of patient risk factors on the PPS-GP subscales

	Feeling of safety with GP			**Practice staff efficiency and teamwork**			**Staff stress and workload**			**Patient knowledge and accountability**			**Safety systems and behaviours**		
	β	*Adj* R^2	*F* change	β	*Adj* R^2	*F* change	β	*Adj* R^2	*F* change	β	*Adj* R^2	*F* change	β	*Adj* R^2	*F* change
Step 1		.03	5.44**		.04	6.71**		.03	5.55**		.11	16.44**		.03	4.88
Gender	-.09*			-.06			-.01			-.01			-.10*		
Age	.14*			.15**			-.18**			.34**			.11*		
Nationality	.11*			.15**			-.08*			.06			.10*		
GMS status	.05			-.00			.02			.01					
Step 2		.03	.54		.05	1.45		.03	.74		.10	.19		.03	.98
N visits	.02			.04			-.03			.04			.05		
Recent fall	-.05			-.08			.06			.01			-.07		
Hospitalisation	-.01			.04			.02			.01			-.00		
Step 3		.03	.75		.04	.56		.03	.45		.10	.37		.03	1.39
Polypharmacy	-.02			-.02			.03			-.03			-.07		
Multimorbidity	-.05			-.04			.02			-.02			-.07		

*p<.05, **p<.001

4.5.4 Open-ended responses of patients

Initially, 128 participants provided free-text responses to 'additional comments in relation to safety'. Of these, 32 were considered 'neutral' (e.g. 'I'm satisfied with my GP') and excluded from further analysis. Data regarding the frequency of the SC domains identified across the remaining 96 free-text responses, in addition to exemplar quotes related to both good and poor safety practices, are presented in Table 4.3. A total of 130 codes were identified across the 96 responses, the majority (*n*=85, 65.4%) of which related to poor SC practices.

A total of 440 comments relating to areas where changes could be made to GP care were also listed but are not further reported in the current paper as these are the focus of a separate study.

Table 4.3 Good and poor practice examples, frequency of emergence data, and exemplar quotes for safety climate domains identified in free-text comment responses

Safety Climate Domain		n (%)*	Exemplar quotes
Communication & feedback	Good practice	14 (14.6%)	*"I was particularly impressed by the communication between nurses and doctors within the practice"* *"One GP is very good at their job and listens to my concerns"*
	Poor practice	15 (15.6%)	*"My GP rushed a phone call about scan results and took no time to answer questions"* *"As a parent, I felt my theory/opinion was ignored and antidepressants were early on for a child"*
Access & timeliness	Good practice	2 (2.1%)	*"They are very efficient with appointment time and the longest I have waited in the waiting room is 10 minutes"* *"This* [waiting time] *doesn't bother me as they are usually fitting me in"*
	Poor practice	17 (17.7%)	*"It is difficult to get an appointment. There is usually a wait of at least a week unless it's an emergency"* *"My GP couldn't see me that day to just check it so I had to wait a day to get in, unable to walk"*
Staff competence	Good practice	8 (8.3%)	*"My GP is exceptional…She's extremely highly skilled and seems to know everything about everything"* *"My GP was always very knowledgeable"*
	Poor practice	13 (13.5%)	*"GPs should learn more about ethnic minorities and the health issues that affect them. I usually get misdiagnosed when I go to the GP"* *"In one situation the GP explained himself that he did not know how to do a speculum exam and referred me to another doctor"*
Dignity & respect	Good practice	8 (8.3%)	*"I'm blessed to finally have found a practice that treats patients with ME/CFS with care, respect, dignity and time"* *"Doctor, practice nurse and staff are very kind and always treat patients with patience and respect"*

	Poor practice	8 (8.3%)	*"Feel like a burden, treated with disrespect at times"* *"The doctors can be a bit condescending sometimes when you're telling them information you don't know is relevant or not"*
Job demands	Good practice	-	-
	Poor practice	16 (16.7%)	*"They are extremely busy, and you get the sense it is a stressful environment to work in"* *"I feel the GPs are so rushed that sometimes they just don't have sufficient time to spend with acute patients"*
Co-ordination of care	Good practice	1 (1.0%)	*"GP practice is quite new and seems to be well organised"*
	Poor practice	9 (9.4%)	*"Have to follow up to ensure referrals are made"* *"We often see different doctors, so part of the appointment is taken up giving the GP your history"*
Risk perceptions	Good practice	8 (8.3%)	*"I would consider my GP practice to be very safe and efficient"* *"Always felt the safety of care was adequate"*
	Poor practice	1 (1.0%)	*"If I was a new patient in the practice, I would not feel totally safe"*
Facilities & equipment	Good practice	1 (1.0%)	*"Waiting area is clean and tidy"*
	Poor practice	4 (4.2%)	*"I'm a wheelchair user, examination bench is not accessible to me. Toilet facilities also not accessible"* *"No alcohol/disinfectant hand gel anywhere in the waiting/public areas"*
Team work	Good practice	3 (3.1%)	*"The staff get along so well, and I receive exceptional treatment at all times from all staff"* *"The receptionist is a valued member of the medical staff. Just as helpful and always ensures that all messages are sent to the GP.*

	Poor practice	1 (1.0%)	*"Two GPs in the practice seem to disagree and one has criticised the instructions the other gave me on several occasions"*
Safety systems	Good practice	-	-
	Poor practice	1 (1.0%)	*"There is no 'red flag' system, if for example, someone has severe chest pain"*

*Percentages do not add to 100%, as there were more than one safety climate domains identified across comments. The denominator is 96, the total number of comments.
GP=General Practitioner; ME/CFS= Myalgic encephalomyelitis/chronic fatigue syndrome

4.6 Discussion

The growing complexity of primary health care delivery presents significant challenges for GPs.[4] Given the important, and under-utilised insights of patients into the care process, the aim of this study was to assess patients' perceptions of SC in Irish general practice, determine whether perceptions differed according to various patient risk factors, and explore whether open-ended responses of patients enhanced our understanding of patient safety information.

Overall, participants reported positive perceptions of safety across all subscales of the PPS-GP. Responses to global safety items were also positive, with participants scoring a median response of 9.0 (*IQR*=2.0) for overall practice safety rating, on a scale from 0-10, and 84.9% 'likely' or 'extremely likely' to recommend the practice to friends and family. Few other studies have administered patient-report questionnaires to assess safety in the primary care setting,[15] which limits our ability to draw extensive comparisons with existing research. Of those in existence, the PREOS-PC conducted in England[30] found that patients had generally positive perceptions of the safety of care provided in general practice, with a mean score of 84.6 out of a potential 100, and 91% agreeing that their HCPs were trustworthy. In a study of patient perceptions of the safety of primary chronic care in Finland,[7] 68% either agreed or strongly agreed that they received safe care at home. In a patient-report measure of patient experience of patient-centred medical homes in the US,[31] 63% gave positive ratings to their clinic on confidence in quality/safety. It therefore appears that patient perceptions of safety in Irish general practice are more positive than those from other international studies.

The level of favourable views in relation to the 'Staff stress and workload' subscale is perhaps surprising, given that a 2015 study of GPs in Ireland reported that 74% rated their stress levels as 'high' or 'very high'.[32] Further, in a survey of burnout amongst a sample of GPs working in Ireland,[33] 52.7% reported high levels of emotional exhaustion, and 6.6% fulfilled the criteria for burnout. However, O'Dea et al.[33] acknowledge that despite high stress levels, Irish GPs continue to derive satisfaction from their work as compared to their international counterparts, and patients are less likely to receive substandard care. This may partly explain why staff workload does not appear to translate to poor patient perceptions of safety. Although this is a relatively positive finding, it is important to also consider the possibility that

patients may not actually 'see' such system issues. Indeed, a number of qualitative comments which were excluded from the content analysis suggested this (e.g. *'It's difficult to answer some of the questions in the survey as its often not possible for me to know. For example, my doctor is stressed- how would I know unless they told me so. They could be extremely stressed but either hiding it well or not even aware if their own stress levels')*. Future research may therefore consider incorporating multiple perspectives of safety climate (e.g. patient and HCP perceptions) in order to obtain an accurate, full picture on systems factors.

Regarding patient risk factors, older age and being of Irish nationality were the only predictors that were significantly associated with positive SC perceptions. Similarly, De Voe et al.[34] report that patients aged over 65 years had positive perceptions of communication with HCPs. These patients felt that providers listened to them, showed respect for what they had to say, and spent enough time with them as compared to those aged 18-64. Such perceptions are in spite of findings that older patients are at a greater risk of experiencing a PSI in primary care,[35] most commonly related to medication-related incidents, communication-related incidents, and clinical decision-related incidents.[36] Nevertheless, our study demonstrates that older patients feel safer receiving care in Irish general practice- despite their increased risk profile and greater susceptibility to PSIs. We would have also that expected participants reporting the presence of certain risk factors such as multimorbidity and polypharmacy would report lower perceptions of safety, given that their complex health profile places them at an increased risk of safety issues,[18] and has been associated with a higher occurrence of PSIs[5, 6]; however, poorer SC perceptions were not evident amongst these participants. That non-Irish respondents to our survey felt less safe receiving care than Irish people warrants further exploration to ensure culturally sensitive, safe primary healthcare delivery by targeting language barriers, training needs, and developing guidelines for effective cross-cultural communication[37]; particularly in light of health equity research finding that people of colour are more likely to experience patient safety events.[38]

The majority of free-text responses were related to communication and feedback, which is unsurprising given that effective communication has been consistently identified by patients[39, 40] as a key contributor to PSIs. Deficits in relation to access and timeliness were also frequently identified, such as difficulty in

obtaining an appointment, which has been cited as a driver of safety problems in other studies.[30] It is, however, surprising that over two-thirds of the open-ended responses related to 'poor' SC practices, given that the overall SC perceptions were so positive. This finding is similar to research conducted in a hospital setting, whereby patients cited widespread criticism of the hospitalisation experience in response to an open-ended question, despite reporting high satisfaction scores in response to closed-ended questions.[41] The use of an open-ended option in the current study therefore allowed for the exploration of divergent responses to closed-ended questions, and raised issues that would likely have been less noticeable otherwise. This highlights the advantages of using qualitative methods to derive data that provide a deeper and more nuanced understanding[41] of the care experience than collecting quantitative data alone. However, given the disadvantages associated with the use of one format alone (e.g. item non-response to open-ended questions due to time burden[42]), we would suggest that future research combines the use of both qualitative and quantitative methodology when exploring patient-reported safety perspectives. Additionally, these findings emphasise the valuable role that patients can play in identifying poor practices, thus providing information that can be used by GPs to inform safety improvements. This is particularly useful in light of research reporting that primary care physicians have cited difficulty in understanding how best to measure and improve patient safety in their practices.[17]

4.6.1 Future research

Our finding that patients predominantly identified 'poor' SC practices, despite reporting generally positive SC perceptions suggests a need to explore isolated incidents of safety in general practice in greater detail. Previous research has found that even patients with generally positive perceptions of care could recall at least one safety incident they had witnessed previously.[43] Similarly, Ricci-Cabello et al.[30] found that despite participants reporting that providers took adequate measures to ensure safe healthcare delivery, 45% reported experiencing at least one safety problem in the previous 12 months. While the examination of specific incidents was outside the scope of our novel measure, this suggests that despite favourable general perceptions of SC, there may exist a need for future research to further explore the occurrences of isolated incidents of harm.

It has been suggested that 'a single measure of safety is a fantasy'[11] and given our findings, the gathering of patient-reported safety information is no exception. There are various purposes, strengths and weaknesses associated with the use of each patient safety measure, which must be considered as complementing each other by providing different levels of qualitative and quantitative information.[44] Therefore, the triangulation of various data collection methods has been recommended to obtain a full view[44, 45] of the safety experience, and ought to be applied to the general practice setting.

Although participants had generally positive perceptions in relation to 'Patient knowledge and accountability', just over half reported knowing how to report issues with their care. Similarly, Ricci-Cabello et al.[30] reported low levels of patient activation, with the majority of participants reporting that they 'never' or 'rarely' raised a concern when they thought something was wrong. In a study of patient complaints, O'Dowd et al.[46] cite a lack of knowledge of the complaints process as a potential reason for patients not complaining.[47] Efforts should be made to ensure that patients are aware of the processes involved in reporting issues with their care, either at a practice or a national level.

4.6.2 Strengths and Limitations

There are a number of limitations that should be considered when interpreting the results of the current study. First, we were unable to calculate a response rate for the online version of the questionnaire, as the recruitment strategy used did not make it possible to collect data on how many patients were invited to complete it. Further, it is reasonable to suggest that it may be lower than the paper version of the survey, given that web response rates have been consistently found to be lower than rates achieved using traditional data collection methods in public health research.[48] Despite this, our response rate is considerably higher than other patient-report safety measures conducted across primary[30] and secondary[49, 50] care settings.

Second, our study sample may not be representative of the population as a whole. Participants self-selected into the study, which may have imparted a self-selection bias, whereby certain types of participants were more likely to participate (e.g. those who were more motivated and more positive[51]). Further, 75% of respondents were female; although Irish data has suggested that women use GP

services more frequently than men,[52] our figure is disproportionate. Despite contacting a number of chronic illness support groups to share study information, only 14% of participants reported multimorbidity. It would be expected that this would be higher in a representative sample, given that approximately 27% of Irish adults report the presence of at least one long-standing illness or health problem.[52] The majority of respondents were also of Irish nationality, which may be partly explained by the PPS-GP being solely administered in English. Therefore, future research in this area ought to give further consideration to targeted recruitment strategies to capture the safety perceptions of those less well represented populations (i.e. male and multimorbid patients), with a particular emphasis on engaging non-Irish participants (e.g. by translating the measure into different languages), particularly in light of our findings that non-Irish respondents have poorer SC perceptions.

Third, although some significant regression coefficients were observed, suggesting that age and nationality are related to SC perceptions, a small portion of the variance in SC was explained by our set of predictors. This would suggest that our regression models provided poor fit. However, it has been reported that low variance in regression models have been consistently found in previous patient-report studies of healthcare[41] and this is relatively common in social sciences research.

Finally, some, but not all, of the participants were recruited in the midst of the COVID-19 pandemic. Although there is no known research to date specifically on patient-reported perceptions of safety in primary care during COVID-19, as we have acknowledged previously,[16] some studies have reported that patient satisfaction has been found to be higher in the COVID-19 period than in the period immediately before.[53] It is therefore possible that there was an artefact from the pandemic (e.g. positive skewness of item responses), given the established links between patient safety perceptions and patient satisfaction.[43]

4.6.3 Conclusion

Our findings indicate that despite being under-utilised, the perceptions of patients are a valuable source of information for measuring safety climate, with promising implications for safety improvement. Further consideration ought to be given on how

best to harness these perceptions to allow GPs to access and capitalise on them. Given that our application of a novel, patient-report measure of safety climate yielded deviant responses between quantitative items and an open-response qualitative item, the use of a quantitative survey alone may not adequately capture the entire patient safety experience. We recommend further qualitative exploration of isolated incidents of safety from the patient perspective, and the combined use of qualitative and qualitative methodology to obtain safety information in future research.

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Chapter Five: Study Four

The patients' 'story': An examination of patient-reported safety incidents in general practice

The patients' 'story': An examination of patient-reported safety incidents in general practice

5.1 Declaration

Alignment with the thesis

In addition to collection and analysis of quantitative data reported in the previous studies in this thesis, I wished to adapt a qualitative approach to derive data that provide a deeper and more nuanced view of the care experience.[1] Therefore, the study described in this chapter examined the value of assessing *Past harm* via 'patient stories' (i.e. first-hand accounts of experiences by patients) to better understand safety and identify deficiencies. While this approach has been taken to understand patient safety incidents from the perspective of GPs,[2] the value in considering incidents from the perspective of patients in this way has not been explored.

Peer-reviewed publication

This study has been published in a peer-reviewed journal; Family Practice, the citation of which is:

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This chapter is a formatted version of the published manuscript in the journal.

Authors' contributions

The authors of this study were: Madden C, Lydon S, Murphy AW, O'Connor P. The contributions of the individual authors are as follows:

- CM: Conceptualization, Investigation, Data Curation, Formal Analysis, Methodology, Writing- Original Draft Preparation, Writing- Reviewing and Editing.
- SL: Conceptualization, Methodology, Data Curation, Formal Analyses, Writing- Reviewing and Editing.
- AM: Conceptualization, Methodology, Writing- Reviewing and Editing.

- POC: Conceptualization, Methodology, Data Curation, Formal Analyses, Writing- Reviewing and Editing.

Ethical approval

Ethical approval was granted by the National University of Ireland, Galway Research Ethics Committee (REF: 18-Jun-10).

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5.2 Abstract

Introduction

Patient Safety Incidents (PSIs) are typically studied through engagement with healthcare providers, without input from patients despite their privileged viewpoint of care experiences. The aim of this study was to examine the potential of the patient viewpoint as a lens for future safety improvement initiatives, by: (1) collecting and analysing patients' accounts of PSIs; and (2) comparing patient and clinician perceptions of PSIs.

Methods

Firstly, Critical Incident Technique (CIT) interviews were used to obtain rich descriptions of PSIs, which were then condensed into patient stories. Deductive content analysis was used to code the safety deficiencies described in patient stories using patient-derived safety categories. Secondly, General Practitioners (GPs) and patients individually rated the perceived severity and likelihood of each story.

Results

A total of 32 eligible patient stories were obtained from 25 interviews. Stories commonly described deficiencies related to communication, staff performance, and compassion/dignity/respect. There were significant differences in GP (n=14) and patient (n=11) severity and likelihood ratings. GPs were significantly more likely to consider stories to be a lower severity, and occurring with a lower frequency than patients.

Conclusion

Elicitation of the patient perspective using the CIT allowed for the rich description of safety deficiencies that occur in general practice. Given that patients bring a unique and important viewpoint on safety, there is a need to make greater efforts to include the patient perspective of safety in healthcare.

Keywords

General practice; Family medicine; Primary health care; Patient involvement; Patient safety; Qualitative research.

5.3 Introduction

The study of patient safety in the primary setting has lagged considerably behind secondary care,[1] a disparity likely influenced by the perception of primary care as a 'low risk' endeavour.[2] However, the sheer volume of patient contacts in general practice creates an increased potential for Patient Safety Incidents (PSIs; defined as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient[3]) to occur.

PSIs are commonly studied using narrative accounts from healthcare providers (HCPs), submitted via incident reporting systems,[4] as opposed to examining patient accounts.[5] Therefore, PSIs tend to be described in a structured, concise, scientific and factual manner, with feelings and emotions rarely playing a part in conveying potentially damaging events for patients.[6] This aspect of harm can be best captured via patient narratives, or 'patient stories' (i.e. first-hand accounts of experiences by patients[6]). Given that previous research has utilised clinician 'stories' to better understand safety and identify deficiencies,[7] the use of patient stories in this way may also be insightful.

Due to the central position of patients in the care process,[5] patients have a unique perspective which enables them to actively and consistently collect observations about the healthcare experience[8] that HCPs may miss (e.g. breakdowns in the continuity of care, medication incidents[9]). Further, greater understanding is needed of how patients can contribute to improving the safety of care in general practice.[10] Although findings from quantitative measures (e.g. surveys[11]) have obtained general perceptions about safety in primary care, it has been found that even patients with generally positive care experiences could still convey a story about problems they had witnessed previously.[12] Finally, there have been concerns regarding the dependability of patients' to reliably assist in the safety of their care.[13-16] Therefore, there is a need to explore the dependability of the patient perspective further if we are to consider widespread initiatives that capitalise upon it.

The aim of this paper was to examine the potential of the patient viewpoint as a useful lens for future safety improvement initiatives, and explore comparisons between patient and clinician perceptions of PSIs. Specifically, our research questions were:

1. Can patients provide valuable data about safety deficiencies they have experienced in general practice?
2. Do patients' perceptions of: (a) whether events described in patient stories were considered to be PSIs; (b) their severity, and; (c) their likelihood of occurring in practice align with clinician perceptions?

5.4 Methods

This study consisted of two phases. The first phase employed a qualitative descriptive design using Critical Incident Technique (CIT)[17] interviews to elicit patients' complete and rich descriptions of incidents that occurred in general practice. The second phase of the study employed a quantitative survey design to explore and compare GP and patient perceptions of PSIs.

