Patients’ and carers’ views and their involvement in safety in Australian primary care

by

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THESIS SUMMARY

Primary care is the first point of contact for most people entering the health system and most patient journeys begin and end in primary care. While the extent of safety incidents are unknown for a range of reasons, error rates in primary care are likely to be significant.

Patients are valuable sources of information about ways to prevent safety incidents. Evidence from secondary care settings suggests patients and carers are willing and able to provide feedback on the safety of healthcare and can identify a range of error producing and latent conditions which contribute to safety incidents. Patients' views and potential involvement in patient safety in primary care is an under researched area, particularly in Australia.

The aim of this thesis was to investigate patients' views of safety in Australian primary care and to develop a tool which captures these views of safety in order to facilitate practice safety improvement. This thesis includes three peer reviewed manuscripts which address this aim.

The research undertaken during this thesis occurred in three phases. *Phase 1* explored patients' and carers' experiences of primary care and their perceptions of safety. Four focus groups were conducted with n=26 patients and carers from the Greater Green Triangle (GGT) region of south east Australia. Patients generally had an assumed sense of safety which was mediated by the trusting and the continual nature of the doctor-patient relationship. These factors impacted on patients' perceptions of overall risk in primary care. These results suggested a need to further explore what latent and error producing

conditions in the primary care environment patients can identify that may contribute to safety incidents.

Phase 2 explored the contributing factors to safety incidents that patients and carers can identify in primary care. Qualitative data from Phase 1 was combined with n=8 semi-structured interviews with patients, carers and consumers from the GGT region. Thirteen factors that contribute to safety incidents in primary care were identified by participants. Phases 1 and 2 findings provided the evidence for developing a tool that systematically captures the multiple contributory factors to patient safety from the patients' perspective.

Phase 3 developed and tested the face validity of a primary care patient measure of safety (PC PMOS) tool. A modified Delphi methodology was employed to develop the domain and items of the questionnaire. Face validity testing occurred with both patients (n=11) and primary care staff (n=9). The PC PMOS consists of 50 items covering 15 contributory factor domains. These factors include but are not limited to communication, access to care, patient related factors, organisation and care planning, task performance and information flow.

In conclusion, this thesis demonstrates that patients are willing and able to provide feedback on factors that contribute to safety incidents in primary care. Patient feedback captured on the PC PMOS tool could help primary care professionals, organisations and policy makers better understand and identify potential safety concerns and make appropriate service improvements and policy changes with the aim of reducing incidents in this setting.

CANDIDATE DECLARATION

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signed: Andrea

Date: 8th June 2018

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LIST OF RELATED PUBLICATIONS BY THE CANDIDATE

All publications listed below emanated partially or entirely from the research described in this thesis.

Peer reviewed publications

Hernan A, Giles S, O'Hara J, Fuller J, Johnson J, Dunbar J. Developing a primary care patient measure of safety (PC PMOS): a modified Delphi process and face validity testing. *BMJ Qual Saf*. 2015; DOI: 10.1136/bmjqs-2015-004268

Hernan A, Giles S, Fuller J, Johnson J, Walker C, Dunbar J. Patient and carer identified factors which contribute to safety incidents in primary care: a qualitative study. *BMJ Qual Saf*. 2015; 24(9):583–93.

Giles S, Panagioti M, **Hernan A**, Cheraghi-Sohi S, Lawton R. Contributory factors to patient safety incidents in primary care: protocol for a systematic review. *Systematic Reviews* 2015;4(1):63.

Hernan AL, Walker C, Fuller J, Johnson JK, Abou Elnour A, Dunbar JA. Patients' and carers' perceptions of safety in rural general practice. *Med J Aust* 2014;201 (3):S60-3.

Abou Elnour A, **Hernan AL**, Ford D, Clark S, Fuller J, Johnson JK, Dunbar JA. Surveyors' perceptions of the impact of accreditation on patient safety in general practice. *Med J Aust* 2014;201 (3):S56-9

Project reports

Hernan A, Walker C, Fuller J, Johnson J, Abou Elnour A, Dunbar J. Patients' and consumers' perceptions of and involvement in safety and quality in Australian general practice. *APHCRI report for Centre of Research Excellence in Primary Health Care Microsystems*, The University of Queensland, 2014: http://aphcri.anu.edu.au/files/Safety%20Study-Full%20report.pdf

Conference research presentations

Hernan A, Giles S, O'Hara J, Morgan M, Fuller J, Johnson J, Dunbar J. *Primary Care Patient Measure of Safety (PC PMOS) Questionnaire: A Tool for Improving Patient Safety*. 2015 NAPCRG Annual Meeting; 24-28 Oct 2015. Cancun, Mexico.

Hernan A, Walker C, Abou Elnour A, Fuller J, Johnson J, Dunbar J. *Patients' and carers' views of safety in primary care*. "Towards Better Health in the Western Region" Symposium; 11 Nov, 2014. Geelong, Victoria.

Dunbar J, Abou Elnour A, **Hernan A**, Walker C, Johnson J, Fuller J, Ford D. *Lessons from high performing general practices*. 3rd APAC Forum; 1-3 Sept, 2014. Melbourne.

Hernan A, Walker C, Abou Elnour A, Fuller J, Johnson J, Dunbar J. *Towards developing a model of patient involvement in safety in general practice*. PHC Research Conference; 23-25 July 2014. Canberra, Australia.

Abou Elnour A, **Hernan A**, Clark S, Dunbar J. *Accreditation of Australian general practices*. PHC Research Conference; 23-25 July 2014. Canberra, Australia.

Hernan A, Walker C, Abou Elnour A, Dunbar J. *Patients as active agents: Patients’ and consumers' views of safety and quality in general practice in Australia*. 2013 NAPCRG Annual Meeting; 9-13 Nov 2013. Ottawa, Ontario, Canada.

Hernan A, Walker C, Abou Elnour A, Dunbar J. *Safety and quality of care in general practice: patient and consumers views*. 2013 PHC Research Conference; 10-12 July 2013. Sydney.

Hernan A, Walker C, Abou Elnour A, Dunbar J. *Patients at the heart of the microsystem: Patients' perspectives of safety and quality in general practice*. 10th Clinical Microsystem Festival; 27-28 Feb 2013. Jonkoping, Sweden.

Hernan A, Walker C, Abou Elnour A, Dunbar J. *What do patients think? Literature review of patient perspectives of safety and quality in general practice*. PHC Research Conference; 18-20 July 2012. Canberra.

LIST OF ACRONYMS

ACSQHC	Australian Commission for Safety and Quality in Health Care
ABS	Australian Bureau of Statistics
ACEPP	Assessing Communication about Evidence and Patient Preferences
ADE	Adverse Drug Event
AGPAL	Australian General Practice Accreditation Limited
AHRQ	Agency for Healthcare Research and Quality
APCC	Australian Primary Care Collaboratives
APHCRI	Australian Primary Health Care Research Institute
BEACH	Bettering the Evaluation and Care of Health
BMJ	British Medical Journal
CI	Confidence Interval
COAG	Council of Australian Governments
DALY	Disability-adjusted Life Years
EMR	Electronic Medical Record
GGT	Greater Green Triangle
GP	General Practitioner

HADS	Hospital Anxiety and Depression Scale
HCH	Health Care Homes
IOM	Institute of Medicine
IT	Information Technology
MaPSaF	Manchester Patient Safety Framework
MBS	Medicare Benefit Schedule
ML	Medicare Locals
MRC	Medication Record Card
NGT	Nominal Group Technique
NHS	National Health Service
NPSA	National Patient Safety Agency
OTC	Over the Counter
PC PMOS	Primary Care Patient Measure of Safety
PDSA	Plan Do Study Act
PFPS	Patients for Patient Safety
PHN	Primary Health Network
PIP	Practice Incentive Payment

PMOS	Patient Measure of Safety
PPI	Patient and Public Involvement
PRASE	Patient Reporting and Action for a Safe Environment study
RACGP	Royal Australian College of General Practitioners
RCT	Randomised Controlled Trial
SEAPS	Seniors Empowerment and Advocacy in Patient Safety survey
SEIPS	Systems Engineering Initiative for Patient Safety
TAPS	Threats to Australian Patient Safety Study
UK	United Kingdom
US	United States
USP	Unannounced Standardised Patient
WHO	World Health Organisation
YCFF	Yorkshire Contributing Factors Framework

CHAPTER 1: THESIS OVERVIEW

The potential for patients to be involved in improving safety has many assumed benefits, with a growing yet inconclusive knowledge in this field. Given the documented challenges and uncertainties around patient involvement in safety it is important to explore this issue in more depth.

Patients’ views and experiences of safety are the starting point to understand how patients can be involved in safety improvement activities. While there is some evidence from secondary care settings, research investigating patients’ views of safety in primary care is scarce, particularly in the Australian context.

Chapter 2 will elucidate the emergence of safety as an issue in health care, and how patient involvement in safety may be facilitated. Current approaches to safety and patient involvement in safety within the Australian primary care context will be reviewed in Chapter 3. The practice and knowledge gaps identified in this chapter will help to position the thesis’ theoretical approach to patient involvement in safety in primary care, which is described in Chapter 4. A systems approach to accident causation and patient involvement in safety will be the theoretical basis for the research conducted in this thesis. These models focus on the multiple contributing factors to safety incidents and the position of the patient in the health care system.

Chapter 5 reviews the empirical evidence relating to patient views of safety, including the contributory factors to safety and patient involvement in safety. The literature review will highlight the gaps in knowledge and provide justification for thesis aims and methods used in the following chapters.

Chapter 6 provides an overview of the main discussion points in Chapters 2-5, and Chapter 7 details the specific methods of data collection and analysis utilised in the three studies that make up this thesis, as well as outlining the main results.

1.1 Thesis aims and objectives

The research question for this thesis is *How can patients be involved in improving safety in Australian primary care?*

The specific objectives for the thesis were:

- to understand patients' and carers' views of safety in Australian primary care
- to investigate whether patients and carers can identify factors that contribute to safety incidents in Australian primary care
- to develop a patient feedback tool that prospectively identifies the latent and error-producing contributing factors to safety incidents in primary care.

1.2 Structure of the thesis

The findings for this thesis are structured around three chapters (8, 9 and 10). Patient and carer experiences and views of safety in primary care were explored using focus groups, with results presented in Chapter 8. The findings demonstrated that patients and carers had an assumed sense of safety in primary care, and only those who had experienced an adverse event were able to adequately comment on safety. This discovery led to further exploration in Chapter 9, which employed additional patient interviews to investigate whether patients and carers can identify contributing factors to safety incidents without having experienced an adverse event themselves. Patients and carers were able to identify a range of error-producing and latent factors that contribute to safety incidents. These findings were then used to create a patient feedback tool that captures patients’ views of factors that contribute to safety incidents in primary care. The process for developing this tool is described in Chapter 10.

The final chapter of the thesis summarises the main conclusions resulting from the studies in chapters 8, 9 and 10. The limitations of the research undertaken in the thesis are discussed, as well as recommendations made for future research and the potential application of the patient measure of safety tool in Australian primary care practice.

Chapters 8, 9 and 10 comprise published peer-reviewed journal articles. They have been reproduced verbatim with minor modifications (e.g. numbering of tables and appendices) to allow a cohesive thesis format. Declarations by co-authors for all papers are provided in Appendix 2 in alphabetical order, according to co-author surname. These signed declarations summarise my role in the preparation of each manuscript. I am first author on all publications included as chapters in this thesis in recognition of my contribution to the conception, design, analysis and writing of each manuscript.

Brief summaries at the end of chapters 8 and 9 contain any necessary additional information about the chapter and provide justification for further enquiry in the subsequent chapter.

CHAPTER 2 - EMERGENCE OF SAFETY AND PATIENT INVOLVEMENT IN SAFETY AS HEALTH CARE ISSUES

This chapter explores the origins of safety in health care and the extent of the safety problem in secondary and primary care settings. The difficulties in measuring error in primary care and how patients can be involved in capturing safety information are discussed. The potential for patient involvement to improve safety and its various challenges are also considered. The challenges and knowledge gaps identified in this chapter will provide justification for the thesis inquiry into patients' views of safety and their potential involvement in improving safety in Australian primary care.

Safety and quality in health care were primarily brought to the world's attention by two landmark reports from the Institute of Medicine (IOM) in the United States (US), namely *To Err is Human*[1] and *Crossing the Quality Chasm*.[2] While patient safety had been discussed in the literature in terms of medical errors, adverse events and patient harm prior to these reports,[3-7] it was the release of information detailing the extent and effect of errors on patients that inspired investment into changing the way health care services were delivered on an international scale.

To Err is Human was the first report released by the IOM and its main focus was on revealing the many medical errors recorded in US health care institutions and the effect these had on patients.[1] The report identified that between 44,000 and 98,000 people died in hospitals each year as a result of medical errors that could have been prevented.[1] The alarming statistics demonstrated that errors were due to both human and system factors and that much of this harm could be prevented. The *To Err is Human* report pinpointed shortcomings in health care delivery that led to the development of strategies that could assist government, health care providers, industry, and consumers contribute to improve safety.[1] The various recommendations from the report included the establishment of a centre for patient safety, development of mandatory and voluntary reporting systems, as well as extension of peer-review protections to include patient safety data. Other recommendations suggested organisations and professionals having increased expectations in performance standards relating to safety, organisations and professionals introducing patient safety declarations and programs that promote commitment and responsibility for safety, as well as a focus on medication safety practices and marketing.[1]

Crossing the Quality Chasm was the subsequent report released by the IOM that had a broader aim than *To Err is Human*. Its aim was to describe how the health care system could be designed to innovate and improve care to bridge the quality gap.[2] To improve the quality of care provided to patients the IOM outlined six key dimensions that health care could, and should aspire to. These six dimensions were that health care should be safe, effective, patient-centred, timely, efficient and equitable.

Together these two reports from the IOM have led to great advancement in the science and practice of safety and quality in health care. The success stemming from these evolutionary health care improvement initiatives included a considerable increase in the amount of published literature on patient safety and research awards.[8] Additionally, Leape and Berwick (2005) report that the main outcome of these reports was the spread of substantial efforts to improve safety in hospitals and other health care organisations.[9] They state that the increase in discussion and attitudes towards patient safety has had a profound impact on changing the culture of blaming errors on the individual towards a focus on the system. Gaining support from crucial stakeholders was also key to advancing patient safety, as well as emphasising changing practices.[9] Furthermore, a recent overview on the progress made in patient safety over the last decade since the release of the IOM reports has described advances in significant areas such as regulation and accreditation, reporting systems, malpractice accountability, research, organisational leadership, and national and international interventions.[10]

While there have been positive and effective examples of improvement since the introduction of the IOM's landmark reports and recommendations, there is still much to be done by way of progressing patient safety. Longo et al. (2005) stated that hospital safety was not meeting the IOM recommendations,[11] with Stelfox et al. (2006) also asserting that the extent of translation of the many research studies on safety and quality into practice is unknown.[8] There are also too few robust evaluations of patient safety interventions, with most of the activity focusing on the direct error-producing conditions rather than the wider system, including the organisational culture and context; boundaries between care processes, services and organisations; a focus on the role of the patient and public in safety improvement; and the costs and financial implications of patient safety.[12]

2.1 Safety in health care: what is the extent of the problem?

Most of the research on safety has been undertaken in hospital settings, given its high risk profile and the advances in data availability and collection methods.[1, 2] The World Health Organization (WHO) declare that one in ten patients are harmed while receiving hospital care in developed nations, and as many as seven per 100 hospitalised patients will acquire a hospital-associated infection.[13] A recent review estimated that 42.7 million adverse events occur annually throughout the world, and these events lead to approximately 23 million disability-adjusted life years (DALYs) lost per year. Most of these adverse events and associated DALYs occurred in low- and middle-income countries.[14] One study has shown that 8.2% of hospital admissions in developing countries have resulted in adverse events, with a range of 2.5% to 18.4% per country.[15] Patient safety incident data from developed countries indicated that deaths from hospital care range from 210,000 to 400,000 per year in the US.[16] Data from Canada, New Zealand and the United Kingdom (UK) revealed that between 7.5% and 12.9% of hospital admissions resulted in adverse events.[17-19] In Australia, the Quality in Australia Care Study revealed that 16.6% of hospital admissions were associated with adverse events, with 51% of these events being considered preventable.[20] These estimates demonstrate the global public health problem associated with unsafe health care.

2.2 Safety in primary care: what is the extent of the problem?

Research in the primary care setting has commenced but has not advanced at the same speed as within hospitals. This is due to the higher frequency of errors occurring in secondary care and its emergence as a high risk industry. The risks to patient safety in primary care are also quite different from the risks present in a secondary care setting,[21] hence the types and incidence of errors and level of harm are expected to also differ and to encounter difficulties in estimation. The epidemiology of the safety incidents literature is discussed below.

2.2.1 Frequency and types of safety incidents in primary care

A recent meta-analysis of patient safety incidents in primary care revealed that between <1 and 24 patient safety incidents occur per 100 consultations – of these incidents it is estimated that 4% will result in patient harm.[22] This review conducted by Panesar et al. (2015) included nine systematic reviews and 100 primary studies and is the largest and most comprehensive study of the frequency of safety incidents in primary care conducted to date.[22] The wide frequency of patient safety incidents obtained by Panesar et al. (2015) is related to the various methodologies employed in the primary studies, the diversity in sample sizes, and distinct primary care contexts within and between countries. Higher quality primary studies employed retrospective methods, such as record review, and yielded lower incident rates than lower quality studies that relied on self-reported data or small sample sizes.[22]The most common types of incidents identified in the meta-analysis primary studies were administrative and communication incidents, diagnostic incidents, and prescribing and medication management incidents.[22]

Taxonomies of error or taxonomies of adverse events have been developed by various researcher teams to classify and categorise the types of safety incidents occurring in primary care.[23] These extend and detail some of the broad categories of error identified by Panesar et al. (2015).[22] Types of incidents contained within these taxonomies include, but are not limited to, administrative, appointments and access, communication, confidentiality, diagnostic, documentation, equipment, medication, occupational health and safety, patient and relative, preventative, treatment, surgical or procedural errors.[23-30]

2.2.2 Contributing factors to safety incidents in primary care

The root causes of incidents in primary care are often referred to as the contributory factors to safety incidents. These underlying causes of events are important to understand and reflect where prevention efforts could be aimed.

An early review of factors that contributed to safety incidents in primary care identified four process categories that encompassed clinician factors, communication factors, administration factors, and blunt end factors.[23] Blunt end factors are considered to be “the less obvious factors’ institutional context, organisation and management, and work environment, the ‘blunt end’ of the system” (Nolan 2000, pp. 771).[31] Research subsequent to this review specified several sources of incidents to include case complexity, discontinuity of care, failure to follow protocols or practices, gaps in practitioner knowledge, high practitioner workload, insufficient information on medication and side-effects, team and relationship dynamics, and practice structural problems.[25] Likewise, McKay et al. (2009) categorised a range of error-producing and latent conditions in the primary care environment that make it susceptible to safety incidents. These include health care professional mistakes and behaviour, patient and carer factors, disease management and diagnosis; as well as factors pertaining to administration, medication, test investigations and results, patient records, equipment, adhering to practice protocols and guidelines, appointments and settings (external visits and care).[28] Underlying causes of safety incidents were categorised to be technical factors, human factors, organisational factors and patient-related factors in a record review study.[24] Avery et al. (2012) identified a wide range of underlying causes of error when considering medication safety specifically in primary care. These related to the prescriber, the patient, the team, the working environment, the task, the computer system and the primary–secondary care interface.[32]

Evidently, there are similarities and cross-overs between the types of safety incidents and the sources of safety incidents. This indicates that some misunderstanding could be possible regarding the differences between a safety incident and the contributing factors; or the causal factors that lead to an event being complex and not easily determined; or the safety incident being interchangeable with the source, for example communication errors are considered both a type (safety incident) of error and source of error.

The misconceptions about the latent or error-producing conditions and the difficulties with classifying types of safety incidents can be attributed to the absence of a standardised taxonomy of errors, and the lack of evidence-based frameworks using a systems approach to safety in the primary care setting. McLeod, Kingston-Riechers and Jonsson (2012) have attempted to address this gap by conceptualising the sources of risk to patient safety in primary care.[21] They use the Health Care Error Proliferation Model (based on James Reason's system theory[33]) to illustrate five defensive layers in the primary care system that contribute to error. These include organisational leadership, management, situations for unsafe practice, practitioner performance, and patient performance.[21] While this framework is a positive example for primary care providers and researchers to identify and prevent sources of risk to patient safety, it is not based on empirical evidence from studies that provide sufficient detail or add to the discourse on contributing factors to safety in primary care. Researchers from the Greater Manchester Patient Safety Translational Research Centre are aiming to overcome this limitation to the McLeod, Kingston-Riechers and Jonsson (2012) model through the development of a comprehensive model of contributing factors to safety incidents in primary care. This model will be based on the Yorkshire Contributing Factors Framework for hospital settings that employed a systematic review of the empirical evidence to develop the final framework.[34]

The inconsistencies between studies investigating safety incidents in primary care, the types of incidents prevalent and their various contributing factors indicate that evaluation methods used to capture safety are inadequate. These challenges are explored below.

2.3 Safety in primary care: what are the measurement difficulties?

One of the main problems with quantifying error or harm in primary care is the different definitions used by various studies to describe safety incidents. Some studies measure error, some measure incidents, others measure harm, and some use the terms interchangeably. Definitions of safety are also intangible and dependent on the ever-changing context and environment in which safety is enacted or not.[12] Furthermore, the latent and error-producing conditions that contribute to creating safe systems are also important to consider when assessing patient safety in health care, but also prove difficult to capture adequately.[35, 36]

2.3.1 Defining safety and quality

Safety in health care is merely one dimension in the overarching quality umbrella.[37, 38] This is seen in the IOM Crossing the Quality Chasm report[2], and in the Australian context through the Australian Charter of Health Care Rights,[39] the Australian Safety and Quality Framework for Health Care,[40] and the quality framework for general practice.[41] In the literature, safety often appears as the first dimension of quality or as separate entities.[42]

Safety is paramount in medical ethics with the phrase, ‘First do no harm’ remaining one of the essential foundations of the Hippocratic Oath and medical practice worldwide.[43] The IOM’s widely accepted definition of safety is “freedom from accidental injury”.[1] The WHO has stated that patient safety is “the absence of preventable harm to a patient during the process of health care”.[44] The Australian Commission for Safety and Quality in Health Care (ACSQHC) defines safety as “the degree to which potential risk and unintended results are avoided or minimised”.[45] Emanuel et al. (2008) has taken a broader approach to defining patient safety from an organisational or system view:

> patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimises the incidence and impact of, and maximizes recovery from, adverse events. (Emanuel, 2008, pp 6.)[38]

Within this thesis the broad definition of safety used is "freedom from preventable harm to patients during the process of health care". This definition is an adaptation of both the IOM and WHO definitions; it was chosen as it focuses on harm and this is what matters most to patients[42, 46] and it also includes the safety of patients throughout the course of their care. This definition was used during data collection, analysis and reporting of results in this thesis.

There are also differences between the concepts of error, harm, incidents, slips, lapses and mistakes. Vincent (2010) has pointed out that not all errors will necessarily lead to harm, and not all harms can be linked back to an error, but harm is what patients care about the most.[42] Definitions of the various terms used in the patient safety literature are listed in Appendix 1. The same definitions will be applied to the concepts discussed in this thesis.

2.3.2 Context of primary care

The context of primary care is inherently different from secondary care and consequently, the methods for measuring safety also differ. The heterogeneity between and within primary care practices makes it difficult to study patient safety accurately. Factors such as lack of national or local policies to guide measurement and monitoring, lack of understanding and appreciation of the safety issues in primary care, lack of resources to fund investigation, lack of coordination or leadership at the organisational level to determine primary care practice operations, and lack of staff culture and team dynamics that focus on safety, all contribute to the measurement gap.[47]

2.3.3 Methods to measure safety incidents

While there are significant and well-documented challenges associated with measuring and monitoring safety in primary care,[48] there are a few methods used to capture incident data. These include retrospective review of individual patient records, formal incident reporting, and patient and staff feedback.[49]

Case note or record review is a common method used for patient safety work in hospitals, but it is not as widely practiced in the primary care setting. Case note review can be performed either manually or electronically and usually employs the use of trigger tools. Development and use of trigger tools are beginning to become apparent in the UK and US,[49] but little evidence is available from the Australian context. Record review is also time-limited and practitioner-dependent. Unlike one-off interactions with hospitals, primary care episodes occur over many weeks, months, and years and may be spread across multiple practitioners with no central record to capture all the information needed for record review.[50]

Incident reporting is the main method of safety measurement in most health care systems in developed countries.[51, 52] The incident reporting systems in primary care are diverse and consist of either voluntary or compulsory systems that may be anonymous or identifiable. Incident reporting is usually practice-based with no central policy outlining the procedures for incident reporting or systematic data collection.[47] Furthermore, incident reporting has traditionally been used for quality improvement work and research and is seldom embedded in primary care systems.[50]

Significant event audits, root cause analyses or systems analysis aim to capture the systematic latent and error-producing conditions that lead to the event, and aid future learning and safety improvement work.[51, 52] These investigations often yield poor quality information without the use of structured protocols or guidelines.[53]

Incident reporting often under-estimates the number of adverse events,[54] and tends to focus on proximal causes of incidents.[51, 52] Practitioners do not like incident reporting and reporting bias is common, as demonstrated in the highly variable number of incidents reported between primary care studies.[50] Nonetheless, incident reporting has been used as the main method for development of primary care error taxonomies, which forms the only semi-reliable data available to researchers.[26, 27, 55-57]

Although there are considerable amounts of high-quality information that can be gathered from incident reporting and record review, interviews with the people directly involved in incidents have been stated as yielding the most useful information and often reveal insights into the contributory factors that led to the incident.[50, 51] While this may be the case, questionnaires and surveys are the most frequently employed tool to receive staff and patient feedback about safety.

Staff evaluations of safety have mainly consisted of completion of safety culture surveys. The safety culture assessments – such as the Manchester Patient Safety Framework (MaPSaF) Primary Care[58] and the Agency for Healthcare Research and Quality (AHRQ) Medical Office Survey on Patient Safety Culture[59] – aim to promote discussion and idea generation for safety improvement work in primary care. Both of these tools were recently endorsed as the most useful and appropriate for collection of data on adverse patient events[60] – but many of these tools are not routinely used and the evidence showing their utility is lacking.[61] Modification of these safety culture tools has been undertaken to test their acceptability and utility. One study by Wallis and Dovey (2011) showed they were successful in adapting the

MaPSaF for the New Zealand context with a large and representative sample of general practices.[62]

Internationally, huge investment has been made in seeking patient evaluation of services, particularly through patient-reported outcome or experience measures. These measures, while potentially beneficial for assessing things like waiting times, communication and access to services, rarely cover issues to do with safety or the factors that contribute to safety incidents.[63] Patient feedback in primary care usually addresses issues concerning satisfaction or quality of care, rather than specific safety issues. Satisfaction and quality of care surveys are said to suffer from several limitations including positive-reporting biases, lack of clarity of aims, non-standardisation and unreliability.[64, 65] However, there are some existing patient-report instruments to measure patient safety in primary care but these surveys are focused on patients' experiences of harm after an event has occurred.[61, 66] One particular survey of relevance is the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire.[67] This 58 item questionnaire aims to collect information from patients about their experiences and outcomes of safety incidents. While this questionnaire is similar to the majority of surveys focused on patients' experiences of harm after an event has occurred, there are ten questions that specifically target contributory factors to safety incidents in the general practice environment.[67] These factors include access to care, time in consultation, communication, coordination of care, team factors and information management. The preliminary validity and reliability results show this tool may provide a measure of patient-centred evaluations of patient safety in primary care, but there is no single tool that thoroughly considers the latent or error-producing conditions from the patient perspective.[i]

Other limitations of patient feedback include its subjective nature and reliance on recall. Patient characteristics also influence how and what they report about safety.[52] Another challenge is that patient feedback is not often used effectively or acted upon in general practice.[68] Nevertheless, incident reporting is a method of measurement that can be performed by patients. Patient complaints are a useful source of information about incidents but many organisations fail to see complaints as adverse events or the complaints are not taken seriously.[69] Patients do not always complain when they are dissatisfied (for various reasons), which can also contribute to underestimation of the true number of potential incidents that patients experience.[70] Given the potential for patients to be involved in evaluating safety in primary care, their role is explored in the following section.

2.4 Safety in primary care: How can patients be involved?

Patients and carers are thought to have an important role to play when preventing safety incidents and reducing harm. The firsthand experience of care has been linked to a patient's ability to provide detailed information about the processes, systems and structures that have led to the occurrence of an adverse event.[71] Although there are well-recognised benefits for involving patients to improve the safety of their care, there are still some unresolved contentions regarding the effectiveness of interventions,[72] the roles and responsibilities of both patients and health professionals,[73] and the kind of health care

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[i] Please note the development and validation results of PREOS-PC questionnaire was published in 2016. This paper was identified after the formal literature review was completed in 2015 (Chapter 4), and after the results from this thesis were published in 2014-2015 (Chapters 5, 6 and 7).

culture and organisational governance required for patient involvement in safety to occur successfully.[74]

The potential contribution of patients to safety improvement is explored below.

2.4.1 What can patients contribute to primary care safety?

The value placed on patients as important sources of information about safety has not only come from increased research and advocacy in the area, but also in response to public inquiry into high-profile patient safety cases in the UK such as the Bristol Inquiry and the Francis Inquiry, and similar events from Australia at the Bundaberg Base Hospital, Canberra Hospital, Campbelltown Hospital, Camden Hospital, and King Edward Memorial Hospital.[75]

A recent review of patient safety in the National Health Service (NHS) was conducted by Professor Don Berwick in response to the Francis Inquiry at the request of UK Prime Minister, David Cameron. The conclusions and recommendations stemming from all of these inquiries focused on actively involving patients in the safety of their care.[76-79] The Berwick review, in particular, outlined specific actions for patient involvement at all levels of care from the front line; to the interface between patient and clinician; at the organisational level; and within the wider community. Berwick (2013) states that the overarching goal for the NHS should be to “achieve a pervasive culture that welcomes authentic patient partnership – in their own care and in the processes of designing and delivering care” (Berwick, 2013 pp. 18).[79]

Russell and Dawda (2014) have discussed the implications of the Berwick report for Australian health care. They state that Australia has much to learn from these inquiries and that the recommendations are directly applicable to our health care environment, especially with regard to partnership and learning from patients' views and experiences of safety.[80]

Evidence suggests that patients have intimate and detailed knowledge and experience of their health care journey, have been able to identify a range of errors, and can adequately comment on when and why things have gone wrong.[81] Patients can provide real-time information about patient safety that is a direct reflection of what is important to them regarding potential risks and how they can be prevented.[42, 82-84] Patients have also displayed insight into safety issues that professionals or others may not recognise,[74] and reported safety incidents that may have gone undetected using other safety reporting methods.[42]

Research investigating the reliability of patients' accounts has verified patients to be a trustworthy source of information. The information they provide has been used as part of wider patient safety learning systems and interventions.[85-89]

Furthermore, patients have been proposed as co-producers or partners in the safety of their care, similar to them being already considered as engaged and involved in other aspects of their care.[90-92] Hor et al. (2013) suggest that patients are already acting as 'safety vigilantes' through various behaviours and actions within and outside the health care process to prevent harm from occurring. Examples of patients' vigilance include: "checking and documenting their medications and by checking and questioning staff when something was wrong" (Hor 2013 pp. 6).[93]

Developing partnerships with patients and learning from their experiences occurs in the health care setting, particularly for primary care, but this is complex and diverse. Some of the proposed opportunities for patients to be involved in safety improvement are outlined below.

2.4.2 How can patients contribute to improving primary care safety?

Two reviews by Longtin et al. (2010) and Coulter and Ellins (2007) have summarised the types of interventions patients can potentially be involved with to improve safety.[94, 95] The main types of interventions found in the literature concern patient-directed hand hygiene campaigns, and speaking up about unsafe care and safe medicine use.[94, 95] Longtin et al. (2010) state that patients' potential role in error prevention consists of more than just these kinds of low level of participation activities. Patients can be involved in strategies that cross multiple contributing factors to safety, including providing feedback and participation in interventions regarding health care professionals' skills, competence and approaches to care; equipment design and function; measurement systems; the health care environment, culture and management of services; policies and procedures at various levels of care; and patient-related characteristics.[94]

Coulter and Ellins (2007) have listed specific initiatives that seek patient involvement in safety such as making informed choices about health care providers; assisting with diagnosis, treatment and care processes; checking the accuracy of medical records; identifying and reporting treatment complications and adverse events; and participating in safe medication use and infection control strategies. The authors agree that the effectiveness of these initiatives is unclear and various challenges remain to successfully involving patients in safety.[95]

2.4.3 Challenges of patient involvement in safety

While progress for patient involvement in safety has been made at a national and international level, there remain barriers and challenges to full engagement in this activity.

2.4.3.1 Professional barriers

Health professionals have reported barriers to receiving patient instruction regarding safety concerns. The traditional power differentials between patients and doctors, professional introversion (exclusion of non-professionals in safety), and the organisation's culture can prevent the patient's view from being heard.[91] Longtin et al. (2010) and Trier et al. (2015) state that time, personal beliefs, practitioner speciality, and insufficient skills and training for patient involvement in safety are additional barriers reported by health professionals.[94, 96] Lack of defined roles and responsibilities for both patients and doctors, and examples of good working patient–practitioner relationships are also missing from the safety literature.[97]

Conversely, the shift in responsibility for safety from practitioners to patients may allow professionals to become complacent and reduce their awareness of safety.[98] Professionals may also deflect blame for safety incidents onto patients.[99]

Doherty and Stavropoulou (2012) assert that professionals have an important influence on patients' willingness to be involved in safety, but they often do not promote patient engagement in such activities. Actions by professionals such as actively listening, taking patients' concerns seriously, providing a clear explanation; making time to talk and involving relatives in their care were shown to be effective for patient engagement in safety.[100]

2.4.3.2 Patient barriers

It is assumed that patients desire to be, and are willing to be, involved in the safety of their care given they are the recipients and will be directly affected if their care is not safe;[101]

however, this might not always be the case. Issues of culture, power, support, education, confidence, access, health status, literacy and a range of other characteristics all influence whether patients can be involved in their own safety.[73, 94, 96] Furthermore, there are specific patient population groups that are not invited to participate or would have limited ability to participate actively in their safety. For example: those with severe physical and mental disabilities, infants and children, those seeking emergency care, or patients who are critically ill,[73] and in situations where patients' technical knowledge and understanding about some aspects of patient safety are also acknowledged.[91]

Patients' trust in health professionals also contributes to a lack of patient ability to detect safety and system failings.[102, 103] High profile cases, such as the Shipman case, have demonstrated that patients trust their clinicians and hold them in high regard without knowledge of the harm they undertake. In Shipman's case there was no long history of patient complaints or concerns, and his colleagues were also unaware of his criminal activities.[104] Although the Shipman case is an extreme event, patient trust has been identified as a mediating factor between safety and the patient–doctor relationship.[102]

Entwistle (2007) also asserts that lack of professional or organisational accountability for safety places unnecessary responsibility and burden on the patient;[105] it relies too heavily on the patients rather than involving them as part of a systematic approach to safety improvement.[106] Patient burden may also be exacerbated for patients who are socially disadvantaged and may increase patients' feelings of guilt and stress as they worry about what they could have done to prevent incidents.

There are also many questions and unresolved answers regarding the time needed for developing patient involvement;[107] the ability of the patient to identify causes for incidents;[73] and whether it is appropriate for patients to be involved in specific tasks such as clinical decision-making.[97]

Kountantji et al. (2005) states that the patients' perspective is often ignored by health care professionals and managers, researchers, and policy makers.[83] Patients find it difficult for their voice to be heard; or when they are asked for their participation it is usually tokenistic or a compliance-driven 'tick-the-box' exercise.[108] Challenging health professionals directly is also problematic. Patients have reported concerns about speaking up and fear their care being compromised due to negative feedback.[91, 109] Patients have also reported feeling uncomfortable speaking directly about their safety as they do not wish to appear as challenging or 'difficult' by the health professional.[110]

Patients' perceptions of safety are well documented for specific settings and experiences like adverse events during hospital admission,[87, 89, 111-113] with most of the work investigating patient feedback mechanisms being carried out with patients in secondary care settings.[61, 111, 114] Yet there has been minimal research undertaken that examines patients' views of safety in primary care, or that has explored the development of prospective, theory-based approaches and appropriate patient feedback tools for safety improvement in this setting. This gap in knowledge provides justification for further investigation and will inform the basis of this thesis. The thesis overview in the next section will describe how the following chapters address this knowledge gap in more detail and what research was undertaken to address the thesis aims.

CHAPTER 3 - CONTEXT OF AUSTRALIAN PRIMARY CARE: OVERVIEW OF SAFETY AND PATIENT INVOLVEMENT IN PRIMARY CARE

This chapter describes the Australian primary care context and summarises the problems related to safety. The frequency and sources of safety incidents in Australian primary care are highlighted as well as the macro-, meso- and micro-level approaches to managing patient safety and the kinds of patient involvement in safety activities undertaken. The knowledge gaps reviewed at the end of the chapter explain the theoretical investigation in the next chapter and direction of inquiry for this thesis.

3.1 Primary care context and health reform

The purpose of the Australian primary care system is to provide accessible and well-delivered services that are effective, efficient and appropriate.[115] Australia performs reasonably well against indicators of performance such as access, effectiveness, quality and safety, responsiveness, health outcomes, and financial sustainability.[115] Primary health care in Australia encompasses a range of services that includes general practice, community health, allied health (e.g. physiotherapy, dietetics, and chiropractic services), community pharmacy, community and public health services, and other health practitioner services.[115]

Primary health care is administered by the Australian federal government through the Medicare insurance scheme, which is a universal, simple, fair and affordable insurance system that provides basic health cover to all Australians. Medicare provides free care in public hospitals, and care from public practitioners (general practitioners [GPs], specialists and others) and is free or subsidised against a specified rebate.[116, 117] There are some remaining challenges to ensure that primary care is not only accessible, well-delivered, effective, efficient and appropriate, but is also proactive when considering future population health demands and needs.

Reforms to Australia's national primary health care system is an ongoing process. Reforms were recently introduced through the National Health Reform Agreement in 2011.[118] This agreement aims for the states, territories and Commonwealth to work together in partnership to organise, deliver and fund health care. This agreement was developed in response to the inadequacies of the fee for service episodic treatment model of the health system, the ageing population and escalating rates of chronic and preventable diseases, as well as to centralise and distinguish specific roles for local, state and Commonwealth activities.[119] While this agreement has much focus on hospital, secondary and aged care, primary care is distinguished as comprising a central element to strengthening a person-centred approach to the health system.[119] A further reform discussion paper was released in 2015 focusing on people with chronic and complex health conditions. This reform document outlines the introduction of the 'Health Care Home' (HCH) with the aim to enhance access to holistic care services that are coordinated and effective for patients with chronic diseases. Each general practice enrolled as a HCH will receive blended monthly or capitation payments instead of Medicare fee-for-service payment for 70 eligible patients requiring chronic disease care.[120] In Stage 1, 200 general practices can serve as HCHs to coordinate and manage care for patients with complex conditions. The first Primary Health Networks (see section 2.3.4 below) to enrol HCHs are due to commence in October 2017.[121]

Primary care is considered to be the first contact with the health system for most people. The most frequently visited primary care service in Australia in 2015–16 was the GP with

82% of the population consulting a GP in the previous 12 months. This was followed by 48% of Australians visiting a dentist in the previous 12 months.[122]

3.1.1 General Practice

Given that general practice is the most commonly accessed service within the primary care sector it is important to discuss it in more detail. General practice represents a gate-keeping role whereby most care coordination between hospitals, specialists, and other services are managed by GPs (some common exceptions to this gatekeeping role are access to pharmacy and dentistry). People are free to see multiple GP's and visit multiple GP practices of their choice, and there are no requirements for patients to register with one GP practice.[115, 123] With the changing needs of the population over the past 50 years there has been increased recognition and value placed on the generalist role. The rise of chronic disease has determined the nature of the general practice caseload which is primarily responsible for chronic disease management and prevention.[124]

GP's are independent contractors, working single-handed or in groups, often supported by practice managers, practice nurses, and other staff.[125] The structure of general practice is that it operates as a private provider with substantial government support and funding through Medicare. As such, general practice is autonomous and can make independent decisions about a range of factors to do with their service, namely the out-of-pocket expenses patients may encounter.[126] In this regard, general practice is a private business and consequently, public policy coverage that comprehensively and centrally regulates, monitors, and reviews aspects such as safety and quality of services, or staff development and support, is dispersed amongst organisations funded by government to provide these services to GP. But the Australian Government does have some means to influence care and service delivery through the Medicare Benefit Schedule (MBS) items numbers and the Practice Incentive Payment (PIP).[125] The MBS item numbers are a list of services that are subsidised by the government in an effort to guide what activities GPs undertake during the consultation, and what they can be reimbursed for. The PIP is another regulatory funding arrangement by the Australian Government that financially incentivises practices to deliver continuing improvements, quality care, enhance capacity, and improve access and health outcomes for patients.[127]

Public measuring and reporting outcomes in general practice are also problematic due to the absence of any national or local data collection system.[117] Most practices do have practice-based patient data but these are not publicly available for research or national reporting purposes. The Australian Institute for Health and Welfare (Bettering the Evaluation And Care of Health [BEACH] studies) did collect some general practice activity data but these only captures about half of all general practice encounters in Australia.[123] MedicineInsight is an Australian Government Department of Health funded program managed by the National Prescribing Service (NPS Medicine Wise) which collects data on several million general practice patients from over 500 general practices. Data are collected longitudinally on medicine use in Australia to support safety and quality improvement activities. This includes general prescribing behaviour, inappropriate prescribing behaviour and adverse event data.[128] The ABS also collects patient experience data about general practice from approximately 30,000 Australians over 15 years of age. This national survey examines use, frequency of visits, waiting time, care coordination, and barriers to access.[122] These data that is reported mainly focuses on use and access to service and no measure of safety is included.

But there have been some attempts to determine the frequency and sources of safety incidents or level of harm in Australian primary care.

3.2 Frequency and sources of safety incidents or harm in Australian primary care

Given the variability between how practices undertake incident reporting and record their processes of analysis and safety improvement there are no data available to accurately determine the incidence or the types of safety incidents in Australian general practice. Only a few studies provide enough information to make some assumptions about the level of error and their sources.

The first Australian study about the level of error in general practice was conducted by Bhasale et al. in 1998.[129] This study was an incident reporting study with 324 enrolled GPs that was conducted from October 1993 to June 1995 and where 805 incidents were reported. The most common incident type was omitted or delayed treatment. Incidents related to pharmacological management (51 per 100 incidents), non-pharmacological management (42 per 100 incidents), diagnosis (34 per 100 incidents) or equipment (5 per 100 incidents). The most common contributory factors were poor communication between patients and health care professionals and actions of others (23 per 100 incidents each) and errors in judgement (22 per 100 incidents). GPs in the study considered 76% of incidents to be preventable and 27% had potential for severe harm.[129]

Following the Bhasale et al. (1998) study,[129] the most comprehensive patient safety study in primary care was undertaken by Makeham et al. in 2006 – the Threats to Australian Patient Safety (TAPS) study.[130] This was an anonymous, prospective, error-reporting study using a web-based questionnaire for data collection. The incidence of anonymous reported errors by GPs per Medicare patient encounter item per year was found to be 0.078%, and the incidence of reported errors per patient seen per year was 0.240%. This equates to about one error reported for every 1000 Medicare items related to patient encounters billed, and about two errors reported for every 1000 individual patients seen by a GP.[130] As part of the TAPS study Makeham et al. (2008) also developed a taxonomy of errors based on incident data.[27] The majority of errors in this taxonomy can be attributed to process errors (such as investigation errors, treatment errors, medication errors and systematic errors) and errors related to the knowledge and skills of health professionals (i.e. diagnosis error).[27]

A more recent study by Miller et al. (2013) aimed to determine the prevalence of adverse drug events (ADEs) in patients aged 45 years or older presenting to general practice.[131] The rate of ADEs in the 6 months of the study was 11.6%. The most common type of ADE was recognised side effects of the drug, followed by drug sensitivity, overdose and contraindications, which were few in number. Half of the reported ADEs were considered mild events, and 11.8% were rated as severe, with 5.4% that resulted in hospitalisation. This study highlighted the frequency of ADEs and the associated level of morbidity.[131]

The TAPS study,[27, 130] the Bhasale et al. (1998) study[129] and the Miller et al. (2013) study[131] are limited in their ability to accurately predict the incidence of error in general practice due to the self-reported method used for data collection, which can result in underestimation of the true error rate. Additional limitations were the sampling process that limited the generalisability of results, and the use of only one perspective (the GP). One other study has attempted to obtain an alternative viewpoint about error in Australian general practice; that of the patient perspective.

The only patient-reported level of harm study in primary care was conducted by Clark in 2002.[132] A survey was administered to 1501 patients from predominantly metropolitan areas across Australia. The risk of an adverse event occurring at a primary care consultation was predicted to be 7.4%. This was based on the number of adverse events occurring in the previous 12 months of 9.7%. The majority of adverse events that occurred concerned medications errors, misdiagnosis or treatment error, or a mistake that occurred during a procedure.[132] This paper is further critiqued in Chapter 4.

The error rates obtained from these studies range widely due to the various methods used to capture error data, therefore it is difficult to make comparisons between them. But, the rates of error are consistent with Panesar et al.'s (2015) meta-analysis of patient safety incidents in primary care, which estimated that between <1 and 24 patient safety incidents occur per 100 consultations.[22] These studies' error rates are also less than what is observed in hospitals nationally and internationally.[13, 20] Consistency with the meta-analysis and hospital data is an encouraging sign for the reliability of their findings.

3.3 Patient safety – current approaches in Australian primary care

The Royal Australian College of General Practitioners (RACGP) Standards, and accreditation against the 'Standards', are the major approach to patient safety in Australian primary care.[133]

3.3.1 RACGP Standards

The RACGP is Australia's largest general practice organisation and is responsible for "defining the nature of the discipline, setting the standards and curriculum for education and training, maintaining the standards for quality clinical practice, and supporting GPs in their pursuit of excellence in patient care and community service".[134]

The most recent edition (4th) of the RACGP Standards that specifically deals with safety is found in section 3.1. This standard's particular criteria focus on quality improvement activities, clinical risk management systems, clinical governance and patient identification. There are also standards related to the contributing factors to safety incidents such as access and coordination of care, equipment, and education and training.

The RACGP promotes a systems approach to thinking about and analysing adverse events. The clinical risk management standard states that general practices can use both formal and informal methods of incident analysis, and that all practices must have a process in place to notify when near misses, mistakes or adverse events occur. Practices must be able to demonstrate how and why they have made changes to care delivery based on the incident reporting process.[133]

The standards endorse the use of patient feedback through either surveys, interviews, focus groups or other methods as determined by the practice. The current approved surveys are patient experience evaluations,[135] and are not specific for safety. Practices are also able to develop their own questionnaire or use other methods to obtain patient feedback, but interviews with top-performing practices in terms of safety in quality in Australia have revealed that little patient feedback is sought regarding safety.[136]

These standards form the basis by which general practices are accredited.

3.3.2 Accreditation in Primary Care

Accreditation is an approach to quality and safety improvement in primary care. Practices are assessed against a set of indicators and criteria and receive certificates or payment as reward for good performance. The primary purpose of accreditation is both an external quality assurance and internal quality improvement tool. Practices are externally assessed against a national set of guidelines and the results of which are meant to inform internal quality improvement activity, organisational development or practice learning.[125] It has been an important quality improvement method in many countries but there has been variable success for this method.[137]

In Australia, general practice participation in accreditation is voluntary, with approximately 95% of practices participating in accreditation nationally. The two independent accreditation bodies include the Australian General Practice Accreditation Limited (AGPAL) and the Australian General Practice Network. Accreditation also attracts a PIP from the government.

During accreditation two surveyors visit general practices and assess the practice using the RACGP Standards of Practice as indicators of care. While most of the indicators focus on practice services; rights and needs of patients; safety, quality improvement and education; practice management and physical factors (RACGP 4th edn.), the standards of clinical care are not assessed during accreditation.[125]

A recent study investigated the impact of accreditation on safety in general practice. This study revealed that practices lacked sufficient verifiable evidence needed to demonstrate acceptable levels of safety. Current clinical risk management indicators include having a significant incident register; providing documentation of near misses, slips, lapses or mistakes; and engaging in regular clinical meetings to discuss incidents and how to avoid them in the future—but this evidence is only collected by approximately 5-10% of Australian general practices.[138] There is a clear gap in how clinical safety can be assessed through the accreditation process, and how practices can become more accountable regarding clinical risk management. Recommendations include practices understanding where risks are occurring and how these data can be captured on the risk management register. The Australian Primary Care Collaboratives program has been suggested as a potential vehicle to drive safety improvement work, as it has for many quality improvement initiatives.[138]

3.3.3 Australian Primary Care Collaboratives

The Australian Primary Care Collaboratives (APCC) program was funded by the Australian Government Department of Health and Ageing through the Chronic Disease Prevention and Service Improvement Fund. The APCC was a program of cyclical quality improvement activity in general practice based on the Institute of Healthcare Improvement Breakthrough Collaboratives methodology in the US[139] and modified for primary care by Professor Sir John Oldham in the UK.[140] The collaborative approach has also been applied to other countries' quality improvement work including the UK, Canada and New Zealand. The APCC program was an improvement tool that provides a framework for practices to develop, test and implement changes. Practices participated in 'waves' of improvement work at a national, local or virtual level.[141] Since 2004 approximately 1,200 Australian general practices and Aboriginal Medical Services had participated at some level in the program.[142]

Recent APCC waves addressed improvements in diabetes prevention, coronary heart disease, access, chronic obstructive pulmonary disease, patient self-management, and Aboriginal health and has revealed promising results.[143-145] There has not yet been a collaborative for patient safety in Australian primary care, but the manual has been developed.[146]

While accreditation bodies and the APCC did have some influence on safety practices in primary care, there are other meso-level organisations that facilitate safety improvement in the context of the small businesses of general practice.

3.3.4 Meso-level primary care organisations in Australia

The first type of meso-level organisation was the introduction of the Divisions of General Practice in 1992. The ‘Divisions’ were 112 formalised local networks of GPs working collaboratively within the same geographic area and aimed to improve patient health outcomes and links with other health professionals to upgrade the quality of health service delivery at the local level. Divisions were especially connected to practices locally and were better supported to influence safety and quality through activities such as the APCC program.[147] The effect of the Divisions on general practice activity was considerable, particularly regarding practice infrastructure, support for practice nurses, multidisciplinary care planning, chronic disease management, and consultation length, and access to care.[148]

During the primary care health reform in 2011 one of the main outcomes was the amalgamation of the Divisions and the establishment of Medicare Locals (MLs). The Divisions were reduced to 61 regional meso-level primary care organisations (MLs) that had similar aims as the Divisions—including to improve access to care, plan services to meet local needs, promote prevention and management of chronic disease and integrate with state hospital and community services.[124] With the election of a new government in 2013, the MLs were disbanded and reframed to be ‘Primary Health Networks’ (PHNs). As a consequence of the short timeframe for activity little information is available about the effect of the MLs on safety and quality of care.

The 31 created PHNs have the “key objectives of increasing the efficiency and effectiveness of medical services for patients, particularly those at risk of poor health outcomes, and improving coordination of care to ensure patients receive the right care in the right place at the right time.”[149] Safety and quality were listed as one of the top four priorities listed in the

PHN guidelines.[150] An interest in attaining high standards in safety and quality through research and evidence of best practice demonstrates a commitment from policymakers to improve the safety of primary care. Furthermore, this will include collecting and reporting safety and quality data to support continuous improvement. As these organisations are relatively new it will take some time to see the types of initiatives that individual PHNs undertake and the effectiveness of these.

The reach of the meso-level organisations to locally based general practice clinics has reduced from the Divisions to the PHNs. This has affected the kinds of safety activities occurring locally and the measures used to assess their effectiveness. The centralised nature of safety improvement and reporting safety outcomes is congruent with the establishment of macro-level organisations to oversee safety and quality initiatives on a national scale.

3.3.5 Australian Commission on Safety and Quality in Health Care

The leading government authority for safety and quality of health care in Australia is the Australian Commission on Safety and Quality in Health Care. The ACSQHC coordinates safety and quality improvements nationally.[40]

Although much of the ACSQHC work is directed at secondary care, their work is becoming more focussed on safety in primary care. Accordingly, ACSQHC undertook a wide consultation regarding patient safety in primary care and released a literature review and discussion document outlining a range of recommendations for improving safety at the policy and organisational levels. The literature review identified major gaps in knowledge related to the conceptual basis of patient safety in primary care; the evidence related to patient safety hazards; risk; error and incidents associated with primary care; and solutions to improve patient safety in primary care.[151] The concluding findings from the discussion document emphasised that there is limited research and evaluation of the nature of risks to patient safety in primary health care; uncertainty about the roles and responsibilities within the primary care sector; lack of communication; as well as absence of consistent guidelines or standards of clinical care.[152] The discussion document also highlighted the lack of patient involvement in health care generally, and safety in particular. Furthermore, ACSQHC in collaboration with RACGP have developed the National General Practice Accreditation Scheme. This scheme supports the consistent assessment of Australian general practices against the RACGP Standards for general practice. Accrediting agencies apply to ACSQCH to be assessed and approved to carry out accreditation in general practice. ACSQCH also collect accreditation data and evaluation of accreditation outcomes information. The National General Practice Accreditation Scheme commenced in January 2017.[153]

3.4 Patient involvement in safety in Australian primary care

At a macro policy level there are no policies or Acts, like the *Queensland Health and Hospital Boards Act 2011*, which mandate consumer or community engagement and consultation in primary care.