5.4.1 Phase One: Patient descriptions of safety deficiencies in general practice

The methodology and findings for this phase are reported in accordance with the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist.[18]

Participants

Convenience and purposive sampling was used to recruit participants who were over 18 years old, English-speaking, and believed they had experienced a PSI in general practice in the Republic of Ireland. For the purposes of recruitment, the term 'mistake' was used,[8] broadly defined as 'an event which could have resulted, or did result, in harm to a patient receiving care'. The study was advertised on social media, through patient advocacy groups, in local newspapers, and on local radio. Participants were also invited to take part via an opt-in option at the end of a separate survey study.[11] Participation was voluntary, with a prize draw for four €50 gift vouchers used to incentivise participation at the initial recruitment stage.

Data Collection

The CIT interview is a procedure for gathering certain important facts concerning behaviour in defined situations,[17] consisting of a flexible set of principles that can be modified and adapted to meet the specific context. CIT interviews have more

recently been employed in the health sciences to describe experiences of HCPs (e.g. [7]) and patients (e.g. [19]).

The interviewer (CM) was a female PhD candidate conducting patient safety research and previously trained in conducting CIT interviews. Interviews were conducted between October 2019 and July 2020, either in person in a neutral location (*n*=6), or over the telephone (*n*=24). The CIT interview followed a semi-structured format. The primary focus of the interviews was to obtain the participant's description of the incident, with the interviewer enriching this initial summary by soliciting further information and pertinent detail.[7, 20] This was achieved by using the participants' own recollection of the PSI as the starting point of the interview, then conducting a number of 'sweeps' through the incident[20] to explore participant cues and expand on the incident (see Figure 5.1). The interviewer generated field notes throughout, which were relayed back to participants throughout to allow further elaboration and clarification of details. Interviewing continued until the researcher considered data saturation to be achieved. Interviews were audio recorded and later transcribed verbatim.

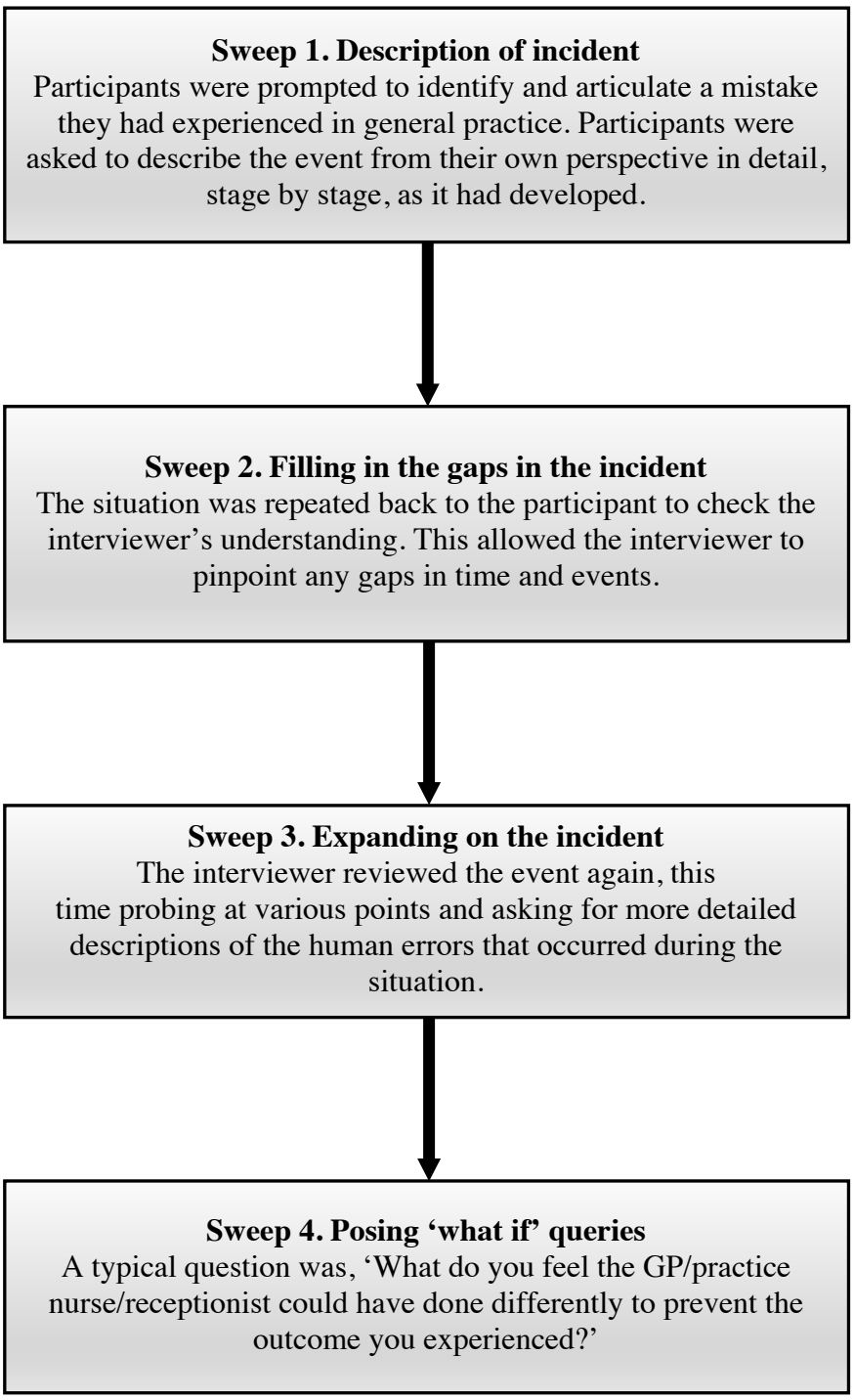

Figure 5.1 Interview format, adapted from O'Connor et al.[20]

Data analysis

The interview transcriptions and field notes were used to generate a rich chronological description of each PSI. As part of a peer consultation process,[21] descriptions were reviewed and condensed independently by three members of the research team in order to ensure brevity whilst maintaining a sufficient level of contextual detail within each description, referred to hereafter as the patient 'story'.[7] The average word length of the final patient stories was approximately 284 (see Appendix I for exemplar patient stories).

Three members of the research team (CM, SL, and POC) carried out a deductive content analysis process to code the patient stories. Deductive content analysis is used when the structure of analysis is based on previous knowledge,[22] and was considered appropriate given the stories were coded using existing patient-derived safety categories adapted from O'Hara et al.[23] As these categories were developed to code patient experiences in hospital care, a consultation exercise was conducted, whereby two patient representatives assisted with adapting the categories for use in a primary care context (see Table 5.1). To enhance trustworthiness of this process, the research team independently coded five stories selected at random, and discussed their analyses to ensure consensus. The remaining stories were then double coded, with any discrepancies resolved via discussion.

Reflexivity

Reflexivity is a form of self-appraisal in research, which involves "turning the researcher lens back onto oneself" to recognize one's own situatedness within the research and the effect that it may have on the questions being asked, data being collected and its interpretation.[21] Therefore, a systematic reflexive process was followed to enhance openness and transparency in gathering and analysing the data[21,24] (e.g. a log of the encounters was kept, recording the researchers' interpretation of the verbatim).

Table 5.1 Coding of patient stories according to patient-derived safety categories[22] with identified exemplary quotes

Coding category and description (n; %*)	Exemplar quote from patient story
Communication (23; 71.9%)	
Staff to patient • Staff member (GP, practice nurse, receptionist) did not communicate effectively with patient • Staff member did not listen to the patient • Patient anxieties or concerns not addressed or ignored	*'She didn't explain why she was carrying out the swab, she just said, "I'm doing this swab, it's just something that needs to be done when a woman is pregnant, is that ok?" '* (PS5) *'I did not get all of the information from my GP that I should have. I was never told and still don't know what can be done and what exactly the condition means for me'* (PS10) *'He [the GP] literally didn't do anything, he just said "*it's the ME, you'll be fine"*…everything I had was just ME, there was never anything else wrong with me in his eyes'* (PS22) *'I thought my GP knew me well and they knew I wasn't a hypochondriac; this isn't a child or a mother who usually complains and I really thought that they'd listen to the parent. I just felt they never did'* (PS30)
Staff to staff • Poor communication between staff members • Misunderstanding between healthcare providers • Poor co-ordination of care between practice staff providers and other relevant members of secondary care	*'It seems like lack of communication might have been an issue between the receptionist and the doctor, or both receptionists'* (PS4) *'Really my opinion is that the GP should check with the consultant if he is planning on changing her medication or taking a patient off a medication'* (PS7) *'I feel there's some disconnect between hospital doctors and GPs that has an impact on the big picture of patient safety and patient care'* (PS18) *'It's also a lack of joined-up thinking- why did the physiotherapist have the knowledge that the GP didn't or why couldn't it be shared between them?'* (PS30)

Patient to staff • Patient not relaying information to staff member • Patient not listening to or following staff member's advice	*'I probably downplayed my symptoms in retrospect* (PS2)
Staff performance (20; 62.5%) • Staff not knowing how to do things • Lack of knowledge about illness • Delayed diagnosis • Misdiagnosis • Inadequate treatment of wound • Insufficient examination • Poor hygiene practices	*'I think if he had done the physical exam it would have been immediately clear'* (PS2) *'He* [the out-of-hours GP] *said he had a distended tummy, gave him a suppository, and we were sent home. At home, our baby became stiff and we brought him to the hospital. He died from meningitis within 24 hours'* (PS6) *'What's striking is that someone with so much compassion and clinical skills could still make those mistakes'* (PS12) *'There's this massive misconception about the illness* [ME] *being a psychiatric condition that many GPs still hold so we're met with stigma and ignorance wherever we go'* (PS21) *'The GP was professional…But I felt I was better treating it by myself, because I was going over and over again'* (PS24) *'He was misdiagnosed with having a mental health issue and not a heart issue, because he died from a heart attack the following evening'* (PS26) *'If the GP would have done a physical rectal examination in the beginning, he would have felt the tumour there, but he never did that, he didn't do any kind of a physical exam'* (PS28)

Compassion/dignity/respect (12; 37.5%) • Inappropriate conduct from staff • Poor/dismissive attitude • Rude behaviour • Patient intimidated or poorly treated • Failing to acknowledge/indicate regret for errors or failings in care	*'He just didn't seem to give a toss'* (PS3) *'They definitely weren't admitting they had made a mistake'* (PS4) *'It's disrespectful. I think the truth would mean a lot to me, for the person that did to say "look, it was an error, I made a mistake, I'm sorry. I opened the results" But there wasn't respect enough to do that'* (PS5) *'We were made feel like we were bothering them… new parents who were being ridiculous, overly cautious and overly concerned'* (PS6) *'I told one GP I would have been happier if my uterus and ovaries were taken, and he told me that "my future husband might want kids, so I should get over it*"' (PS14) *'We were disgusted with the first GP because he actually told me that I was putting it on, and so consequently I did not go back to that GP or that practice'* (PS23)
Delay (10; 31.3%) • Delay or difficulty getting an appointment • Long wait time in practice • Test results not available • Required equipment not available • Delay in referring to appropriate specialist/services	*'It just means that I've had back and shoulder pain for the past two months while I've been waiting. I've also been holding out on going back to physio until I had the results of my MRI, and I've been in constant pain'* (PS4) *'I understand at the very beginning I was very young, but I might not need as much surgery now if I had been taken seriously'* (PS14) *'This has been an ongoing situation now for over 10 years. I still deal with it…I do feel that if it had been followed up or caught earlier… even if that first GP had referred me to physiotherapy back then, I wouldn't be in this position'* (PS19) *'He left me sitting in the waiting room for two hours with my sister and I couldn't actually hold myself up, I kept falling on top of my sister and my face was drooping'* (PS23) *'I got an appointment eventually days later, but I still had to bear the pain'* (PS31)

Medication issues (7; 21.9%) • Medication unavailable • Incorrect medication prescribed • Poor monitoring of medication • Patient unprescribed essential medication • Known allergy to medication prescribed • Contraindication	*'He prescribed and kept her on a high dose of steroids for a longer period than she should have been on without monitoring it, and just kept repeating her prescription every time she went in'* (PS1) *'Her GP took her off a medication that had been prescribed to her by a heart specialist which was facilitating her pacemaker to work effectively at regulating her heart'* (PS7) *'When the pharmacy looked at the prescription, they noticed that the GP hadn't linked the impact of my Parkinson's medication on the steroids and they said that it would have a serious impact on my health if I took the drugs'* (PS16) *'Difene is actually contraindicated for people who have asthma so she probably should never have given it to me in the first place because I have asthma'* (PS20) *'I was alerted then to the fact that the ingredient I was allergic to might be in the prescription that he gave me. I read the leaflet and found that yes, there was Metoclopramide in it'* (PS29)
Practice management (3; 9.4%) • Lack of consistency • Lack of overview • Missing/mislaid documents or medical information • Referral issues • Test results not communicated to patient	*'I don't know who the fault lies with, but it seems it was the receptionist that never sent the referral'* (PS4) *'The GP openly said in the inquest that "the patient didn't get her test results, one of us in the surgery opened them. It was either myself or the other doctor in the practice"'* (PS5) *'The details about her referral were incorrect and those files came from the GP'* (PS13)
Equipment and systems failure (2; 6.3%) • Equipment or systems not working/failing/insufficient/poorly designed.	*'Every GP should have a system that's not going to accidentally harbour important results that could be overlooked'* (PS5) *'We made 10 or 11 continuous calls…we found out afterwards that when calls are coming in, they actually prioritise them and that we got the lowest priority'* (PS6)

Staff issues (1; 3.1%) • Staff unavailability • Insufficient numbers of grade of staff • Staff shortages	*'Because of COVID, it was a phone consultation, she just asked me about the symptoms'* (PS32)
Environment (1; 3.1%) • Dirty facilities • Inaccessible practice • Inappropriate space • Parking not available	*'You had to queue outside the building, I remember throwing up in the garden, so it wasn't a great set up'* (PS2)

* Percentages do not sum to 100% as some stories contained more than one type of safety category.
PS= Patient Story; GP= General Practitioner; ME=Myalgic Encephalomyelitis

5.4.2 Phase Two: Comparing patient and clinician perceptions of PSIs

Participants

Convenience and purposive sampling were used to recruit GP and patient raters. GP raters were required to have at least five years of experience in a practice based in the Republic of Ireland. An invitation to partake as a GP rater was sent via email and a brief presentation at an annual meeting to clinically active GPs affiliated to a Department of General Practice at an Irish university.

Patient raters were required to be aged 18 or over, and have visited a GP practice in the Republic of Ireland at least once in the past 24 months. Advertisements were placed on social media platforms and an email was circulated amongst patient advocacy groups. None of the participants included in Phase One of the study were recruited to partake in Phase Two. Participation was voluntary, and all GP and patient raters received €100 gift vouchers to incentivise participation.

Data collection

Each of the 32 patient stories were provided to participants, and responses collected, via a survey on an online platform. After each patient story was presented in the online survey format, the raters were asked three questions: (1) whether they considered the event described in the story to be a PSI ('yes' or 'no'); (2) to rate the perceived severity on a scale that ranged from '0' ('no harm') to '5' ('death'),[25] and; (3) to rate the likelihood of such an experience occurring in general practice on a scale from '1' ('rare') to '5' ('frequent')[26] (see Table 5.2). This was repeated for each of the 32 individual patient stories.

Table 5.2 Distribution of GP and patient ratings of whether stories were considered PSIs, their level of harm, and likelihood of occurrence in general practice

	Overall n (%/800[a])	**GP Raters n (%/448[b])**	**Patient Raters n (%/352[c])**
PSI Classification			
Yes	669 (83.6%)	387 (86.4%)	282 (80.1%)
No	131 (16.4%)	61 (13.6%)	70 (19.9%)
Level of Harm			
No harm No harm occurred to the patient	85 (10.6%)	40 (8.9%)	45 (12.8%)
No harm due to mitigating action Incident had the potential to cause harm, but this was prevented	105 (13.1%)	64 (14.3%)	41 (11.6%)
Mild harm Patient harmed with mild and short-term impact on physical/mental/social functioning No or minimal intervention/treatment Patient or loved ones experienced mild emotional distress not requiring treatment	165 (20.6%)	97 (21.7%)	68 (19.3%)
Moderate harm Patient harmed with medium-term impact on physical/mental/social functioning Medical intervention (e.g. treatment/short-term hospitalization) Patient or loved ones experienced psychological difficulty of a more longstanding nature, but not requiring formal treatment	198 (24.8%)	126 (28.1%)	72 (20.5%)

Severe harm Patient harmed with major long-term impact on physical/mental/social functioning Major medical or surgical intervention; prolonged hospitalization Patient or loved ones experienced enduring psychological difficulty requiring specialist treatment.	144 (18%)	65 (14.5%)	79 (22.4%)
Death On the balance of probabilities, death of the patient was caused or brought forward in the short term by the incident.	103 (12.9%)	56 (12.5%)	47 (13.4%)
Frequency			
Rare Unlikely to occur (may happen every 5-30 years)	106 (13.2%)	75 (16.7%)	31 (8.8%)
Unlikely Possible to occur (could occur at some time in 2-5 years)	215 (26.9%)	128 (28.6%)	87 (24.7%)
Possible Might occur at some time (may happen every 1-2 years)	277 (34.6%)	164 (36.6%)	113 (32.1%)
Likely Would probably occur (several times a year)	158 (19.8%)	64 (14.3%)	94 (26.7%)
Frequent Expected to occur in practice (most weeks or months)	44 (5.5%)	17 (3.8%)	27 (7.7%)

[a] The denominator is derived from the 25 overall ratings for each of the 32 patient stories (total *n* for analysis= 800).
[b] The denominator is derived from the 14 GP ratings for each of the 32 patient stories (*n* for analysis =448).
[c] The denominator is derived from the 11 patient ratings for each of the 32 patient stories (*n* for analysis=352).

Data analysis

In order to determine whether perceptions of: (1) whether the event described in the story was considered a PSI; (2) severity, and; (3) likelihood differed between the GP and patient rater groups, three separate chi square tests of independence were conducted.

5.5 Results

5.5.1 Phase One: Patient descriptions of safety deficiencies in general practice

Participants

The mean duration of interviews was 24 minutes 42 seconds (*SD*=17 minutes 33 seconds). Initially, 30 interviews were conducted, describing 37 separate PSIs. Of these, five were excluded; one participant withdrew, two were not specific to general practice, and two did not describe a PSI. The unit of analysis was the remaining PSI descriptions[17](*n*=32).

Most of the PSIs (*n*=22; 68.8%) were described directly by the patient affected, with ten (31.3%) reported by a family member or a healthcare provider. Incidents involved 11 (34.4%) male and 21 (65.6%) female patients, with an age range of between six weeks and 88 years of age. Most involved patients or Irish nationality (90.6%), with three stories (9.4%) relating to patients from Zimbabwe, Uganda, and Lithuania. Four (12.5%) of the patient stories were related to out-of-hours GP services, while the remainder occurred in practice settings.

Content analysis

Findings from the content analysis, in addition to exemplar quotes in relation to each of the patient safety categories are provided in Table 5.1.

Communication. As shown in Table 5.1, in the situations described, effective, timely and clear communication related to participants' care was often lacking (*n*=23; 71.9%). Communication issues predominantly related to exchanges between staff members and patients (e.g. failure to address patient concerns). Communication issues among HCPs were also evident, including poor co-ordination of care and a lack of effective information transmission either amongst staff within a practice

environment, or between practice staff providers and other relevant members of secondary care. One instance of inadequate communication from a patient to a staff member was identified.

Staff performance. Issues associated with poor staff performance were common (*n*=20; 62.5%). These included misdiagnoses of fatal conditions including meningitis and myocardial infarction, and delayed diagnosis of illnesses such as cancer, appendicitis, and gallstones. Other issues included GPs failing to conduct sufficiently thorough examinations of patients, resulting in delayed or missed diagnoses. There were also reports of GPs demonstrating a deficit of knowledge regarding the patient's illness, providing inappropriate advice, and providing inadequate wound treatment.

Compassion/dignity/respect. In over a third of the patient stories, staff members failed to demonstrate compassion, dignity, and/or respect towards the patient, typically relating to staff failing to acknowledge or indicate regret for errors or failings in care. Staff members also demonstrated a poor or dismissive attitude or exhibited rude behaviour in some of the stories.