At a meso-level the Council Of Australian Government (COAG) National Health Reform Agreement in 2011 required all MLs to include the views of local communities when making decisions about primary care service delivery, particularly in the area of safety and quality of patient care.[118] This COAG agreement is based on the National Primary Health Care frameworks' strategic outcome to engage with patients and consumers more effectively when developing service delivery models, access plans, care coordination management and conducting needs assessments.[154]

With the replacement of MLs with Primary Health Networks a similar consumer involvement strategy has been proposed through the use of Community Advisory Councils, which aim to ensure that PHNs' decisions are informed by community needs. The specific requirements for the roles and impact these councils have on safety and quality are unknown at the time of writing this thesis.

At a practice level, the RACGP Standards describe a core standard about the rights and needs of patients that specifically outlines indicators on how general practices can collaborate with patients. This standard is particularly detailed about seeking and responding to patient feedback on their experience of general practice to support quality improvement activities. The other indicators focus on culturally appropriate delivery of care and patient identification.[133]

Patient feedback on their experiences or satisfaction with care are often used as a proxy for patient involvement and often this feedback does not concern issues directly about safety. Measuring patient and consumer experience in primary care has had limited application in Australia.[155] The applicability of measuring patient experience as a proxy for patient engagement is also contentious. Patient experience is said to be based on the patient's perception of quality, whereas patient engagement is considered to be the patient's actions and behaviours that sustain participation in managing their health or their participation in service delivery and design.[156]

General practices who have participated in the APCC program were required, as part of their evaluation activities, to seek patient feedback or measure improvement in patient outcomes. Patient involvement in the APCC is also centred on self-management and engagement in prevention activities for chronic diseases such as diabetes, coronary heart disease and chronic obstructive pulmonary disease. Self-management activities are lower forms of patient involvement and the evidence for their effectiveness shows mixed results in Australian primary care.[157-159] Self-reported levels of patient engagement with a regular doctor (assumed to be the GP) for Australian people with chronic conditions has been compared with other countries by the Commonwealth Fund. The findings suggest that Australian patients rated their level of engagement higher than patients from countries like Norway, Sweden and Switzerland, and were similar to patient ratings from the UK, US and New Zealand. But patient engagement in this study was classified as the doctor spending enough time, explaining things in a way that is easy to understand, and encouraging patients to ask questions,[160] which are considered some of the least active forms of engagement.[161] In conclusion, self-management for chronic disease management does not translate directly into patient involvement in safety of care.

3.5 Summary of the problems related to safety of Australian primary care

Firstly, the primary care system in its current fragmented state does not allow for coordinated action or measurement of safety. The ACSQHC has corroborated this observation in their consultation report that recommends the need to develop “a nationally coordinated, systematic and effective means of reporting errors and near misses within primary health care, based on an agreed set of safety measures”.[162] Greater collaboration and partnership across and within the sector was also advocated as a way to effectively implement existing frameworks and guidelines and to enhance accountability for safety.[162] While the ACSQHC does have a major role in promoting and assisting with national coordination of safety, there are no local- or state-based bodies that can undertake such a venture. The structure and business model of general practice does not facilitate integration or regulation of safety at a national level. The RACGP could potentially assist with enhancing accountability for safety by making increased demands for verifiable evidence through the implementation of the standards of practice,[138] but collecting national- or practice-based data on safety will be impossible without an adequate IT system enabled for this purpose.

Secondly, the approach to safety in primary care is currently reactive rather than proactive, and lacks a systematic understanding, or implementation, of accident causation theory and prevention of error. Clinical risk management procedures are usually comprised of retrospective methods such as significant event audits, root cause analysis, or responding to patient complaints. These techniques do not allow for prospective identification of potential sources of safety incidents and ways error or harm could be prevented. A prospective approach that uses real time feedback or measurement of safety incidents through quality improvement activities would be more valuable to practices and patients.

Thirdly, there is no robust evidence that attempts to deduce level of harm in the Australian primary care setting. While the actual level of harm is not necessarily needed to help improve safety, adequate information about the sources or contributory factors that lead to patient safety incidents is required. Some taxonomies for threats to patient safety in primary care have been developed.[21, 26, 55] This kind of information is helpful to practices when attempting to gain a more complete picture of patient safety and to be more solution-based rather than problem-focused. But, linked with the points above, primary care practices rarely use this kind of information when undertaking patient safety improvement work.

Fourthly, the patient voice has been relatively absent in patient safety in Australian primary care. The patient view is often ignored or placated when safety incidents occur, contrary to the evidence that suggests they may be able to make substantial contributions to preventing harm and identifying safety incidents that health professionals or others may not recognise.[92, 93] Many of contributing factors to safety identified in various taxonomies lack patients' perspectives or insights, and are professionally- or academically-derived. Only one study undertaken by Clark (2002) has actively sought the patients' perspective of safety in Australian primary care. Although this study provides valuable information, there are some limitations that reduce its usefulness. These data are now over 10 years old, the sample size of 1501 may not be generalisable, and the sample was primarily from metropolitan areas. Moreover, many of the predictors of safety incidents were mainly attributed to proximal factors (such as patient, practitioner or task factors) and not system factors,[132] which is contrary to the evidence from hospital settings that suggests patients can identify a range of error-producing and latent factors contributing to safety incidents.[111, 114]

Summarised, these knowledge gaps include:

- The lack coordinated action or measurement of safety within the current fragmented state of the primary care system.
- A reactive rather than proactive approach to safety in primary care that lacks a systematic understanding, or implementation of accident causation theory and prevention of error.
- Absence of adequate information about the sources or contributory factors that lead to patient safety incidents.
- The relative absence of the patient voice in patient safety in Australian primary care.

The knowledge gaps demonstrate a need to further explore patients' views of safety and their potential involvement in improving safety in Australian primary care. Obtaining such information may enhance the current processes used to undertake safety improvement work and provide a comprehensive, prospective, and systems thinking approach to safety incident prevention in primary care. These knowledge gaps will be the foundation for this thesis, and will also be the basis for exploration in the next chapter about theoretical considerations for safety in health care, and will contribute to informing the literature review aims in Chapter 4.

CHAPTER 4 – THEORETICAL CONSIDERATIONS OF SAFETY IN HEALTH CARE AND THE POSITION OF THE PATIENT IN SAFETY

This chapter elucidates the theories of safety in health care, their historical context and adaptations. The position of the patient in safety is also explored, as well as the challenges of applying a systems approach to accident causation in health care. The specific models chosen for this thesis are expanded and supported for use in the studies that make up this thesis and the literature review presented in the next chapter.

4.1 Learning from industries outside health care

Safety in health care has many overarching theoretical backgrounds that have originally stemmed from aviation, business, organisational change,[163] human factors and ergonomics.[164] Accident investigation and research in high-risk industries and workplaces became prominent in the 1940s when aviation, military, and nuclear power generation organisations were trying to develop ways to prevent major disasters and avoid public scrutiny.[165] Engineers, managers, human factors researchers, ergonomics researchers, psychologists, and sociologists all began to consider the reliability of the systems in which accidents take place from a variety of perspectives. A focus was on either the human (person) or the system contribution to error.[166] The first approach focuses on the errors of individuals and attributes blame and responsibility to that individual. The second approach recognises that humans are fallible and errors are inevitable, but they can be prevented through understanding and learning about the systemic factors that contribute to causing errors within the organisation.[167]

4.1.1 The development of safety in aviation

Aviation was one of the first high-risk industries to move to a blame-free approach in accident management. Highly visible accidents were becoming common occurrences in the 1970s; for example, the fatal TWA Flight 514 crash near Washington DC. Investigation into the cause of the accident revealed that simple misunderstandings in terminology used for pilots to begin their own navigation during descent were at fault. This resulted in the pilot flying into terrain with no apparent awareness of the surroundings and hence crashing into a mountain. Responsibility for the accident was then placed on the airline and industry for not having clear procedures when communicating the approach of an aircraft. Furthermore, ground proximity detection equipment was developed and mandated for the airlines as a result of the TWA Flight 514 crash. This was one of the first incidents where systemic factors outside the individual were attributed as causal factors for the accident and hence development of the blame-free approach began.[168]

Around this time in aviation, near misses were rarely reported due to fear of disciplinary hearings and punishment. Another aircraft on the same approach to Washington, like the TWA Flight 514, had a near miss and did not report it. Together the realisation of systemic factors influencing safety and the increasing propensity to not report near misses resulted in a ‘no blame culture’ in aviation. These important developments resulted in an industry considered one of the safest in the world, and one on which industries such as health care model their safety systems.

4.2 The changing context of medicine and its impact on safety

In the 1990s and 2000s the context of health care was changing as such different and greater threats to safety became apparent.[38, 42, 167] The practice of medicine had also become increasingly complex with the use of innovative technologies and procedures to enhance health, yet it also presented a higher probability of unpredictable effects and fatal outcomes for patients.[42] Consequently, interest in the quality and safety of health care grew, along with the rising number of high-profile cases of harm being reported to the public and increasing frequency of litigation. Medicine was now regarded a high-risk industry and there was increased demand from the public for accountability in delivering safe and effective care.[38, 169]

4.2.1 Accountability for incidents in health care

In response to the need for accountability in health care, a culture of professionalism and organisational development was emerging which included team work and relationship building as essential elements for system change. Open disclosure and accident investigation enhanced learning and application of 'systems thinking' in health care.[38, 42]

A systems thinking approach accepted that upstream factors in the design of systems, organisations, management, training and equipment played a large part in events occurring in the downstream, or sharp end during patient–practitioner interaction.[38, 167, 170] In addition to policies and processes influencing delivery of care at this end of service delivery, economic regulators, technology suppliers, policymakers and insurance administrators were all perceived to influence the health care organisation in one way or another.[38] Given this new way of thinking, making practitioners accountable for such errors seemed flawed.

Attribution of blame has been said to be inherently limited and weak in comparison to a system view. As Reason (1995 p.1710) states “the attribution of blame, although often emotionally satisfying, hardly ever translates into effective counter-measures”.[171] Focusing on blaming individuals also prevents inquiry about the external error-producing conditions in the organisational environment. Research from the aviation industry has shown that 90% of quality lapses are blameless and are a result of the wider system, rather than directly attributable to individuals.[167, 172] Furthermore, Gawande et al. (1999) found that 75% of adverse medication events were attributed to systemic factors rather than frontline errors.[173]

Thinking about safety differently led to new ways of understanding risk management and quality improvement in health care and moved away from blaming errors on practitioners, instead recognising that system breakdowns were often the foremost explanation for the occurrence of most adverse events.[38] A ‘no blame’ culture was established on a large scale in the 1990s and was viewed as a refreshing change from the increasing occurrence of malpractice claims that were generally regarded as ‘punitive and arbitrary’.[174]

Conversely, there are some situations where a blame-free environment can be considered too primitive. There are extreme circumstances in health care where a blameworthy approach to incidents is required. These include deliberate attempts to cause harm or negligence, conducting criminal behaviour, or being under the influence of drugs or alcohol.[1] Finding a balance between a no blame culture and accountability has been challenging for health care organisations.[174, 175] As such, a ‘just culture’ that differentiates between blameworthy and blameless acts has been endorsed as a potential solution to enhancing safety systems. The just culture identifies inadvertent human error such as slips, lapses and mistakes; at-risk behaviour as a result of choices that are not recognised or believed to be justified; and reckless behaviour that is conscious disregard of unreasonable risk and is therefore blameworthy or publishable.[176]

While there are some complexities when contemplating a human factors or a system view of health care, the systems approach to safety is the most prominent and postulated theory in the literature.

4.3 Theories of safety in health care

In the 1990s human factors researchers, engineering researchers and ergonomics theorists began to see the similarities between aviation and health care, and believed there was a significant opportunity for progress.[177, 178] Health care was comparable with aviation, as Vincent described, they were both “hazardous activities carried out in large, complex organisations by, for the most part, dedicated and highly trained people” (Vincent 2010, pp. 123).[42] Consequently, adverse events were considered as consequences of poorly designed systems by the major contributors to accident causation theory such as the Institute of Medicine,[1, 2] Leape and Berwick,[9] Charles Vincent,[42] and most notably James Reason.[167]

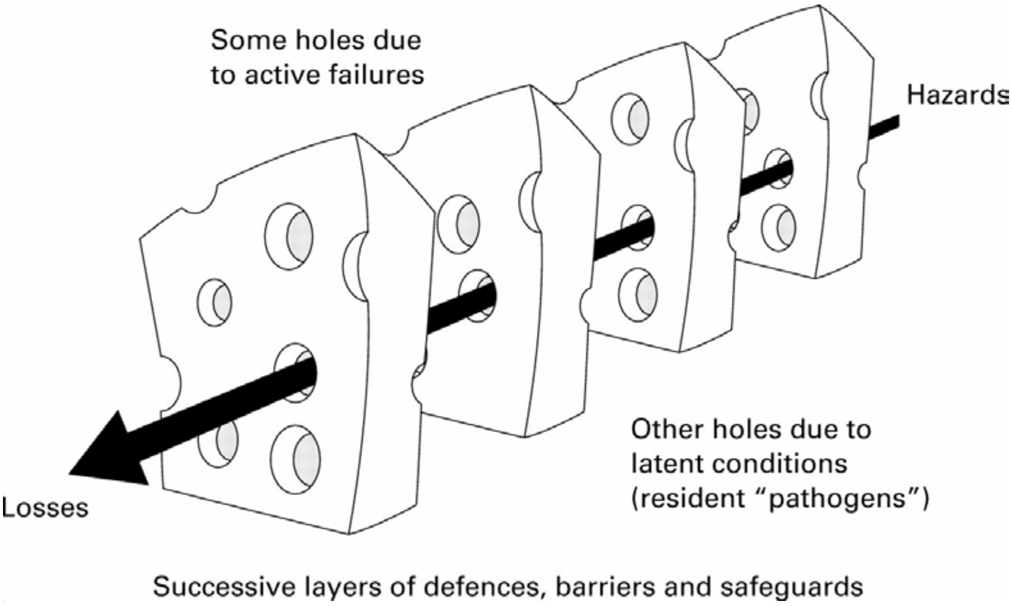
These initial promoters sparked enthusiasm and altered perspectives of health professionals, managers, organisations, policymakers and researchers about how to contend with safety incidents in health care. Consequently, theorists postulated various frameworks that used a system approach for safety in health care. James Reason’s ‘Swiss cheese model’ and the subsequent ‘Framework of contributory factors influencing clinical practice’ by Charles Vincent are two such frameworks.[167, 170]

The contributory factors influencing clinical practice framework based on James Reason's Swiss cheese model was chosen as the theory behind the investigations undertaken in this thesis as it is a model in patient safety that has been frequently cited and applied. These frameworks' prominence in the patient safety field supports their use in attempting to understand ways that patients may be involved in safety. These frameworks also focus on factors that prevent safety incidents rather than reactive or blame-allocating approaches to safety once an adverse event has occurred.

4.3.1 The Swiss cheese model

The major contributor to systems thinking in patient safety was publication of the 'Swiss Cheese Model' of accident causation made famous by Reason in 2000 (Figure 4.3.1.1).[167]

Figure 4.3.1.1 James Reason's Swiss Cheese Model



Reproduced from Quality in Health Care 2001;10:ii21-ii25 (Reason 2001).

Reason proposes that health care systems (like other high-reliability organisations) have multiple layers of defence to prevent hazards to patients, but there are always areas of weakness. The weakness in each layer of defence has been described as the holes found in Swiss cheese, and sometimes these holes line up and the defence fails, thereby allowing error to occur.[167] These hazards are said to be caused by two factors, active failures and latent conditions. Active failures are the people-based errors, mistakes, slips or violations; the latent conditions are the system-based failures that arise from management and organisational decisions that indirectly affect delivery of care.[167]

The Swiss cheese model originally appeared in Reason's book *Human Error* in 1990 (p. 208),[33] but it did not appear in the health care literature until 2000 when it was published in *British Medical Journal* (BMJ). The theory that led to the development of the model was based on Reason's accident causation framework, which considered the aetiology of accidents in complex technological systems.[33]

Reason's work is reflective of the theoretical and methodological developments within cognitive psychology from the mid-1970s that emerged due to public concern about tragic accidents such as the Tenerife runway collision, Chernobyl disaster and the Kings Cross Underground station fire. Growing interest and understanding of the causes, consequences, and preventability of error was considered a fundamentally useful psychological process. Reason (1990) states that the major influences on his work came from human cognition theorists such as James Sully, Charles Spearman, Sigmund Freud, William James, Hugo Munsterberg, Joseph Jastrow, the Gestalt psychologists, post-World War I neuropsychologists, Frederic Bartlett, post-World War II natural and cognitive scientists, and the 1970 and 80s rule-based and global performance psychologists.[33] These theorists conducted studies on various aspects of human cognition including everyday error, slips and lapses of speech and action; memory illusions and recall; perception; thoughts; personal habit and will; decision-making; skilled and practised behaviour; automatic performance; processing; attention; learning; comprehension; problem-solving; reasoning and action.[179] Reason states that the other influences on the development of his work were systems engineering and computer programming, which were prominent schools of thought in the 1980s.[180-182] Reason combined the natural science and engineering approaches to think critically about models of error detection, and applied some of the emerging ergonomics research regarding active and latent errors in complex systems to develop his accident causation framework and subsequent Swiss cheese model.

4.3.2 Framework for analysing risk and safety in clinical medicine

Prior to Reason publishing the Swiss cheese model in the health care literature in 2000, Charles Vincent described in detail a framework for analysing risk and safety in clinical medicine.[170] This framework was based on Reason's earlier organisational accident theory.[33, 171] In the framework, Vincent details factors that influence clinical practice and thereby the factors that could contribute to safety incidents, which he categorises as proximal or distal factors (Table 4.3.2.1).[170]

Table 4.3.2.1 Framework for analysing risk and safety in clinical medicine

Distal factor	**Institutional context** Economic and regulatory context National Health Service Executive Clinical negligence scheme for Trusts
Distal factor	**Organisational and management factors** Financial resources and constraints Organisational structure Policy standards and goals Safety culture and priorities
Distal factor	**Work environment** Staffing levels and skills mix Workload and shift patterns Design, availability, and maintenance of equipment Administrative and managerial support
Proximal factor	**Team factors** Verbal communication Written communication Supervision and seeking help Team structure
Proximal factor	**Individual (staff) factors** Knowledge and skills Motivation Physical and mental health
Proximal factor	**Task factors** Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results

Proximal factor	**Patient characteristics** Condition (complexity and seriousness) Language and communication Personality and social factors

Proximal factors are the individual patient characteristics, task, staff and team factors (also known as the sharp end of care). Distal factors include the work environment, organisational factors and the institutional context (also known as the blunt end of care).[183]

Vincent's work was one of the first comprehensive frameworks of factors that influence safety in the medical field. The framework was intended to be used by researchers and risk managers as a way to formalise or extend current analysis and examination of adverse events, to help inform the development of risk assessment tools, and to assess the influence of these factors on patient outcomes.[170]

Vincent's contributory factors framework served as the basis for the development of the 'Systems Analysis of Clinical Incidents', or otherwise known as the 'London Protocol',[184] which is a practical application of the tool. The London Protocol outlines a structured procedure for accident investigation and analysis in health care. It functions as a practical tool to assist health care managers and teams learn from safety incidents and prevent future incidents. The first edition was originally intended for use in hospital settings, but the second edition can be applied to other health care fields including mental health, ambulances and primary care.[184] The London Protocol has been used effectively in various health care contexts and by various accident investigation teams.[184] It has been said to ensure a comprehensive assessment of incidents that identify the key systemic issues which contribute to creating an adverse event. Clinicians benefit from such a systematic approach as it promotes “a greater climate of openness and to move away from finger pointing and the routine assignment of blame” (Vincent, 2000 p.780).[52] Furthermore, patients benefit from such inquiry as recommendations, new policies and procedures, and actions are put in place to prevent such an accident from occurring again.[51] This particular model was chosen as a framework to clearly categorise and present the literature review findings in the next chapter (Chapter 4). Vincent’s framework illustrated where the studies were situated along the contributory factors to safety continuum, and to identify gaps in knowledge for further exploration in this thesis.

4.3.3 Adaptations to the Swiss cheese model

There have been further adaptations to Reason’s accident causation model applied to the health care context over the past decade. These include the ‘Systems Engineering Initiative for Patient Safety’ (SEIPS) and SEIPS 2.0,[164, 185] the ‘Patient Safety in Primary Care Framework’,[21] the ‘Health Care Error Proliferation Model’,[172] the ‘Prevention and Recovery Information System for Monitoring and Analysis’,[186] the’ Safety Evolution Erosion and Enhancement model’,[187] and the ‘Yorkshire Contributing Factors Framework’ (YCFF).[188] The YCFF is of particular interest because it is the only adaptation that has been developed from a systematic review of the empirical evidence about contributory factors to safety incidents in the hospital setting.[188] The YCFF developers closely aligned their investigation and resulting framework based on Reason’s Swiss cheese model[167] and Vincent’s London Protocol,[184] thereby ensuring the theoretical consistency of the YCFF.

4.3.3.1 The Yorkshire Contributing Factors Framework

The YCFF represents a hierarchically ordered framework that describes contributory factors to safety incidents in the hospital setting from proximal (sharp end) to distal (latent) points. The domains containing the contributory factors are depicted as “a series of concentric circles, with active failures at the centre and external policy context as the outer circle. This helps to illustrate the extent to which a domain is proximal to the active failure" (Lawton 2012 p.376) (Appendix 3).[188] Some of the contributory factors include the external policy context, communication systems, safety culture, the physical environment, policies and procedures, management of staff and staff workload, lines of responsibility, team factors, task characteristics, patient factors and active failures.

Although this is one of the most comprehensive and theory-derived contributory factors framework published in the literature, there are some limitations to its development and application. Lawton et al. (2012) state that most of the empirical evidence on which the framework is based originated from a focus on active failures or more proximal factors such as knowledge and experience of the health care professionals, communication, and equipment and supplies; few studies described more latent conditions or system failures that contributed to safety incidents.[188] Lawton et al. (2012) recognise other limitations of the framework, including that not all possible contributory factors were captured in this framework. An additional limitation is that the YCFF does not encompass a patient's perspective on the causes of safety incidents, as these were lacking in many of the primary studies included in the systematic review.[188]

The YCFF is intended to be used for several purposes, such as during root cause analysis of patient safety incidents, during data collection needed to redesign of services or systems, or to assist with guiding and developing risk management strategies for clinicians or managers to proactively identify poor safety performance.[188] The latter example of the YCFF application has been achieved through the development of a measurement tool called the

Patient Measure of Safety (PMOS). The PMOS is a tool for patients to report on the local and organisational factors that impact on their hospital care.[111]

The PMOS tool was developed by the same research team that was responsible for creating the YCFF. The PMOS provides a way of systematically assessing the factors which contribute to safety in the hospital setting from a patient's perspective. The intention of the PMOS is to support clinicians and organisations to make service improvements based on patient feedback and to involve the patient in harm reduction.[111] The patient feedback provides insight into potential interventions that staff and organisations can undertake to improve safety. Researchers facilitate meetings with staff who develop intervention ideas based on patient feedback obtained on the PMOS. The PMOS has undergone validation testing[114] and has been evaluated for its effectiveness as a tool for improving safety as part of a large randomised controlled trial – the 'Patient Reporting and Action for a Safe Environment' (PRASE) intervention across 32 hospital wards in England.[189] The PRASE intervention has shown good feasibility and acceptability results among patients and hospital staff,[190] as well as high intervention retention and uptake on wards;[191] however, no significant improvements in safety outcomes were found.[191] The authors propose that while uptake and completion of the PMOS was high, adherence to the interventions to address safety problems identified through PMOS undertaken by staff were poor and the safety outcome measurements were considered too blunt to obtain significant findings.[192]

A methodological limitation of the development of the PMOS was that it was based on domains contained from the YCFF, which does not include evidence directly concerning patients' views of contributing factors to safety incidents. The patient view is important because the patient is at the heart of the health care system. In 1935 Henderson described patients and caregivers as part of the same social and medical system.[193] This viewpoint has been remained a central feature when considering how health care is enacted, particularly through Paul Batalden's conceptualisation of the clinical microsystem and more recent work on coproduction of healthcare,[90, 194] and through Don Berwick's call for patient partnership as a result of his inquiry and review of the NHS.[79] Consideration of the patient in the health care system is further explored in the next section of this chapter.

4.4 The patient in the health care system

Historically, the patient was viewed as a passive receiver of care within the patient–provider relationship where the doctor held power or a dominant position over the patient. This power dynamic was mostly influenced by the growing ability of medical professionals to diagnose and treat disease. Disease and illness was often perceived by professionals as 'other' or 'separate' from the patient, thereby "removing illness as experienced by the patient from the centre of the medical stage" (Reiser 1993 p.1013).[195] The patient experience and view was minimal until the 1950s, when advancements in life-saving medical technology stimulated the medical community to reflect upon their ethics and ways of practice.[195]

During the 1960s and 1970s there was a shift towards greater equality and a change in the power dynamic within this doctor–patient relationship.[196, 197] This period, often described as the 'patient movement', was also a product of the 'consumerism' social movement (described in more detail in the next section), which was becoming more prevalent in developed nations such as the US, UK and Australia, and which ultimately then led to a greater focus on 'patient-centred care'.[197-201]

The patient movement has been linked to the restructuring and institutionalising of political, economic and social services that shifted public perspectives, values and beliefs on what constituted quality health care.[197, 198] Public attention and concern was drawn to the most vulnerable people in the community—the elderly, those with disabilities, mental illness, or chronic conditions. A focus on civil and human rights flowed over to patient rights, where issues such as patient consent and information provision became more prominent.[195]

The patient movement was also influenced by advocacy or patient groups who “challenged governments, organisations and institutions traditional ideologies of health care delivery in order to support individuals’ autonomy and emancipate themselves from the repression, coercion or harms related to power differentials between patients and doctors” (Williamson, 2010 p.40).[198]

Alongside the civil rights movement in the 1960s and 1970s, the consumerist movement was also gaining momentum and contributing to changing health care. Consumerism views health care as a product or service that could be sold to patients who are purchasers or consumers of the health product. Consequently, consumers' rights, wishes, needs, complaints, satisfactions, and dissatisfactions were considered through a shared perspective approach leading to better reported quality health care interactions and patient–practitioner relationships.[197, 201] Thus, consumers have been considered to be optimistic, empowered, informed, responsible, rational, and pro-active in their health care.[197, 201] Yet there have been reported shortcomings in the benefits of these new-found roles for patients.[202, 203] These include obligation and pressure to become an informed consumer, gaps in knowledge and ability to understand complex medical information, and increased burden from responsibility and accountability during decision-making processes.[203]

Patient-centred care is considered as a product of the patient movement and consumerism. Patient-centred care evolved during the 1960s and 1970s when the biomedical model of health was reconceptualised and advanced to view sickness and disease as encompassing more than just a clinical, diagnostic and curative approach.[204, 205] During this time the 'biopsychosocial' perspective, the 'patient-as-person' and 'doctor-as-person', the 'therapeutic alliance', and 'sharing power and responsibility' were the five key dimensions that contributed to the development of patient-centred care.[204]

Enhancing equality and access to care were the primary drivers for social change during this time. The relationship between doctors and patients became increasingly more important as the population was diversifying and getting older, and prevalence of chronic disease and medication reliance was growing.[199] The evolution of patient-centred care was impacted by the increase in medical lawsuits and hence the need for quality assessment and assurance that used patient perspectives of care.[206]

A by-product of creating care that was patient-centric was that patients then became more powerful, resourceful and knowledgeable. Patient engagement was seen as a way to ensure sustainability of the health system through reduced costs and improved health outcomes.[207] During the late 1980s and early 1990s patients were encouraged by health professionals, health organisations and private insurers to participate in self-help and self-management programs and to take care of their health or illness where appropriate.[208] Promotion of lifestyle modification was in response to the growing burden of chronic disease and empowering patients with problem solving skills and goal setting abilities was considered more successful than simply telling patients what to do.[209] The media and development of the internet was also very influential during this time, which increased community access to medical information and popularised health and wellbeing.[208] This shift in power and refocused mission of health systems has resulted in some considering patient engagement and partnership to be the 'blockbuster drug' of the century.[210] Furthermore, terms such as 'patient involvement', 'patient participation', and 'patient engagement', 'patient activation', 'public and citizen engagement, 'patient and public involvement' have been increasingly cited in the literature.[211, 212]

Patient engagement has been used synonymously as an umbrella term for all the activity coined as 'patient involvement', 'patient participation' and the like, but consensus on what these terms actually mean for policy and practice has been neglected. Theoretical and empirical understanding of concepts associated with 'patient engagement' is therefore varied and multifaceted, with no one universal definition being available.[213, 214]

Nonetheless, there are postulated theories, such as Arnstein's (1969) ladder of citizen participation, that have been applied to various patient involvement frameworks in health care.[215] Most of these models for the health care setting range from paternalism, tokenistic approaches or patient exclusion, to mid-level patient involvement such as shared decision-making, and then to full patient partnership and co-design of services.[216] While this ladder is widely used, some have stated that such a static conceptualisation with the ultimate aim of citizen control may be flawed and lack the ability for more nuanced or context-specific goals of participation to be attained. Tritter and McCallum (2006) propose that participation should not only be focused on outcomes, but should also be interested in the processes that lead to user involvement.[217] They go further to say that different forms of participation, lower down the ladder, are as equally desired as citizen control in some settings, particularly health care. Additionally, emphasis should be placed on sustainability of participation and inclusiveness of hard-to-reach groups, rather than priorities of the majority who are more able to assert power at the citizen control end of the hierarchy.[217]

Carman et al. (2013) have attempted to overcome some of the limitations to Arnstein's model, described above, and have developed a multidimensional framework that outlines a continuum of patient and family engagement specific for health and health care.[161] In this model, engagement is said to occur at three different levels; during direct care, at the organisational design and governance level, and at the policymaking level. Patient engagement is also differentiated along a continuum from consultation (e.g. patient feedback), involvement (e.g. shared decision-making) and partnership (e.g. patient representation on committees). This engagement model also describes the various factors that influence how and why patients are able to engage at different levels and at different points along the continuum. These factors exist at the patient level (beliefs, health literacy, education), the organisation level (culture, policy and practice), and the societal level (social norms, regulations and policies). This framework highlights how interventions are designed to promote each level of engagement and how interventions can be improved or modified so that patient engagement is shifted from more paternalistic practices to a more collaborative approach, when appropriate.[161]

Over the last few decades, the concept of patient-centred care has been extensively discussed and researched, with contrasting evidence about its effectiveness on patient outcomes or quality of care.[195, 204, 218-221] There is also a lack of consensus on what characterises patient-centred care.[200, 222-224] The most widely used definition is the Picker Institute's proposed eight dimensions of patient-centred care which include; respect for patients' preferences and values; emotional support; physical comfort; information, communication and education; continuity and transition; coordination of care; the involvement of family and friends; and access to care.[225, 226] Most definitions encompass commonalities of respect for patient's needs, wants, preferences or values[222] and patient satisfaction with the health care practitioner interaction.[227]

More recently, co-production of health care services with patients has been proposed as a way of overcoming some of the limitations noted in previous patient involvement efforts such as patient-centred care, patient engagement and patient experience. Co-production with patients considers health care as a service rather than a product and, like most service industries, they are developed *with* the consumer rather than as a product *for* the consumer.[90] In the model of co-production proposed by Baltalden et al. (2015) patients and professionals interact as participants within a health care system as part of a wider society.[90] Patients and professionals both have agency to shape the health care system within the service, and also outside of the service through community and social activities. Relationships, communication and interaction are prominent components of the model to enable co-execution, co-planning, and civil discourse to co-produce high-value health care services. High-value services are those that provide good health outcomes and satisfaction for all (patients and professionals), are efficient, low in cost, functional, are safe and of high quality. While encouraging in theory, the co-production of health care services may also encounter limitations to its application. Some patients are not able to participate in co-production for various reasons, the responsibility for outcomes may be too burdensome on either patients, or health professionals, during the co-production process; patients and professionals may have different values and encounter difficulties in coming to a common goal; and a health professional culture resistant to change are all challenges to the implementation and effectiveness of co-production of health care services.[90]

4.4.1 The patient in the safety system

As discussed, the patient's role in the health care system has changed over time with more stakeholders acknowledging the need for patient involvement in all levels of the system. Varying models of patient participation have been developed, from more tokenistic practices through to co-production of services; nonetheless, specific theories or hypotheses about the patient's role in the safety system are relatively absent from the literature.[228] This kind of exploration or philosophical approach is different from the countless discussion papers, literature reviews, and editorials explaining how patients may be involved with safety improvement, the potential outcomes and benefits of such interventions, and the barriers for undertaking such practices.[74, 91, 92, 110, 229]

In 2012, Ocloo and Fulop initiated the discourse about the "atheoretical nature of much of the literature on patient and public involvement in patient safety" (p.425).[228] They base their arguments for a theoretical exploration of patient involvement in safety on issues of empowerment for service users observed more broadly in the public sector. Ocloo and Fulop (2012) articulate a critical approach for understanding the contested nature of involvement and propose some key ingredients necessary for patient and public involvement (PPI) in safety.[228] These include recognition of the history and context of involvement, drawing on the values and theories that address empowerment of patients, applying differentiated approaches to involvement and challenging the barriers to involvement and/or supporting the involvement process.[228] The authors conclude that these key ingredients constitute a preliminary framework or theory for PPI in safety. The use of patient empowerment as a theory to try and construct some historical context and foundation to the PPI debate is novel; but the other contributory cultural, structural and organisational factors that are essential for any patient involvement in safety theory are absent.

A framework or theory that positions the patient within a safety system and considers the social, emotional, historical, cultural, physical, structural, and organisational contexts that influence patient involvement in safety is needed.[228, 230] This kind of theory could help to systematically address the factors that inhibit or support patient involvement, broaden the debate about patient involvement in safety, develop effective ways of measuring its impact, and embed patient involvement within the systems of safety in health care.[228]

Since there is no established theory that positions the patient within the safety system, this thesis will use adaptations of Reason's systems thinking in accident causation for the examination of patients' views of safety in primary care, and the exploration and development of patient feedback tools for safety improvement in primary care. Although systems thinking is a recommended and justified approach for safety improvement activity, there are some challenges in its application in health care.

4.5 Challenges of applying systems thinking in patient safety

Given the theoretical underpinnings and endorsement of a systems approach to safety in health care, one could question why this model has not been applied more widely or effectively to reduce patient safety incidents.

Firstly, health care is invariably different from other high-reliability organisations. Elwyn and Corrigan (2005 p.303) have said that "error in medicine is on a different scale from error tolerated elsewhere and has different consequences from error in other service sectors".[178]

Vincent (2010) stated that health care is essentially more diverse and has greater levels of uncertainty, unlike the aviation, military or nuclear power industry which are more predictable and routinised. Furthermore, health care is often organisationally fragmented and decentralised, often underfunded and under-resourced, and professionals are more autonomous when compared with other high-reliability industries.[42] Reason (2004) has also added that the health care environment is significantly different from other industries, particularly in the diversity of its equipment and operations, the rate of emergencies and, most importantly, the way the product is delivered.[231] Primary care is usually delivered on a one-to-one or few-to-one basis, unlike other hazardous industries; therefore, many of the defence layers that exist in ‘safe systems’ are removed or made redundant in these highly personal situations.[231] Nonetheless, this model of care is changing in various healthcare systems which now support a ‘many healthcare professionals to one patient’ model. It remains to be seen whether the defence layers in a health care team are effective in reducing errors compared with a one-to-one model.[232]

Secondly, and linked with the first point, the complexity evident in health care systems does not lend itself to linear approaches of accident investigation like Reason’s Swiss cheese model. Essentially, explanations or causes of incidents are shifted from the error-producing conditions (sharp end) to latent conditions (blunt end). Relocation of blame to the organisational end of the defence continuum has been argued as the ‘old view of human error’ by Dekker (2006),[233] and suffers from the same limitations as a human factors approach. The solutions for dealing with the problems at either end of the spectrum are just as problematic, complex, and inherently focused on understanding and fixing issues when they arise, and not concerned with what goes right and why.[187] Yet, in the absence of a model that helps to explain safety as a complex and dynamic process the linear approaches to accident investigation are likely to be endorsed and used. Future systems theory development will need to take the complexity of health care systems into consideration.

Thirdly, the health care industry continues to endorse accident investigation at the sharp end of care which focusses more on the individual rather than the system as a whole. There has been increased pressure from the wider society to place blame on individual clinicians when errors occur. This is demonstrated through the ease of litigation, and other forms of punishment. Individual accountability has taken prominence over a culture that should be just.[234] 'Blame and shame' attitudes have led medical professionals to avoid disclosing or even hiding mistakes from patients and management. This is done in fear of being subjected to significant public scrutiny, humiliation and hardship, loss of status in the workplace and medical community or criminal prosecution, or all of these factors.[172] Lack of education and awareness about a system view of safety among frontline staff and middle managers, the presence or absence of a just culture, demands for self-protection and organisational loyalty, and ease of accountability shifting have all reinforced the attribution of blame to single individuals.[234] Furthermore, current procedures for learning from safety incidents are retrospective, use hindsight, and are fraught with outcome bias due to the propensity for holding decision makers responsible for negative events beyond their control. These methods of enquiry are narrow in focus and often miss the wider factors contributing to the incident. These methods also provoke human responses which humanise the error and, consequently, humans are being attributed as primary causes for incidents occurring.[234]

While there are various challenges to adopting a systems approach to safety in health care, there have been some successful attempts to use an accident causation approach in the management and prevention of safety incidents. Most of these efforts have been implemented in developed countries and predominantly in hospital settings.[235, 236]

Patient safety in primary care lags behind that of secondary care regarding models, measurement and improvement interventions.[235, 237] The reasons for this marked difference between secondary and primary care are multifactorial and have been described in Chapter 2. Briefly, patient safety in primary care is emerging internationally[238] but the evidence and activity within the Australian context is particularly scarce. Furthermore, most of the approaches to safety are reactive and lack a systematic understanding or implementation of accident causation theory and prevention of safety incidents.

Taking into account the theoretical foundation of using a systems approach for accident investigation, and the current gap in utilisation of such a model in patient safety in primary care, this thesis will use Vincent's framework for analysing risk and safety in clinical medicine[170] (based on Reason's Swiss cheese model) and the YCFF[188] to build a contribution of new knowledge in this field.

Chapter 4 will use Vincent's framework for analysing risk and safety in clinical medicine to review the available literature concerning factors that contribute to safety incidents in primary care from the patient's point of view.

CHAPTER 5 - CRITICAL REVIEW OF EMPIRICAL EVIDENCE ON PATIENT VIEWS AND THEIR INVOLVEMENT IN PRIMARY CARE SAFETY

While chapters 1 to 3 have explored much of the literature regarding the emergence of safety in health care, the context of Australian primary care and current approaches to safety, and the theoretical foundation supporting systems thinking and patient safety, this chapter will review the empirical evidence on patient views and their involvement in primary care safety.

A review of the empirical evidence specifically concentrating on patients' self-reported types or error and/or harm, patients' views of factors contributing to safety incidents, and patients' perceptions of their involvement in primary care safety is required as this literature has not been considered in the previous chapters.

Importantly, review of the evidence contained in this chapter informs the basis of the thesis' main objectives which were to explore patient and carer views of safety in depth. A thorough examination of this literature will assist with establishing the significance of the research question and where a contribution to new knowledge could be made. The different methodologies apparent in the literature will also be critically evaluated so as to identify an appropriate approach for investigating the research question and objectives.

A structured approach was used to review the English literature. The international literature was searched using EBSCOHOST databases including CINAHL, Global Health, Health Source: nursing/academic edition, and MEDLINE complete; as well as Scopus. Search terms were derived from initial reading of the safety and quality literature and included 'patient', 'carer', 'consumer', 'client', 'safety', 'error', 'harm', 'adverse event', 'mistake', 'safety incident', ‘contributing factors’, ‘latent condition’, ‘error-producing condition’, ‘error causation’, ‘view’, ‘perspective’, ‘evaluation’, ‘experience’, ‘involvement’, ‘participation’, ‘engagement’, ‘primary care’, ‘primary health care’, ‘family practice’, ‘family medicine’, ‘general practice’.

Snowballing of reference lists and relevant papers from the grey literature were other methods of identifying evidence to include in the review.

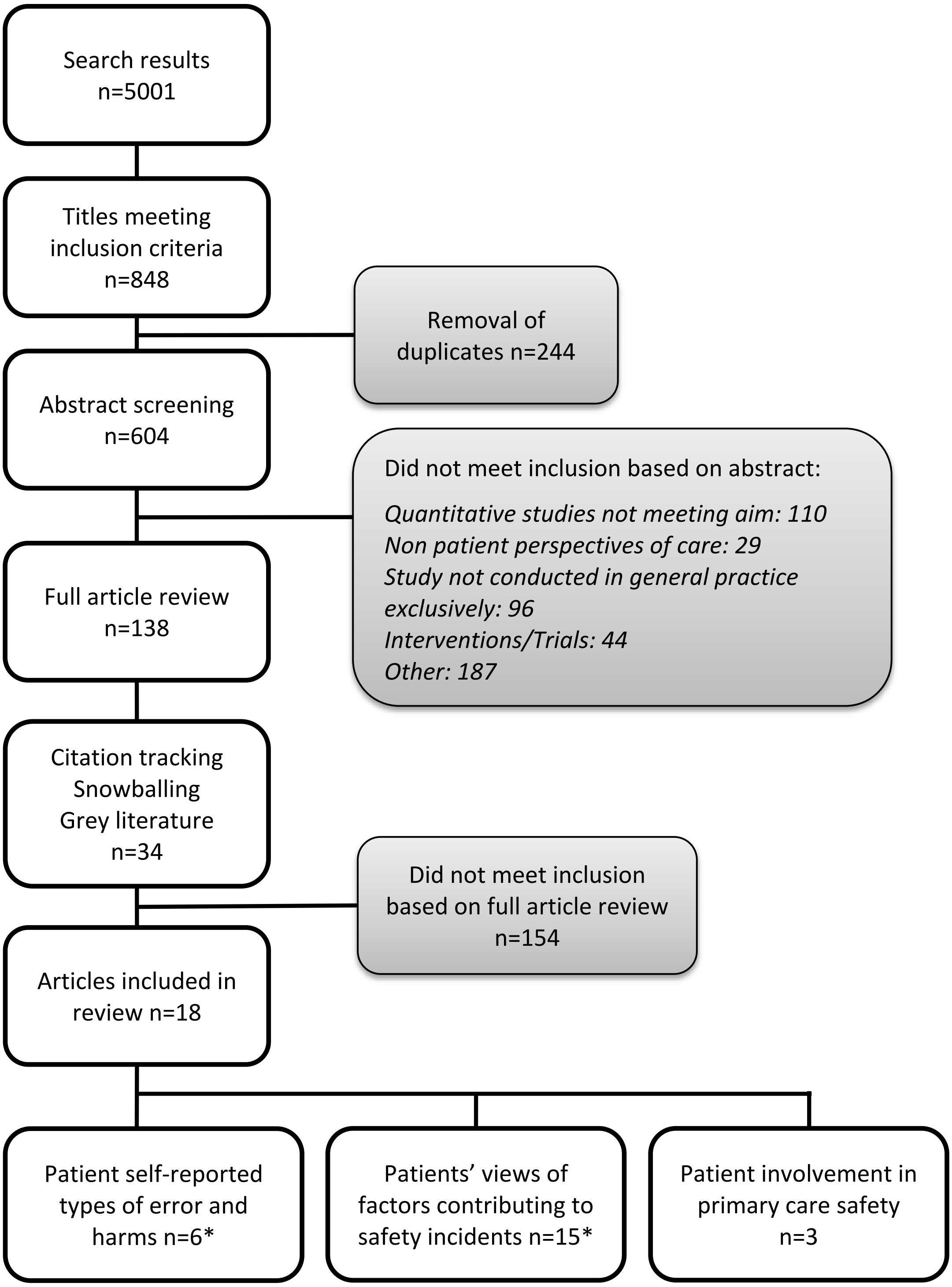
The inclusion criteria applied to the search were:

- Papers published between January 1990 and December 2015.[ii]
- Literature containing only patient or carer reports of safety. This excludes health professionals’ views of safety. Papers that analysed both patients’ and health professionals’ views of safety together were excluded. Papers that included separate reports of patients’ and health professionals’ views of safety were included.
- The setting of the studies had to occur exclusively within primary care. Patient views of safety in hospitals, specialist clinics, community health centres, outpatient clinics or unknown settings were excluded.
- The studies had to explicitly state in the aim that they were investigating safety in primary care and not concern aspects of quality of care.

The flow chart in Figure 5.1 illustrates the process of the literature review search and results.

[ii] While the formal literature review was conducted between these time points, additional relevant literature was identified and included for review in this chapter and the conclusion (Chapter 8) prior to submission of this thesis in July 2017.

Figure 5.1 Flow chart of literature review search and results



*Some papers contained patient reports for both ‘types of error and harm’ and ‘factors contributing to safety incidents’ in one paper.

The initial search obtained n=5001 papers which were narrowed down for relevance based on title and abstract screening, and full paper review. A total of 18 papers met the inclusion criteria were included in this review. A brief summary of the articles are presented in Table 5.1. The strengths and weakness of the included papers are critically reviewed in Appendix 4.

Table 5.1 Summary of the articles obtained in the literature review

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
Schoen et al. Toward Higher-Performance Health Systems: Adults' Health Care Experiences In Seven Countries, 2007[239]	Australia Canada Germany Netherlands New Zealand UK US	International telephone interview study with primary care patients.	11,910 adults from seven countries. AUS (1,009), CAN, (3,003), GER (1,407), NET (1,557), NZ (1,000), UK (1,434), US (2,500).	12%–20% of adults across seven countries experienced any medical, medication or laboratory test error in the previous two years.	Large international sample size. Comparisons between countries performed using appropriate statistical tests. Definition of primary care indirectly related to medical home. Findings not explained in detail in discussion.	YES	NO	NO
Panagioti et al. Patient-reported safety incidents in older patients with long-term conditions: a large cross-	England	Cross-sectional analysis of data from a longitudinal study with older patients with chronic conditions in primary care.	3378 primary care patients (33.6% response rate). 51.2% (n=1726) women. 98.5% (n=3309)	11% of patients (n=367) reported at least one type of safety incident. 8.5% (n=291) reported unavailability or inappropriateness of test results. 3.3% (n=102) reported being prescribed a wrong type or dose of medication.	Large sample size. Dichotomous reporting of safety incidents prevents other incidents to be expressed. Error rate not compared with objective measure.	YES	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
sectional study[240]			white. Mean age 74.5 years. Mean number of long-term conditions 5.6.	Four factors were significantly associated with patient-reported safety incidents; experience of multiple long-term conditions, diagnosis of depression, greater involvement and support, and greater relational continuity of care were associated with increased odds for patient reported safety incidents. Perceived greater support and involvement in self-management was associated with lower odds for patient-reported safety incidents.				
Mira et al. Patient report on information given, consultation time and safety in primary care [241]	Spain	Descriptive study. Telephone survey of random patients who attended 21 primary care health centres.	15,282 adults and children (response rate 79.6%)	17.6% of adults and 13.7% of children reported adverse or unexpected reactions to treatment. Consultation time, doctor rotation and information on treatment precautions were significantly associated with	Indirect questions about returning to doctor after unexpected event used to assess error rate rather than direct questioning on adverse events.	YES	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
				higher risk of adverse reactions to treatment.				
Kistler et al. Patient perceptions of mistakes in ambulatory care[242]	US	Mixed method study design. Cross-sectional survey with patients from 7 primary care practices. Telephone interview with patients who had experienced a medical mistake.	1697 adults (response rate 63.9%) responded to survey. 52 patients participated in an interview.	Medical mistakes were reported by 15.6% of patients. Wrong diagnosis was reported by 13.4% of patients with 47.7% of these patients reporting 'a lot' or 'severe' harm. Wrong treatment was reported by 12.5% of patients with 45.7% reporting 'a lot' or 'severe' harm. Three types of mistakes were categorised from the 52 interviews: communication/ relationship issues, normal diagnostic/treatment challenges, and possible adverse events/near misses. Patients with high levels of education; poor physical health; and chronic back pain had higher likelihood of	Opportunistic participant recruitment may have resulted in sampling bias of participants and overestimation of error rate. Error rate not compared with objective measure. Unexplained findings about level of harm and patient characteristics associated with ability to perceive mistake. Generalisability to populations outside US lacking.	YES	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
				perceiving mistakes. African-American patients were less likely to perceive mistakes. Age and sex were not associated with patients' ability to perceive mistakes.				
Solberg et al. Can patient safety be measured by surveys of patient experiences?[243]	US	Record review and patient cross-sectional survey. Mailed survey to patients from a large multidisciplinary practice.	1998 adults (response rate 65.1%)	Safety incidents were reported by 11% patients. Chart review showed that 2% (n = 5) of the 11% patient report incidents were a result of clinician error. Remaining patient-reported errors were categorised as medical or non-medical errors, misunderstandings, behaviour or communication problems, or unable to be classified. Harm from error was reported by 29.1% (n = 72) patients. Gender was unrelated to reports of errors, but women were more likely to report 'misunderstanding' errors. Reports for medical errors and	Objective record review of patient-reported error strengthens credibility of error rate obtained. Categorisation of error was self-derived and not based on evidence in the literature. Underestimation of error rate due to survey questions and potential response bias in staff coding. Findings related to associations	YES	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
				'behavioural or communication' problems increased with age until 60 years of age. Hispanic patients were more likely to report errors and 'behavioural or communication' problems. Dissatisfaction with care was associated with reporting errors.	between patient characteristics and ability to perceive error were not discussed or explained.			
Kuzel et al. Patient reports of preventable problems and harms in primary health care[244]	US	Qualitative interview study with random patients who received care from primary care physicians to develop a patient-focused typologies of medical errors and harm.	38 patients from rural, suburban and urban communities. Female (76%)	Patients described 221 problematic incidents (errors), of which there were 170 reported harms. Common incidents (errors) were clinician–patient relationship breakdowns (n = 82, 37%), access to clinicians (n = 63, 29%) and technical errors (misdiagnosis or adverse drug events, n = 54, 24%). Patient views of factors contributing to clinician–patient relationship breakdown were disrespect or insensitivity.	Qualitative design appropriate for research question. Study weaknesses include random sampling and recall bias of participants.	YES	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
				Factors contributing to access problems were difficulty in contacting the office, delays in obtaining appointments, and excessive waiting times. Self-reported harms were psychological or physical.				
Buetow et al. Approaches to reducing the most important patient errors in primary health-care: patient and professional perspectives[245]	New Zealand	Nominal group exercise to identify and rank importance of patient-related errors in primary care.	Eight patient groups from suburban community with low socio-economic status. Total 64 patients.	A wide selection of patient-related errors were identified and ranked according to the characteristics of each respective group. Action errors and mental errors were considered as equally important.	Uniqueness of findings is limited. Sampling bias may generalise results to specific patient groups only. Strength of study is the findings on importance of patient-related errors.	NO	YES	NO
Cunningham et al. Quality and safety issues highlighted by patients in the handling of laboratory test	Scotland	Qualitative focus group study with a purposive sample of patients from	19 participants took part in four focus groups. Patients were	Six main themes were identified from these data. Patients lacked awareness of the results-handling process, and of how results would be conveyed to them. Patients were concerned about the	The findings were sufficiently described and discussed. Purposive sampling may have biased results.	NO	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
results by general practices-a qualitative study[246]		four general practices.	sampled from practice lists of patients who received numerous laboratory tests due to chronic medical problems or identification of high-risk medicines.	appropriateness of administrators' involvement in the handling of test results and had concerns about confidentiality. Some patients believed a dedicated results staff would improve safety and effectiveness, and using technology like mobile phones and texting should be offered to patients.	Data analysis was not adequately described.			
Litchfield et al. Patient perspectives on test result communication in primary care: a qualitative study[247]	England	Qualitative focus group study with a purposive sample of patients from four general practices.	26 participants took part in six focus groups. Patients were recruited according to experience	Patients were able to identify system-type issues that contributed to frequent delays and inconsistency in both the level of information and the method of communication used to relay test results. Patients also discussed dissatisfaction with non-clinical staff relaying results,	New and unique themes about practice improvement for handing test results emerged. Limited transferability of findings due to	NO	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
			with receiving test results.	and provided recommendations for improvements in communication of the test result.	patient characteristics. Number of patients in half of focus groups < 3.			
Brown et al. Diagramming patients' views of root causes of adverse drug events in ambulatory care: An online tool for planning education and research[248]	US	Modified root cause analysis interview with primary care patients.	22 patients who had experience of taking three or more medications. Patients recruited through practices.	A total of 164 causes were ascribed to eight major pathways including patient non-adherence, patient and prescriber miscommunication, patient medication error, failure to read or understand medication label or instructions, polypharmacy, patient characteristics, patient and pharmacist miscommunication, and complications with self-medication. These contributory factors were used to create a causal diagram intended for improvement purposes by practice staff and researchers.	Data collection and analysis utilised evidence-based model. Patient sample may not be representative of wider population.	NO	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
Serper et al. What patients think doctors know: Beliefs about provider knowledge as barriers to safe medication use[249]	US	Structured interview study with primary care patients about their beliefs about provider knowledge of their medication regimen.	500 adult patients who were capable of participating in a structured interview.	There was large gap between what medicines patients were taking and whether their practitioner had knowledge about it. Patients' reported high levels of belief that their doctors knew all the medicines they were taking (between 85% and 91%). This is contrasted with the prevalence of medication review by a practitioner (51.3%) and discussion of medication side effects with physicians (42.9%). Associations between patient characteristics and beliefs about provider medication awareness and medication-related provider–patient communication were also found.	Large and random sample. No objective data source to confirm self-report findings.	NO	YES	NO
Rhodes et al. Trust, temporality and	England	Interviews with patients from 19 general	38 patients from varied socio-	Three main themes identified: trust and psychosocial aspects of professional–patient	Detailed findings authenticated with patient quotes and	NO	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
systems: how do patients understand patient safety in primary care? A qualitative study[102]		practices across the north of England about their perspectives of safety in primary care.	economic backgrounds. 24 women and 14 men.	relationships; choice, continuity, access, and the temporal underpinnings of safety; and organisational and systems-level tensions constraining safety	sociological literature. Transferability of findings limited due to specific UK primary care policies on access and continuity of care.			
Rhodes et al. Relationship continuity: when and why do primary care patients think it is safer?[103]	England	Interviews with patients from 19 general practices across the north of England about their perspectives of safety in primary care.	38 patients from varied socio-economic backgrounds. 24 women and 14 men.	Relationship continuity allowed the doctor to be a repository of information; develop specialist knowledge of patient's health and their consulting behaviour; provide holistic care; and foster trust. Relationship continuity also had risks such as a false sense of security and lack of a fresh perspective. Patients' need for relational continuity varied depending on the kind of health concerns, their perceived vulnerability, and perception of the doctor's knowledge and skill.	Detailed findings backed up with patient quotes and sociological literature. Transferability of findings limited due to specific UK primary care policies on access and continuity of care.	NO	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
Dowell et al. Urban outpatient views on quality and safety in primary care[250]	US	Three focus groups with 21 primary care patients to identify characteristics of high-quality care and characteristics associated with substandard care and errors.	21 urban patients from three primary care practices. 14 women and 17 men. Twelve patients were African-American, five Latino and four Caucasian. Mean age was 55 years.	Four main themes were identified. Systems Issues (44% of comments) included long waits for providers and lack of access. Understaffing, underfunding and lack of health insurance contributed to poor quality of care. Interpersonal Skills (37% of comments) included value placed on physician listening skills. Patient attitudes also affected care. Knowledge and Technical Skills (9% of comments). Errors (7% of comments) included medication errors, errors of inattention and technical errors.	Small sample limits transferability of findings. Content analysis used but not described in methods. Lack of in-depth exploration of themes and subthemes.	NO	YES	NO
Scobie et al. The medical home in Canada: Patient perceptions of	Canada	Telephone survey with primary care patients.	Canadian adults (n = 2997), 54.4% female, 32% aged 35–49 years.	Absence of a medical home was associated with medication errors, medical mistakes, test results not being available, having to undergo unnecessary or	Large sample size using standardised sampling and weighting methods. Variable for medical home was created	NO	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
quality and safety[251]				repeat tests, inability to obtain timely appointments or out-of-hours care, less coordination of care, and reduced patient–practitioner relationship.	using four indirect questions.			
Clark R, *Australian Patient Safety Survey*, PhD thesis, School of Health Sciences, Deakin University 2002.[132]	Australia	Telephone survey with randomly selected Australian patients.	1501 patients from mainly metropolitan areas across Australia.	Risk of adverse event was 7.4%, based on 9.7% prevalence of adverse events occurring in the previous 12 months. Adverse events were classified as medications errors, misdiagnosis or treatment error, or mistake occurring during a procedure. Factors contributing to safety incidents attributed to carelessness or negligence of the staff, staff being stressed, communication issues, staff incompetence, human error, misdiagnosis and inadequate staff training.	Only relevant Australian study obtained. Sampling from mainly metropolitan areas limits generalisability. Self-reported data is subject to over or under reporting of actual occurrence of adverse events. Findings are 10 years old and may not be applicable to current context of primary care.	YES	YES	NO