Delay. Of the patient stories that involved a delay, the most commonly identified issue was patients feeling that they had not been referred to an appropriate specialist or services within an adequate timeframe. Difficulties in getting an appointment were also cited, in addition to participants experiencing long wait times in the practice whilst feeling acutely unwell.

Medication issues. Participants cited problems related to medication management, commonly relating to poor monitoring of patients whilst on high-risk medication (e.g. steroids). A number of participants experienced known drug allergies to medication, despite alerting the GP to the allergy in advance of it being prescribed, whilst others experienced drug contraindication. In some cases, patients were de-prescribed medication they perceived to be essential, and in one story, there was a lack of clarity regarding the correct dosage the patient was required to take.

Practice management. Practice management issues included incorrect information on the patient's medical record, practice staff repeatedly failing to organise a referral, or communicate important test results to the patient despite them being received by the practice.

Equipment and systems failure. Poorly designed practice software systems were considered by one patient to be problematic in the context of patient safety, as it resulted in them not receiving important test results. Insufficient telephone triaging procedures were also cited, which had severe consequences in the case of one patient.

Staff issues. Although staffing issues were infrequently cited, lack of access to a face-to-face consultation was referenced in one case, which one participant felt impeded the quality and safety of care.

Environment. Finally, there was one instance where a patient cited a lack of access to appropriate waiting facilities.

5.5.2 Phase Two: Comparing patient and clinician perceptions of PSIs

Participants

A sample of 25 participants (15 males, 10 females), consisting of 14 GPs and 11 patients with a mean age of 45 years (*SD*=12.84; range: 22-64) was recruited in phase two. The GP participants contained GP principals (*n*=10) and GP assistants (*n*=4), with a mean of 20.92 (*SD*=12.49, range: 5-37) years of experience in practice. All patient participants had a third-level qualification (i.e. post-secondary, obtained from a college or University).

Ratings of PSIs, severity, and likelihood

Ratings of whether the event described in the story was considered a PSI, severity, and likelihood by the 25 raters are depicted in Table 5.2. Overall, patient stories were predominantly considered to fit the definition of a PSI. Regarding severity, a quarter of the stories were considered to constitute 'moderate harm'. Regarding likelihood,

patient stories were most frequently considered 'possible' by over one-third of GP and patient raters combined.

Group comparison

Using chi-square tests, we found statistically significant relationships between rater groups and PSI categorisation, harm rating, and probability ratings. The significant relationship between the rater groups and PSI categorisation (X^2 (1, N=800) = 5.66, p=.02) suggested that GP rater group were more likely to rate stories as PSIs than the patient rater group (see Table 5.2). The significant relationship between the rater groups and harm ratings (X^2 (5, N=800) = 16.02, p<.007) revealed that GPs were more likely to rate stories as 'mild' and 'moderate', while patients were more likely to rate stories as 'severe' and 'death'. Finally, GPs were more likely to rate stories as 'rare' 'unlikely' and 'possible', while patients were more likely to rate stories as 'likely' and 'frequent' (X^2 (4, N=800) = 32.39, p<.001).

5.6 Discussion

Despite their unique position observing the care experience,[5,8] the patient perspective is typically omitted from patient safety research. This study explored the potential of the patient viewpoint as a lens for future safety improvement initiatives, by examining whether the qualitative elicitation of the patient perspective enhances understanding of PSIs that occur in general practice and exploring comparisons between patient and clinician perceptions of PSIs.

Patients provided rich descriptions and valuable data about safety deficiencies they had experienced in general practice- predominantly relating to communication, staff performance, and attitude issues like compassion, dignity, or respect. Poor communication has consistently been identified by patients as a key contributor to harm,[12,23,27] as have various aspects of inadequate staff performance.[10] However, dignity and respect are vastly underexplored in patient safety measurement and discourse despite findings suggesting that treating patients with a lack of dignity and respect can result in patients being less forthcoming about safety concerns.[28] Given the identification of dignity and respect in over a third of the patient stories,

our findings further confirm that patients provide additional and unique information about safety outcomes beyond that of HCPs.

Practice environment, staffing, and equipment and systems failure were infrequently reported in the patient stories, suggesting that patients may not 'see' system factors associated with PSIs. It has been postulated that healthcare consumers typically focus on processes of care and interpersonal dynamics of care providers.[12] Previous studies of patient-reported safety in healthcare[11,27] noted that patients did not comment on facilities, equipment and supplies, staffing levels, management, or co-ordination of care, suggesting that these were not visible to patients and/or patients may not understand the impact of these factors on their care.

Although findings suggest that there is merit in considering the patient perspective of PSIs, there exists a need to triangulate multiple perspectives of safety; for example, by examining patient stories in conjunction with those of primary care staff. This approach has been previously demonstrated in hospital settings,[29] whereby focus groups were conducted with both patient and nursing staff to describe safety practices. Patients recognised that nursing staff were under stress and the impact this had on their care, whilst examination of the nursing perspective supported an understanding of the contextual factors associated with contributing constraints of the health system (e.g. patient caseloads, lack of time). Such approaches highlight the benefits of examining specific issues pertaining to safety from the perspective of both healthcare workers and patients to inform safety improvements.

There was a significant difference between the GPs and patients in the way they categorised stories as PSIs. Further, the patient raters actually considered fewer of the stories to fit the criteria of a PSI than the GP raters. This finding suggests that patients are capable of recognising errors,[23] and contradicts concerns surrounding the dependability of patients' to reliably assist in the safety of their care.[13-15] However, consistent with previous findings,[16] patients considered the severity and likelihood of PSIs to be greater than GPs. It may be reasonable to suggest that discrepancies in frequency ratings between patients and GPs are at least in part related to the patients lack of clinical knowledge. However, it is difficult to conclude whether patients also rate stories as having greater harm implications than GPs due to their lesser clinical knowledge, or whether GPs under-estimate the perceived harm as they are unable to fully appreciate the patients' perspectives of the impact of the harm. Future research

should focus on why these disparities exist between GP and patient perceptions of PSIs.

Given these findings, we encourage the use of patient stories as a method to support safety improvement initiatives. Patient stories could be used to support the identification of appropriate interventions and in shaping and prioritising research. This could be achieved by involving patients in the formal review of PSIs (e.g. by including patient reports as an integral part of the safety management system[8]). Using the patient as a source of input to a health system is particularly important, as it establishes an obligation that requires the system to respond to concerns and address issues raised.[8]

5.6.1 Limitations

There are a number of limitations associated with the current study. First, stories are in essence the patient's recollection of what occurred, and were included for analysis if patients perceived them to be harmful. It is therefore possible that patients could have interpreted quality lapses (i.e. dissatisfaction with care received despite no risk of harm) as safety incidents.[14] However, given our findings that the GP rater group considered a higher portion of the stories to constitute PSIs, we are confident that the patients in our rater sample did not over-estimate their occurrence.

Second, the purposive sampling strategy adapted may have resulted in an over-representation of certain groups; for example, Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome was reported in three patient stories, despite an estimated prevalence of .9%.[30] Further, recruiting via convenience sampling resulted in participants self-selecting into the study, which may have led to an over-representation of participants with strong perceptions about PSIs. Greater detail might have been gleaned if people making claims or who had been involved in incident investigation had been recruited.

Third, the CIT interview method could be criticized due to the potentially biased nature of patients reports.[7] However, it has been argued that although such biases pose a weakness in epidemiological measurement, they can be advantageous in terms of safety management, by allowing specific issues to be subjected to increased scrutiny.[31] Finally, there is the potential for subjectivity in the reporting and analysis of the data. However, given that a rigorous approach was taken to both

the data collection and analysis, we are confident that these potential issues were sufficiently minimised.

5.6.2 Conclusion

Our elicitation of the patient perspective using the CIT demonstrated that patients are a valuable source of information, providing a unique and important viewpoint of safety in general practice. Therefore, there exists a need to make greater efforts to include patient perspectives in the measurement and improvement of safety in healthcare going forward.

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Chapter Six
General discussion

General discussion

6.1 Chapter outline

The rationale for including patients in the measuring and monitoring (MMS) of patient safety is clear. Patients can play a pivotal role in patient safety initiatives,[1] given the contextualised information (e.g. about risks, problems and incidents[2, 3]) they acquire from their unique position at the epicentre of the care process.[4-6] Involving the patient in safety has been found to highlight issues of which healthcare providers (HCPs) may be unaware.[7-13] Further, patients are willing and able to be involved in patient safety efforts.[2, 14, 15] This involvement, combined with theoretical perspectives pertaining to patient activation,[16, 17] socio-technical systems,[18] and safety climate,[19-21] build a convincing body of evidence for the inclusion of patients in MMS. Consequently, there has been a growing awareness of patient involvement in safety initiatives in recent years; for example, patient involvement has become a key government and health service concern as reflected by national-[22-24] and international-level[25] policy priorities. However, research on how best to include patients in the MMS of safety in general practice is lacking. Therefore, this thesis aimed to: (1) identify an approach to how patients can contribute to the measurement and monitoring of safety climate; and (2) ascertain the value of patient data for identifying and learning from past harm in primary care. These two aims were addressed through the completion of four studies, each addressing a specific research question. This final chapter of the thesis will summarise the answers to these four research questions. Then, implications for research and practice arising from these findings will be suggested. The key strengths and limitations of the thesis will be discussed and finally, concluding comments will be remarked.

6.2 Summary of findings

6.2.1 What patient-report safety climate measures have been described in the literature, and what are the psychometric properties of, and coverage of safety climate domains, within these measures?

Given the lack of research specifically considering the patient-report safety climate (SC) measures for healthcare settings, the first study described in the thesis (Chapter

Two) utilised a systematic review methodology in order to critically appraise such measures. The findings allowed a number of recommendations for best practice in using patient-report measures of SC to be made. Once the patient-report SC measures had been identified, the individual items from these measures were analysed to consider their alignment with previously established SC domains, and the validity, reliability and usability of these measures was assessed.

Of over 5000 articles returned, 44 studies were included describing 31 separate measures. Most measures were designed for use by patients in secondary care settings, with notably fewer in existence for examining the attitudes of primary care patients. This was considered problematic, and reflective of the greater emphasis of improving safety in secondary care settings as compared to primary care settings.[26-28] There was much variability in the coverage of SC domains across included studies. For example, domains that are important contributors to patient safety (e.g. 'job demands/personal resources' and 'dignity and respect') were infrequently assessed. There was also considerable variability in the extent to which the validity and reliability of the included measures were assessed, and none of the measures fulfilled all requirements of validity and reliability. This was concerning, considering such psychometric properties are essential for the collection of meaningful and trustworthy data.[29] Further, there was an overall lack of consideration of measure burden and acceptability for respondents, which may result in non-representation of patients from vulnerable groups, who are most at risk of experiencing a Patient Safety Incident (PSI) (e.g. the elderly[30]).

In conclusion, the shorter variations of the original Patient Measure of Safety[31] (PMOS-30 and PMOS-10) were identified as the most suitable valid, reliable and acceptable measures of patient safety in secondary care. However, such a measure was not explicitly recommended for use in primary care. The refinement and/or design of a patient-report measure of SC specifically for use in the general practice setting was identified as a priority for future research.

6.2.2 What is the validity, reliability, and usability of a patient-report measure of safety climate among a sample of Irish general practice patients?

In order to address the deficits of existing patient-report SC measures identified in the systematic review,[32] the second study of this thesis (Chapter Three) described an

iterative process, with patient and practitioner input, to develop a novel, patient-report measure of SC specifically for completion by general practice patients. Next, a cross-sectional design was employed to establish the psychometric properties of the SC measure (i.e. validity, reliability, and useability) with a sample of 584 patients in Irish general practice.

The resultant Patient Perspective of Patient Safety in General Practice (PPS-GP) demonstrated adequate psychometric properties. The methods involved in constructing the measure demonstrated content and face validity. Upon subjection to an Exploratory Factor Analysis (EFA) to assess construct validity, five distinctive factors pertaining to safety climate were revealed: (1) Feeling of Safety with GP, (2) Practice Staff Efficiency and Teamwork; (3) Staff Stress and Workload; (4) Patient Knowledge and Accountability; and (5) Safety Systems and Behaviours. These factors strongly correlated with two global safety measures, indicating convergent validity, and all factors demonstrated strong internal consistency. Further, the PPS-GP was considered user-friendly on assessment of readability metrics and duration of completion. Finally, the PPS-GP assessed domains which had been infrequently considered by previous measures despite their importance and relevance to safety. After the EFA was conducted, items within the five subscales retained coverage of the majority of SC domains.

However, four domains of SC were not retained in the PPS-GP; 'organisational factors', 'co-ordination of care', 'management', and 'facilities and equipment'. Although such domains are relevant to SC, it is likely that they are not necessary visible to patients, therefore qualitative engagement with patients was recommended to elucidate means of understanding and eliciting patient's insights into these issues. Further, given that the PPS-GP was found to be valid and reliable, further exploration of its use in identifying patient or practice characteristics that predict perceptions of safety was recommended, in order to highlight potential areas of suboptimal safety requiring improvement in Irish general practice.

6.2.3 What are patients' perceptions of, and insights on, safety in general practice, and do these differ according to patient characteristics?

The third study in this thesis (Chapter Four) utilised a cross-sectional design to examine the application of the PPS-GP amongst an Irish patient population to

understand patient perceptions of SC in general practice and identify potential areas for improvement.

The 584 respondents generally reported positive perceptions of safety across all five subscales of the PPS-GP, with the majority (85%) either 'likely' or 'extremely likely' to recommend their practice to friends or family. In terms of patient risk factors, younger age and being of non-Irish nationality were consistently associated with more negative SC perceptions. Surprisingly, respondents with clinical risk factors (e.g. polypharmacy or multimorbidity) did not differ in their SC perceptions as compared to respondents without such risk factors. Analysis of free-text responses to 'additional comments in relation to safety' revealed that over two-thirds of the responses related to 'poor' SC practices, which was surprising given that overall SC perceptions were so positive, although this pattern (i.e. criticism of care experience in response to open-ended questions despite high satisfaction scores in response to closed-ended questions) has been previously reported among secondary care patients.[33]

Such findings highlighted the advantages of considering the use of qualitative methodology to derive data that provide a deeper and more nuanced of the care experience[33] than collecting quantitative data alone. Therefore, the exploration of isolated incidents of safety in greater detail was identified as a recommendation for future research.

6.2.4 What can we learn from patient accounts of patient safety incidents in general practice, and do patients and GPs differ in their perceptions of the likelihood, severity and preventability of the patient safety incidents described?

The final research question was addressed in the fourth study described in this thesis (Chapter 5). This study examined the value of utilising a qualitative approach to assessing *Past harm* via 'patient stories' (i.e. first-hand accounts of poor care from patients) to better understand safety and identify deficiencies. Further, GP and patient perceptions regarding PSIs, their severity, and likelihood of occurring in practice were compared.

Elicitation of the patient perspective using Critical Incident Technique (CIT) interviews demonstrated that patient stories are a valuable source of information, and provided rich descriptions about safety deficiencies in general practice. The safety

issues identified predominantly related to 'communication', 'staff performance', and 'compassion/dignity/respect'- confirming that patients provide additional and unique information about safety outcomes often unrecognised by HCPs. There was a statistically significant difference in how patients and GPs viewed the stories. Patient raters considered fewer of the stories to constitute a PSI than the GP raters. This is an important finding, as it suggests that patients are capable of recognising errors, and contradicts prior concerns suggesting the tendency of patients to overestimate the occurrence of error in clinical settings.[34-36] Consistent with prior research,[9] patients perceived the severity and likelihood of PSIs to be greater than GPs. Therefore future research ought to focus on why such disparities exist between GP and patient perceptions of PSIs.

Given these findings, it is concluded that patients provide a unique and important viewpoint of safety in general practice, and greater consideration of efforts to include patient perspectives in the measurement and improvement of safety in healthcare going forward were recommended. Utilising the patient as a source of input could give rise to numerous implications for both research and clinical practice.

6.3 Implications of the findings for research

This thesis has highlighted the value of utilising the patient perspective to gather SC information pertaining to general practice. Next, it is important to consider the implications arising from such findings that should be considered in the conduct of future research. These are detailed and discussed below.

6.3.1 Identification of the most appropriate methods of for measuring and monitoring of safety

'*A single measure of safety is a fantasy*'[37, p675]; indeed, safety cannot be encapsulated in one single measure. There are widely differing purposes, strengths and weaknesses associated with safety measures, and it is necessary to ensure they complement each other by providing different levels of qualitative and quantitative information.[38] For example, although a quantitative approach allowed me to gain information about general perceptions of SC from a large group of Irish general

practice patients, exploration of individualised experiences using qualitative methodology provided more nuanced, detailed information regarding specific instances of harm. It is therefore recommend that the use of multiple data collection methods be considered when measuring and monitoring safety in general practice.

There is much value in evaluating multimethod assessments of safety to determine the utility, necessity, or sufficiency of particular measures within a multimethod toolkit[39] and previously, the triangulation of different data collection methods in healthcare has been proposed.[37, 39-42] Utilising a single method may result in an underestimation,[41] or indeed an overestimation of safety incidents. In a study comparing the usefulness of five different methods for identifying adverse events in general practice,[40] there was no overlap between the methods detected. Examination of multiple methods of patient safety measurement would provide insight into the comparability of estimates of harm arising from the use of various measures and allow for the identification of measures that overestimate or underestimate patient safety in primary care.[39]

6.3.2 Examine how to integrate multiple perspectives of safety

Although the findings from this thesis highlight the merit in considering the patient perspective of safety, a consistent finding across all of the included studies was that, regardless of the research methodology utilised, issues pertaining to systems factors (e.g. practice environment, staffing and equipment/ systems failure) were infrequently reported by patients. However, as discussed in Chapter One (section 1.8.2), numerous safety theories posit that a range of both human and organisational factors influence the behaviour of HCPs in relation to safe patient care, resulting in the occurrence of human error. It is therefore most likely that patients may not 'see' some or indeed all the system factors associated with safety. Therefore, HCPs are best placed to provide information about the practice physical environment, equipment, and workload that may contribute towards a greater risk for the occurrence of PSIs. In order to attain a comprehensive assessment of safety, it is suggested that there is a need to examine patient perceptions of safety alongside, rather than instead of, the perceptions of HCPs.

Although the examination of multi-stakeholder perspectives of patient safety in primary care has been identified as an important consideration,[41] this has not yet

been addressed in this healthcare setting. Prior research conducted in other healthcare settings provide evidence supporting this approach. In a systematic review of measurement tools used to measure the safety of transitional care,[43] studies which combined patients' and HCPs' perspectives were found to provide a more complete view of safety. For example, in focus groups conducted to obtain nursing staff and patient perceptions about patient involvement in a hospital setting,[44] patients identified patient-nurse interaction as a key facilitator for effective patient safety involvement. Nurses identified workload as the main constraint to patient interaction and involvement, and provided an understanding of the contextual factors associated with contributing constraints of the health system such as patient caseloads and lack of time. These findings highlight the benefits of examining safety issues from the perspective of both patients and HCPs to inform safety improvements. A UK study[45] aimed to investigate the relationship between patient and staff measures and the extent to which these predicted safety outcomes. Staff on hospital wards were asked to complete the Hospital Survey of Patient Safety Culture, while patients were asked to complete the Patient Measure of Safety (PMOS). Publicly reported safety outcome data for 'harm-free care' was also collated on each ward. These findings suggested that although the views of patients and staff predicted some overlapping variance in patient safety outcomes, both also offered a unique perspective on patient safety, contributing independently to the prediction of safety outcomes. These findings highlight the value of utilising feedback from patients about the safety of the care that they receive, in addition to data from staff to drive safety improvements in healthcare.

In the primary care setting, such an approach could be facilitated by administering the PPS-GP, developed in Chapter Three (Study Two), in conjunction with a HCP-focused measure to identify where improvements could be made. Potential HCP measures that could be considered include PC SafeQuest,[46] the Frankfurt Patient Safety Climate Questionnaire[47] and SCOPE.[48] A systematic review including 17 HCP SC measures found that these surveys had the greatest evidence of validity.[29]

6.3.3 Identify how to increase the inclusion of specific at-risk patient groups in safety research

The findings from this thesis highlight the need for future research to ensure that specific patient groups, particularly those who are at a greater risk for experiencing PSIs, are adequately represented in patient safety research. For example, respondents of non-Irish nationality reported significantly poorer SC perceptions in the PPS-GP as compared to Irish respondents. Health equity research has reported that ethnic minorities are more likely to experience deficiencies in patient safety.[49] Further, research has found that migrant communities demonstrate mortality below those of the host population.[50, 51] In addition they also exhibit a greater vulnerability to certain communicable diseases, occupational health hazards, injuries, poor mental health, diabetes mellitus, and maternal and child health problems.[52] A recent scoping review examining migrant health research in Ireland[53] report that evidence about migrant health is typically found in studies whose primary focus was not on migrant health (i.e. studies providing information on the topic through an analysis of findings by demographic characteristics, including country of birth). This further demonstrates the lack of priority of research in this area. Therefore, it is suggested that further exploration is warranted to identify methods to ameliorate specific barriers (e.g. poor cross-cultural communication[53]) to culturally sensitive, safe primary healthcare delivery in Ireland.

Further, no significant difference in SC perceptions were found amongst participants who are known to be at a greater risk of experiencing PSIs (i.e. those reporting the presence of multimorbidity and polypharmacy[54-56]). This may have been influenced by a small cohort failing to yield statistical significance. Although considerable efforts were made to include a sufficient sample of high-risk patient populations (e.g. contacting community support groups (n=176)), I expected the sample would have greater representativeness. In the sample, only 14% of participants reported multimorbidity, yet approximately 27% of Irish adults report the presence of at least one long-standing illness or health problem.[57]

Future research should give more consideration to identifying those at greatest risk of experiencing PSIs, and how greater representativeness in research can be achieved (e.g. targeted recruitment strategies). The inclusion of these patient populations will ensure that their safety perceptions are captured, as such insights are

crucial to developing interventions to decrease the burden of iatrogenic harm.[41] Further, as recommended previously, the provision of additional resources to ease participation (e.g. external facilitation[58] or accessible measure versions[59]) should also be considered.

6.3.4 Examine how to include patient perspectives in safety interventions

This thesis has established that patients can contribute to the measurement and monitoring of safety climate. Future research should capitalise upon and expand such findings by utilising patient feedback in the conduct of safety interventions. For example, a Health Research Board (HRB) funded study, on which I was a Research Assistant, assessed the feasibility of a primary care patient safety intervention (SAP-C) to improve safety climate in general practice.[60] One of the key intervention components was serial SC measurement and feedback, as assessed from the HCP perspective using the PC-SafeQuest survey.[46] However, this study did not collect any data on SC from the patient perspective. It is recommended that future SC interventions should also incorporate patient-derived SC data. This was successfully achieved in the Patient Reporting and Action for a Safe Environment intervention (PRASE) intervention,[13, 61] whereby patient feedback was collected and fed back to ward staff, allowing HCPs to respond accordingly.

6.4 Implications of the findings for practice

This thesis has highlighted the value of utilising different patient-report methodologies to gather SC information pertaining to general practice. A future consideration is how the research from this thesis can be applied to practically support the improvement of patient safety in general practice. A number of suggested for how this research could be practically applied in this context are provided below.

6.4.1 Use of the PPS-GP to identify areas for safety improvement and support comparisons across primary care

Research has suggested that clinicians often ignore survey evidence about patient experience,[62, 63] and HCPs have expressed concerns about the reliability and validity

of patient data.[64] Indeed, there has been much variation in the way HCPs view the role patient feedback about safety as a means of service improvement; in the PRASE feasibility study,[61] some staff expressed enthusiasm for the role of patient feedback, whilst others were reluctant and defensive, which resulted in a lack of engagement with the process of action planning further on. However, in light of the findings of this thesis, HCPs should consider capitalising on patient feedback for service improvement, given the range of safety information that can be gained.

At the practice level, the PPS-GP provides a means for GPs to *proactively* assess SC in their practices, as opposed to retrospectively. Given that the PPS-GP constitutes a 'leading' indicator of safety (i.e. identifying valid and reliable precursors, conditions or event before an incident has occurred), it enables the proactive identification of safety deficits and areas for improvement in practice as opposed to 'lagging' measures[65] which require an adverse event to occur before safety can be improved. As discussed previously, it has been suggested that such methodologies that proactively identify deficient safety before harm has occurred may be more palatable to physicians,[39] and contribute more effectively to safety improvement.[37, 66] The use of the PPS-GP in this way would allow practice staff to gain feedback and utilize this to inform improvements at a practice level to prevent the occurrence of PSIs.

At the regulator level, the use of such a measure would allow for comparison between practices, or to monitor the perceived SC of patients over time. This may help to overcome the difficulties in regulating general practice, given that it is considerably more disparate than secondary care.[67] General practices typically operate autonomously and independently within their own unique organisational practices.[26] In Ireland, the National Care Experience Programme,[68] a joint initiative from the Health Information and Quality Authority (HIQA), the Health Service Executive (HSE) and the Department of Health, recently launched a range of surveys (e.g. the National Inpatient Experience survey, the National Maternity Experience survey) to gain information from patients about their experiences of care to improve health care quality. Such an approach would be beneficial for gathering routine data from the general practice setting at a national level.

6.4.2 Use of qualitative engagement with patients when planning safety improvement actions

However, there remains difficulty regarding how to actually use patient data, and as a result, patient feedback is underused by health organisations, thereby rarely leading to improvement.[62, 69] This may, in part, explain the lack of evidence that patient-reported information has led to improvements in healthcare. In a study of general practice staff in the UK regarding the utility of patient experience surveys, respondents expressed difficulty with translating patient feedback into action.[64] In the PRASE intervention,[13, 61] which provides hospital staff with patient-report feedback on the safety of the care environment, to which they are asked to respond by implementing local changes, staff expressed difficulty on how to interpret, synthesise and act on the feedback to implement what seemed like relatively simple changes. Similarly, a previous study found that feedback of patient experience to staff had little impact unless supported by ward meetings that were facilitated by research staff.[70]

In light of the difficulties expressed by staff on how to sufficiently use data about patient perspectives about their care as a basis for improving services,[61, 64, 70, 71] it may be worth extending the inclusion of the patient to identifying the actual actions or changes needed to bring about improvements in practice. This may be best achieved through qualitative engagement with patients. In a qualitative study of patient-report adverse events in a hospital setting,[72] patients were asked to offer suggestions on how to prevent adverse events in the future. Patients identified specific actions for improvement (e.g. development of an open disclosure policy, increased placement of hand hygiene facilities). In a large-scale Citizen Science study amongst a French cohort,[73] patients provided 3613 ideas to improve care received in primary care consultations, hospitals/clinics and the wider healthcare system. Findings demonstrated that there is much to gain from leveraging patients' practical knowledge and experience of the care system to improve it. Bowie et al.[74] developed and refined the 'Always Events' concept in the primary care context, which resulted in the identification of themes of high importance to patients (e.g. respect, clinical care management and communication). This highlighted the value of improvements being informed by the desires and preferences of patients, rather than on the assumptions of care providers about their wants and needs. Using a similar

approach, a study in a Scottish hospital had patients identify 'Always Events' in the emergency department,[75] the findings of which were used to inform the development of educational interventions to be implemented, which specifically addressed patients suggestions. Given the encouraging findings of such studies, future research assessing the capability of patients to identify actions for improvement in the general practice setting is warranted.

6.5 Strengths of the thesis

The strengths of the individual studies within this thesis have been discussed previously within the discussion sections of the corresponding Chapters (Two through Five). Therefore, in this section I will consider the strengths of the thesis as a whole.

A notable strength of this thesis is the adaptation of a multi-method approach to measuring safety in general practice. The application of a quantitative survey measure (Chapter Four, Study Three) provided a general overview of SC in Irish general practice. Qualitative elicitation of patients' experiences in the form of open-ended questions in the survey measure (Chapter Four, Study Three), and adapting the use of patient 'stories' (Chapter Five, Study Four) allowed us to gain rich descriptions of PSIs at a deeper level. This use of multiple methods is particularly advantageous given there has been a tendency in health sciences research design to give insufficient weight to qualitative methods.[42] The use of both quantitative and qualitative methodology ultimately allowed for a thorough exploration of the patient perspective of safety in general practice.

Throughout this thesis, significant emphasis was placed on methodological rigour. From the outset (Chapter Two, Study One), the importance of assessing psychometric properties of existing measures was emphasised. In the development of the PPS-GP (Chapter Three, Study Two), numerous strategies (e.g. cognitive interviewing, piloting) were adapted to ensure patient input at an early stage and enhance the face and content validity of the measure. Further, the reliability, construct and convergent validity, and useability of the measure was established, imperative for the collection of meaningful and trustworthy data.[29] Finally, numerous practices were adapted to ensure trustworthiness of the analyses undertaken across studies (e.g. having two authors extract data independently, double coding the

patient stories, resolving disagreements via discussion until consensus was achieved[76]). This amplifies the extent to which our methodologies are replicable, in addition to enhancing the confidence with which our findings and conclusions can be interpreted.

This thesis was designed and conducted in accordance with theoretical perspectives that are seminal in the patient safety literature, most notably the MMS framework.[37, 66] This framework was developed specifically for the measuring and monitoring of safety in healthcare and was derived from extensive work including the conduct of three scoping reviews of safety across high-risk industries, models of systems safety and safety in healthcare. Further, the research questions are derived from three different theoretical perspectives- patient activation theory, socio-technological systems theory, and safety climate/culture theory.

6.6 Limitations of the thesis

As with the strengths, the limitations associated with each of the individual studies have also been discussed within the corresponding chapters. Therefore, in this section I will consider the limitations of the thesis as a whole.

A large proportion of the research in this thesis was conducted during the COVID-19 pandemic. The pandemic likely negatively impacted upon the willingness of people to participate in my studies, and effected how data was collected. To illustrate, I planned to recruit participants for studies two and three in GP practices from patients waiting for an appointment. This recruitment methodology would also have allowed comparisons to be made of the responses across the participating practices. Instead, a combination of purposive and convenience sampling were adapted due to the restrictions implemented regarding the visiting of practices. Further, the practice innovations implemented as a result of COVID-19 (e.g. video/remote consultations[77]) may have implicated patient perspectives of SC. For example, some research suggest that patients have adapted favourably to telemedicine consultations,[78] while others suggest that remote consultations may increase health inequalities, negatively impact doctor-patient relationships, continuity of care, patient satisfaction, and potentially patient safety outcomes.[79, 80] Patients may also be more 'supportive' of their healthcare providers

and services during a pandemic. Future research is needed to establish the impact of COVID-19 and related practice shifts on patient experience,[80] therefore we cannot determine for sure whether the findings from this thesis are independent from an artefact of the pandemic.

The MMS framework[37, 66] is comprehensive, consisting of five dimensions and associated questions pertaining to safety. My decision to focus on two key dimensions; *Anticipation and preparedness*, and *Past harm* could be criticised. However, addressing all five domains was considered too extensive, and not feasible for a PhD thesis. *Past harm* was frequently assessed previously from the patient perspective, although typically with the use of a survey. I adapted a novel methodology (i.e. patient stories), given that a qualitative approach to this dimension was rarely reported. Vincent et al. consistently identified *Anticipation and preparedness as* 'under-developed' in healthcare, with organisations providing far fewer examples of dimension than the other four classes of safety information in their investigations. This under-development highlights the pressing need for the exploration of this particular dimension in research and practice. Few studies examine the *Reliability of safety clinical processes* and *Sensitivity to operations* in primary care, with even less measuring these dimensions from the patient perspective. Although undoubtedly relevant to primary care, and with a clear evidence gap, such dimensions were not considered to be as strong a priority as those addressed within this thesis. In sections 6.3 and 6.4 of this General Discussion chapter, I have made recommendations pertaining to both research and practice that encompass the sentiments of *Dimension 5: Integration and learning from safety information*. Therefore, I believe that focusing on two dimensions of the MMS framework was both feasible and appropriate.

Although the importance of gaining multiple perspectives of safety is stressed at numerous points throughout this thesis, I focused solely on gathering safety information from patients across all of the studies. Including the HCP perspective in addition to the patient perspective was considered outside of the scope of the thesis aims, given that I sought to ascertain the value of patient-reported data. However, I did examine differences in GP and patient perceptions of PSI severity and likelihood as a secondary investigation in Chapter Five (study four). Further, I acknowledge this triangulation of perspectives as an important next step, and provide

recommendations as to how this could be achieved in subsection 6.3.2 in this General Discussion chapter.

Finally, each of the studies reported in this thesis were conducted in the Republic of Ireland, which may limit the generalisability of findings to other countries. Caution should be taken in generalising about SC across industries with widely differing characteristics.[81] This applies to general practice, given that practices vary greatly in terms of work practices and organisational structures. Previous research has found that national and healthcare-specific differences limited the extent to which SC surveys were applicable outside of the country they were developed in.[82] Therefore, it will be important for the methods employed (e.g. the PPS-GP) to be validated in other countries or comparable healthcare systems[82] to determine whether these findings generalise to these contexts. This would also facilitate the benchmarking of findings across healthcare systems in different countries. Such aggregation of data has been found to inform safety and educational opportunities in secondary care settings.[83] This was demonstrated in Irish primary care,[84] whereby HCP-reported SC was compared to SC data from English[85] and Scottish[86] samples which facilitated international comparison of perceived SC across Ireland, Scotland and England.

6.7 Conclusions

The importance of involving patients in improving the safety of healthcare has increased in recent years,[87, 88] as reflected in national- and international-level policy priorities.[23-25] Despite this, patients remain an underutilised source of safety information. This is particularly the case in the general practice setting, as healthcare has not captured the patient role in safety and translated it into meaningful patient-centred metrics. Patients are capable of providing some of the most pertinent warnings of deteriorating organisations and are willing to be involved in patient safety. Within the Introduction section of this thesis (Chaper One), a pressing need to examine the value of adding the patient perspective to the '*tapestry of measures*' that provide an overview of safety[89] was identified. Subsequently, four studies were successfully conducted in line with the overarching aims of this thesis, the findings of which provide an approach to how patients can contribute to the measurement and

monitoring of safety climate and demonstrate the value of patient-generated safety data for identifying and learning from past harm in general practice.

This thesis has established that patients can make a unique contribution to the understanding of safety, and what matters most to them. A concerted effort is now required to make use of this evidence in the emerging field of patient involvement in healthcare. Going forward, the combination of quantitative and qualitative methodologies should be utilised to effectively harness the patient perspective in conjunction with other sources of safety data, to gain a comprehensive view of safety in general practice. Further, clinicians and policymakers should be encouraged to capitalise on patient-reported safety information to ameliorate deficiencies in practice, and furthermore, consider the patient viewpoint in planning such actions. These are the next steps in aiding the journey towards practically including the patient perspective in safety research and practice in the general practice setting.

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Appendices

Appendix A (Chapter 2): Systematic review protocol as published on PROSPERO

PROSPERO

International prospective register of systematic reviews

Citation

Caoimhe Madden, Paul O'Connor, Sinéad Lydon, Andrew W. Murphy, Emily O'Dowd. Involving patients in safety measurement in healthcare: a systematic review. PROSPERO 2019 CRD42019131913 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42019131913

Review question

What is the content, intended use, and psychometric properties of extant questionnaire tools for proactively measuring patient safety from the patient perspective in primary and secondary healthcare settings?

Searches

Systematic searches were conducted within five electronic databases: MEDLINE, Academic Search Complete, Web of Science, CINAHL, and PsycINFO. The search protocol included Medical subject Headings (MeSH) search terms and other keywords. The language was restricted to English, with no limits placed on publication year. Additionally, the reference lists of all included studies were manually screened, to identify additional potentially relevant studies.

When data extraction is completed (April 2019), the search protocol will be repeated across the five databases in order to capture recently published studies.

Search strategy

https://www.crd.york.ac.uk/PROSPEROFILES/131913_STRATEGY_20190411.pdf

Types of study to be included

Qualitative and quantitative studies will be eligible for inclusion. There will be no restrictions on the types of studies to be included, other than the fact that they must include original, empirical data.

Condition or domain being studied

1: The content of the current range of instruments available to measure patient perspective of safety in primary and secondary care.

2: The intended use and psychometric properties of such instruments.

Participants/population

Primary or secondary care patients that have filled in a questionnaire tool pertaining to the safety of care perceived during their period of care.

Inclusion criteria:

In order to be included, studies must: (a) be published in an English language, peer-reviewed journal; (b) report original research and; (c) describe the development and/or use of a questionnaire tool to proactively assess patient safety from the perspective of the patient in either primary or secondary care. The questionnaire tool should include more than one closed-ended safety item.

Exclusion criteria:

Studies will be excluded if (a) questionnaire items focus solely on the safety of the care facility environment as opposed to the safety of care; (b) questionnaire items examine the occurrence of one specific adverse event/safety incident as opposed to general safety climate of care; and (c) the questionnaire items are referred to in text, but cannot be obtained after being requested from the relevant author.

Intervention(s), exposure(s)

This review will examine existing questionnaire tools aimed at patients regarding the safety of care received in the primary or secondary care setting. It will specifically focus on the content, usage, and psychometric properties of these.

Comparator(s)/control

Not applicable.

Context

Studies focused on safety of care received in primary or secondary settings will be included.

Main outcome(s)

The main outcome of this review will be the recommendations made for best practice in utilizing patient- report measures of SC in healthcare. Such information will be useful for clinicians to select the most suitable tools for safety climate measurement in healthcare.

Additional outcome(s) Not applicable

Measures of effect Not applicable

Data extraction (selection and coding)

Titles and abstracts will be screened by the first author (CM) to assess suitability for inclusion, based on the criteria outlined above. If these provide insufficient information to determine inclusion or exclusion, then the full-text of the paper will be examined. Final inclusion decisions will be made by the first author and a second independent reviewer.

A structured tool will be used to extract data from articles deemed suitable for inclusion. The following data will be extracted from each included study: Author(s) and year of publication; country of publication; healthcare setting; study purpose (tool development or validation); number of patient respondents; number of items pertaining to safety; description of safety items; and response options (e.g. rating scale).

Two authors will conduct the data extraction independently and disagreements will

be resolved through discussion (with a third author where necessary). Missing data will be requested from study authors via email.

Risk of bias (quality) assessment

The included tools will undergo systematic critical appraisal by two authors using an appraisal checklist. This will include the following psychometric criteria: reliability; content validity; construct validity; criterion-related validity; interpretability (i.e. ability to assign easily understood meaning to the tool's quantitative scores); burden/feasibility (i.e. length of time to complete, minimal effort for scoring and data collection); acceptability (i.e. acceptability of tool by respondents is addressed); and availability (i.e. no fees attached, easy to access).

Strategy for data synthesis

A narrative synthesis of the findings from the included studies will be provided, structured around the main outcomes listed above.

Analysis of subgroups or subsets

It is intended that the extracted data will be presented by tool, rather than by each individual study. This will allow for a closer examination of individual tool content, usage, and properties, and enable comparisons to be drawn between the extant tools.

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Type and method of review

Narrative synthesis, Systematic review

Anticipated or actual start date

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Anticipated completion date
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Conflicts of interest
None known

Language
English

Country
Ireland

Stage of review
Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Delivery of Health Care; Humans; Patient Safety

Date of registration in PROSPERO
21 October 2019

Date of first submission
11 April 2019

Stage of review at time of this submission

Stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.
The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Appendix B (Chapter 2): Search strategy for MEDLINE

1: Primary Health Care.ti,ab.

2: (general adj1 practi*).ti,ab.

3: (family adj1 practi*).ti,ab.

4: exp Hospitals/

5: exp Secondary Care/

6: (acute adj2 care).ti,ab.

7: 1 or 2 or 3 or 4 or 5 or 6

8: safe*.ti,ab.

9: exp Patient Safety/

10: exp Quality of health care/

11: exp Medical Error/

12: (patient adj1 harm).ti,ab.

13: (adverse adj2 event*).ti,ab.

14: 8 or 9 or 10 or 11 or 12 or 13

15: exp Surveys/ and Questionnaires/

16: exp health care survey/

17: Tool.ti,ab.

18: instrument.ti,ab.

19: Scale.ti,ab.