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
Flink et al. Beliefs and experiences can influence patient participation in handover between primary and secondary care—a qualitative study of patient perspectives[252]	Sweden	Semi-structured interviews.	23 patients with chronic diseases presenting to emergency department.	Two main themes; the experience of the patient's role in the handover process and what enabled their participation. Patients' experiences concerned with information exchange during handover and whether they were active or passive in this process. Enablers for participation were influenced by encounter-related factors, patient-related factors and organisation-related factors – such as provider's attitude and empathy, feelings of trust, and patient empowerment and preference.	Theory driven framework for analysis. Findings presented with detailed themes and associated patient accounts. Sample characteristics limit transferability of findings. Setting from one local area in Sweden limit applicability of findings to other contexts.	NO	NO	YES
Flink et al. The key actor: a qualitative study of patient participation in the handover	Netherlands, Spain, Poland, Italy and Sweden	Semi-structured interviews and focus groups with patients from 9 hospitals across five countries.	90 patients with chronic diseases who were discharged home after a recent	Three themes emerged: patient positioning in the handover process; prerequisites for patient participation and patient preferences for the handover process. Patients'	Recommendations for future research and practice implications are clear.	NO	NO	YES

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
process in Europe[253]			hospital admission.	participation ranged from being the key actor, to sharing responsibility with healthcare professional(s), to being passive participants.	Lack of detail about study population characteristics. Secondary analysis of data prevents validity checks. Translation of data into English was not back translated. Cross analysis between or within patient groups was not conducted.			
Rhodes et al. Sensemaking and the co-production of safety: a qualitative study of primary medical care patients[254]	England	Interviews with patients from 19 general practices across the north of England about their perspectives of safety in primary care.	38 patients from varied socio-economic backgrounds. 24 women and 14 men.	Patients' conceptualisation of safety were fluid, contingent, multi-dimensional, and negotiated. Participant accounts revealed the invisible and inaccessible architecture of safety, the importance of psycho-social as well as physical dimensions and the interactions between them, informal strategies for negotiating safety, and the	Use of theory and framework to conceptualise findings. Detailed findings authenticated with patient quotes and sociological literature. Transferability of findings limited due to specific UK	NO	NO	YES

Author/Title	Country/s	Method	Participant profile	Key findings	Assessment of rigour	Rates and types of error and harms	Factors contributing to safety incidents	Patient involvement in safety
				moral dimension of safety. Participants reported being proactive in taking action to protect themselves from potential harm.	primary care policies.			

5.1 Patient self-reported types of error and harms

There were six studies that investigated patient self-reported types of errors or harms experienced in the primary care setting.[239-244] Five studies provided the percentage of patients reporting errors or harms. This self-reported error rate ranged between 11% and 20%.[239-243] Five studies detailed patient self-reported types of errors or harms and are reviewed below.[239, 240, 242-244]

A large international telephone survey of adult primary care patients was conducted by the Commonwealth Fund and reported in the paper by Schoen et al. in 2007.[239] A total of 11,910 adults from seven countries (Australia, Canada, Germany, the Netherlands, New Zealand, the UK and the US) participated in the survey. This study provides responses to a range of survey questions focusing on the importance of having a medical home. Having a medical home was used as a proxy for primary care. The study provides comparisons between countries but mainly focuses on US findings. The survey asked a range of questions regarding experiences of medical, medication and laboratory result errors. In the past two years 12%–20% of adults across the seven countries reported experiencing medical, medication or laboratory test errors. Medication errors were defined as wrong or incorrect dose of medication and laboratory test error was defined as delays in notification and incorrect results. The lowest reported combined error rates were from Germany (12%) and the highest reported rates were from Australia and the US (20%). Medical, medication and laboratory errors were presented separately for the seven countries. Between 5% and 11% of survey participants reported that a medical mistake had occurred in their care in the past two years, and between 5% and 8% reported being given the wrong medication or wrong dose in the past two years. Australian participants reported the highest number of medical or medication mistakes compared with four of the six other countries (Canada, Germany, the Netherlands, United Kingdom; significantly different at $p < 0.05$ level). Of adults who had received blood tests, X-rays, or other tests in past two years, between 4% and 14% had experienced an error.[239] The findings from this study highlight the elevated number of self-reported medical or medication mistakes for Australian patients when compared with other developed countries. This makes the Australian patient population of particular interest when investigating their views of safety in this thesis as they self-report higher levels of incidents.

In 2017 Panagioti et al. undertook a study investigating patient-reported safety incidents in older patients with long-term conditions.[240] Cross-sectional analysis of data from a longitudinal English study was undertaken with older patients (≥65 years) who had at least one long term health condition. Questionnaires were used to collect data on patient demographics and self-reported patient safety incidents. A total of 3378 out of 12,989 invited patients returned data that could be used in the study. Of the 3378 patients, 11% (n=367) reported at least one type of safety incident. The types of safety incidents were comprised of four categories; unavailability of the results of medical tests (n=182, 5.18%), ordering unnecessary medical tests (n=109, 3.5%), given wrong type of medication (n=56, 1.8%), and given wrong dose of medication (n=46, 1.48%). The types of errors reported in this paper are limited to two types of errors; medical tests and errors in prescribing. This is a consequence of the patient questionnaire which only asked about these two types of errors with no option for other error types to be self-reported. Although the findings are restricted when attempting to meet the aims of this literature review and thesis which was to create a comprehensive understanding of the types of errors patients experience in primary care, they provide a starting point to build on in additional studies. This study also highlights the potential weaknesses of study designs that utilise dichotomous response options in surveys, and will be important when selecting the methodology for this thesis.

Patient reports of medical mistakes in primary care were published in a study by Kistler et al. in 2010.[242] The study was a mixed methods design firstly beginning with a cross-sectional survey with a relatively large sample (n = 1697) from seven diverse primary care practices the US. The survey was self-completed by patients and questions assessed patients' demographics, their health status, and four questions about their perceptions of the prevalence and severity of medical mistakes. The term 'medical mistakes' were used as a proxy for 'medical error'. Those patients who reported receiving a wrong diagnosis or wrong treatment participated in a subsequent telephone interview about their experiences. Medical mistakes were reported by 15.6% of patients, 13.4% of patients reported wrong diagnosis and 12.5% of patients reported wrong treatment. Of the 13.4% of patients who reported harm from wrong diagnoses, 41.7% (n = 92) reported suffering 'a lot' or 'severe' harm from the wrong diagnosis. Of the 12.5% of patients who reported wrong treatment, 45.7% (n = 95) reported suffering 'a lot' or 'severe' harm from the wrong treatment.[242] Like the Panagioti et al. (2017) paper, a small number of error types were reported, but the findings from this study are relevant to the thesis aims as it adds to the range of errors types being reporting. Furthermore, this provides information about the level of harm patients' experience, which is often lacking from literature concerning patient reports of safety incidents in primary care. Additional studies described below may help to address the limited number of error types reported in this paper.

A study undertaken by Solberg et al. (2008)[243] did not face the same limitations observed in the Kistler et al. (2010)[242] study as they compared patient reports of medical errors with chart audits conducted by nurses and physicians in primary care. A total of 1998 patients from a large multidisciplinary medical group in a metropolitan area in the US completed a survey on experience of medical error within the last 12 months. Participants were randomly sampled from a list of adult patients who had attended the practice in the preceding two weeks. Record review of patient reports of error were initially screened by a nurse and then reviewed by a primary care physician to categorise the type of error and determine severity of harm. Consensus processes were used when disagreement between reviewers arose. Possible or probable medical error cases were subsequently reviewed by the practice department chair. The number of error reports for primary care was 2.65 reports per 1,000 visits. After patient chart review 2% (n = 5) of the 247 patient report incidents were considered to be a result of clinician error. The remaining patient-reported errors were categorised as 'medical or non-medical errors' (19.4%), 'misunderstandings' (45%), 'behaviour or communication' problems (20%), and 13% of errors were unclassified during the chart review due to lack of information. Medical errors were defined using the IOM definitions of error and mainly included prescribing errors, delayed or missed diagnoses and inappropriate treatment. Non-medical errors included problems with insurance or billing, scheduling of appointments, wrong information, prescription and test result delays. Misunderstandings were defined as instances where the "medical record showed that the care appeared to be appropriate, even though the patient believed that the diagnosis or treatment actions were incorrect" (Solberg et al. 2008 pp. 269).[243] Behaviour and communication problems concerned waiting times, rudeness or inadequate explanations from clinicians or staff. Harm from error was reported by 29.1% (n = 72) of patients. Clinician review categorised these harms as physical harm in 43 cases (60%) and mental (mostly emotional distress) in the other 29 cases.[243] The patients from the Solberg et al. (2008) study identified a more comprehensive range of error types that further address the aims of the thesis. Misunderstandings and behavioural problems accounted for most of the safety incidents reported in this study which is different from wrong treatment, diagnosis errors, medical testing error and prescribing errors in the Kistler et al. (2010) and Panagioti et al. (2017) studies. This study also shows the differences between patient and practitioner views of safety and highlights the broad definition of safety that patients use when describing incidents. This broad definition of safety obtained in this paper is important to further explore with participants in the thesis research.

A study conducted by Kuzel et al. (2004) investigated patient reports of error and harm in primary care to create a typology of medical error and harm.[244] Thirty-eight patients from the US participated in qualitative interviews about preventable incidents in primary care that resulted in a perceived harm. Patients were randomly selected to participate in the study via telephone recruitment. Analysis of these data was undertaken using an editing style initially, then followed by use of consulting and reactor panels[iii] for validation of findings. The analysis resulted in a taxonomy of types of errors and subsequent harms. Patients described 221 problematic incidents (errors), in which there were 170 reported harms. Common incidents (errors) were clinician–patient relationship breakdowns (37%, n = 82), access to clinicians (29%, n = 63) and technical errors (misdiagnosis or adverse drug events; 24%, n = 54). Patient views of factors contributing to clinician–patient relationship breakdown were

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[iii] Reactor panels consisted of focus groups of 6 to10 patients each, recruited from urban, suburban, and rural communities to assess the ecological validity and authenticity of the analysis and findings. Ecological validity is the explicit and implicit norms and understanding shared by members of a community, and authenticity includes incorporating notions of fairness and a raised level of awareness.

disrespect or insensitivity. Factors contributing to access problems were difficulty in contacting the office, delays in obtaining appointments, and excessive waiting times. The most common types of self-reported harms were considered psychological harms (70%, n = 119) followed by physical and economic harms.[244] The findings from this study differ from what was found in the Kistler et al. (2010)[242] and Solberg et al. (2008)[243] studies regarding types of error and harm. Kuzel et al. (2004) found that psychological harm was more prevalent than physical harm and that errors were a consequence of the clinician–patient relationship and access to clinicians rather than technical errors such as adverse events.[244] This result may be attributed to the qualitative study design that may elicit more detailed and in-depth responses from patients compared with a survey. Considering emotional distress as harm to patients is a unique interpretation of the findings but this was validated through the use of expert external consulting and reactor panels. These findings are important to the aims of this thesis which were to obtain a thorough understanding of patients' views of safety. The addition of emotional distress as a type of harm, and relationships and access as types of errors are distinct and build on this broad view of safety that emerge from the Kistler et al. (2010) and Solberg et al. (2008) studies.

5.1.1 Summary of literature on patient self-reported types of error and harms

In summary, an emerging understanding of patients' views of errors and harms was prevalent in the studies. These included both known technical errors such as adverse events, and unique patient derived errors such as behavioural, or relationship errors. The issue of what patients consider an error and what practitioners and others consider an error is a recurring challenge observed in the studies reviewed. But given the limited number of studies (n=6) more research is needed to understand these differences in perceptions of safety in more detail. The next section of the literature review describes and evaluates studies concerning patients' views of factors that contribute to safety incidents in primary care.

5.2 Patients' views of factors contributing to safety incidents

The six studies mentioned above and nine additional papers were identified in the literature review that detailed patients' reports of factor(s) contributing to safety incidents in the primary care setting. The studies, or the themes presented in the studies, were categorised using Vincent's (1998) contributing factors to safety in health care framework.[170]

5.2.1 Patient-related factors

Patient-related factors that contribute to error have been investigated in a study by Buetow et al. (2010) conducted with primary care patients in New Zealand.[245] Eight patient groups (n = 64) from a suburban community with low socio-economic status participated in a nominal group exercise where they were asked to identify and rank five individual errors that they considered most important as a threat to patient safety. A wide selection of patient-related errors was identified and ranked according to the characteristics of each respective group. Action errors and mental errors were considered as equally important. For example, taciturnity was considered a barrier to safety by a men's group, a high-health literacy group, and an informal carers group, whereas teenagers, independent elders and a women's group classified lack of patient understanding, low literacy, carelessness, and expecting too much of themselves as barriers to safety. The Maori group stated different patient-related factors again, including mistakes in budgeting and sacrificing personal health interests to group cultural needs as threats to patient safety. Other patient-related factors in all other groups included untimely or under-attendance at primary care, mistakes in self-management, low self-confidence, and selfishness. These findings were then used for a secondary aim of the study, which was to develop approaches for reducing error in primary care.[245] The various patient related factors that influence safety are important when considering how patients can be involved in improving safety. Patient literacy levels, for example, can prevent engagement in error reducing interventions such as patient feedback to primary care practices which is an expected outcome of the thesis research.

Associations between patient-related factors and patients ability to perceive or experience safety incidents were conducted in three studies.

Panagioti et al. (2017) identified four factors that were significantly associated with patient-reported safety incidents. Factors associated with increased odds for patient-reported safety incidents were experience of multiple chronic conditions (OR=1.09, 95% CI 1.05 to 1.13), depression (OR=1.36, 95% CI 1.06 to 1.74), and greater relational continuity of care (OR=1.28, 95% CI 1.08 to 1.52). Lower odds for patient-reported safety incidents was associated with greater support and involvement in self-management (OR=0.95, 95% CI 0.93 to 0.97). Gender, age, education and health literacy were not associated with patient-reported safety incidents.

In addition to the main aim of the Kistler et al. (2010) study,[242] which was to determine the patients' self-reported rates of error, the authors also investigated associations between different patient-related factors and their ability to perceive a mistake in their care. They found patients with high levels of education, poor physical health, or chronic back pain had a higher likelihood of perceiving mistakes made by primary care providers, whereas African-American patients were less likely to perceive mistakes. Other patient characteristics such as age and sex were not associated with patients' ability to perceive mistakes made by primary care providers.[242]

Similarly, the Solberg et al. (2008) also investigated the patient-related factors that were associated with patients perceiving a mistake in their care, in addition to the main aim of the study which was to compare patient reports of medical errors with chart audits conducted by nurses and physicians in primary care.[243] They found that gender was unrelated to reports of errors generally, but women were more likely to report ‘misunderstanding’-type errors. Misunderstanding-type errors were classified as situations where the medical record showed that the care was appropriate but the patient believed the diagnosis or treatment actions were incorrect. Reports for medical errors and ‘behavioural or communication’ problems increased with age until 60 years of age. Hispanic patients were more likely to report any errors and ‘behavioural or communication’ problems. Dissatisfaction with care was also associated with reporting errors.[243]

The findings from the three studies demonstrate the variability of patient characteristics influence on perception of safety incidents. Different types of patients will understand safety in different ways, and this variability is important to capture and further investigate when analysing these data collected as part of this thesis research.

5.2.2 Task factors

5.2.2.1 Communicating and handling of test results

There were two papers from the literature review that concerned patients’ views of test result communication and handling in primary care. In a study undertaken by Cunningham et al. in 2014, 19 Scottish patients took part in four focus groups to discuss their experiences with the handling of test results in general practice.[246] Patients were purposively sampled according to the number of laboratory tests or high-risk medicines. Six main themes were identified from the patients’ view. These included patients’ lack of awareness of the results-handling process; patients not contacting the practice for results, patients’ concern about appropriateness and breaches of confidentiality of administration staff involved in results handling, patients preferring dedicated staff to handle test results, and patients approval of the use of technology to inform them about result availability and the ability to choose this option of communication.[246] Although a small study, the findings demonstrate that patients had intimate knowledge of the results-handling process and were able to provide a range of recommendations for practice improvement.

In another focus group study by Litchfield et al. (2015) 26 English patients were asked to describe their perspectives on the organisational and technological aspects of current and prospective systems for communicating laboratory test results in primary care.[247] Six focus groups were conducted with patients purposively recruited from four general practices located in Birmingham. Patients who had experience with receiving test results were invited to participate. Patients from this study were able to identify system-type issues that contributed to frequent delays and inconsistency in both the level of information and the method of communication used to relay test results. Similar to the study by Cunningham et al. (2014),[246] patients from this study also discussed dissatisfaction with non-clinical staff relaying results. Patient recommendations for improvements in communication of the test result centred on better access to GPs, development of protocols for communicating results, and better training for staff.[247] While some of the findings are similar to the Cunningham et al. (2014) study,[246] some new and unique themes emerged specifically around the improvements for practice where multiple options for action are suggested.

These two studies show that patients are able to comment on a range of potential task specific processes that can cause errors in primary care, such as test result communication.

This patient knowledge is essential to acquire in this thesis in order to further understand where potential patient involvement safety could be effective in reducing harm.

5.2.2.2 Prescribing

There were two studies obtained from the review that concerned patients' views of prescribing in primary care. The first study examined patients' views of the causes of ADEs and the second study investigated patients' beliefs about practitioner awareness of medication use and prevalence and type of medication counselling.

A modified root cause analysis was undertaken with 22 American primary care patients to determine the characteristics of the causes of ADEs in a study by Brown et al. (2006).[248] Patients who had experience with taking three or more medicines were selected for participation in the study. Patients were recruited through face-to-face contact, referrals from health care providers, prior interview subjects, and promotional material at primary care clinics. Patients were able to identify a wide range of causes of ADEs. A total of 164 causes were ascribed to eight major pathways, including patient non-adherence, miscommunication between patient and prescriber, patient medication error, failure to read or understand medication label or instructions, polypharmacy, patient characteristics, miscommunication between the patient and pharmacist, and complications with self-medication. These contributory factors were used to create a causal diagram to be used for improvement purposes by practice staff and researchers.[248] The diagram contains a comprehensive range of factors at both the error-producing and latent end of the spectrum and help to pinpoint where interventions could be addressed to prevent the occurrence of ADEs.

In the second study by Serper et al. (2013) a moderately large sample of patients (n = 500) from the US completed a structured interview about practitioner awareness of medication use and opportunities for counselling about medicines.[249] Participants self-reported a large gap between what medicines they were taking and whether their practitioner had knowledge about it. Patients reported high levels of belief that their doctors knew all the medicines they were taking due to the assumed integration of medical information, between 85% and 91% of the sample had these beliefs. This is contrasted with the self-reported prevalence of medication review by a practitioner (51.3%) and discussion of medication side effects with physicians (42.9%). Associations between patient characteristics and beliefs about provider medication awareness and medication-related provider–patient communication were also conducted. Women were more likely to believe their doctor knew about all medications prescribed by other physicians. Patients from the safety-net clinic (under- or uninsured patients) were less likely to believe their doctor knew of all the medications they were taking. Patients with low literacy and younger patients were less likely to report over-the-counter drugs, herbal supplements or vitamins to their doctor. Patients from the academic practices (insured patients) were more likely to report that their physician explained how to take medications or reviewed their medication list.[249]

As prescribing is a task that is known to be a source of error in primary care, patient's awareness about the contributory factors associated with this task, and their views about their physician's knowledge of their medications is important to explore further in this thesis.

5.2.3 Individual (staff) factors

5.2.3.1 Patient–practitioner relationship

In the Kuzel et al. (2004) study, breakdowns in the patient–provider relationship were the most common incidents (n = 82 out of n = 221 incidents) reported by patients during interviews about medical errors (see above for more information about the study methods, results and critique).[244] Relationship breakdowns were defined as deficiencies in patient-centred care. Disrespect and insensitivity accounted for (77%, n = 63) of the n = 82 relationship breakdown incidents. Moreover, the Kuzel et al. (2004) study also found harms from medical errors resulted in effects on the patient–provider relationship that including diminished trust and relationship with the clinician.[244] The finding that patients were more likely to report relationship breakdown as errors in care, rather than technical errors such as misdiagnosis or treatment errors, is new and different from what is commonly reported in the literature. The authors discussed the potential problems with loss in the patient–practitioner relationship as this aspect of care is a crucial part of the primary care interaction and for the safety of the care being delivered. Given the novel finding from this paper, the importance of the patient-practitioner relationship and its association as a contributing factor to errors in care requires further exploration with an Australian population in this thesis.

The authors from the Kistler et al. (2010) study categorised the types of mistakes identified by 52 interview participants.[242] One of these categories was ‘communication/relationship issues’, in addition to normal diagnostic/treatment challenges, and possible adverse events/near misses. Yet, the authors do not go on to explore this finding in the paper, indicating that relationship issues are difficult to define as errors in care. Like in the Kuzel et al. (2004) paper, the lack of consideration dedicated to this finding suggests further investigation is warranted. Patients' perspectives of safety in primary care were explored in interviews conducted by Rhodes et al. (2014, 2016) with 38 patients from England.[102, 103] The findings from this study were published in two separate papers. The study published in *Health Expectations* in 2016 identified three main themes from patients' accounts; trust and psychosocial aspects of professional–patient relationships; choice, continuity, access, and the temporal underpinnings of safety; and organisational and systems-level tensions constraining safety. Trust was identified as a mediating factor between safety and the patient–doctor relationship. Trust and 'feelings of safety' were determined from psychosocial aspects of care such as being taken seriously, being treated with dignity and respect, not rushed, disbelieved, dismissed, judged negatively, or patronised, and respecting patient privacy.[102] The other paper by Rhodes et al. published in the *British Journal of General Practice* in 2014 explored the finding of relationship continuity in more depth.[103] Patients described two differing perspectives of relationship continuity, one being psychosocial security and the other a false sense of security or lack of fresh perspective. The impact of this positive sense of security translated into actions of safety such as a central information source, ability to acquire specialist knowledge of a patient's condition, be familiar with the patient's consulting behaviour, provide holistic care, and foster the development of trust. A false sense of security translated into increased risk of initial failure to diagnose, or that a mistake in diagnosis or treatment would be perpetuated.[103] The need for relational continuity was varied and dependent on the patients' health concerns, their perceived vulnerability and their judgement of the doctor's knowledge and skill. Unlike the Kuzel et al. (2004) and Kistler et al. (2010) studies, the Rhodes et al. (2014, 2016) study extends the knowledge regarding the patient-provider relationship association with errors in care. Trust and provider continuity are unique findings that underpin a sense of safety for patients. These characteristics of the relationship are directly related to the aims of this thesis which were to understand patients' views of safety and how they develop a sense of safety in primary care.

5.2.3.2 Patient–practitioner communication

The interpersonal skills of doctors were a prominent theme (70/187 comments) in a focus group study undertaken with 21 primary care patients in the US.[250] Dowell et al.'s (2005) study aimed to identify the characteristics that patients believe contribute to high-quality care and the characteristics they associate with substandard care and errors. Good listening skills, positive attitude, knowledge of the patient, and attending to patients' complaints were considered valuable characteristics in a doctor. Education, partnering, goal-setting and encouragement were examples of communication between the patient and doctor that facilitated safe and high-quality care to occur. Patients also recognised their own interpersonal skills as impacting on the communication between doctor and patient. A positive attitude on the patient's part was believed to empower them and help shape their health care environments.[250] The list of communication characteristics in this paper is a basis for beginning to understand how communication can influence safety in primary care from the patient view. But, more evidence from the literature is required to gain a complete picture of this contributing factor to safety incidents.

Miscommunication between the doctor and patient was the most prominent theme identified in the Brown et al. (2006) study, which investigated patients' views of root causes of adverse drug events in primary care.[248] Miscommunication consisted of the patient not asking questions or providing information to the doctor, the patient being distracted when talking to the doctor, doctor does not give information or ask questions, or the doctor or patient differ in culture or language.[248] This paper satisfies some of the shortcomings of the Dowell et al. (2005) study and provides practice recommendations aimed at improving communication between the doctor and patient such as “address patients’ motives for withholding questions or information from the prescriber, and recognize the influence of psychological and environmental distractions on the patient (e.g., worry, fear, embarrassment; time constraints)” (Brown, 2006 p. 312).[248] Brown et al. (2006) also recommend intervention at the practitioner level such as “improving prescribers’ listening skills and providing a safe, open, shame-free environment will assist patients to disclose relevant information or ask questions during doctor visits” (Brown et al. 2006 pp. 313).[248]

Serper et al. (2013) examined the prevalence of patient-reported beliefs about medication-related provider–patient communication.[249] In a structured interview study, 46% of patients (n = 500) told their doctor about the Over the Counter (OTC) drugs they were currently taking, and 34.1% told their doctor about the herbal supplements or vitamins they were currently taking. There were 190 of the 500 patients studied who had received a new medication in the past three months. Of these 190 patients, 51.3% reported that a physician had reviewed their medication list, 77.4% reported that a physician explained how to take medicine, and 42.9% said that a physician described the side effects of the medicine. Pharmacist communication was also examined and of the 190 patients taking a new medication, 43.3% reported that the pharmacist explained how to take the medicine, and 25.8% reported that the pharmacist described the side effects of the medicine. Associations between patient characteristics and medication-related provider–patient communication were also conducted. Patients with low literacy and younger patients were less likely to report OTC drugs, herbal supplements or vitamins to their doctor. Patients from academic practices (insured patients) were more likely to report that their physician explained how to take medications or reviewed their medication list.[249] The authors suggest that the high frequency of missed communication opportunities between patients and physicians and pharmacist about medicines may result in serious and costly adverse outcomes. The findings linking certain patient characteristics with communication about medicines are of interest, and potential practice interventions to reduce adverse events need to be further explored in this thesis.

Rhodes et al. (2014, 2016) papers on patient–practitioner discussed communication in terms of trust, continuity of care and the psychosocial aspects of professional–patient relationships.[102, 103] Communication was seen as an important aspect of safety. Patients who were unwilling to be open about "treatment adherence, lifestyle, circumstances and concerns" due to fears about being treated negatively, received in a hostile manner, or dismissed, risked delayed or missed treatment opportunities (Rhodes 2016 p. 5).[102] Having a continuing relationship with the same GP allowed patients to feel safe and communicate honestly about sensitive topics. Feeling safe meant being confident that the GP would be responsive to their concerns, they would be given sufficient time, and treated with respect.[103] Viewing communication as part of the patient–practitioner relationship is similar to how the Kuzel et al. (2004) study conceptualised this contributory factor to safety.[244]

The Rhodes et al. (2014, 2016) studies were the only papers reviewed that sufficiently explained the patients' view of patient–provider communication as a contributory factor to safety.[102, 103] The previous studies listed the good or poor aspects of the physician that enabled or inhibited adequate communication, or conducted surveys about the types of communication that occurred during a consultation,[249, 250] but the Rhodes et al. (2014, 2016) studies elaborate in detail about why, when and how patient–practitioner communication influences safety in primary care.[102, 103] This is largely due to the qualitative study design which facilitates an in-depth exploration of patient views of safety. Such study design features will be considered and employed as part of the methods for data collection in the research undertaken as part of this thesis.

5.2.3.3 Practitioner knowledge and skills

Kuzel et al. (2004) studied patient reports of safety incidents in primary care, technical error accounted for 24% of the incidents reported.[244] The types of technical error varied widely and some examples included deficiency or failure in diagnosis, treatment or follow up; insufficient patient education; deficiency or incomplete medical history; deficiency or incomplete physical exam; wrong medication dosage; results of investigation not shared with patient; and incorrect injection technique. The small number of incidents categorised as technical errors, as compared with the large number of relationship and access breakdown incidents, demonstrates that patients are concerned with other safety aspects of care rather than the technical knowledge and skills of the practitioner.

In the Rhodes et al. (2014, 2016) studies there were particular contexts where technical skills were valued over interpersonal skills, and vice versa.[102, 103] These specific contexts were not further elaborated in the publications other than to state that patients discriminated between different GPs based on interpersonal skills. While patients may value a practitioner's technical skills depending on the context, they also noted that they had limited ability to make judgements on clinical competence. In these instances they used trust to mitigate their safety in general practice.

A small aspect of the Dowell et al. (2005) study on patients' views of safety investigated the knowledge and technical skills of physicians and other staff.[250] Knowledge and technical skill accounted for 9% of the total number of patient comments on safety. Examples of 'good' physician technical knowledge and skill included having knowledge of specialities and procedures, knowing patient histories and having accurate medical records. Examples of 'good' nurse or other staff technical knowledge and skill included taking careful blood pressure measurements, and being skilful at phlebotomy. Some of the patients indicated that they evaluate the skills of staff to a greater extent than staff realised.[250]

This finding from Dowell et al. (2005) contests what was found in the Kuzel et al. (2005)[244] and the Rhodes et al. (2014, 2016) studies[102, 103] and suggests patients are evaluating other safety aspects of care (such as access and the patient–practitioner relationship) rather than knowledge and skill of the practitioner, or have limited ability to make judgements on clinical competence. Postulations about patients understanding, appraisal and preference for providers' technical knowledge and skills requires further examination in this thesis to confirm or contest these mixed results found in the literature.

5.2.4 Team factors

Team factors comprised the written and oral communication between staff in primary care, and outside to specialist and secondary care, and the structure and supervision that occurs within the primary care team.[170]

Patients from the Cunningham et al. (2014) study described their lack of awareness of how the primary care team handled their test results, and the process associated with staff communicating these results to the patient.[246] Most patients received their results from administration staff. Some patients were surprised that administrators from the practice would alert patients about their results, while others agreed that administrator involvement in test result communication was effective and efficient. Patients from the Litchfield et al. (2015) study also described a lack of understanding of the results-handling systems used by primary care practices.[247] Both of these studies investigated one area where communication within the team and external to the practice contributes to patient safety, but patients did not have knowledge or understanding to adequately comment on this more latent factor.

There were no other team-related factors that patients identified in the remaining papers included in this review, suggesting that research in this thesis should target patients understanding of the more latent factors to safety incidents in primary care as this is a gap in the current literature.

5.2.5 Institutional context and organisational and management factors

In a qualitative study by Dowell et al. (2005) urban US patients were able to identify a range of system-level issues that impact on safety; these factors comprised 44% of patient comments.[250] Access to, and waiting times to be seen by, primary care practitioners were common system factors, along with acknowledgment of understaffing, underfunding and underinsurance issues. Inability to access care was associated with safety incidents such as near misses and psychological harm. Underinsurance and underfunding of resources were associated with delays in care and treatment.

In the Kuzel et al. (2004) study there were 63 out of 221 incidents of access breakdown that were associated with preventable harm to patients.[244] Inability to obtain an appointment, excessive waiting time, and delays in referrals to specialists were examples of the kinds of safety incidents patients described. These issues were not elaborated in the results or discussion sections of the paper, which make it difficult to adequately critique the usefulness of this information to the review.

In the study by Rhodes et al. (2016) published in *Health Expectations* patients recognised the contribution of organisational and system-level tensions that constrain safety.[102] Problems regarding access to care with a preferred GP, gatekeeping roles undertaken by primary care practitioners and funding problems were prominent themes emerging from patient experiences. Scheduling and allocation of appointment times were seen as a specific practice and policy problem the UK. The structure and rigidity patients described prevented individualisation of care at the patient level and was seen as a threat to safety. Threats to safety due to these system factors included lost test results, inaccurate prescriptions, or delays in diagnosis and treatment.

The proportion of patients' comments on system-level contributory factors to safety incidents in the three papers demonstrates that they exhibit a broad view of latent conditions in the environment. But, these system factors are directly related to patients' interaction with the system, such as access to care issues. These system-level factors will be examined with patients in in an Australian setting in this thesis to confirm or context these literature review findings with a different population group in a different primary care system.

5.2.5.1 Continuity of care

Organisation and management of the primary care practice to promote continuity of care is an important contributing factor to safety. Relationship or practice continuity was mentioned in a number of papers.[102, 103, 241, 251]

In a study by Scobie et al. (2009), Canadian patients' responses to the Commonwealth Fund survey on patient experiences of safety and quality in primary care were reported.[251] This study focused on presence of a medical home, which is a proxy for continuity of care. There were 2997 patients who provided responses to a series of questions related to access to care, coordination of care, frequency of errors, confidence in care, and patient–practitioner relationships. These variables were examined to identify if patient responses were associated with the presence of a medical home. Absence of a medical home was significantly associated with medication error (6.7% vs 4.7%, $p = 0.019$) or a medical mistake (8% vs 4.7%, $p = 0.019$). Absence of a medical home was also associated with test results not being available (14.4% vs 8.1%, $p = 0.01$) or having to undergo unnecessary or repeat tests (7.2% vs 2.7%, $p < 0.01$). Ability to access care out of hours easily and ability to obtain an appointment on the same day were significantly associated with presence of a medical home (11.2% vs 5.1%, $p < 0.01$, and 26.5% vs 18.1%, $p < 0.01$, respectively). Patients with a medical home were significantly more likely to report greater coordination between hospital and primary care, and that their primary care doctor received information after being discharged (13.2% vs 9.4%, $p = 0.13$, and 14.1% vs 7.0%, $p < 0.01$, respectively). Having a doctor that explains things in a way that can be understood by patients, involving patients in treatment decisions, and spending enough time with patients were significantly associated with having a medical home (86.6% vs 50.0%, $p < 0.01$; 76.1% vs 38.4%, $p < 0.01$; and 74.2% vs 37.4%, $p < 0.01$, respectively).[251]

The Mira et al. (2010) study found that doctor rotation (a proxy for discontinuity of care) was significantly associated with treatment error (OR 2.04, 95% Confidence Interval (CI) 1.85 to 2.25, $p = 0.01$).[241]

The survey data obtained in both the Scobie et al. (2009) and Mira et al. (2010) studies provide a starting point to identify patient reports of continuity of care and if these reports are associated with error in care. Yet, patient perceptions of continuity of care as a latent contributory factor to safety incidents remain unknown and need further exploration with patients from an Australian setting.

5.2.6 Evidence from Australia

There was little published evidence from Australia that investigated primary care patients' self-reported types of errors and harms or the contributing factors to safety incidents.[255] The Australian studies that were identified through snowballing and grey literature sources were mostly concerned with patient satisfaction or quality aspects of care[135, 256] and did not explicitly state patients' views of safety, although these may have been assumed as a number of researchers, policymakers and health care professionals use the terms safety and quality interchangeably.

Only one study undertaken by Clark in 2002 has actively sought the patients' perspectives of safety in primary care.[132] A survey was administered to 1501 patients from predominantly metropolitan areas across Australia. A Computer Assisted Telephone Interviewing survey was used for data collection. The sample was based on a random selection of telephone numbers from the Australian White Pages directory with a response rate of 43%. The survey questions asked about patients' experiences of an adverse event, their perceptions and preferences for participation in medical decision-making, and their perceptions of risk in health care generally. Most questions were phrased to include both doctor and hospital experiences but some questions directly asked about experiences with primary care. The risk of an adverse event occurring at a primary care consultation was predicted to be 7.4%. This was based on the 9.7% prevalence of adverse events occurring in the previous 12 months. The types of adverse events that occurred were not differentiated between health care settings (hospital or general practice). These included medications errors, misdiagnosis or treatment error, or a mistake occurred during a procedure. The perceived factors that led to the experience of an adverse event by patients were also not differentiated between health care settings, but were attributed to carelessness or negligence of the staff, staff being stressed, communication issues, staff incompetence, human error, misdiagnosis and inadequate staff training. Length of time going to a regular GP was a predictor for experiencing an adverse event. Risk perception of different health care settings and their associations with patient characteristics were examined. Patient characteristics that were significantly correlated with higher safety perceptions of general practitioner clinics included being male, over the age of 55 years, being satisfied with the last medical encounter, and being informed of the risks and benefits of treatments by staff other than the GP. General practitioner clinics were also rated as being ‘moderately to very safe’ (5.5 on a 1 to 7 scale) when compared with hospital care and other risky settings and situations. The likelihood of encountering an adverse event in a general practitioner clinic was considered likely by 33.7% of patients, compared with 52% who considered an adverse event to be likely in hospital settings. Women were significantly more likely to consider encountering an adverse event in a general practice clinic and a hospital than men.[132]

Although this study provides relevant and valuable information, there are some limitations. These data are now over 10 years old and the sample was primarily from metropolitan areas. Moreover, many of the predictors of adverse events lack detail regarding patients’ views of latent and error-producing conditions in primary care that make it susceptible to safety incidents. They were mainly attributed to error producing conditions in the environment and not latent or system-level factors,[132] which is contrary to the evidence from hospital settings that suggests patients can identify a range of error-producing and latent factors contributing to safety incidents.[111, 114] Furthermore, the self-reported nature of the survey means that the results could be an over or under report of the actual occurrence of adverse events.

Due to the scarcity of recent and robust Australian studies investigating patients' views of safety in primary care, this thesis will attempt to address this gap in the literature.

5.2.7 Summary of literature on patient views of contributory factors to safety incidents

When using Vincent et al.'s (1998) Contributing Factors to Safety in Health Care Framework, the literature mainly focused on factors at the error-producing or visible end of the doctor–patient interaction, rather than the latent or upstream system or institutional context.[170] The error-producing factors identified in the papers included in this review included patient factors, task factors, individual (staff) factors and team factors. The work environment, organisational and management factors and the institutional context were the latent conditions that were only briefly touched on in the review studies.

Possible reasons for this finding include the study's specific aim to address a single error-producing factor (e.g. test result communication,[247] or the study's aim was very broad so both error-producing and latent contributory factors were only briefly discussed.[244, 248, 250, 251]) Additionally, the context of primary care usually consists of short visits involving one-to-one care, as opposed to lengthy hospital stays where latent environmental factors may be more observable by patients;[111, 257] or the trusting nature of the doctor–patient relationship may prevent patient awareness and understanding of potential error-producing and latent contributory factors to safety incidents.[102, 103]

Furthermore, the studies reviewed all note that patients' understandings of safety is diverse, and "one person's interpretation of what it means to be safe might be different from that of another and different in different contexts" (Rhodes et al. 2016 p. 10).[102] This variation between patients' perceptions of safety impacts on the nature of further research in this area and the effectiveness of interventions aimed at involving patients to improve safety in practice. The literature on patient involvement in primary care safety is reviewed in the following section.

5.3 Patient perceptions of their involvement in patient safety literature

Flink et al. (2012) published two separate papers investigating patient beliefs and experiences in the handover from primary to secondary care in Sweden.[252, 253] In the first study, Flink et al. (2012) conducted interviews with 23 patients with chronic diseases sampled from one emergency department.[252] Content analysis of these data revealed two main themes; the experience of the patient's role in the handover process and what enabled their participation. Patients' experiences were primarily concerned with information exchange during handover and whether they were active or passive in this process. Enablers for participation were influenced by encounter-related factors, patient-related factors and organisation-related factors – such as provider's attitude and empathy, feelings of trust, and patient empowerment and preference.[252]

The second paper by Flink et al. (2012) continues on from where the first paper finished. This study undertook a secondary analysis of patient experiences in the handover process with a larger sample of patients across nine hospitals from five European countries (Netherlands, Spain, Poland, Italy and Sweden).[253] Individual interviews and focus groups were conducted with 90 patients using a similar interview schedule to the first study.[252] These data were analysed using a grounded theory approach that resulted in three main themes and eight subthemes. The first theme describes the patient position in the handover process and is categorised by either the patient or the health professional operating as a key actor in the process, and sharing of responsibility for handover between the patient and health professional. The second theme details prerequisites for participation and includes particular patient actions, resources and discipline required for this patient role, and the particular enablers and barriers for participation. The third theme outlines patient preferences for handover being conducted by either the patient or the health professional. Communication, information transfer and past experience were factors that also influenced the patient experience and preference for handover between primary and secondary care.

The two papers by Flink et al. (2012) go some way towards exploring patient perceptions of involvement in safety.[252, 253] Patient involvement in the handover process is assumed to improve the quality of patient transitions and may reduce hospital readmissions. The methodological limitations regarding the sampling and analysis reduce the transferability of the findings and focus on one specific process of care. Further evidence is needed to understand patient perceptions of their involvement in safety in more general terms or during other processes of care.

Rhodes et al. (2016) investigated how patients make sense of safety and how they coproduce safety in primary care.[254] This paper follows on from this research team's previous work in the patient views of factors contributing to safety incidents section outlined earlier in this chapter. Accordingly, the sample characteristics and analysis methods are the same.[102, 103] In the narratives presented in this paper patients reflected on their experiences in primary care and conceptualised a sense of safety based on these experiences. Patients described their feelings of safety, instances when their safety was compromised, and what they did to enact their safety. Perceptions of involvement in safety were influenced by the patients' experiences, their assumed health literacy, their health status and context of the primary care practice. Proactive patients were usually frequent users of primary care and had greater awareness of risks due to greater exposure. These patients exhibited a range of skills and behaviours that protected their safety, including:

> checking prescriptions and communications between hospital and surgery; alerting unfamiliar health practitioners to specific risks, such as adverse reactions to specific medication; becoming knowledgeable about their own condition/s and vulnerabilities; finding out about different treatment options; challenging clinicians' decisions and practice procedures. (Rhodes et al. 2016 pp. 278)[254]

Patients also acknowledged the 'architecture' surrounding safety and their role in it. The architecture included the governance for safety and quality, such as guidelines and procedures for ensuring patient safety. They noted the limitations placed on them by their particular individual context, the practice context or the wider primary care policy context. These patient strategies for safety were informal and did not conform to formal safety structures or policies. Rhodes et al. (2016) conclude that patients acted only on things in the psychosocial domain they had experienced or were knowledgeable about and presumed that there were safety systems in place for aspects of care they did not know about. This presumption is a threat to safety and limits how patients can be more involved to protect their safety in primary care in the future.

5.3.1 Summary of literature on patient perceptions of their involvement in primary care safety

The three papers that examine patient perceptions of involvement in primary care safety provide some insights into patient views about specific risky processes of care[252, 253] and more general activities that occur in consultations.[254]

The literature review revealed that the area of patient involvement in primary care safety is a developing field with more research needed to accurately determine: the types of interventions that are effective in reducing harm, ways to overcome barriers to implementation of such interventions, and in what primary care contexts or circumstances these activities are occurring.[105]

This thesis will attempt to address the gap in literature by exploring practical and effective ways for patients to be involved in safety in Australian primary care.

5.4 Critical review of empirical evidence limitations

Although a formal systematic review was not performed, a structured approach was undertaken to review the literature. Use of the search term ‘safety’ or derivatives of safety such as error, harm, or mistake may have reduced the number of papers identified that referred to a safety issue or contributory factors for safety that did not use that particular terminology. As previously discussed, quality is often used as a proxy for safety and many researchers do not distinguish between the two concepts, with much of the available evidence indicating its primary aim as relating to quality of care. Additionally, factors contributing to safety terms such as ‘access’ ‘communication’ or ‘continuity of care’ were not used as specific search terms in this review. There could have been more studies uncovered if such terms were used, but several opinion pieces and grey literature articles[74,

[257] have noted the dearth of available evidence about patient safety in primary care and the scarcity of studies investigating patients' views of safety in primary care. There may have also been some studies published between the time of submission of this thesis and publication.

CHAPTER 6: OVERVIEW OF CHAPTERS 2-5

Chapters 2 to 5 have outlined gaps in knowledge concerning patients’ views of safety and their potential involvement in improving safety in Australian primary care.

Chapter 2 introduced the concept of safety in health care and identified the various challenges and uncertainties surrounding the need for capturing patient feedback on safety and how this can be used to improve practice. Chapter 3 described the particular approaches to safety in Australian primary care and showed that the primary care system, in its current fragmented state, does not allow for coordinated action or measurement of safety, particularly regarding patient involvement in safety. This chapter also revealed that the approach to safety in primary care is reactive rather than proactive, and lacks a systematic understanding or implementation of accident causation theory and prevention of safety incidents. Systems theory was elaborated in Chapter 4 and its application in primary care was noted as absent in practice. Chapter 5 critically appraised the research literature on patients’ views of safety and the interventions aimed at involving patient involvement in safety. This chapter concluded that there was little evidence that comprehensively described Australian patients’ views of safety in primary care or the factors that contribute to safety incidents in primary care.

There were three main findings from the literature review. Firstly, patient-self reported rates of safety incidents are higher than what has been published in record review and incident reporting studies.[22] Secondly, the findings about patients’ views of contributing factors to safety contrasts with the growing evidence for the hospital setting internationally[111, 257] and in Australia.[258, 259] Patient’s from hospital settings are able to identify a range of error producing and latent conditions in the environment which contribute to safety incidents whereas the findings from this literature review in primary care show that patient reports are mainly focused on factors at the error-producing or visible end of the doctor–patient interaction. Thirdly, evidence about patient perception of their involvement in patient safety in primary care is limited to a few studies and illustrates that patients undertake some self-protection practices and are aware of factors that could enhance or hinder their potential involvement in safety improvement, but generally patients have a reduced role in error reduction.

In summary, there is little research on patients' views safety generally, and the literature that is available lacks a theoretical framework which informs the aims, data collection, analysis and interpretation of findings. Furthermore, the methodology employed to capture patients' views of safety is mixed between basic surveys that yield little practical information to in depth explorations about a specific aspect of safety such as prescribing in primary care. While informative, these in-depth explorations often fail to provide a complete understanding of all the possible contributory factors to safety incidents or the numerous ways patients could be involved to prevent safety incidents in primary care.

The research undertaken in this thesis aims to address the gaps identified above in the literature.

The research undertaken in this thesis also aims to be of value to the Australian primary care system by adhering to the notion that patients are 'patients are sophisticated observers' of their care[250] and their perspectives can help primary care professionals, organisations and policy makers to reduce safety incidents in primary care.[257] It may also be able to inform the development and implementation of strategies to improve safety that are appropriate, practical and effective. Furthermore, research is needed to determine if patient involvement in safety in primary care can contribute to reducing safety incidents in primary care and what barriers and enablers exist to help or hinder this process.

CHAPTER 7. OVERVIEW OF THE METHODS AND RESULTS

7.1 Overview of methodological approaches used in this thesis

Safety issues have been said to be more amenable to investigation via qualitative methods.[230, 260] Curry, Nembhard & Bradley (2009) propose that qualitative methods can contribute to outcomes research and is particularly useful when trying to investigate complex phenomena that are difficult to measure quantitatively, generate data necessary for a comprehensive understanding of a problem, gain insights into potential causal mechanisms, develop rigorous quantitative measurement processes or instruments, or study special populations.[261] Both Kuzel et al. (2003)[262] and Lempp and Kingsley (2007)[263] have argued that qualitative methods are particularly useful when trying to obtain patients' accounts of adverse events and how quality of care could be improved. For these reasons qualitative methods underpinned the approach for data collection in this thesis.

7.1.1 Data collection methods – focus groups and interviews

The specific qualitative approaches are detailed in Chapters 8, 9 and 10. Briefly, focus group methods were employed in Phase 1 and 2. Focus groups were employed due to the exploratory nature of the research question. Focus groups were deemed flexible enough to attain general concepts that could be further refined and revised during future data collection. Focus groups were also well suited to the population group recruited into the study, as many patients and carers had not experienced a safety incident per se but could provide their perspectives on safety issues when other participants discussed their experience of an incident. The focus group interview schedule was broad and concentrated on patient and carer's experiences of care, and it was revised and reviewed after each focus group to probe particular safety points of interest.

Phase 2 data collection methods also utilised semi-structured interviews with patients and cares. The purpose of the interviews were to elicit a detailed and rich description of patients' experiences and to further pursue particular safety points of interest that surfaced in the focus groups and to confirm or contest these issues. The interview schedule was semi-structured and included more specific questions around experiences of safety incidents, how they could be prevented, and how patients could be involved in safety in primary care.

Phase 3 data collection methods utilised 'think aloud' methodology to conduct face validity testing of the PC PMOS tool. This method was selected because of its established effectiveness in eliciting information from patients and staff about their perspectives of the hospital version of the PMOS tool.[111] The 'think aloud' method involved asking participants (both patients and health professionals) to talk aloud about their thoughts and feelings as they read and decided how to respond to each question in the draft version of the PC PMOS questionnaire.[264, 265] Participants were also asked questions following the 'think aloud' process which included the perceived barriers to questionnaire completion, time taken to answer the questionnaire and questionnaire format.

7.1.2 Data analysis methods

Phase 1 and 2 employed narrative and thematic analysis techniques to the qualitative data collected from patients and carers. These analysis methods combined were used to explore and interpret the lived experience of the research participants.[266] Data collected from Phase 1 and 2 was transcribed verbatim and NVivo 10 (QSR International) was used to support the analysis.