20: 15 or 16 or 17 or 18 or 19

21: (patient* or client* or user*) adj1 (perspective* or perception* or perceive* or opinion* or feeling* or impression* or involve* or experience* or attitude* or view*).ti,ab.

26: 7 and 14 and 20 and 21

27: limit 26 to (English language)

Appendix C (Chapter 2): Data extraction table

Measure features				**Study characteristics**				
Measure of Patient Safety (Survey instrument name, when applicable)	***n* items**	**Item content**	**Rating scale**	**Cited by**	**Country**	**Healthcare setting**	**Usage**	***n* respondents**
Child HCAHPS **Subscale: Attention to safety and comfort**	7	Safety systems (*n*=1) Reporting/speaking up (*n*=1) Safety attitudes/behaviours (*n*=1) Communication/feedback (*n*=3) Not related (*n*=1)	5-point Likert scale (totally agree to totally disagree)	Bruyneel et al. (2017)(a)[38]	Belgium	Secondary care	Validation	303 parents of paediatric patients
				Toomey et al. (2015)[39]	USA	Secondary care	Development	17,727 parents of hospitalised children
				Toomey et al. (2017)[40]	USA	Secondary care	Application to sample	17,727 parents of hospitalised children (same population as above)

				Ehwerhemuepha et al. (2018)[41]	USA	Secondary care	Application to sample	1,567 parents of hospitalised children
Cancer Patients Experiences Questionnaire (CPEQ) **Subscale: Patient safety**	3	Communication/feedback (*n*=2) Risk perceptions (*n*=1)	5-point Likert scale (not at all to a very large extent)	Iversen et al. (2012)[42]	Norway	Secondary care	Development Validation	7,212 cancer patients
Consumer Quality Index Inpatient Hospital Care (CQI IHC)(1) **Subscale: Safety**	5	Staff competence (*n*=1) Safety attitudes/behaviours (*n*=2) Safety systems (*n*=2)	4-point Likert scale (never to always)	Krol et al. (2015)[43]	The Netherlands	Secondary care	Application to sample	15,171
Consumer Quality Index Inpatient Hospital Care (CQI IHC)(2) **Subscale: Feeling of safety**	3	Safety systems (*n*=2) Safety attitudes/behaviours (*n*=1)	4-point Likert scale (never to always)	Smirnova et al. (2017)[44]	The Netherlands	Secondary care	Validation	22,924 patients

The Flemish Patient Survey **Subscale: Safe care**	3	Staff competence (*n*=1) Safety systems (*n*=1) Communication/feedback (*n*=1)	4-point Likert scale (disagree to totally agree)	Bruyneel et al. (2017)(b)[45]	Belgium	Secondary care	Development Validation	1,076 patients across 37 hospitals
HEALTHQUAL **Subscale: Safety**	4	Facilities & equipment (*n*=1) Staff competence (*n*=2) Risk perceptions (*n*=1)	5-point Likert scale (very bad to very good)	Lee et al. (2017)[46]	South Korea	Secondary care	Development Validation	385 inpatients and 251 general public/outpatients of a teaching hospital
Press Ganey Medical Practice survey (MPS) (factors revised) **Subscale: Patient safety and health**	5	Safety attitudes/behaviours (*n*=1) Facilities & equipment (*n*=1) Risk perceptions (*n*=1) Dignity & respect (n=1) Not related (*n*=1)	5-point Likert scale (very poor to very good)	Johnson & Russell (2015)[47]	USA	Primary care	Development Application to sample	1,385 patients who had a visit to one of 18 medical group clinics
				Johnson et al. (2016)[48]	USA	Primary care	Application to sample	4,446 patients over three fiscal years
				Nottingham et al. (2018)[49]	USA	Primary care	Validation	4,446 patients across three years

The Needs of Adults in Intensive Care Units (NAPinICU) **Subscale: Need to feel safe (needs met by staff)**	6	Not related (*n*=2) Safety attitudes/behaviours (*n*=2) Teamwork (*n*=1) Facilities & equipment (*n*=1)	5-point Likert scale (strongly disagree to strongly agree)	Aro et al. (2012)[50]	Estonia	Secondary care	Development Application to sample	166 adult patients discharged from ICU
Patient Perspective on care and Rehabilitation (PaPeR) **Subscale: Respect and safety**	7	Communication/feedback (*n*=3) Safety attitudes/behaviours (*n*=1) Risk perceptions (*n*=1) Dignity & respect (n=1) Job demands/personal resources (*n*=1)	5-point Likert scale (totally agree to totally disagree)	Wressle et al. (2006)[51]	Sweden	Secondary care	Development Validation	221 geriatric patients
Primary Care Patient Measure of Safety (PC PMOS) (1) **Entire questionnaire**	50	Not related (*n*=16) Staff competence (*n*=4) Communication/feedback (*n*=9) Co-ordination of care (*n*=4) Job demands/personal resources (*n*=1) Access & timeliness (*n*=5) Management (*n*=1) Safety systems (*n*=2) Safety attitudes/behaviours (*n*=3) Facilities & equipment (*n*=2) Teamwork (*n*=1) Reporting/speaking up (*n*=1) Dignity & respect (n=1)	5-point Likert scale (strongly disagree to strongly agree)	Hernan et al. (2016)[25]	Australia & UK	Primary care	Development	N/A

Primary Care Patient Measure of Safety (PC PMOS) (2) **Entire questionnaire**	28	Safety systems (*n*=2) Co-ordination of care (*n*=2) Communication/feedback (*n*=5) Staff competence (*n*=2) Access & timeliness (*n*=3) Facilities & equipment (*n*=2) Safety attitudes/behaviours (*n*=2) Job demands/personal resources (*n*=1) Dignity & respect (n=1) Not related (*n*=8)	5-point Likert scale (strongly disagree to strongly agree)	Giles et al. (2019)[52]	UK	Primary care	Development and validation	490 adult patients in 9 primary care practices
Patient Experiences on Patient Safety (PEPS) **Entire questionnaire**	21	Safety attitudes/behaviours (*n*=1) Not related (*n*=5) Communication/feedback (*n*=12) Reporting/speaking up (*n*=1) Safety systems (*n*=1) Job demands/personal resources (*n*=1)	5-point Likert scale (totally disagree to totally agree)	Sahlström et al. (2014)[53]	Finland	Secondary care	Development Application to sample	175 patients in either a day surgery or inpatient ward
				Sahlström et al. (2019)[54]	Finland	Secondary care	Application to sample	462 patients across 18 internal medicine wards
Patient Measure of Safety (PMOS) **Entire questionnaire**	44	Not related (*n*=1) Safety systems (*n*=5) Teamwork (*n*=3) Co-ordination of care (*n*=4) Communication/feedback (*n*=6) Staff competence (*n*=2)	5-point Likert scale (strongly agree to	Baxter et al. (2018)[55]	UK	Secondary care	Application to sample	188 patients on elderly medical wards

		Access & timeliness (*n*=3) Facilities & equipment (*n*=7) Safety attitudes/behaviours (*n*=2) Management (*n*=7) Risk perceptions (*n*=1) Dignity & respect (*n*=3)	strongly disagree)	Giles et al. (2013)[56]	UK	Secondary care	Development	N/A
				Lawton et al. (2015)[57]	UK	Secondary care	Application to sample	822 patients across 33 acute hospital wards
				Lawton et al. (2017)[58]	UK	Secondary care	Application to sample	355 patients from 33 hospital wards
				McEachan et al. (2014)[59]	UK	Secondary care	Validation	297 patients from 11 hospital wards
				O'Hara et al. (2016)[60]	UK	Secondary care	Application to sample	379 patients across 6 acute wards

PMOS-30 **Entire questionnaire**	30	Safety systems (*n*=2) Teamwork (*n*=2) Co-ordination of care (*n*=2) Communication/feedback (*n*=5) Staff competence (*n*=2) Access & timeliness (*n*=3) Facilities & equipment (*n*=4) Safety attitudes/behaviours (*n*=1) Management (*n*=4) Dignity & respect (*n*=2) Not relevant (*n*=3)	5-point Likert scale (strongly disagree to strongly agree)	Louch et al. (2019)[61]	UK	Secondary care	Development & validation	751 hospital patients
PMOS-10 **Entire questionnaire**	10	Safety systems (*n*=1) Teamwork (*n*=1) Co-ordination of care (*n*=1) Communication/feedback (*n*=2) Staff competence (*n*=1) Access & timeliness (*n*=1) Safety attitudes/behaviours (*n*=1) Management (*n*=1) Dignity & respect (*n*=1)	5-point Likert scale (strongly disagree to strongly agree)	Louch et al. (2019)[61]	UK	Secondary care	Development & validation	165 hospital patients
PMOS-A **Entire questionnaire**	43	Safety systems (*n*=3) Teamwork (*n*=4) Co-ordination of care (*n*=4) Communication/feedback (*n*=6) Staff competence (*n*=2) Access & timeliness (*n*=3) Facilities & equipment (*n*=9) Safety attitudes/behaviours (n=1) Management (*n*=5) Dignity & respect (*n*=2) Not relevant (*n*=4)	5-point Likert scale (strongly disagree to strongly agree)	Taylor et al. (2016)[62]	Australia	Secondary care	Development	29 hospital patients
				Taylor et al. (2019)[63]	Australia	Secondary care	Validation	911 hospital patients across 27 hospitals

Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) **Entire questionnaire** *entire measure =54 items; items pertaining to adverse events and specific harm omitted from analyses	15*	Access & timeliness (*n*=2) Communication/feedback (*n*=4) Co-ordination of care (*n*=2) Safety systems (*n*=1) Teamwork (*n*=1) Safety attitudes/behaviours (*n*=1) Staff competence (*n*=1) Risk perceptions (*n*=1) Reporting/speaking up (*n*=2)	5-point Likert scale (always to never)/ (strongly agree to strongly disagree) 0 (completely unsafe)-10 (completely safe).	Ricci-Cabello et al. (2016)[64]	UK	Primary care	Development Validation	1,244 patients registered in 45 practices.
				Ricci-Cabello et al. (2017)[65]	UK	Primary care	Application to sample	1,244 patients registered in 45 practices.
Transitional Risk and Incident Questionnaire (TRIQ) **Entire questionnaire**	24	Co-ordination of care (*n*=16) Communication (*n*=3) Staff competence (*n*=2) Teamwork (*n*=2) Management (*n*=1)	4-point Likert scale (always to never), or (very much to very little)	van Melle et al. (2019)[66]	The Netherlands	Transitional care	Development Validation	444 primary and secondary care patients
Untitled measures								
Subscale: Attitudes about patient safety	10	Risk perceptions (*n*=2) Not related (*n*=3) Teamwork (*n*=1) Reporting/speaking up (*n*=4)	5-point Likert scale (disagree strongly to agree strongly)	An et al. (2017)[67]	Korea	Secondary care	Development Application to sample	483 military personnel

Subscale: Sense of safety and receiving support	2	Communication/feedback (*n*=1) Safety attitudes/behaviours (*n*=1)	4-point Likert scale (bad to very good)	Bandurska et al. (2016)[68]	Poland	Secondary care	Development Application to sample	210 psychiatric patients
Subscale: Safe care	5	Communication/feedback (*n*=2) Risk perceptions (*n*=1) Not related (*n*=1) Staff competence (*n*=1)	4-point Likert scale (never to always)	Bruyneel et al. (2018)[69]	Belgium	Secondary care	Development Validation	5,168 patients in residential and ambulatory mental health services
Entire questionnaire	14	Risk perceptions (*n*=2) Job demands/personal resources (*n*=1) Safety systems (*n*=2) Reporting/speaking up (*n*=6) Co-ordination of care (*n*=3)	5-point Likert scale (strongly disagree to strongly agree)	Cox et al. (2013)[70]	USA	Secondary care	Development Validation	172 parents of paediatric patients
Subscale: Perceptions of safety	3	Risk perceptions (*n*=1) Not related (*n*=1) Co-ordination of care (*n*=1)	5-point Likert scale (strongly disagree to strongly agree)	Desmedt et al. (2017)[19]	Belgium	Primary care	Development Application to sample	339 chronic care patients
Entire questionnaire	20	Safety attitudes/behaviours (*n*=7) Risk perceptions (*n*=3) Safety systems (*n*=4) Communication/feedback (*n*=5) Not related (*n*=1)	7-point Likert scale (strongly disagree to strongly agree)	Dixon et al. (2015)[71]	USA	Secondary care	Development Application to sample	102 patients
Subscale: Safety indicators	3	Safety attitudes/behaviours (*n*=2) Facilities & equipment (*n*=1)	7-point Likert scale (very	Duggirala et al. (2008)[72]	India	Secondary care	Development Validation	100 patients across many hospitals

			low to very high)					
Subscale: Quality/safety	4	Communication/feedback (*n*=1) Facilities & equipment (*n*=1) Access & timeliness (*n*=1) Risk perceptions (*n*=1)	Five/six point Likert scale	Malik et al. (2016)[73]	Canada	Secondary care	Development Validation	252 complex continuing care/rehabilitation patients across two hospitals
Subscale: Feeling safe	8	Safety attitudes/behaviours (*n*=2) Staff competence (*n*=1) Communication/feedback (*n*=2) Access & timeliness (*n*=2) Job demands/personal resources (*n*=1)	5-point Likert scale (strongly disagree to strongly agree)	Robinson et al. (2018)[74]	New Zealand	Secondary care	Development Application to sample	116 palliative hospital inpatients
Subscale: confidence in the quality and safety	3	Access and timeliness (*n*=1) Not related (*n*=1) Risk perceptions (*n*=1)	4-point Likert scale (very confident to not at all confident)	Schmidt et al. (2013)[75]	USA	Primary care	Development Application to sample	1,573 patients across 26 clinics
Subscale: Perceptions of safety and staff technical skills	3	Risk perceptions (*n*=1) Safety attitudes/behaviours (*n*=1) Staff competence (*n*=1)	4-point Likert scale (yes, absolutely to no, not at all)	Schwappach et al. (2003)[76]	Switzerland	Secondary care	Application to sample	6,286 ED patients across 2 timepoints
Entire questionnaire	19	Communication/feedback (*n*=6) Access and timeliness (*n*=3) Risk perceptions (*n*=7) Facilities & equipment (*n*=3)	Response options provided in the form of colour-coded smiley faces for safe (green	Scott et al. (2016)[77]	UK	Transitional care	Development	N/A
				Scott et al. (2019)[78]	UK	Transitional care	Application to sample	366 patients (cardiac, care of older people, orthopaedics, stroke) across four hospitals

			smiling face), neutral (yellow impassive face), and unsafe (red frowning face)					
Subscale: Safety measures	3	Safety attitudes/behaviours (*n*=1) Facilities & equipment (*n*=2)	7-point Likert scale (very bad to very good)	Padma et al. (2010)[79]	India	Secondary care	Development Application to sample	204 patients in a government or private hospital

Appendix D (Chapter 2): Quality appraisal table

Measure Name	Cited by	Reliability	Validity			Usability			
			Content validity	**Construct validity**	**Criterion-related validated validity**	**Interpretability**	**Burden/feasibility**	**Acceptability**	**Availability**
Child HCAHPS Subscale: Attention to safety and comfort	Bruyneel et al. (2017)(a)[38]	IC: Not assessed TRR: Not assessed	Yes; -pilot test and pre-test panel where survey was reviewed by parents of children.	Yes; evidence of confirmatory factor analysis.	Yes	Not assessed	Not assessed	Not assessed	Yes
	Toomey et al. (2015)[39]	IC: Yes; Spearman Brown formula for reliability >0.7 TRR: Not assessed	Yes; -literature review -expert panel -survey reviewed by a focus group of patents before being further revised or retested -pilot test.	Yes; evidence of exploratory factor analysis.	Yes; correlations of composites and single-item measures with overall hospital performance.	Not assessed	Not assessed	Yes; cognitive interviews with parents to assess understandability.	Yes

	Toomey et al. (2016)[40]	IC: Yes; Spearman Brown formula for reliability >0.7 TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
	Ehwerhemuepha et al. (2018)[41]	IC: Not assessed TRR: Not assessed	Not assessed	Not assessed	Not assessed	Yes	Not assessed	Not assessed	Yes
Cancer Patients Experiences Questionnaire (CPEQ) Subscale: Patient safety	Iversen et al. (2012)[42]	IC: No; Cronbach's alpha of 0.61 and 0.67 for safety subscale TRR: No; correlation coefficient of 0.57 for outpatients and 0.62 for inpatients	Yes; -expert panel review -literature review to inform survey development -semi-structured interviews with patients -pilot test of survey -pre-test panel where survey was reviewed by a focus	Yes; evidence of EFA and CFA.	Yes; scores correlated with patient experience scores.	Yes	Not assessed	Not assessed	Yes

			group of experts before being further revised or retested.						
Consumer Quality Index Inpatient Hospital Care (CQI IHC) (1) Subscale: Safety	Krol et al. (2015)[43]	IC: Yes; Cronbach's alpha of >0.69 for safety subscale TRR: Not assessed	Not assessed	Not assessed	Not assessed	Yes	Not assessed	Not assessed	Yes
Consumer Quality Index Inpatient Hospital Care (CQI IHC) (2) Subscale: Feeling of safety	Smirnova et al. (2017)[44]	IC: No; Cronbach's alpha of 0.64 for safety subscale TRR: Not assessed.	Not assessed	Yes; evidence of CFA.	Not assessed	Yes	Not assessed	Not assessed	Yes
The Flemish Patient Survey (FPS) Subscale: Safe care	Bruyneel et al. (2017)(b)[45]	IC: Not assessed TRR: Not assessed	Yes; -literature review to inform survey development -focus groups -preliminary field test.	Yes; evidence of both EFA and CFA.	Yes; correlated with HCAHPS scores.	Not assessed	Not assessed	Not assessed	Yes

HEALTHQUAL Subscale: Safety	Lee et al. (2017)[46]	IC: Yes; Cronbach's alpha > 0.69 for safety subscale TRR: Not assessed	Yes; -literature review to inform survey development -expert panel review -pilot study	Yes; evidence of CFA and EFA.	Not assessed	Not assessed	Not assessed	Not assessed	No
Press Ganey Medical Practice survey (factors revised) (MPS) Subscale: Patient safety and health	Johnson & Russell (2015)[47]	IC: Yes; Cronbach's alpha >0.69 for safety subscale TRR: Not assessed	Not assessed	Yes; evidence of CFA	Not assessed	Not assessed	Assessed, but considered too lengthy.	Not assessed	Yes
	Johnson et al. (2016)[48]	IC: Yes; Cronbach's alpha >0.69 for safety subscale TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
	Nottingham et al. (2018)[49]	IC: Yes; Cronbach's alpha >0.69 for safety subscale	Not assessed	Yes; evidence of CFA	Yes; scores correlated with overall model of care and likelihood of recommending practice.	Not assessed	Not assessed	Not assessed	Yes

		TRR: Not assessed							
The Needs of Adults in Intensive Care Units (NAPinICU) Subscale: Need to feel safe (needs met by staff)	Aro et al. (2012)[50]	IC: Cronbach's alpha >0.69 for safety subscale TRR: Not assessed	Yes; -literature review to inform survey development -expert panel review -pretest panel of patients,	Not assessed	Not assessed	Not assessed	Assessed, but considered too lengthy.	Not assessed	Yes
Patient Perspective on care and Rehabilitation (PaPeR) Subscale: Respect and safety	Wressle et al. (2006)[51]	IC: No; Cronbach's alpha 0.68 for safety subscale TRR: Not assessed	Yes; -literature review -expert panel where survey was reviewed by a group of experts before being further refined or revised -qualitative interviews w/ patients	Yes; evidence of EFA performed.	Not assessed	Not assessed	Assessed; time for completion up to 20 mins	Not assessed	Yes

			-pilot study performed.						
Primary Care Patient Measure of Safety (PC PMOS) Entire questionnaire	Hernan et al. (2016)[25]	IC: Not assessed TRR: Not assessed	Yes; -expert panel review -literature review to inform survey development -pre-test panel where survey was reviewed by a focus group of experts before being further revised or retested.	Not assessed	Not assessed	Not assessed	Not assessed	Yes; formal assessments carried out to test understandability and readability.	Yes
Primary Care Patient Measure of Safety (PC PMOS) 28-item version	Giles et al. (2019)[52]	IC: No; no overall Cronbach's alpha provided, and inadequate Cronbach's alpha	No; no evidence of content validity within instrument, but reference made to	Yes; evidence of CFA	Yes; assessed by correlating scores with the staff AHRQ MOS on patient safety culture (correlation not significant)	Yes	Yes	No	No; copyrighted