Patient and carer transcripts were reviewed by two authors in both Phase 1 (AH & CW) and Phase 2 (AH & SG) and analysed using the constant comparative method to inductively generate a coding structure that outlined themes and subthemes. Discrepancies between researchers were resolved through discussion and constant comparison with these data. After the researchers reached consensus on the coding structure, the codes were applied to the entire set of focus group and interview data.

The Yorkshire Contributing Factors Framework (YCFF) was also used as a starting point for analysis and open inquiry during Phase 2 data analysis.[188] Data relating to participants' disclosure of particular errors or mistakes were not analysed. Only the data relating to factors influencing the particular safety incident were analysed. Other factors not represented in the YCFF and specifically related to safety in primary care were also captured in the patients' and carers' accounts. These were inductively generated from the data using in vivo and self-derived codes. The final coding structure was discussed among the research team until agreement was reached. These codes were then applied to the entire dataset. When several factors appeared in single quotes or patient stories, multiple factors were coded to these single quotes.

Phase 3 data analysis comprised a modified Delphi technique and nominal group technique to develop and reach consensus on questionnaire domains and items for the PC PMOS tool. The Delphi technique was chosen as it has been shown to be an effective method for gaining consensus and has been used successfully to develop quality indicators in primary care.[267] Modification of the Delphi technique included the addition of two round table discussions with panel members after rating and review rounds were completed. Modification was incorporated into the study design as discussion among panel members was required to generate different ideas about the subject matter and reduce group conformity which can influence the quality of findings. The social interaction during the round table discussions was thought to facilitate group acceptance and ownership of the results.[268]

The round table discussions applied a Nominal Group Technique (NGT)[269] approach to agree on the final domains and items to be included in the draft version of the questionnaire. NGT is a group process that usually involves sharing and discussion of reasons for the choices made by each group member.

The combination of two consensus methods has been advocated by contrast with a Delphi process that has preceded NGT for initial item generation.[270, 271]

7.1.3 Researcher reflexivity

In keeping with the best practice principles of undertaking qualitative data collection and analysis, researcher reflexivity was practiced throughout my candidature. Reflecting on the researcher’s position in the research process is important to ensure that interpretations of these data are clearly understood and acknowledged as resulting from a particular stance, frame or setting. My own reflective process is documented in Appendix 5.

7.2 Overview of the main results from this thesis investigation

Phase 1 (Chapter 8) aimed to explore the views of Australian primary care patients’ and carers’ regarding their experiences of primary care and particular focus on safety incidents and beliefs and attitudes towards safety. Focus groups with n=26 primary care patients’ and carers’ were conducted to obtain and broad and general understanding of safety which was then used to refine the enquiry in subsequent phases of the thesis. The main finding from Phase 1 was that patients had an assumed sense of safety in the primary care setting. This perception was mitigated by feelings of trust and the doctor–patient relationship and limited patients’ risk awareness and ability to comment directly on potential safety issues. The study presented in this chapter was published in the Medical Journal of Australia in 2014 and the text appears as it does in print.

Phase 2 (Chapter 9) aimed to identify the contributory factors to safety incidents in primary care from the patient and carer view. Data from Phase 1 and additional extensive semi-structured interviews with n=8 with primary care patients and carers were conducted to provide an in depth analysis of the contributing factors to safety incidents. This was the primary source of data used in the final study of this thesis. The main finding from Phase 2 was that patients were considered as a valuable source of information about contributing factors to safety incidents in primary care. Their insights and experiences helped to identify both error-producing and latent conditions in the primary care setting which may not have been identified through other methods of investigation. The study presented in this chapter was published in BMJ Quality & Safety in 2015 and the text appears as it does in print.

Phase 3 (Chapter 7) aimed to develop a patient feedback tool about contributing factors to safety incidents in primary care – the Primary Care Patient Measure of Safety (PC PMOS). A modified Delphi process was used to develop the domains and items contained in the tool. The PC PMOS also underwent face validity testing with patients and primary care professionals. The study presented in this chapter was published in BMJ Quality & Safety in 2015 and the text appears as it does in print. The PC PMOS tool is the main outcome of this thesis.

CHAPTER 8 – PHASE 1: PATIENTS' AND CARERS' PERCEPTIONS OF SAFETY IN RURAL GENERAL PRACTICE

Citation details:

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Co-author declarations confirming the nature of my involvement in this publication are detailed in Appendix 2.

8.1 Abstract

Objectives: To explore patients' and carers' experiences of rural general practice to identify their perceptions of safety of care.

Design, participants and setting: Four focus group interviews were conducted with 26 rural patients and carers in south-west Victoria between September and December 2012. Frequent users of general practice were recruited from local allied health self-management programs and a mothers' group. Focus groups were audio recorded, transcripts were independently analysed and interpreted using narrative methodologies.

Results: Participants who had experienced some level of harm were able to comment more extensively on safety aspects of care. Several key themes related to safety were identified from the analysis of all participant narratives. An assumed sense of safety in general practice was predominant, and was influenced by participants' level of risk awareness and trust in their GP. Additional unique themes included feelings of vulnerability, desire for an explanation and apology, a forgiving view of mistakes, and preference for GP interpersonal skills over competence.

Conclusions: This study revealed new insights into the factors that influence patients' and carers' perspectives of safety, and demonstrated the value of incorporating the patient voice into safety research. An assumed sense of safety due to a default position of trust, coupled with limited risk perception, directly contests the current literature on patient involvement in safety. Further exploration is required to determine how patients and carers can effectively engage in and assist with improving safety in general practice.

8.2 Introduction

Engaging with patients to gain an in-depth understanding of their preferences, beliefs, values and contexts facilitates delivery of safe, high-quality care.[273] Patient-centred care[225] and being responsive to patient needs and desires is an international concept that is well recognised in the patient safety and health care quality literature.[273]

The importance of obtaining patients' views about the health care they receive has been endorsed through the promotion of the Royal Australian College of General Practitioners standards.[133] For accreditation to the standards, practices must regularly use an approved patient feedback tool, and must have a process for receiving and managing patient complaints.[133] While such feedback enables comparisons at a health system level, it does not elucidate how patients think about safety and their involvement in health care. Qualitative methods can be used to uncover the complex, multifaceted issues concerning patients' views of safety and quality in health care.[260]

In Australia, there has been ample research on patient preferences regarding quality of care in general practice[256, 274-278] and what constitutes the major incidences and causes of harm in this setting.[26] Additionally, there has been some work on understanding what Australian patients know about problems and failures in health care,[258] and adverse event and incident disclosure.[259] A recent review found that only a small number of qualitative studies have been conducted with rural populations concerning quality of care, but none has focused on patient perceptions of safety in general practice.[255] It is important to understand rural patients' perspectives of safety, as they may have specific needs or different perspectives from urban populations.

With this in mind, we aimed to explore patients' and carers' experiences of rural general practice and to identify their perceptions of safety in this health care setting. We chose to conduct focus group interviews to gain a rich understanding of people's attitudes, beliefs and views about their lived health care experiences.[279]

8.3 Methods

We targeted rural and regional patients and carers from south-west Victoria who were frequent users of general practice, such as those with a chronic condition, on repeat medication, older people and mothers with children. These patients were believed to have more experience with general practice, and therefore to have greater insight into specific safety issues.

Participants were recruited through local community health or allied health organisations between August and November 2012. Recruitment sources comprised education and support group meetings for type 2 diabetes self-management, cardiac rehabilitation, group exercise and a mothers’ group. Individuals were provided with study material, and if they were interested, they self-selected into the study.

The Flinders University Social and Behavioural Research Ethics Committee granted ethics approval (project no.5667). Participants provided informed written consent and received a $50 shopping voucher for their time and travel expenses.

8.3.1 Focus group protocol

We conducted a series of focus group interviews between September and December 2012. They were recorded and transcribed verbatim. We administered a questionnaire to obtain basic demographic information before the start of each focus group.

A semi-structured focus group interview protocol was developed to gain a broad understanding of patients’ and carers’ experiences of care (Box 8.3.1.1).

Box 8.3.1.1 Focus group interview questions and prompts

The primary questions posed in the focus groups were:

1. Can you describe what is involved in a normal visit to your general practitioner?

Prompts: Ringing to make an appointment, arriving at the clinic, waiting time

2. Can you describe your relationship with your GP?

Follow-up question: What makes a good relationship?

Prompts: Communication, trust, information provision

3. What other staff do you come across at the GP clinic?

Prompts: Reception staff, practice nurse, practice manager.

4. Is there anything about the clinic that influences you wanting to go there?

Prompts: Car parking, disability access, cleanliness

5. What is most important to you about the care you receive at your GP clinic?

Prompts: Patient-centred care, patient involvement in care

6. If you could improve something about the care you receive, what would it be?

Follow-up question: What do you do when things go wrong?

Prompts: Awareness of safety issues, risk perception

This exploratory study required a flexible approach and the use of general concepts that could be further refined and revised during data collection. Questions were adapted and follow-up questions were asked to probe particular safety points of interest from previous focus groups, and to confirm or contest these issues.

Focus group data were analysed using a thematic and iterative approach to identify the safety issues evident in participants' narratives. Narrative analysis was used to explore and interpret the lived experience of individuals.[266]

Transcripts were reviewed by two authors (ALH and CW) and analysed using the constant comparative method to inductively generate a coding structure that outlined themes and subthemes. After the researchers reached consensus on the coding structure, the codes were applied to the entire set of interviews. NVivo 10 (QSR International) was used to support the analysis.

8.4 Results

During recruitment, 114 individuals were approached, with 32 providing consent. Twenty-six participants took part in one of four focus group interviews in the Victorian towns of Balmoral, Hamilton, Merino and Portland. Each group had three to 10 participants. Reasons for not participating in the focus groups included being too ill to attend, not able to attend at the specified time and date, loss of interest, and failing to attend. Box 8.4.1.1 shows participants' demographic characteristics.

Box 8.4.1.1 Demographic characteristics of the 26 focus group participants

Characteristic	
Women, no. (%)	14 (54%)
Pension card holder, no. (%)	18 (69%)
Health care card holder, no. (%)	15 (58%)
Married, no. (%)	16 (62%)
Secondary education (years 7–10), no. (%)	10 (38%)
Retired, no. (%)	15 (58%)
Repeat prescription, no. (%)	18 (69%)
Common health conditions, no. (%)	
High blood pressure	11 (42%)
High cholesterol	10 (38%)
Arthritis	10 (38%)
Mean age in years (SE); range	59 (3.8); range, 27–83
Mean number of health conditions (SE); range	3 (0.6); range, 0–14
Mean number of visits to general practitioner in previous year (SE)	12 (2.3); range, 3–50

SE = standard error

Participants who had experienced some level of harm were able to comment more extensively on safety aspects of care; however, themes related to safety were identified from the analysis of all participant narratives. Box 8.4.1.2 provides illustrative quotes associated with the key themes.

Box 8.4.1.2 Participant quotes associated with safety themes

Risk awareness

If I know I'm being looked after I feel safe. Like if I know, all right, they may not have all the answers but people are onto it … people are working together with me and then I feel safe. Whether it's like my current doctor who doesn't know anything much about my condition anyway, but he's working together with my cardiologist and they're working it out together and so I feel quite, far safer than I have in a very long time so. But not so with the hospital. That's a different thing. (37-year-old woman with a congenital chronic condition)

[Hospital acquired infections] are the things you see in the major hospitals that cause havoc. Where … what you end up with is worse than what you went in with. (83-year-old man with multiple chronic conditions)

Trust

The thing is … when you don't have confidence in a doctor either a) because of something they've done or b) because you don't know them, it makes life even that more difficult. (69-year-old man with multiple chronic conditions and a carer)

Conversation between two participants:

P1: You don't know I don't reckon … I'm just like "whatever" you know like I didn't want to be there so they kept coming and saying "oh we'll try this", and I'm like "yep whatever go for it", you know … (27-year-old mother)

P2: You trust, yeah. (28-year-old mother)

P1: … you just “OK”, you’re just in there, you know, emotional to say the least … you have no idea what’s about to happen … Well they’re doctors and they’re nurses and they’ve probably done it 100 times before, they all know. You just go with it, like that’s me and I’m one of those personalities to just say “yep, yep OK”. I just trust that they know what they’re doing.

Vulnerability

… [we] told her that his bowel habits had got worse, they changed, he wasn’t feeling that well and everything. And he said I wouldn’t mind a colonoscopy and she’s saying “you don’t need it, I’ll give you something else for your haemorrhoids”. After she finished we were getting ready to leave and he said “I’d really like a colonoscopy” and I can still see her sitting there, she was kinda half turned her back to us with the computer and she looked over like that [over shoulder] and she said “I cannot send you for a colonoscopy like that for haemorrhoids” … he felt really stupid for asking then … We did feel rather foolish the way she spoke with us … (64-year-old woman carer)

Conversation between two participants:

P1: You’re vulnerable. You’re vulnerable to them … (37-year-old woman with a congenital chronic condition)

P2: Yeah, yeah. (73-year-old man with multiple chronic conditions)

P1: And you’d prefer if they don’t abuse that …

P2: We’re pretty frail creatures, aren’t we, when it comes to sickness?

A forgiving view of mistakes

I felt that, ah, more should have been done when I went to doctor for a respiratory problem … Not a sign of sounding me or doing anything like that, but he was busy and as I was told he was having a bad day, and the phone had gone out and a few things like that. Well OK, he's only human. (83-year-old man with multiple chronic conditions)

Desire for explanation and apology

I'd prefer someone to say to me "look I've made a booboo", "yes you're right", "OK, we'll make sure that doesn't happen again". All over red rover. (73-year-old man with multiple chronic conditions)

Conversation between two participants:

P1: Like, I feel like you need an explanation and why everything went chaotic. I think they should explain this is what happened. They can't tell you at the time because it's all happening. (28-year-old mother)

P2: No, nobody was telling me anything. (35-year-old mother)

P1: But afterwards I think you definitely need a, your doctor should debrief you and say this is what is happening; this is why we did this and that.

Appreciation of general practitioner interpersonal skills over competence

… so I went to there and, um, this fella was a lovely fellow but he had no idea about five of the illnesses that I had suffered from. He had no idea about what medications I ought to take. He still doesn't figured out what the blood tests I get for the leukaemia, and um, so you know, that's where, but he is a lovely fellow, and I love going to him because we have a good chat … (70-year-old man with multiple chronic conditions)

P1 = participant 1. P2 = participant 2.

8.4.1 Risk awareness

Although not explicitly recruited with these criteria in mind, there were two types of participants —those who had experienced harm and those who had not. Harm was experienced in hospital care and general practice care, with the former being more common in the participants’ stories.

The severity and seriousness of the circumstances that led to hospitalisation and the errors that occurred during the hospital journey created a heightened sense of awareness for safety in the hospital. Compared with hospital care, perception of risk in the general practice setting was perceived differently by some participants. Continuity of care and trust in the doctor–patient relationship allayed perception of risk.

8.4.2 Trust

Participants spoke of the characteristics of GPs that contributed to a sense of trust, which included confidence in their clinical competence and having personal knowledge of the patient.

When participants had experienced harm in general practice, their trust was compromised to varying degrees. Some patients took action to rebuild this trust, while others ended their relationship with that GP and sought care elsewhere.

Participants who had not experienced harm relied heavily on their trust in provider. Some were forthcoming about their lack of knowledge or understanding of safety, and their limited ability to accurately identify when risks could occur. Experience and expertise of the GP were additional factors which promoted trust.

8.4.3 Vulnerability

Participants described feelings of vulnerability in their experiences of care. Many suffered from multiple chronic conditions and therefore considered themselves more at risk of harm, whether these were clinical or psychological harms. Reported clinical harms included misdiagnosis, delays in treatment, not adhering to standard care procedures, and medication errors. Psychological harms that some participants experienced included verbal abuse, name calling and other disrespectful or dehumanising behaviours or practices such as lack of eye contact, and dismissive, rude or aggressive interactions.

Even participants who had not experienced harm emphasised their need to be treated with respect as an individual by the GP, demonstrating a collective sense of vulnerability faced by the general population of patients.

The power dynamics between the patient and the doctor also contributed to patient vulnerability. When participants attempted to voice their real or perceived fears about their health conditions to their GP, power imbalances between patient and provider led to feelings of embarrassment and foolishness.

8.4.4 A forgiving view of mistakes

Some participants considered mistakes or errors in their care as “normal”. They expressed an understanding and sympathy towards the GP’s situation and considered mistakes as part of being human. Many viewed the GP as an ordinary person in their community, not “god-like” or omnipotent.

The familiarity and continuity of the doctor–patient relationship in general practice may have enhanced this forgiving view of mistakes, when compared with one-off and short encounters with health professionals in hospital settings. The sense of closeness experienced in a rural community may also account for the differential tolerance of hospital versus GP mistakes.

8.4.5 Desire for an explanation and apology

Participants lacked appreciation of the systemic nature of medical error, and as a result they placed responsibility for errors solely on the GP. In contrast with accountability for errors, participants described system barriers that prevented GPs or other health care professionals from apologising and acknowledging patient harm, including a medical culture fearful of litigation.

Nevertheless, they reported a need for an explanation of what went wrong and why, and they described apology as the most effective way for patients to recover and move on from an incident. Some participants described feelings of admiration for those clinicians who apologised to patients when errors occurred despite the perceived threats of litigation.

8.4.6 Appreciation of general practitioner interpersonal skills over competence

Some participants did not focus on the safety of their care, but rather the GP’s interpersonal skills. In these instances, participants appeared to value the interaction and relationship with their GP without seeming to question the GP’s clinical competence. A desire for a caring GP and other relational attributes were considered to be more important, and care was assumed to be safe.

8.5 Discussion

Our study aimed to identify patients’ perceptions of safety in general practice and explore the factors contributing to the development of these perceptions. Many of the participants had an assumed sense of safety in the rural general practice setting. Only those who had experienced harms were able to comment extensively on safety, and much of this concerned experience with or awareness of hospital safety issues. Those who had not experienced harm did not conceptualise it, and furthermore, when these participants were in a trusting relationship with their GP, they assumed that the care provided was safe.

These findings directly contest previous research, which found that patients who have experienced harms in hospital settings could accurately identify and report on safety incidents,[86, 87] and make recommendations on improvements to safety.[258] Even the general public have an awareness and understanding of safety in health care due to increased amount of research, media attention, and political interest in recent years.[9] However, much of this research has occurred in hospital settings and may not be applicable to the general practice setting, where issues of trust, vulnerability and preferences for interpersonal skills are prominent over safety.

Individual contribution at the beginning and throughout the focus group discussions was emphasised through the use of a skilled facilitator to minimise agreement bias. Interpretation bias was acknowledged and avoided through independent data review and analysis. Although there were only 26 participants, the issues raised reflected a diversity of views and experiences.

An assumed sense of safety is a concern, given that general practice is the first point of contact for most people seeking medical care, and its high volume of repeat interactions and frequency of adverse events.[32] In our study, risk perception in general practice was mediated by a variety of different factors. Trust was the most prominent factor, and it may mask the patient's ability to identify possible threats to safety and hence reduce risk awareness. Trust in the patient–provider relationship has been researched,[280] and has been used as a model to improve patient involvement in safety, with mixed results.[281, 282] The nature of general practice makes it amenable to the creation of trusting relationships between patients and doctors. However, patients reverting to a default position of trust when they believe they do not have sufficient knowledge or skills, or are not in a position to adequately comment on safety,[100] is problematic because patient awareness of and involvement in safety has been shown to improve clinical effectiveness, health outcomes and satisfaction with care.[283]

This study also revealed unique safety-related themes. Feelings of vulnerability have been reported by patients with chronic diseases.[284] Interaction and communication between the patient and the GP is important to reduce feelings of vulnerability and ensure that patients feel comfortable and confident with their GP. Effective communication during the consultation is the key to facilitating safe and high-quality care; however, there is no “one size fits all” approach, as patients’ preferences and desires for a style of interaction vary widely. Being flexible and adaptable to patients’ different communication needs has been recommended as a solution to the limitations of general communication guidelines.[285] Further, communication with patients extends to the disclosure of errors when they occur. Patients in our study and in others[286] expect an honest and timely apology where appropriate and explanation of what went wrong. While there is a code of conduct in Australia referring to open disclosure of medical errors, there are still gaps in compliance and patient satisfaction with this process.[259]

We found that only patients who had experienced harm were able to comment on safety issues, and safety was largely seen as a problem in secondary care. New insights into the factors that influence the development of safety perspectives have demonstrated the value of incorporating the patient voice into safety research. These findings contest current research on patient involvement in safety, and warrants further exploration.

8.6 Acknowledgements

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8.7 Competing interests

No relevant disclosures.

8.8 Overview of Phase 1 and link to Phase 2

The main finding from Phase 1 was that participants had an assumed sense of safety in the primary care setting. This perception limits their risk awareness and ability to comment directly on potential safety issues. Given that only those participants who had experienced harm were able to adequately comment on safety and ways to prevent error, finding potential ways that patients and carers can contribute prospectively to the safety discourse is needed. This also needs to take into account the issues identified in Phase 1 such as vulnerability, preference for relational aspects rather than competence, forgiveness and trust.

A potential approach to address the recommendations suggested from Phase One would be to explore if patients and carers' can identify factors can contribute to safety in primary care. This recommendation was also relates to the findings from the literature review, and the theoretical position of the thesis which was to apply a systems thinking approach towards the enquiry of safety in primary care.

As summarised at the end of the literature review there is little evidence in the primary care setting that describes factors that patients can identify which contribute to safety incidents. There is evidence from secondary care demonstrating that patients can identify a range of factors that contribute to safety incidents.[111] The Giles et al. (2012) study[111] used a contributory factors framework for analysis – the Yorkshire Contributory Factors Framework (YCFF). This framework is based on Reason's accident causation model and developed using empirical evidence from a systematic review.[188] Using the study from Giles et al. (2012) as a methodological example, the aim of Phase Two was to explore patient and carer identified factors which contribute to safety incidents in primary care.

Chapter 9 will describe how secondary analysis from data collected in Phase One and new data collected from interviews with patients, carers and consumers were used to categorise the error-producing and latent conditions in primary care that contribute to safety incidents from the patients' perspective. These findings are compared with the YCFF,[188] and the Giles et al. (2002) study[111] to identify unique contributory factors in primary care, as well as discuss the practical applications of the results.

CHAPTER 9 – PHASE 2: PATIENT AND CARER IDENTIFIED FACTORS WHICH CONTRIBUTE TO SAFETY INCIDENTS IN PRIMARY CARE: A QUALITATIVE STUDY

Citation details:

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Co-author declarations confirming the nature of my involvement in this publication are detailed in Appendix 2.

9.1 Abstract

Background: Patients can have an important role in reducing harm in primary-care settings. Learning from patient experience and feedback could improve patient safety. Evidence that captures patients' views of the various contributory factors to creating safe primary care is largely absent. The aim of this study was to address this evidence gap.

Methods: Four focus groups and eight semi structured interviews were conducted with 34 patients and carers from south-east Australia. Participants were asked to describe their experiences of primary care. Audio recordings were transcribed verbatim and specific factors that contribute to safety incidents were identified in the analysis using the Yorkshire Contributory Factors Framework (YCFF). Other factors emerging from the data were also ascertained and added to the analytical framework.

Results: Thirteen factors that contribute to safety incidents in primary care were ascertained. Five unique factors for the primary-care setting were discovered in conjunction

with eight factors present in the YCFF from hospital settings. The five unique primary care contributing factors to safety incidents represented a range of levels within the primary-care system from local working conditions to the upstream organisational level and the external policy context. The 13 factors included communication, access, patient factors, external policy context, dignity and respect, primary–secondary interface, continuity of care, task performance, task characteristics, time in the consultation, safety culture, team factors and the physical environment.

Discussion: Patient and carer feedback of this type could help primary-care professionals better understand and identify potential safety concerns and make appropriate service improvements. The comprehensive range of factors identified provides the groundwork for developing tools that systematically capture the multiple contributory factors to patient safety.

9.2 Introduction

Primary care is the first point of contact for most people entering the health system, and most patient journeys begin and end in primary care. While the level of harm is relatively low compared with secondary care, diagnostic or prescribing errors are predicted to occur in 1 in every 20 patients.[32, 288]

Given these predicted rates of error, it is crucial to find ways for patients to be involved in improving safety. Evidence has emerged suggesting patients and carers are willing and able to provide feedback on the safety of healthcare.[85, 111] Patients are uniquely placed to observe their care, treatment and physical environment throughout their journey in the health system. Patients' views and understandings of safety can also help to identify issues that staff or others may not recognise.[74]

Most of the research described above has been conducted in secondary-care settings. Furthermore, patient feedback about healthcare has mainly used complaint systems and patient satisfaction surveys of which the latter has been criticised for positive-reporting biases, lacking clarity of aims, non-standardisation and unreliability.[64, 65] In more recent times, patient feedback websites have been developed, such as NHS Choices, ‘iWantGreatCare’ and Patient Opinion (Patient Opinion available in the UK and Australia). While these websites are beneficial for patients, they often contain little information about safety, are secondary care focused and the quality of data is poor.[289, 290]

Little evidence exists in the primary care setting about patients’ views of safety. There is some literature that reports patient identified issues regarding their care,[291-294] but these studies have focused on patient concerns from a quality rather than safety perspective. One study undertaken by our research group indicated that patients have an assumed sense of safety, which was mediated by the trusting and the continual nature of the doctor–patient relationship. These factors impacted on patients’ and carers’ perceptions of overall risk in this setting.[272] We hypothesise that, regardless of an assumed sense of safety, patients and carers may still be able to identify environmental or organisational factors, which contribute to patient safety incidents in primary care. This has been shown to be the case in UK hospital settings where patients have been able to identify a range of factors that contribute to safety incidents.[111]

A greater understanding of the factors that contribute to creating safe healthcare environments is important for everyone, including patients, staff and policy makers to help prevent harm from occurring. This approach corresponds with a ‘system view’ of healthcare, which aims to ‘seek out and remove the error provoking properties (latent and error producing conditions) within healthcare systems'.[167] The latent conditions or blunt end factors are the organisational structure, management systems, workplace culture and the policies and procedures that affect how care is delivered. The error producing conditions or sharp end factors directly relate to the work environment and human performance more proximate to the error such as team (e.g., supervision, leadership, inter professional communication), task (e.g., use of protocols and guidelines) and individual factors (e.g., knowledge, skill, experience and attitude) and patient characteristics (e.g., complexity of health conditions, personality and communication ability).[167, 170]

In the absence of in-depth evidence about this research area, the aim of our study was to analyse data describing patients' and carers' experiences of Australian general practice to identify the factors that contribute to patient safety incidents in primary care. The contributory factors to safety incidents were defined as any patient and carer-reported latent or error-producing condition, which resulted in real or perceived harm that could have been prevented or avoided. The intention was to undertake a broad descriptive study of possible contributing factors to patient safety incidents in primary care so that more detailed studies could follow that fully explored this phenomenon in greater depth.