		(<.69)/Inter-item correlation (<.2 or >.5) for 5 of 9 of safety domains TRR: No; correlation coefficients not above 0.7 for 5 of 9 safety domains	previous validation before adaptation.						
Patient Experiences on Patient Safety (PEPS) Entire questionnaire	Sahlström et al. (2014)[53]	IC: Yes, Cronbach's alpha >0.69 for all safety domains TRR: Not assessed	Yes; -literature review -expert panel review -pre-tested on patients.	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
	Sahlström et al. (2019)[54]	IC: Yes, Cronbach's alpha > 0.69 for all safety domains TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes

Patient Measure of Safety (PMOS) Entire measure	Baxter et al. (2018)[55]	IR: Not assessed TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
	Giles et al. (2013)[56]	IR: Not assessed TRR: Not assessed	Yes; -reviewed by a focus group of experts and patients before being further revised or retested.	Not assessed	Not assessed	Not assessed	Yes; respondents able to understand items and complete questionnaire in short timeframe, and satisfied with length.	Yes; Tested for readability using formal assessments.	Yes
	Lawton et al. (2015)[57]	IC: Yes; Cronbach's alpha >0.69 for overall measure. Individual domains not reported TRR: Not assessed	Not assessed	Not assessed	Yes; Correlated with other quality and safety indicators.	Yes	Assessed; large number of items, onerous to complete, up to15 mins to completion.	Not assessed	Yes

	Lawton et al. (2017)[58]	IC: Yes; Cronbach's alpha >0.69 for overall measure. Individual domains not reported TRR: Not assessed	Not assessed	Not assessed	Not assessed	Yes	Not assessed	Not assessed	Yes
	McEachan et al. (2014)[59]	IC: Yes, Cronbach's alpha >0.69 for 5 of 8 safety domains TRR: No; Pearson's r of .75 for PMOS positive index, but >.7 for only 2 of 8 safety domains	Not assessed	Yes; evidence of exploratory factor analysis.	Yes; correlations with staff questionnaire scores.	Yes	Not assessed	Not assessed	Yes

	O'Hara et al. (2016)[60]	IC: Not assessed TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
PMOS-30 Entire questionnaire	Louch et al. (2019)[61]	Yes; Cronbach's alpha of >.69 for overall measure, and inter-item correlations within acceptable ranges for all safety domains TRR: Not assessed	Yes; 'shortening exercise' included an iterative consensus approach with researchers, and pre-test patient panel.	Not assessed	Not assessed	Yes	Yes; completion could be facilitated by a research nurse or volunteer.	Yes; 'easy read' versions have been produced.	Yes
PMOS-10 Entire questionnaire	Louch et al. (2019)[61]	Yes; Cronbach's alpha of >.69 for overall measure, individual domains not reported	Yes; pre-test patient panel.	Not assessed	Yes; correlated with measure of patient experience.	Yes	Yes; quick to complete. Completion could be facilitated by a research nurse or volunteer,	Yes; 'easy read' versions have been produced.	Yes

		TRR: Not assessed							
PMOS-A Entire questionnaire	Taylor et al. (2016)[62]	IC: Yes; Cronbach's alpha of >0.69, or inter-item correlation of >.2 for 8 of 9 safety domains TRR: Not assessed	Yes; -pre-test panel where survey was reviewed by a focus group of patients.	Not assessed	Not assessed	Yes	Assessed; areas for improvement to the type and format of resources that need to be provided for data collection.	Not assessed	Yes
	Taylor et al. (2019)[63]	IC: No; Cronbach's alpha of >0.69 for 4 of 9 subscales TRR: Not assessed	No; evidence of content validity within instrument, but reference made to previous validation.	Yes; evidence of confirmatory factor analysis	Yes; PMOS-A correlated with adherence to clinical guidelines.	Yes	Not assessed	Not assessed	Yes
Patient Reported Experiences and Outcomes of Safety in Primary	Ricci-Cabello et al. (2016)[64]	IC: Yes; Cronbach's alpha of > 0.69 for all	Yes; -literature review to inform	Yes; evidence of CFA.	Yes	Not assessed	Not assessed	Not assessed	Yes

Care (PREOS-PC) Entire Questionnaire		safety domains TRR: No; correlation coefficient greater than 0.7 for only 2 of 11 domains	survey development -expert panel review -pilot test -pre-test panel where survey was reviewed by a focus groups of experts before being further revised or refined.						
	Ricci-Cabello et al. (2017)[65]	IC: Not assessed TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
TRIQ Entire Questionnaire	van Melle et al. (2019)[66]	IC: Guttman's lower bound and composite reliability; acceptable to good. TRR: Not assessed	Yes; -literature review -expert panel review -pre-test panel where survey was reviewed by a focus group of patients before being	Evidence of EFA. Scores correlated to rating of satisfaction.	Not assessed	Not assessed	Assessed; 15-20 mins completion.	Not assessed	Yes.

			further revised.						
Untitled Measures									
Subscale: Attitudes about patient safety	An et al. (2017)[67]	IC: Yes; Cronbach's alpha >0.69 for safety subscale TRR: Not assessed	Yes; -literature review -pre-test panel of experts -pilot test.	Construct validity tests: Goodness of fit index; Non-normed fit index; Comparative fit index; Standardized root mean square residual; Root mean square error of approximation.	Not assessed	Yes	Not assessed	Not assessed	Yes
Subscale: Sense of safety and receiving support	Bandurska et al. (2016)[68]	IC: Not assessed TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	No
Subscale: Safe care	Bruyneel et al. (2018)[69]	IC: Not assessed TRR: Not assessed	Yes; -literature review -patient and stakeholder focus group to inform development	Yes; evidence of EFA and CFA.	Yes; criterion-related validity. Multilevel logistic regression analysis used to estimate the association	Not assessed	Addressed; input was too time-consuming, short time span in which the data collection and uploading	Not assessed	Yes

			-pre-test panel.		between factors and global rating of the hospital.		needed to be completed.		
Entire questionnaire	Cox et al. (2013)[70]	IC: Not assessed TRR: Not assessed	Yes; -literature review -expert panel and patient review -pilot test of survey.	Yes; evidence of CFA.	Not assessed	Yes	Not assessed	Not assessed	Yes
Subscale: Perceptions of safety	Desmedt et al. (2017)[19]	IC: Not assessed TRR: Not assessed	Not assessed	Not assessed	Yes; safety items correlated with PACIC scores.	Not assessed	Not assessed	Not assessed	Yes
Entire questionnaire	Dixon et al. (2015)[71]	IC: Not assessed TRR: Not assessed	Yes; -literature review -expert panel review -pre-test panel where survey was reviewed by a group of experts.	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes
Subscale: Safety indicators	Duggirala et al. (2008)[72]	IC: No; Cronbach's alpha 0.62 for safety subscale	Yes; -literature review -pilot study of survey where	Evidence of CFA	Yes; scale scores correlated with overall patient satisfaction	Not assessed	Not assessed	Not assessed	Yes

		TRR: Not assessed	survey was reviewed by respondents before being further revised.						
Subscale: Quality/safety	Malik et al. (2016)[73]	IC: Cronbach's alpha >0.69 for safety subscale TRR: Not assessed	Yes; -literature review -pre-test panel where survey was reviewed by experts before being revised.	Evidence of EFA; evidence of inter-dimensional correlation assessment (scores correlated with overall satisfaction).	Not assessed	Yes	Not assessed	Not assessed	Yes; in table.
Subscale: Feeling safe	Robinson et al. (2018)[74]	IC: Cronbach's alpha >0.69 for safety subscale TRR: Not assessed	Yes; -literature review -focus groups	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes; in appendix.
Subscale: confidence in the quality and safety	Schmidt et al. (2013)[75]	IC: Not assessed TRR: Not assessed	Yes; -literature review	Not assessed	Yes; scores correlated with clinic PCMH score	Yes	Not assessed	Not assessed	Yes; in table.
Subscale: Perceptions of	Schwappach et al. (2003)[76]	IC: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes; in table.

safety and staff technical skills		TRR: Not assessed							
Entire questionnaire	Scott et al. (2016)[77]	IC: Not assessed TRR: Not assessed	Yes; -focus groups carried out to develop survey -pre-test panel where survey was reviewed by a focus group before being further revised or retested.	Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Yes; in table.
	Scott et al. (2019)[78]	IC: Not assessed TRR: Not assessed	Not assessed	Not assessed	Not assessed	Not assessed	Addressed; staff members interviewed and suggested that time constraints impacted the distribution to patients. Also possibility of patients being overburdened with paperwork.	Yes; evaluation forms filled in by patient participants to examine survey acceptability	Yes; in appendix.
Subscale: Safety measures	Padma et al. (2010)[79]	IC: No; Cronbach's alpha 0.62	Yes; -literature review	Evidence of CFA	Yes; scale scores correlated with	Not assessed	Not assessed	Yes; readability, language,	Yes; in appendix.

		for safety subscale TRR: Not assessed	-pilot study where survey was reviewed by a panel of experts before being further revised.		overall patient satisfaction			and scale assessed by patient panel	

Appendix E (Chapter 3): Examples of structural and cognitive issues identified, and suggestions made by general practitioner (*n*=5) and patient (*n*=5) participants during think-aloud cognitive interviewing process.

	Examples of issues identified/suggestions made	**Participant**	**Resolution**
Structural	GMS status is not determined in the demographics	GP1	GMS status requested in the demographics section
	Medication list is lengthy and confusing	P2, GP1, GP2, GP4,	Changed multiple choice option for medications to yes/no response option to 'are you on >5 medications?'
	Items are too close together, difficult for older individuals/those with impaired vision to read	GP2	Increased spacing between items
	The global safety question seems unsuitably placed at the start of the questionnaire	GP3, GP4	Placed the global safety question at the end of the questionnaire
	There is no way of identifying frequent attenders of general practice	GP4	Question added to demographics section; 'How many times in the previous 12 months have you visited a GP practice?'
	The global safety question response option is not clear, as there are no labels on the thermometer diagram	P1	'Very safe' and 'Very unsafe' labels added to thermometer diagram
	The item 'It is just by chance more serious mistakes do not happen in the practice' is asked too early in the questionnaire; given it is more inflammatory that other questions, it could come later.	P3	Item was moved to appear later in the questionnaire
Cognitive	There are no options for participants to provide open comment/free text responses	GP2	A free-text box was added at the end of the questionnaire; 'Do you have any other comments to add about the safety of the care you have received while visiting the GP practice?'
	Where the definition of safety is provided, change 'doctor' to 'practice staff', and list various professions.	GP3, GP4	'Doctor' changed to 'staff in the practice (doctors, nurses, receptionists)'.

	The definition of safety is not phrased in Layman's terms	GP5	'Safety' rephrased as 'the efforts made by staff in the practice (doctors, nurses, receptionists) to prevent any mistakes from happening in your care, and reduce the risk of patient harm'
	Patients identify better with terms such as 'mistake' or 'harm' as opposed to 'error'	GP3, GP5	Replaced 'error' with 'mistake' or 'harm' throughout
	Suggest using active phrasing in items	GP3	Items rephrased accordingly; 'was rushed' to 'is usually rushed', 'were' to 'are, 'gave' to 'gives', 'I was given' to 'I have been given, 'the GP told me' to 'the GP tells me'
	Consider an additional item to examine delay in referral to adequately encapsulate co-ordination of care	GP4	Item added; 'There is a delay when I am referred to other services'
	Provide an example of services for item 'Information gets lost when I am referred to other services'.	P3, P5	Item changed to 'Information gets lost when I am referred to other services (e.g. hospital services)'.

**Note:* GP= General Practitioner, P= Patient

Appendix F (Chapter 3): Initial safety climate measure administered to patient respondents

The ASPIRE Study
pAtient Safety imProvement In pRimary carE

Patient Safety Questionnaire

Safety Questionnaire: Measuring patient perceptions of safety in general practice

This questionnaire will examine your experience of safety in general practice. 'Safety' refers to the efforts made by staff in the practice (doctors, nurses, receptionists) to prevent any mistakes from happening in your care, and reduce the risk of patient harm.

When answering the questions that follow, please think about the care you have received during recent visits at your GP practice:

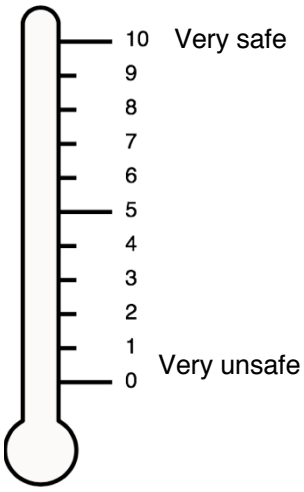
	1. Strongly disagree	2. Disagree	3. Neither agree nor disagree	4. Agree	5. Strongly agree
Getting an Appointment					
When I am really sick, the practice staff make sure I get an appointment	1	2	3	4	5
My appointments are long enough to ensure safe care	1	2	3	4	5
In the Practice					
Staff in the practice work well together	1	2	3	4	5
Staff in the practice help each other	1	2	3	4	5
There is good communication between the staff in the practice	1	2	3	4	5
The atmosphere in the practice always seems pleasant	1	2	3	4	5
Staff work together to ensure patient safety	1	2	3	4	5
Staff deliver effective care	1	2	3	4	5
All staff in this practice are good at their jobs	1	2	3	4	5
Patient safety is a priority in this practice	1	2	3	4	5
I felt safe being treated as a patient in the practice	1	2	3	4	5

	1. Strongly disagree	2. Disagree	3. Neither agree nor disagree	4. Agree	5. Strongly agree
I see safety issues that could be improved in the practice	1	2	3	4	5
The practice has systems in place to prevent error	1	2	3	4	5
There are enough staff here to care for patients	1	2	3	4	5
The attitude of staff towards me is good	1	2	3	4	5
Safety is better here than at other practices	1	2	3	4	5
Staff are stressed in the practice	1	2	3	4	5
Patient safety is affected by workload in the practice	1	2	3	4	5
Staff communicate clearly with patients	1	2	3	4	5
Serious mistakes could happen here	1	2	3	4	5
With the GP					
The GP washes their hands	1	2	3	4	5
I feel safe receiving care from the GP	1	2	3	4	5
I am always given clear instructions on how to take medications	1	2	3	4	5
The instructions I am given about my care are clear	1	2	3	4	5
The GP tells me about potential side effects of my treatment	1	2	3	4	5
The GP tells me about any risks related to my care	1	2	3	4	5
The GP gives me time to ask questions	1	2	3	4	5
The GP treats me with dignity and respect	1	2	3	4	5
The GP is good at their job	1	2	3	4	5
The GP takes time to understand my medical history	1	2	3	4	5
I trust the GP	1	2	3	4	5
The GP always has access to the necessary equipment to care for me	1	2	3	4	5
The GP has enough time to spend on my care	1	2	3	4	5
The GP is usually rushed	1	2	3	4	5

	1. Strongly disagree	2. Disagree	3. Neither agree nor disagree	4. Agree	5. Strongly agree
The GP is usually distracted	1	2	3	4	5
The GP is usually stressed	1	2	3	4	5
The GP has the skills required to care for me	1	2	3	4	5
The GP listens to me	1	2	3	4	5
The GP speaks to me in a way I can understand	1	2	3	4	5
After my Visit					
I know how to report issues with my care	1	2	3	4	5
The practice answers questions about my care outside of appointments	1	2	3	4	5
I am comfortable raising concerns about my care	1	2	3	4	5
I know how to access the GP after-hours service	1	2	3	4	5
I can contact the practice if I have questions about my care	1	2	3	4	5
The practice is responsive to concerns about my care	1	2	3	4	5
Test results are clearly communicated to me	1	2	3	4	5
Information gets lost when I am referred to other services (e.g. hospital services)	1	2	3	4	5
There is a delay when I am referred to other services	1	2	3	4	5

Do you have any other comments to add about the safety of the care you have received while visiting the GP practice?

On a scale from 0-10, with '0' being 'very unsafe', and 10 being 'very safe', how safe is the care in your practice? Please indicate on the thermometer:



How likely are you to recommend the GP practice to friends and family if they needed similar care or treatment?

Extremely likely	
Likely	
Neither likely nor unlikely	
Unlikely	
Extremely unlikely	

Background Information

Please tell us a little about yourself by answering the following questions:

Please provide your gender	What age are you?	What is your nationality?

Which of the following ethnic groups do you identify with?					
White		Asian		Mixed	
Irish Traveller		Black/African/Caribbean		Other (please specify): ----------	

Please tick which applies to you:					
I have a medical card		I have a GP visit card		I am a private patient	

Please answer the following questions:
Have you been admitted to hospital in the past 12 months?
Have you had a fall in the past 12 months?

How many times have you visited the GP practice in the past 12 months?
Do you have any chronic/long-term health conditions (e.g. diabetes, dementia, COPD, cardiovascular disease)? If so, please list:
How many different medications do you take?

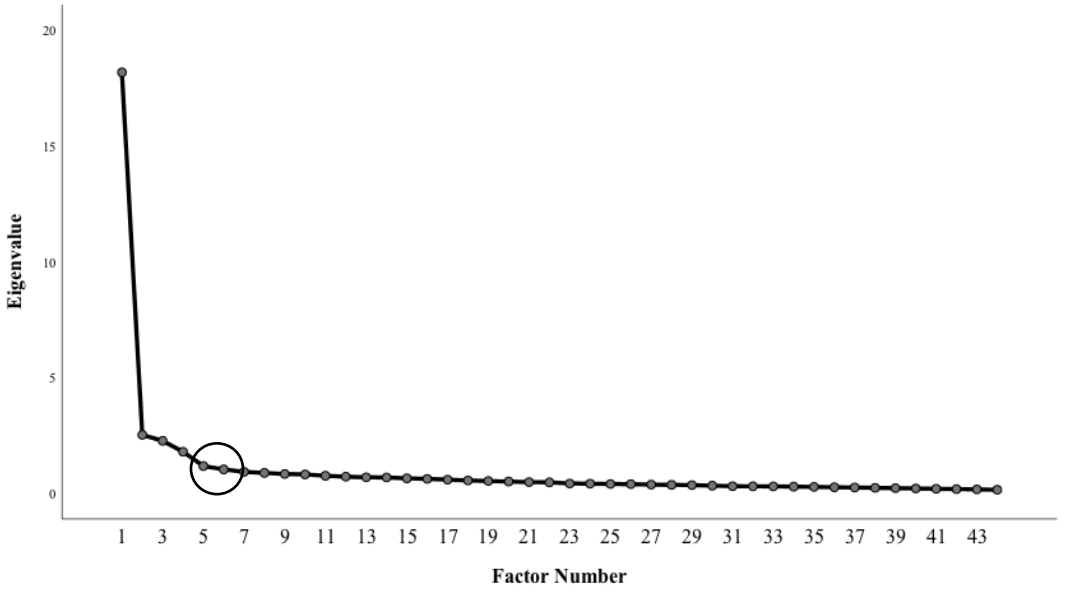
If you had a magic wand, what would you change about your GP care?

Thank you for taking part.

We are also recruiting patients who have experienced a 'medical error' in general practice. A 'medical error' is described as an event which could have, or did, lead to harm for a patient receiving healthcare (e.g. missed or delayed diagnosis, incorrect drug dosage, lapse in communication).

If you would also like to take part in this study, please provide your contact details, and the researcher will be in touch:

Appendix G (Chapter 3): Scree plot showing an inflexion at five, and a slight inflexion at six, indicating the retention of either four or five factors



Appendix H (Chapter 3): The patient perspective of safety in general practice measure (PPS-GP)- items retained following the Exploratory Factor Analysis

Measuring patient perceptions of safety in general practice

When answering the questions that follow, please think about the care you have received during recent visits at your GP practice:

	1. Strongly disagree	2. Disagree	3. Neither agree nor disagree	4. Agree	5. Strongly agree
Feeling of Safety with GP					
The GP listens to me	1	2	3	4	5
The GP treats me with dignity and respect	1	2	3	4	5
The GP is good at their job	1	2	3	4	5
I trust the GP	1	2	3	4	5
The GP gives me time to ask questions	1	2	3	4	5
The GP speaks to me in a way I can understand	1	2	3	4	5
The GP takes time to understand my medical history	1	2	3	4	5
Practice Staff Efficiency and Teamwork					
Staff in the practice help each other	1	2	3	4	5
There is good communication between the staff in the practice	1	2	3	4	5
Staff in the practice work well together	1	2	3	4	5
Staff work together to ensure safety	1	2	3	4	5
The atmosphere in the practice always seems pleasant	1	2	3	4	5
Staff deliver effective care	1	2	3	4	5
All staff in the practice are good at their jobs	1	2	3	4	5
The attitude of staff towards me is good	1	2	3	4	5

Patient safety is a priority in the practice	1	2	3	4	5
I feel safe being treated as a patient in the practice	1	2	3	4	5
When I am really sick, the practice staff make sure I get an appointment	1	2	3	4	5
Staff communicate clearly with patients	1	2	3	4	5
Staff Stress and Workload					
Staff are stressed in the practice	1	2	3	4	5
The GP is usually stressed	1	2	3	4	5
Patient safety is affected by workload in the practice	1	2	3	4	5
The GP is usually rushed	1	2	3	4	5
The GP is usually distracted	1	2	3	4	5
Serious mistakes could happen here	1	2	3	4	5
The GP has enough time to spend on my care	1	2	3	4	5
Patient Knowledge and Accountability					
I know how to report issues with my care	1	2	3	4	5
I can contact the practice if I have any questions about my care	1	2	3	4	5
I am comfortable raising concerns about my care	1	2	3	4	5
The practice answers questions about my care outside of appointments	1	2	3	4	5
The practice is responsive to concerns about my care	1	2	3	4	5
I know how to access the GP after-hours service	1	2	3	4	5
Safety Systems and Behaviours					
I am always given clear instructions on how to take medications	1	2	3	4	5
The instructions I am given about my care are clear	1	2	3	4	5
The GP washes their hands	1	2	3	4	5
The GP tells me about any risks related to my care	1	2	3	4	5
I feel safe receiving care from the GP	1	2	3	4	5

Appendix I (Chapter 5): Patient stories

Incident 1 (PP#2)
Reporting on behalf of mother, deceased
Female, 80s

My Mum had *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome* [ME/CFS; chronic condition causing extreme fatigue] and *fibromyalgia* [disorder causing muscle pain and fatigue], and it sounded like her GP didn't really care about her. The GP kept her on a high dose of steroids for a longer period than she should have been on them without monitoring their impact, and just kept repeating the prescription every time she went in to see the GP. The steroids were damaging her bones and they started pressing on the discs in her back which meant that she lost the ability to walk, became incontinent and was in agonising pain. My mum gained a lot of weight too and she really struggled with that. Mum was also prescribed pain medication in high doses, and so her head was all over the place and eventually she died by suicide.

I really feel the GP should have looked after Mum better. I think if she had been monitored better, she wouldn't have died. I think if she could have changed doctors, it would have definitely prevented the situation from happening. She tried to change to my doctor, but because she was on a medical card, she couldn't switch. She was sort of stuck because she couldn't afford to move.

Incident 2 (PP#3)
Female, 29, Irish

When I was sitting my final college exams, I started to get low-moderate stomach pain for about a week. My health is generally very good, but as the days went on and it wasn't getting better, I started to get concerned. During an exam I got up a few times to go to the bathroom and threw up. Afterwards, I went straight to the college health service. I had to queue outside the building, and I threw up in the garden. When I finally got in to see the GP and I said, "I'm never sick" and described how I'd been feeling. The GP asked me if I had pain on one side of my stomach more than the other and I answered no because that isn't what I had experienced. He didn't do a physical exam which surprised me, he said it was likely stress due to my exams and just told me to take it easy. I went home thinking the GP is probably right, just take it easy and it will pass. I probably downplayed my symptoms in retrospect. The pain got worse that afternoon. The following morning, my parents brought me to their out-of-hours GP. That doctor did a physical examination on me where he felt my stomach and did a 'rebound test', where you press down and it doesn't hurt but it hurts when you release it. That GP then said you definitely have appendicitis. It needed to be dealt with urgently, it was an emergency. My appendix wasn't in danger of bursting, but it was on the way. I had surgery that evening.

Incident 3 (PP#4)
Reporting incident on behalf of father, deceased
Male, 88, Irish

My Dad became very unwell at home on a Sunday, so we called our local out-of-hours GP service. The GP came to the house to see Dad. My husband was watching the doctor and he came into me and said "is he a doctor? He doesn't look like he has a clue of what he's even doing". The doctor was moving in slow motion, like someone who was out the night before.

He just wrote a prescription for *Exputex* [cough medicine] and *Augmentin* [an antibiotic], and I queried "Is that it? Does my Dad not need to be admitted? Does he have *aspiration pneumonia* [severe lung infection] maybe?" We had an experience with that previously when Dad was in hospital, and Dad has to have all his food thickened because he has dementia and severely bad swallowing problems, so I was afraid that we'd have this happen again but the GP said "no, no, no, no". The GP just didn't care; he didn't look like he knew or had any clue and he was guessing bronchitis so that was that. My dad died later that night. I'm not saying that my Dad was going to live another couple of years or anything, but he should have been examined much better and he should have been admitted to hospital. Instead, Dad just got a generic prescription and the GP just didn't seem to give a toss. The thing that upsets me the most was I then ended up going into town to get the prescription, so I was out for a few hours and I could have been at home with my Dad for the last few hours of his life, because I didn't know how bad he was. The GP should have known the signs that Dad was so bad and told us.

Incident 4 (PP#7)
Female, 31, Irish

I had been having trouble with my neck for a while and had had some physiotherapy which kind of fixed the problem in the short term, but it kept coming back. One morning I woke up with really severe pain in my neck and my shoulder and I basically couldn't move, so I went to my GP. The GP did an exam on me and it turned out I had a slipped disk in my neck which was pressing against the nerve in my shoulder. The GP recommended that I go for an *MRI* [scan used to obtain images of the body] to see what was causing it. I couldn't remember at the time which hospitals I was covered for under my health insurance, so she told me to ring the surgery to let them know once I had checked. When I got home, I found the details and rang back immediately and told the receptionist. The receptionist said, "ok that's fine, I'll pass that onto the doctor, and we'll send your referral into the hospital, and they'll contact you". Three weeks went by and I'd heard nothing, so I rang the GP surgery because I had moved to a new house within the last year, so I thought maybe I hadn't told them my address changed. It was a different receptionist and they had my updated address so that wasn't the problem. She looked at my file and said "no, no referral here yet anyway, we'll be in touch". Another few weeks went by, still nothing, so I rang again, and ended up speaking to the first receptionist again. She checked the system and said there was nothing there at all about any referral. The doctor was out, so the receptionist said she'd get her to call me when she returned. There was no phone call back, so I rang again two days later, and the same receptionist again said, "Oh yeah, we've just sent that…I mean, a copy of that has been sent now again". I was suspicious, because she corrected herself on the phone to me and kind of fumbled over her words. Half an hour later, the hospital rang me with a referral. It just means that I've had back and shoulder pain for the past two months while I've been waiting. I've also been holding out on going back to physio until I had the results of my MRI, and I've been in constant pain.

Incident 5 (PP#9)
Female, 43, Irish

I was pregnant with my first child and was under a GP who carried out a vaginal swab. The doctor didn't explain why she was carrying out the swab, she just said, "I'm doing this swab, it's just something that needs to be done when a woman is pregnant, is that ok?" and I said fine. Later that year, I gave birth to a healthy baby boy. After I gave birth, I was told in the delivery ward that I was positive for *Strep B* [bacteria found in a woman's vagina] and that it

was on their records that I had been tested. I was asked if I had been given the test results by my GP. I said no and queried if there was anything to be concerned about. The nurse brushed it aside and told me that it was fine, not to worry, and that one in every four women had Strep B. I brought my son home, and everything was fine.

One night, six days later, he stopped breastfeeding and was crying. I brought him to our local out-of-hours GP service, the doctor completed an examination and we were told he had distended tummy and he was given a suppository. Within an hour of coming home, he went stiff, so we brought him to the hospital, and after 24 hours he died from meningitis. There was an inquest carried out and it came out in the inquest that it wasn't Strep B but Strep A that gave him meningitis. Although no harm did come to my baby because of the Strep B, he was still put in extra danger, he was extra vulnerable, and he should have been as protected as possible. Also, what was clear from the inquest was that I didn't get important results given to me. When the judge enquired about normal practice for when the test results are opened and a woman is Strep B positive, my GP stated clearly in the inquest that it was "imperative" that I was phoned and given the test results from the swab because I needed to get antibiotic cover during labour, because a woman carrying Strep B can pass it to their baby which can possibly cause meningitis. The GP openly said in the inquest that "the patient didn't get her test results, one of us in the surgery opened them. It was either myself or the other doctor in the practice".

Incident 6 (PP#9)
Mother reporting on behalf of son, deceased
Male, six weeks, Irish

Six days after our baby was born, he stopped feeding one night and was crying. My husband rang local out-of-hours GP service, and the advice on the phone was to stop worrying and there was no need to bring the baby to the doctor. We were made feel like we were bothering them and wasting their time, that we were new parents who were being ridiculous, overly cautious and overly concerned. But we felt there was something wrong. This all started at approximately 2am in the morning and went on until 6am. I think we made 10 or 11 calls. At 7am my husband said to the person on the phone "we know there's something serious wrong with our son and we're bringing him in now". When we got in, the out-of-hours doctor took all of our baby's clothes off, he was checking for a meningitis rash even though he didn't tell us. He said he had a distended tummy, gave him a suppository, and we were sent home. At home, our baby became stiff and we brought him to the hospital. He died from meningitis within 24 hours. We found out afterwards that when calls are coming in, they actually prioritise them and that we got the lowest priority.

Incident 7 (PP#13)
Carer reporting incident on behalf of patient
Female, early 80s, Irish

A client I care for in her 80's is on numerous medications for different conditions that she has. This woman just gives the prescription into the pharmacist who fills up a weekly container divided into days of the week and times of day. So she is not fully aware of all the medications and does not get any boxes with warnings – this woman relies on the GP and the pharmacist to get everything right. On two different occasions over the past 5 years, her GP has prescribed her a particular medication that she is allergic to, which caused her breathing difficulties and a nasty cough and the GP has not apologised for making this mistake. But far more seriously, in 2019, her GP took her off a medication that had been prescribed to her by a heart specialist which was facilitating her pacemaker to work

effectively at regulating her heart. This woman then spent several miserable weeks in the ICU and nobody really understood what was going on. When the heart specialist saw her, he straight away noticed the GP's error. The specialist said she's been taken off this medication. It is a vital medication to keep her pacemaker working properly. The specialist informed her that although she would be started back on the medication straight away, being off it may have caused irreparable damage to her heart. Luckily she responded to the medication and is now doing okay again and is out of hospital. Again no apology was offered.

Incident 8 (PP#13)
Carer recalling incident on behalf of patient
Male, early 80s, Irish

A client I care for had lung cancer and had a major operation. The client was not recovering well as he had a lot of pain around the wound which was large and went right round his back. He was told in the hospital not to drive for 6 weeks and was finding relying on other people a bit frustrating. A week post-op, the wound was really painful and weeping a lot so we decided to call out the GP to his home. The GP didn't redress the wound, or really properly examine it. The GP just said the wound was fine and said the man could start driving now. My client took the doctor's word for it. The wound was actually severely infected and because of where it was, driving made it worse because it pulled on the wound. My client had a check-up appointment another week later in the hospital and they were horrified at the state of the wound. My client was put on strong antibiotics immediately and a health nurse was sent out to dress it every other day. As a result, there was a delay with the next stage of his cancer treatment because of the infection.

Incident 9 (PP#13)
Carer recalling incident on behalf of patient
Male, 50, Irish

A client I care for was being treated for severe pain and trauma and was prescribed a drug called *amitriptyline* [pain medication] from a pain clinic in the hospital. Although you get your repeat prescription from the hospital, it must be managed by your GP. When the GP prescribed the medication, he changed the dose. The GP increased the dose without consulting the pain consultant. I noticed a lot of change in my client's behaviour after the increase in dose and he certainly became completely addicted to the drug. My client was on a large amount of other medications too on top of getting this pain medication at the wrong dose, and I think that caused my client's mental breakdown. We flagged the issue with the GP, that we think there's too high a dosage for this medication. The GP said that he increased the dosage because the one that was prescribed by the pain clinic wasn't available on the medical card and what he prescribed was. My client was eventually admitted to hospital for a mental breakdown, where his dosage of the medication was reduced and then he got taken off it altogether.

Incident 10 (PP#5)
Female, 26, Irish

When I was 15, I stopped getting my period, so I went to see my GP. My GP said wait until your 16th birthday and we might put you on the pill because she had checked my bloods and my oestrogen levels were quite low. In that year I didn't get any periods at all. I went back into the GP when I was 16 and she decided to put me on the [contraceptive] pill indefinitely.

At the time there was nothing more said or done, it was like go on the pill it will regulate your oestrogen levels which is important for your bone health and all of that.

A few years later, I wanted to see if we could find out why exactly my *oestrogen* [female sex hormone] levels were low and why I wasn't getting my periods. I made an appointment with an endocrinologist. The endocrinologist took my bloods and checked everything. When I went back a few weeks later to get the results, the endocrinologist told me the results were inconclusive. The endocrinologist thought I possibly had premature ovarian insufficiency, whereby there's a 5% chance of becoming pregnant. I was very upset. Now that I'm 26 I have so many more questions about my fertility and my ability to have kids. Any conversation with the GP since has been "how are you getting on with that pill, is it ok?". Even though the results from the endocrinologist and all that would have been communicated, there were never any questions about the condition itself and how I felt about it. I was never told and still don't know what can be done and what exactly the condition means for me, and how it could have been safeguarded. An earlier referral would have been better as well, and more of a follow up, particularly into my mental health at the time.

Incident 11 (PP#11)
Male, 65, Irish

I experienced extreme pains in my legs when walking for many years. I attended two different GPs from 2000-2011, one was fairly old-school and thought I was experiencing *sciatica* [pain that radiates from the lower back through your hips and buttocks and down each leg]. This GP did not investigate any further. The second GP I saw later referred me to a specialist, but I did not get an appointment. Separately, I had been trying for a long time to get a hold of my father's medical records. When I finally got those, I learned that my father had died from *thrombosis* [a blood clot that can block or obstruct blood flow in the affected area]. The symptoms described in my father's records seemed similar to what I was experiencing. I changed to another new GP in 2011 and explained about the pains in my legs and difficulty walking that was getting worse. This GP did a blood test and referred me to a vascular clinic to have my circulation checked. I was diagnosed with *vascular disease* [condition of the blood vessels] in 2011. I had urgent major vascular surgery in 2012, which consisted of bypass surgery down both legs.

Incident 12 (PP#20)
Female, 53, Irish

I work long hours in a very pressurised work environment and slowly, over a number of years, I noticed that I was getting tingling and pain in my arms, neck, and legs. I used to be really worried about it but just assumed I wasn't being healthy enough, and I knew I was stressed and overweight. I knew the GP was going to say this if I went, so I didn't go. However, the pain got worse. So after 6-8 years, I went to the GP and he referred me for an *MRI* [scan used to obtain images of the body].

When I went back to the GP to get my MRI results, the GP told me there was a problem with the myelin sheath. When I heard myelin sheath, I said "is it *Multiple Sclerosis* [MS; disease of the brain and spinal cord]?" The GP said yes, I had MS. I didn't expect that at all, and I was really scared. I was referred to a neurologist, who I saw after 5 weeks, but those 5 weeks were horrifically scary. I was completely freaked out, I was crying, I was hysterical, I was thinking about suicide. I actually asked my partner to leave me there and then. I thought

that if I killed myself then my partner wouldn't have to go through the suffering and even checked how much the death in service benefit in my job would be if I did.

When I went to the neurologist, he asked me some simple questions, did this little reaction test, looked at the MRI and said, "you don't have MS". The neurologist said I was too old, didn't have the symptoms and that the clinic I had attended was notorious for having poor quality MRIs. It turns out I had a disk protrusion in my neck from wearing a big heavy strap across my body. I went to one physio session and after that I was fine. The GP should have just said that the radiologist is recommending you see a neurologist and left the interpretation it to the neurologist.

Incident 13 (PP#17)
Recalling incident that happened to her mother
Female, 85, Irish

My mother was referred from her GP to old-age psychiatry for dementia. She had a house visit from a doctor on the psychiatry team and the community nurse. I happened to be there when they came to the house to visit her and the doctor was saying "you had this operation, and you're on this medication" and I noticed there were errors in her medical history and medications list. The details about her referral were incorrect and all of that information came from the GP. My mother's prescriptions do change a lot, but the wrong information given was just rushing on the GP's part. I was able to correct the details but had there been nobody with her, it would have been a different story.

Incident 14 (PP#18)
Female, 23, Irish
Incident occurred: prolonged over ten years

My mother had *endometriosis* [disorder where the lining of the womb grows outside the uterus] and our doctors knew this. As soon as I started puberty at 10 or 11, my periods were quite severe. I was struggling with walking, I was *anaemic* [low in iron, causing tiredness], I was in a lot of pain. I saw a couple of different GPs but, because of my family history, my issues were consistently dismissed as being "normal", something I would "grow out of" and I was told that I needed to "toughen up". I told one GP that I would have been happier if my uterus and ovaries were taken out, and he told me that "my future husband might want kids, so I should get over it". I was jumping from medication to medication and on a different pill every couple of years, but my symptoms were getting worse. I had severe cramping, and severe bleeds- my period initially lasted for a minimum of 7-14 days, but eventually I just kept bleeding and didn't stop. It got to the stage where I literally couldn't do anything.

I found a new GP when I was 19, who I've stayed with since then. She was pretty sure I had endometriosis, but it can't be confirmed without surgery. She also tried me on a range of medications, but they didn't help at all and then she referred me on to hospital. I had an ultrasound, but it was completely clear, so the hospital doctor didn't think I had anything. The GP insisted that I have keyhole investigative surgery, while I was having the coil inserted to try and control my periods. When I had the surgery at 21, they had to cut out a lot of my uterus and surrounding areas because it had basically gone *necrotic* [dead/dying tissue]. I was diagnosed with incredibly severe endometriosis; they were quite shocked by the amount of *adhesions* [bands of scar tissue] due to all the scarring and tissue inside. Afterwards the surgeon told me that it was quite advanced and would need more surgeries possibly. The surgeon was quite surprised by it and said that she hadn't seen one that bad in

such a young a patient before. I understand at the very beginning I was very young, but I might not need as much surgery now if I had been taken seriously earlier.

Incident 15 (PP#19)
Male, 26, Irish

I was working as a substitute teacher in different schools and found the routine of it really difficult. I was very disenchanted with the whole thing, thinking where is my career going, and what am I doing? Then I started to become extremely tired every single day. I would wake up after sleeping 8-10 hours feeling exhausted. I was never like this, I just felt awful. I organised an appointment with a GP. Although the GP was friendly and warm, he very much seemed like he wasn't engaged with me. I felt that I wasn't his primary concern. It was very much a slap dash job and he just did a blood test. When I had the follow-up appointment with him to get my results, the GP said, "yeah you're fine, there's nothing wrong with you". That was nearly the worst news I could have gotten because if there was something wrong, I could do something about it. I felt like if I wanted more help, I would almost have to push for it, so I just thought I'll just get over it, get past it. If the GP wasn't as pushed for time, I think that he could have spoken to me more about exactly how I was feeling and what was going on. Maybe he wasn't in a position to do that, maybe it's more of a psychological or clinical issue, and he could refer me or give me some advice on that, but I didn't get any. I experienced a couple more weeks of feeling like that. I changed my environment; got a full-time job and moved away and I just kind of got over it.

Incident 16 (PP#21)
Male, 46, Irish

I went to the GP with a heavy cold and my GP prescribed steroids. When the pharmacy looked at the prescription, they noticed that the GP hadn't identified the potential interaction of my *Parkinson's disease* [nervous system disorder] medication with the steroids and they said that it would have a serious impact on my health if I took the steroids. The pharmacist didn't give me the steroids, they contacted the GP as they're next door to one another. The GP agreed and said that he was wrong and actually came down to the pharmacy and re-did the prescription there and then.

Incident 17 (PP#22)
Female, 40, Irish

I had been quite newly diagnosed with daily persistent migraine, which is the most severe, the rarest, and most aggressive type of migraine. I had some extreme symptoms and had gone through a particular episode and hospital treatment which had left me very weak. I attended my GP one day and she mentioned that I needed to lose weight. My GP suggested that, to achieve this, I should only eat fruit and vegetables. When I later spoke to my specialist (consultant neurologist) about this and explained that was what my GP had recommended the specialist said "absolutely not, that would only cause huge problems with your condition. That's extremely dangerous, don't do that" and so whilst it in some ways seems a very minor thing because it's just a bit of diet advice, doing something so dramatic could have awful implications for my condition and unwise with the drugs I was on at the time. And with migraine, it is a fine balancing act, your diet does play a big part.

Incident 18 (PP#22)
Female, 40, Irish

I was being prescribed *Venlafaxine* [antidepressant sometimes used for pain] by my specialist (consultant neurologist) to try and bring me off *Amitriptyline* [pain medication]. I had a repeat prescription but as the Venlafaxine dosage was being increased, I began to struggle with the side effects and was experiencing palpitations. I wanted to stay at the dose that was comfortable for me, so I went to my GP for advice because I couldn't get hold of the specialist. The GP did not want to prescribe me a dose level that hadn't been cleared by the specialist. In fact, the GP didn't want to do a prescription at all without me having an *electrocardiogram* [ECG; a test to check your heart's rhythm] first, but the ECG was going to cost me a fortune. I felt a huge amount of stress trying to find out whether or not I could get this ECG and trying to get hold of the hospital because they'd never mentioned an ECG to me. And I was wondering, am I going to be allowed to continue on this drug because I'm reliant on the GP prescribing me a top-up until the hospital come back? It felt that I was sort of left free-falling. Eventually when I did get hold of the specialist, they said no you don't need an ECG, and yes you can stay at that lower dose, and they sent me out a prescription in the post. I think it was a problem that the GP didn't have the information about the tablet and how it was being used, didn't have that knowledge. My stress levels were increased, and you shouldn't have your stress levels increased if you've got migraine.

Incident 19 (PP#24)
Male, 26, Irish

From when I was about 12 or so, I started experiencing some pain in the form of a dull ache in my hip and my leg. It was usually worse if I was walking or running and especially at night. We left it for a period of time, but at 14 this pain was still going on, so we went to the GP (GP1). GP1 stretched my leg a little bit, said "ok, it should be ok" and put it down to growing pains and told us that it shouldn't be much of an issue. At 17, I was still experiencing this pain, my movement was becoming more restricted and I was taking pain killers daily. I went to a <u>different</u> GP (GP2) and I was sent for tests in the hospital, but nothing came back conclusive. Then I was sent to a physiotherapist who gave me some stretches to mitigate the pain.

After two more years, I decided again to get my leg checked because the pain had worsened and even though I was doing my stretches. I needed painkillers daily at this point, especially at night in order to sleep. I went back to GP2, was sent for more scans and again nothing came up. I was then referred to a different physiotherapist and they noticed that my hip was mis-aligned. The reason it hadn't been picked up before then is because it's only misaligned when I'm standing up. So when I was being checked before, I was sitting down or lying down and when I'm in those positions, the hip is in place, but when I'm standing up my right hip shifts up just a couple of centimetres, but that's enough to cause the strain on me.

Incident 20 (PP#15)
Female, 49, Irish

I had a shooting pain in my thigh and groin, so I went to my GP and was prescribed *Difene* [pain medication]. I didn't know, and my GP obviously didn't realise, that I was allergic to it. The day after I was prescribed it, I was struggling to breathe and my neighbour rang the GP, and the GP said to bring her back in straight away. My neighbour took me to the GP, and it turned out that I was having an allergic reaction to it and my airway was starting to close so they actually called an ambulance while I was in the GP surgery, and they put me on a drip. Then the paramedics gave me oxygen and they transferred me up to the hospital.

Difene is actually *contraindicated* [not advised] for people who have asthma so the GP probably should never have given it to me in the first place because I have asthma.

Incident 21 (PP#27)
Female, 51, Lithuanian

I visited my GP. I was feeling unwell and just didn't have the energy to get through my day. The GP didn't do any further tests or examinations, just said I was depressed and put me on antidepressants. The medications didn't help me feel better, so I stopped taking them. Three years later I went back to that same GP and insisted that she test my thyroid. Although the findings of the test were not completely conclusive, they did suggest that my thyroid may be underactive. With some encouragement from me, my GP was willing to start prescribing the appropriate medication.

In late 2014, I collapsed and was finally referred to an endocrinologist about my thyroid, but the endocrinologist didn't see anything wrong because I was on medication for it so shouldn't have been feeling as unwell as I did. The endocrinologist believed that I was suffering from some form of fatigue. After the collapse I felt very unwell. I did my own research, and came across this diagnosis of *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome* [ME/CFS; chronic condition causing extreme fatigue]. I found an ex-NHS GP working in Wales who works with ME/CFS patients and she had developed a blood test, so I managed to draw blood with a nurse and send it with FedEx to her office and filled out a patient history questionnaire. That's how I got my diagnosis. I was nearly completely bedbound for three years. I moved GP and my current GP believes I have a physical condition-she said, "I can't treat ME, I don't know anything about it, but I will try and get you the help that you need". Through the ME Ireland patients' group, I heard of a consultant who is familiar with ME treatment. My GP wrote a referral letter, and I visited the consultant and got my first official ME diagnosis from an Irish doctor. So, it had taken 10 years since I first had symptoms. He recognises not only that I have ME/CFS but also *Postural Orthostatic Tachycardia Syndrome* [POTS; a condition that affects blood flow], and *mast cell activation disorder* [type of immune disorder]. He treats me with *Mestinon, Midodrine* and *Eltroxin* [medications to help muscles work properly] and these medications are doing wonders. He also helped me with practical things by writing letters for a wheelchair, and social housing. My current GP is not interested in learning about ME.

Incident 22 (PP#28)
Female, Irish

In 2015/2016, I had abdominal pain. Specifically, I had discomfort in my abdomen after eating and my appetite wasn't right. I also felt very run down. I had a lot of spots on my neck and there was puss in them. I had had *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome* [ME/CFS; chronic condition causing extreme fatigue] since 2008 and when I went to my GP about these symptoms, he literally didn't do anything. He just said, "it's the ME, you'll be fine". The GP actually had no understanding of ME and said everything I had was just ME. There was never anything else wrong with me in his eyes. I went on suffering for a few months, then one weekend, I had to be admitted to hospital through the out-of-hours GP service as they thought I might have appendicitis. I actually had *cholecystitis* [inflammation of the gallbladder] and it turned out I had had *gallstones* [small stones that form in the gallbladder] all along and, at this point, my gallbladder was fit to erupt. I had developed a pustule abscess in the bottom of my liver as the infection from the gallstones had accumulated puss on the edge of my liver. I was in hospital for ten days receiving intravenous antibiotics for the infection. Two weeks after being discharged, I had the

gallstones removed. I had been on *Lyrica* [pain medication] to treat aches and pains from having ME at the time, so it could have disguised a lot of the pain. Once I had the gallstones removed, my neck cleared up immediately, within 48 hours it had completely healed over. That particular symptom was caused by toxins from the gallbladder.

Incident 23 (PP#28)
Female, Irish

I had a dental extraction in 2018 and I ended up with a fractured jaw as my wisdom tooth was fused to it. I had to be put on *oxycontin* [pain medication] to manage my pain. I rang my GP the following morning because I thought I was having a stroke and they said if I came in and waited, he'd fit me in. The GP left me sitting in the waiting room for two hours with my sister and I couldn't actually hold myself up. I kept falling on top of my sister and my face was drooping. When I went into the GP, he took me into a different room, not his surgery, and I couldn't actually verbalise what I wanted to say to him. The GP said, "when you feel like talking to me, I'll come back to you" and my sister explained I actually couldn't speak. The GP just turned to her and said, "when she feels like talking to me herself and wants to tell me what's wrong with her, I will come back and speak to her". When the GP left, my sister took me out of the surgery. The receptionists were very worried when I was leaving and one of them came out to the car after us, saying "look, I'm really not happy". My sister said "we're not here to be spoken to like that, my sister is sick, she's not speaking to him because she doesn't want to. She's actually not speaking to him because she can't". My sister drove me an hour and a half back to my previous GP because I refused to go to A&E. That GP told me it was just the trauma of having the dental extraction the day before had triggered my *Myalgic Encephalomyelitis/Chronic Fatigue Syndrome* [ME/CFS; chronic condition causing extreme fatigue], and this combined with the fact that I was on such a strong painkiller had made me have this reaction. That GP told me everything was fine, that I wasn't having a stroke, to go home and sleep for a couple of hours. He gave me a high dose of diazepam, and when I woke up again, I wasn't as bad.

Incident 24 (PP#29)
Female, 37, Zimbabwean

When I moved to Ireland, I think I developed a food allergy or something. I started to experience pain in my stomach, a rumbling tummy, tiredness, was passing wind a lot and was on the toilet constantly. I had to go to the GP almost every week to see what was wrong with me. The GP gave me tablets to control the pain and got an appointment for me to check if I had *gallstones* [small stones that form in the gallbladder]. However, I think he was misdiagnosing me or something because I tried the tablets and they did not work for me and I didn't have gallstones. I stopped taking the tablets and lived with the pain or whatever I was going through. It thought maybe it was an ingredient in the food in direct provision. I thought this is my life and my health, so I stopped eating the food from the hostel. I stopped taking their food and decided to cook for myself. I ended up making plans with other people in the outside world, for them to help me cook my stuff. As a result, the pain went away and right now I'm fine. The GP was professional and interested in knowing where I came from and what my diet was like. But I felt I was better treating it by myself, because I was going to the GP over and over again and it was not working for me.

Incident 25 (PP#16)
Female, 38, Irish

After experiencing really bad periods throughout my teens, I visited my GP and was referred for a scan in the hospital. There were cysts on my ovaries, and I was diagnosed with

polycystic ovary syndrome [PCOS; condition affecting how the ovaries work] at 21. Throughout my 20s, I was on the pill for 10 years. After coming off the pill, I started to miss periods and have really bad periods again so I thought this can't be right. It seemed the [contraceptive] pill had only masked the issue and not really corrected the problem. I started to question this with the GP but anytime I talked about my symptoms the GP would just suggest the pill as a way to manage them and might enquire about diet and exercise. There was also never a discussion about my fertility. I didn't receive any information even though I had been seeing a GP continually since my early 20s.

I moved GP two years ago, and the new GP referred me on to a gynaecologist. I had keyhole surgery for my PCOS just to see what was going on internally. I also got my hormones checked and an egg reserve test. The surgery revealed I have a small cervix and that could be the reason why I have extreme pain every month. It was also the first time somebody talked to me about fertility and the gynaecologist was so down to earth. I now have concerns about my fertility, and don't understand why all along I was never advised by the GP "well if you do want to have a child, why not freeze your eggs", there was never anything like that. I've went through nearly 20 years of this from 18 to 38 and now it could be too late. Back in my 20s, I think the GP was thinking "oh well you're young, it doesn't really matter" but if I would have known earlier, I could have maybe planned things differently. I suppose if I had changed GPs sooner, and been referred to that gynaecologist in my early 30s, things might have been different.

Incident 26 (PP#16)
Recalling incident on behalf of brother, deceased
Male, 30, Irish

We have a strong family history of heart attacks, high blood pressure, and high cholesterol. My brother was a smoker and a drinker, and he was on medication for cholesterol and blood pressure throughout his twenties. When he was 30, he was feeling unwell one weekend, so he went to the out-of-hours doctors. My brother was very aware of our family history and the medication he was on. The doctor diagnosed him with anxiety and prescribed him anti-anxiety medication. My brother was definitely misdiagnosed because he died from a heart attack the following evening. From what I remember from the autopsy, they discovered there were very high levels of medication in his system and even queried an overdose, but apparently the doses that he had taken matched what he had been prescribed by the GP. If he was sent to hospital, I believe that he'd be still alive today.

Incident 27 (PP#8)
Female, 65, Irish

I banged my head off a pillar at work. It was cut quite deep and bleeding and a lady at work was very good at first aid, so she tended to it. My co-workers insisted I go to my GP, so I rang up the practice. I'm about 30 years attending that practice and there's a few doctors in there. When I heard this particular GP was the only one available, I didn't really want to go in because I don't like her. The GP had to wait for me to arrive, so it was about 6 o'clock in the evening by the time I arrived. The GP took off the plaster, looked at the cut and put a steri-strip type one on. She didn't clean it or do anything else. I was told to come back into the practice nurse a week later, so I did. Then the practice nurse told me "oh I'm afraid you're going to have a scar" and I was awful mad that I had been told it would scar a week later when it was too late to do something about it. I asked to speak to the GP, and I told her off. I said that she should have told me to go to A&E to get stitches in the first place. She

raised her voice at me and said, "didn't I save you time". So, I have a dent there now and I avoid looking in the mirror most days.

Incident 28 (PP#6)
Speaking on behalf of husband, deceased
Male, 68, Irish

My husband went to his GP after experiencing constipation and a dull pain for weeks. The GP said he needed a *colonoscopy* [a medical test used to examine the colon] and referred him. We thought he would get the colonoscopy very quickly because we had insurance, but we ended up waiting 3-4 months for it. While my husband was waiting for the colonoscopy, he started to feel worse and he had a feeling that something was terribly wrong. He went back to the GP a few times during that period. The GP just kept prescribing him different *laxatives* [medicine used to treat constipation], stronger each time, but they didn't work. However, constipation was not the problem. The reason he couldn't move his bowels was because there was a tumour blocking the area. It was found when he eventually went to have the colonoscopy. The hospital doctor explained that they couldn't insert the probe because there was a tumour there. It was stage four, so he was terminal from the beginning. After we got the diagnosis, I rang the GP and told him my husband had colon cancer. The GP said "I'm surprised". I said "really? I'd be surprised if he didn't" because he was so sick. If the GP had done a physical rectal examination in the beginning, he would have felt the tumour there, but he never did that, he didn't do any kind of a physical exam. It spread to his liver and his spine, and he eventually passed away.

Incident 29 (PP#10)
Female, 54, Irish

In 2013, I had been feeling unwell with a severe headache for a few days. On the way home from work, traffic was very heavy, so I decided not to drive over to my GP and decided to go to the doctor on call instead the following morning. I went to the on-call GP and one of the first things that I said to him was that I have an allergy to a specific ingredient in medication, *Metoclopramide* [medication to treat nausea]. I said that I'm never to receive this particular component in a drug, because I had had one previous bad experience with it years ago and I was advised never to have it again. The GP on call proceeded to get my medical history and gave me a prescription. My husband picked it up in the pharmacy and I started taking it as prescribed. Within 48 hours, I was getting worse. My whole body and all my muscles were going into spasm. It brought me back to the symptoms I had experienced 20 years previously and I thought that the ingredient I was allergic to might be in the prescription that he gave me. I read the leaflet and found that there was Metoclopramide in it. I contacted the chemist to confirm this, they did and instructed me to stop taking it immediately and if I became any worse to go to my GP. I did continue to get worse so attended my regular GP. At this stage, I was very unwell and all the muscles in my body were seizing so they rang an ambulance. I was rushed to hospital where I was treated. I was discharged home that night and thought I'd be fine. During the night, I woke up and the right side of my body was all weak, I lost my speech, so I went straight back into A&E. They did all the tests, *MRI* [scan used to obtain images of the body], *lumbar puncture* [medical procedure used to collect spinal fluid], everything and all of them came back normal. I was in hospital for 5 days and ended up having stroke-like symptoms for about 3 months afterwards. It's been one thing after another since that. I've developed chronic daily headache syndrome and my migraines have gotten far worse. I have vestibular migraines,

that's migraine with dizziness and by now I'm on injections for headache and I have a balance problem now. It's just all as a result of that mistake that was made.

Incident 30 (PP#14)
Describing incident that occurred to daughter
Female, 7, Irish

My seven-year-old child had very good health, was rarely sick, very active, happy and bubbly. I went to the GP with her because she had been complaining about a sore ankle. The GP suggested that we go for physiotherapy and the physio said that we needed to look at getting *Ehlers-Danlos Syndrome* [EDS; a connective tissue disorder] ruled in or out. The physio said her joints were very hypermobile and recommended she stop her dancing and gymnastics. We didn't really know what to do so we went back to the GP and told them about what the physio had said. The GP said, "oh don't mind that now, forget about that" and suggested that my daughter had high arches and that we should get orthotics for her. We did that, but her pain actually started to worsen. A couple of months later we went back to the GP because my daughter started to complain of persistent acid reflux and nausea. The GP said that my daughter was obviously worried about her pain and we needed to just stop talking about her pain and get on with it. The GP referred her to a paediatrician to see her what was going on with the joint pain. Meanwhile my daughter's pain continued to increase. I went back and asked the GP if there was anything else, we could give her for the pain while we waited for the referral. The GP asked me if she had friends in school, was she happy, and then she recommended that we try *Prozac* [antidepressant medication]. I was so upset and really shocked but I would have tried anything at that stage if it would help. She explained that in small doses, antidepressants can be used as a painkiller.

We saw the paediatrician the following month. The paediatrician also dismissed EDS and her advice was just to increase her dose of Nurofen. By this stage my daughter had developed severe psychological symptoms. She was self-harming and wanted to die and had stopped talking. However, the pain had come first, before those symptoms. My daughter stopped walking and was in a wheelchair full-time. We weren't happy with the care she had received so decided to attend a rheumatologist in London, who officially diagnosed her with EDS and later *Postural Orthostatic Tachycardia Syndrome* [POTS; a condition that affects blood flow]. A cardiologist in Ireland medicated her for POTS, she's on a long-term steroid and salt tablets. This care has actually made a big difference to her. She finally stood for the first time after 17 months of her feet not touching the ground. When I look back, I still can't understand how a child can be offered an antidepressant so quickly. Even when we eventually got to the stage of child and adolescent mental health, they couldn't understand why she was on an antidepressant so early without input from a consultant.

Incident 31 (PP#30)
Male, 36, Ugandan

I had a bad neck pain and the appointment process was slow. I called the GP surgery on a Thursday and the secretary told me "let's see what I have, I'm afraid I'll have to book you on Monday" as that was the earliest available appointment. I told her I was having a lot of pain in my neck, that I could barely sleep, and the secretary said if I wanted that I could go to A&E. I told her it wasn't an emergency but asked if I could just see the GP sooner to get some medication. The secretary said "ok, I'm going to see if I can get anything for you before 5 today, I'll give you a call". I waited but there wasn't any call and I was like what

the hell is going on. So, I called again. When I called, it was a different staff member who knew nothing about my earlier call or conversation with the secretary. They said there was nothing they could do, maybe take some *Panadol* [pain medication]. I got an appointment eventually, days later, but I still had to bear the pain in the meantime.

Incident 32 (PP#26)
Mother reporting incident behalf of daughter
Female, 13, Irish

I contacted my GP because my 13-year-old daughter was unwell. Because of COVID, it was a phone consultation. The GP just asked me about her symptoms, and I explained she was feeling stinging when passing urine. I had suffered from kidney infections previously myself but if it was a kidney infection, it was her first one, so I wasn't sure. I had to go to the practice and pass her urine sample in through a window and it was being sent to the hospital for testing. A prescription was handed out to me. I wondered why am I being given a prescription so easily? it might not even be a kidney infection. Three days later, the antibiotic had finished, but my daughter was still unwell. It was a Saturday, so I followed up with the doctor on-call service who just handed me another prescription for a stronger antibiotic. I rang the GP surgery a few days later, and the GP told me her urine sample had tested negative for a kidney infection. I said, "how could that be if she had these symptoms and is only feeling better today?". The GP said it could have been lying in the lab for so long that the bugs would have died off. I do believe it was a kidney infection, because I've had them myself. But when I had one, all they literally had to do was take the urine sample and the GP would test it. I feel it would have been a more accurate result, instead of leaving it to sit for days in a lab and then to come back with a negative result. What if it was something different and she had been taking two antibiotics?