The Yorkshire Contributory Factors Framework (YCFF)[188] provided the framework for analysis (see Appendix 3). There are various models to conceptualise potential latent conditions that influence safety in healthcare systems, including Reason's accident causation model,[167] the London protocol[184] and Systems Engineering Initiative for Patient Safety (SEIPS).[185] The YCFF was selected as the authors considered this taxonomy of contributing factors to patient safety incidents to be both comprehensive and specific enough to address the aims of this study. Furthermore, the YCFF was theoretically originated from Reason's accident causation model of organisational safety that has been applied to various healthcare settings and contexts, including primary care.[167] The YCFF succinctly describes both the latent organisational failures and the error-producing conditions in which active failures occur, and is based on a systematic review of empirical evidence.

9.3 Methods

Rural and regional patients and carers from several communities of south-east Australia who were potentially frequent users of general practice were recruited into the study.

Rural and regional areas were classified according to the Australian Standard Geographical Classification Remoteness Index categories.[295] The communities in these rural and regional areas are diverse with some areas having a wide range of primary, secondary, allied and community health services, and others having limited access to any type of health service. The populations in the communities range from approximately 300 to 10 000 people.

Frequent users were considered as those with a chronic condition (ie, diabetes, cardiovascular disease, arthritis), on repeat medication, older people and mothers with children. These participants were likely to have more experience of general practice, and therefore to have greater insight into specific safety issues.

Study participants were recruited from education and support group meetings conducted at local primary care organisations such as type 2 diabetes self-management, cardiac rehabilitation, group exercise and a mothers’ group. Participants who were interested in the study first opted to take part in a focus group. Participants who could not attend a focus group were then asked to take part in a semi-structured interview.

Four focus groups and eight semi-structured interviews were conducted by ALH with patients and carers. Focus groups lasted approximately 90 min, and the semi-structured interviews ranged between 20 and 60 min in duration. Different participants took part in focus groups and interviews.

The focus groups were relatively homogenous in terms of patient characteristics, where possible. Naturally occurring groups such as mothers' groups and exercise groups took part in focus groups when appropriate. Other focus groups consisted mainly of patients and carers with various chronic disease profiles, and were of similar ages.

Focus groups were initially used to obtain a broad understanding of participants' experiences, as previous research demonstrated that many patients were not familiar with direct terms like 'patient safety', and this appeared to discourage participants from engaging in the research.[111] Focus groups were conducted until theme saturation was complete, and the subsequent semi-structured interviews were used to elicit a detailed and rich description of patients' experiences and to further pursue particular safety points of interest that surfaced in the focus groups and to confirm or contest these issues. This approach was used to support and sharpen the thematic summary obtained originally in focus groups.[296, 297]

Accordingly, the interview protocol was broad in nature and designed to focus on patient experience. Questions focused on describing normal visits, relationships with primary-care staff, values placed on care and patient involvement. These questions were further refined during data collection with addition of follow-up questions capturing patient identified factors contributing to safety incidents. The facilitator queried when participants disclosed particular harms they experienced. Questions included: what do you do when things go wrong? If you could improve something about the care you receive, what would it be? How do you think patients could be more involved or active in their care in the future?

All focus groups and semi-structured interviews were audio recorded and transcribed verbatim.

The YCFF was used as a starting point for analysis and open inquiry, apart from the active failures that appear at the centre of the framework.[188] Data relating to participants' disclosure of particular errors or mistakes were not analysed. Only the data relating to factors influencing the particular safety incident were analysed. Other factors not represented in the YCFF and specifically related to safety in primary care were also captured in the patients' and carers' accounts. These were inductively generated from the data using in vivo and self-derived codes. The final coding structure was discussed among the research team until agreement was reached. These codes were then applied to the entire dataset. When several factors appeared in single quotes or patient stories, multiple factors were coded to these single quotes. Analysis was independently performed by two researchers (ALH and SJG). Discrepancies between researchers were resolved through discussion and constant comparison with the data. NVivo 10 (QSR International) was used to support the analysis.

The factors resulting from the analysis were compared with a study on patient identified contributing factors to safety incidents in hospital settings,[111] which also used the YCFF framework.[188]

Flinders University Social and Behavioural Research Ethics Committee approved the study (project no. 5667). Participants provided informed written consent and received a AUD50 shopping voucher for their time and travel expenses.

9.4 Results

Forty-six individuals consented to participate, of which 26 participated in four focus groups and eight semi-structured interviews (Table 9.4.1.1). Reasons for not participating from those who had provided consent included illness, conflicting engagements, loss of interest and failing to attend.

Table 9.4.1.1 Participant demographic characteristics (n=34)

	n (%)
Female	19 (55.9)
Carer	7 (20.6)
Pension card holder	22 (64.7)
Healthcare card holder	17 (50)
Married	24 (70.6)
Secondary school education	15 (44.1)
Retired	19 (55.9)
Repeat prescriptions	24 (70.6)
Common health conditions	
High blood pressure	13 (38.2)
Arthritis	13 (38.2)
High cholesterol	11 (32.4)
Heart disease	10 (29.4)
	Mean (SE) Range
Age (years)	59 (3.1) 27–83 years
Number of health conditions	3 (0.5) 0–14 conditions
Number of GP visits per year	12 (1.8) 0–50 visits

Secondary school education: 7th–10th grade; approximate ages 12–16 years.

Pension card holder: card holders can access Australian Government health concessions and get help with the cost of living by reducing the cost of certain goods and services.

Healthcare card holder: provides help with the cost of prescription medicine under Pharmaceutical Benefits Scheme, Australian Government funded medical services and access to state, territory and local government concessions.

Thirteen patient and carer generated contributing factors to safety incidents were ascertained from the data. These are described in detail below. Eight factors were similar to the YCFF, and five were inductively generated from these data. In accordance with the YCFF, the external policy context, primary–secondary interface and the physical environment were considered to be the latent conditions, and access, patient factors, dignity and respect, continuity of care, task performance, task characteristics, time in the consultation and team factors were considered to be error producing conditions. Communication and safety culture were considered to be cross-cutting factors that were a feature of both the latent and error producing domains.

We have also compared these findings with a study on patient identified contributing factors to safety incidents in hospital settings, which also used the YCFF4 (Table 9.4.1.2).

Table 9.4.1.2 Thirteen primary care contributing factors to patient safety incidents and their relation to the YCFF and patient identified contributing factors to safety from a hospital setting

Thirteen contributing factors to patient safety incidents in primary care	Brief definition	Contributory factor in YCFF	Contributory identified by patients in hospital setting*	Unique to this study
1. Communication	Effectiveness of the exchange and sharing of information between primary-care staff and patients†	✓	✓	
2. Access	Ability to receive timely access to primary care			✓
3. Patient factors	Patient personality, preferences, health status, experience or other individual characteristic that influences safety	✓	✓	
4. External policy context	National primary-care system, structures and policies that impact on the delivery of care and resources available†			✓
5. Dignity and respect	Associated with patients feeling comfortable, in control and valued		✓	
6. Primary–secondary interface	The transition between primary and secondary care. Adequate communication and information sharing is necessary to prevent harm			✓
7. Continuity of care	Connection over time with the same primary-care professional			✓
8. Task performance	Skill and competence of primary-care professional when carrying out a task			✓
9. Task characteristics	Factors related to tasks that make patients vulnerable to error.† Patient identified examples include care coordination and information management, prescribing medication and decision making ability	✓		

10. Time in the consultation	Having enough time to undertake all necessary tasks during the consultation			✓
11. Safety culture	Primary care organisation’s values, beliefs and practices regarding the management of safety and learning from error†	✓		
12. Team factors	Any factor related to the working of different professionals within a group, which they may be able to change to improve patient safety†	✓	✓	
13. Physical environment	Features of the physical environment that help or hinder safe practice†	✓	✓	

**Patient identified factors that contribute to safety in a hospital setting based on the YCFF.*[111] *†Definition adapted from or consistent with the YCFF. YCFF: Yorkshire Contributory Factors Framework.*[188]

There are 19 contributing factors to safety incidents in the YCFF. The factors in the YCFF, not identified in this study, included equipment and supplies, design of equipment and supplies, individual factors, lines of responsibility, management of staff and staffing levels, policy and procedures, scheduling and bed management, staff workload, supervision and leadership, support from central functions and training and education.

Table 9.4.1.3 outlines the potential harm associated with the contributing factors and an illustrative quote from the participants. The factors were listed in descending order from most frequently mentioned to least frequently mentioned.

Table 9.4.1.3 Patient identified factors contributing to patient safety incidents in primary care

Patient identified factor contributing to safety incidents	Potential outcome (type of harm)	Illustrative verbatim quote
Communication	Delay in diagnosis and treatment Psychological harm (upset, belittled) Physical harm (pain and suffering)	I found that after 10 years with the same GP that I was being yelled at […] I […] don't need that […] and it was because doctors didn't listen to me recently that I … had to have eleven hours of surgery and I kept saying, and they said 'nah it's all in your head' … so the specialists in Melbourne in the end said I suffered a lot longer than I needed to because GPs didn't listen. (37 year old woman with a congenital chronic condition)
Access	Delay in treatment Physical harm (pain and suffering) Psychological harm (stress and anxiety)	It's all very well to say you can see your doctor when you want to; you can't. My wife has dementia which is exacerbated by urinary tract infections. It gets exacerbated dramatically and … traumatically … I couldn't see a doctor to get antibiotics for her for three days […] So to not have a doctor available for three days […] [in case of emergency or urgent care] is ridiculous. (69-year-old man carer with multiple chronic conditions)
Patient factors	Inadequate time with GP Delay in diagnosis and treatment Psychological harm (fear, vulnerability)	You know, I can go in there and say … 'look how much time have you got?', 'well 5 minutes', I say 'well I can't do it in 5 minutes so we're wasting each other's time, so don't charge me', and walk out again. I can do that. Other people can't. Other people are so dependent […] they're frightened. People are frightened to think that if they do speak up their treatment is going to be substandard. It's a real fear and that's why we don't get the complaints too …

		because if I complain then next time I need to use the service something bad's going to happen to me […] (55 year old woman carer and consumer representative)
External policy context	Delay in diagnosis and treatment Psychological harm (stress, anxiety)	Conversation between participants: Facilitator: Do you think not bulk billing is a big barrier [to accessing care]? P1: Yes because they don't tell you beforehand that they want the money upfront … (76 year old woman with multiple chronic conditions) P2: It's like having Al Capone with the cannon in the hand; money or your life? (70 year old man with multiple chronic conditions) P1: Yeah, no that's shocking. P3: What happens if you can't afford that? (70 year old woman with multiple chronic conditions) P2: Well they won't see you. P4: You die. (74 year old man with multiple chronic conditions)
Dignity and respect	Psychological harm (upset, belittled) Delay in diagnosis and treatment	My son […] is brain damaged […] So I went up and fixed [the bill] up and there was a balance owing, and it was $40 and I said 'no you must go back to your doctor'. I'm battling to get him to keep going back to the doctor and so he's going to his usual GP who bulk bills him [no payment required], and when he went there to say … 'I've come to see my doctor', they said 'would you go to the accounts department'. And then he got dressed down by a girl who would have been 18 at the least and he's 43 years of age, and he was so confused, humiliated, he didn't know what to do. So he came home to me and said 'I couldn't go to the doctor'. (71 year old woman carer with multiple chronic conditions)
Primary–secondary interface	Physical harm (pain and suffering) Psychological harm (stress, anxiety,	He went through this [acquired brain injury] and he left hospital and of course he didn't know what he was doing so he went to the doctor […] and said I'm not allowed to go back to work until you give me the all clear and he said 'oh well what's, what's been wrong?' He said 'I've had a hypo' […] so he tested his blood pressure, tested his sugar and said 'yes, you can

	depression)	go back to work'. He went back to work and […] He didn't have a clue what he was doing […] and the rest of the men decided they'd bully him because he couldn't remember what to do and how to do it. So they bullied him to the extent that he tried to commit suicide coming home from work. So then I stepped in and went to the doctors […] I told him [what happened] and so he looked it up on the [computer] and he said 'there's nothing here'. Now the hospital do not send their records to the doctors clinic; to your GP. They keep them at the hospital. (71 year old woman carer with multiple chronic conditions)
Continuity of care	Psychological harm (relationship effects—loss of trust)	… you get attached to your GP, it's a personal thing, he … knows more about you, than next to your wife or your partner … what's wrong with you, how you're reacting to certain things […] you form a … bond, a friendship,? And to break away from that all of a sudden […] and to be treated so off-headedly and saying well you know I couldn't care less really … what you do? […] it breaks you up and then you gotta start all over, and that's the hard part you gotta start all over again; now can I trust this bloke? (73-year-old man with multiple chronic conditions)
Task performance (skill, competence)	Delay in diagnosis and treatment Failure to appreciate severity/acuity of problem Psychological harm (loss of trust and confidence)	Conversation between two participants: P1: I went [to the GP clinic] I'm a diabetic, and I had […] a racing heart … which was in de fib and it was … running at 145 beats a minute. And they weren't concerned; they were more worried about why I didn't take a certain tablet. They focused on that rather than trying to help me find the problem so I just walked away. (63 year old man with multiple chronic conditions) P2: It makes you feel like why do you want to go to your local GP because you're not getting the support and help you need. (59 year old woman carer)

Task characteristics—care coordination and information management	Delay in diagnosis and treatment Physical harm (pain and suffering)	I’ve got a friend who […] can’t really walk cos he’s in a wheelchair most of the time and in a lot of pain, and he travels backwards and forwards to [metropolitan suburb] for pain management and they keep telling him that they don’t know what’s causing it and he has to carry the letters back to his GP, they don’t … talk to his GP …] they don’t even talk to the Professor and the pain management doctor. They don’t even talk to each other. And they’re looking for [someone] who can coordinate the information between the five or six people that he is dealing with … so he can get an answer and get relief from the pain. (70-year-old man with multiple chronic conditions)
Task characteristics—prescribing	Unnecessary medication/treatment Physical harm (medication side effects)	… the doctor didn’t find anything wrong … but gave me antibiotics anyway without really telling ‘yes, I’m quite sure this is viral and it needs antibiotics’, it was just like ‘oh no the antibiotics will clear it up’ […] I’ve heard that they can do that just to sort of reassure the mother that ‘[…] at least something’s being done’ cos with a viral thing you just normally […] let it run its course … because [my child] ended up vomiting a bit of blood and so I was also doubly concerned about that. I took him to emergency and they said ‘[…] it’s probably the antibiotics just irritating … his system because he doesn’t even really need them’. (30 year old mother)
Task characteristics—decision making	Unnecessary treatment Psychological harm (stress, anxiety, discomfort)	[…] the doctors say ‘I want you to do this’, and you don’t really want to do it, you can say why you don’t feel comfortable about doing it and then you maybe work around it. But at the moment there’s no such thing because you’re told to do things […] I wasn’t asked ‘did I want that tablet?’ I was told it was going to be prescribed. (60 year old woman with multiple chronic conditions)

Time in the consultation	Delay in diagnosis and treatment Unnecessary repeat visits Psychological harm (stress, anxiety, frustration)	I sometimes have a few matters to discuss but … my time is spot on the 20 minutes. When that magic time that my appointment is [over] I'm out the door, without so much as by your leave … I have […] on occasion had serious matters I wanted to discuss with him but haven't had the opportunity so then … I have to go […] make another appointment, try to discuss it with him and find myself out the door again […] it's … very very unsatisfactory … (69-year-old man with multiple chronic conditions and a carer)
Safety culture	Physical harm (pain and suffering) Psychological harm (loss of trust)	I think some doctors are careful too cos when I had [my child][…] my doctor was looking after me and then I got handed over to another higher up the ranks and my doctor got shoved aside. And I think they're too intimidated by the other doctors to actually say this should happen … when I went back to my doctor he didn't actually say anything negative about [the harm], but obviously things went wrong […] I think they're just too scared to, like the pecking order of the doctors … (28 year old mother)
Team factors	N/A	… how I see it working in a team is for you and your doctor to understand each other. He can talk to me the way he wishes … to explain my problem and I can respond back to him exactly the same way. And then he can refer me to who he thinks is going to be right. And then those two confer with each other about my problem. And also that specialist is given the freedom by my GP to be able to talk to me the same way. So in other words forming a teamwork where I … consider my GP to be in charge, he's in number one, and then he's got these specialists that he's referred me to; reporting back to him; and then he in turn lets me know what's going on […] (73-year-old man with multiple chronic conditions)
Physical environment	Infection	Conversation between two participants: P1: […] you go there and you wait and sit in there for an hour or so with all these people coughing and sneezing everywhere … (73 year old

		man with multiple chronic conditions) P2: But you can’t do anything about it […] maybe the government should be looking at […] the doctors waiting rooms and the facilities in there for looking after patients. People with flu should maybe be made to wear masks, have masks in the waiting room for people to put on […] (73 year old man with multiple chronic conditions)

P1: Participant 1, P2: Participant 2, N/A: Not applicable

9.4.1 Communication

Listening to patients' concerns were considered to be highly important and that active listening assisted with appropriate and personalised treatment and care, increased accuracy of diagnosis, facilitated trust and reduced stress and anxiety. Instances of communication breakdown occasioned a range of patient actual harms, including misdiagnosis, delays in diagnosis and treatment, physical harm (pain and suffering) and psychological harms, including loss of trust, stress and anxiety, and feelings of vulnerability and intimidation.

9.4.2 Access

Timely access to primary care was important for preventing delays in diagnosis and treatment. Patients and carers unable to get an appointment with a doctor at a preferred time described the frustration, stress and anxiety resulting from not knowing where to get help and the potential worsening of their health condition. In some cases, inability to access care led to actual physical harms such as exacerbated pain and suffering and unintended health outcomes such as permanent disability (paralysis).

Participants also considered limited availability, distance from care and choice of doctors as subthemes contained within the access contributory factor to safety.

9.4.3 Patient factors

Participants who took direct actions to intervene and prevent potential harm from occurring considered themselves to be actively involved in managing their own safety. Ability to identify particularly harmful situations or possessing the knowledge and understanding of the contributing factor to safety incidents were attributed to many patient characteristics. These were variable and included but not limited to the patient or carer's personality, their past experiences with healthcare, their health status or the healthcare context. Actions to prevent potential harm included speaking up when dissatisfied, requesting second opinions, navigating access to care, taking responsibility for health and being informed about the risks and benefits of treatment and care. Fear about taking certain actions and potential vulnerability following these actions were perceived as barriers that prevented patient agency from occurring.

9.4.4 External policy context

Patients were conscious of the regulatory environment in which primary care operates. Empathy was expressed when general practitioners were perceived to be constrained by short consultation times as incentivised by Medicare.[iv] The main Medicare issue they identified concerned the inequities and inconsistencies for bulk billing. While concessions were available for pensioners and low income families, there were instances where payment was left to the discretion of the GP. Access to bulk-billing GPs was difficult to obtain. Delays in diagnosis and treatment were a common consequence of not being able to afford medical care. Ongoing costs of essential medications not fully covered by the Pharmaceutical Benefits Scheme[v] created further delays in access to primary care.

9.4.5 Dignity and respect

Participants spoke about feeling valued by primary care staff. In the few instances where there was non-personalised or unapproachable care, this then resulted in patients and carers feeling like a number or 'cattle being herded' within the larger system. In some ways,

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[iv] Medicare is a publicly funded universal healthcare scheme in Australia. Medicare is the funder of primary healthcare for Australian citizens and permanent residents. The standard Medicare rebate is 100% for a general practitioner of the Medicare-determined schedule fee. Many medical practitioners charge more than the schedule fees, and the amount in excess of the schedule fee is paid for by the patient. Where practitioners 'bulk bill' patients, they agree with Medicare to accept 85% of the schedule fee in full payment for their services with no out-of-pocket expense from the patient.

[v] The Pharmaceutical Benefits Scheme is a Federal Government scheme that subsidises the cost of medicine for most medical conditions for all Australian citizens and residents. Patients are required to copay the remaining cost of medicines not covered by the scheme.

these experiences threatened patients' personal identity.[298] This reduced effective communication, and resulted in disrespect towards patients and carers. In some cases, patients' and carers' reported inappropriate behaviour where doctors subjected them to verbal abuse and belittlement. Rude or disrespectful treatment from other practice staff was less frequent, but resulted in actual psychological harms for those who were belittled or upset by the reception staff. Subsequently, patients avoided the practice.

9.4.6 Primary–secondary interface

Transitions between primary and secondary care were perceived as an area where communication and information sharing was problematic. Patients and carers were often responsible for managing this transition and coordinating information between healthcare providers. Participants considered that some patients may not be able to undertake this role. Providing accurate information about specific medical procedures might be burdensome for patients with a disability, those who are ill or had memory problems. Incorrect or delayed information relayed between primary or secondary care obstructed treatment and diagnosis, resulting in inappropriate or wrong treatment and further pain and suffering.

9.4.7 Continuity of care

Continuity of care was equivocal as it was described as both a potential safeguard against harm and as a potential contributing factor to a safety incident. A continuous relationship with a GP facilitated trust and confidence in providers. Prior knowledge of the patient was mentioned as something that influenced accurate diagnosis and treatment. When these relationships were compromised, patients were fearful of having to start over with a new doctor and the safety implications.

Discontinuity is often thought of as an undesirable characteristic in primary care,[299] potentially contributing to unsafe care, but some discontinuity of care may also be an asset. Participants described receiving a second opinion from a different doctor who correctly diagnosed an ongoing health problem and prescribed effective treatment. Furthermore, prior knowledge of the patient (continuity of care) might increase the chances of diagnostic overshadowing. Some believed they were stereotyped by their disease status, and consequently, other diagnostic options and care were not investigated.

9.4.8 Task performance

Certain patients and carers noted awareness of providers who did not have the skill or competence to carry out particular tasks. Awareness was heightened for patients with previous experience of actual harm. Task performance was also recognised retrospectively when discussing particular safety incidents, when other health professionals highlighted errors or when other health professionals accurately performed the task. Loss of trust and confidence and being hesitant to seek care in the future were outcomes for patients whose safety had been compromised. Diagnostic skill and failure to appreciate severity/acuity of the problem were the main tasks participants were able to comment on. Patients and carers noticed it when doctors and nurses were interested in or fixated on problems that were not considered most urgent by the patient or carer or not the primary reason for the visit.

9.4.9 Task characteristics

9.4.9.1 Care coordination and information management

Patients viewed the GP as being at the centre of healthcare encounters. Harm often resulted from misinformation or communication breakdown between the GP and the other healthcare providers, or when patient information was not centralised with one GP. Patient test results were delayed or poorly managed in some instances.

Participants got referrals to specialist services when requested. But some questioned whether GPs had a broad knowledge of all available referring services, which providers offered reduced or no out-of-pocket expenses and the timing of the referral in critical circumstances. Some considered GPs hesitant to refer patients, but the reason for this was unknown.

9.4.9.2 Prescribing

Medication interactions, wrong dosage and inappropriate prescribing were problems that participants discussed. Incorrect or interacting medications were identified by the pharmacist in most cases along with the patient.

Some patients encountered difficulties when attempting to resolve medication problems with their doctors. Actual prescribing error harms were generally pain and suffering, although none were considered by participants to be serious harms. Usually, patients intervened before serious medication harms occurred, for example, by seeking a second opinion or discontinuing use.

9.4.9.3 Decision making

Opportunities to be involved in decisions about care and treatment were desired by participants. Knowledge of the risks and benefits, and making appropriate decisions were important to these patients to ensure care was tailored to their needs and was safe. Engaging with them to make decisions, in their view, prevented unnecessary, unwanted or invasive treatment. Sharing in decisions gave these patients a sense of trust with their healthcare providers and reduced feelings of stress or anxiety.

9.4.10 Time in the consultation

All participants appreciated and valued having enough time in the consultation to communicate all their concerns. Adequate time reduced unnecessary subsequent visits, out-of-pocket expenses and further delays in care. Sufficient consultation time also facilitated patient and carer engagement, and their sense that the GP understood them and had knowledge of their needs and personal context. Moreover, patients and carers recognised that having enough time allowed for accurate diagnosis and treatment, improved patient satisfaction and generation and sustainment of the doctor–patient relationship.

9.4.11 Safety culture

Patients were aware of the culture and hierarchies evident within the organisation and its influence on care delivery. Patients identified practice leaders and how other staff interacted with them based on their role and responsibilities. Intimidation and restriction of staff to speak up about safety concerns to prevent actual patient harm were examples of poor organisational culture.

9.4.12 Team factors

Working collaboratively was seen to occur in two domains. First, patients aspired to be in a team with their doctor or nurse, which also extended to specialists and secondary-care providers. This sense of teamwork enabled patient involvement in care and increased satisfaction with the doctor–patient relationship. Second, teamwork between the GP and practice nurse was viewed as useful for recognising things the other person may not have identified, and facilitated transparency of information sharing and coordination of care.

9.4.13 Physical environment

Participants were satisfied with the physical layout of the practice. Infection control was mentioned by a few patients who were concerned about risks to health in the waiting-room from other patients who were contagious with cold and flu symptoms.

9.5 Discussion

The results from this study reveal that patients and carers were able to identify various latent failures and error-producing conditions in the primary-care environment that influence patient safety, and how those factors could contribute to creating patient safety incidents. This finding extends previous research that found patients and carers had an assumed sense of safety in general practice, as only those who had experienced some level of harm were able to adequately comment on safety.[272] These findings show that, regardless of patients' and carers' experiences and awareness of safety, they have considerable understanding of, and ability to comment on the elements of primary care that impact on patient safety.

The utility of the YCFF when tested in an Australian primary-care context proved useful to develop an evidence base in the absence of other available models and literature. Other frameworks such as Reason's accident causation model[167] or the London protocol[184] may be suitable for the primary care setting like the YCFF, but further research is needed to confirm their applicability. There were commonalities between secondary and primary care contributing factors to safety incidents contained in the YCFF. These were centred on things that are present in all health systems, such as team work, communication, the physical environment and patient factors. Contributory factors in the YCFF not commented on by patients were the design of equipment and supplies, scheduling and bed management, lines of responsibility, management of staff and staffing levels, staff workload and support from central functions. Some of these factors, such as bed management and support from central functions, are not relevant to the primary-care setting, and were not expected to emerge from the patient accounts. The remaining factors are possible contributing factors to safety for primary care, but were not mentioned by participants in this study. Further work is needed to understand patients' and carers' views of these factors.

The five unique primary care contributing factors to safety incidents represented both the latent conditions and direct error-producing conditions. This finding contrasts with what has been found for hospital patients' views of contributing factors to safety incidents, which are more centred towards factors that patients could explicitly observe on the ward, or the sharp end of care.[111] The continuity of care that characterises primary care makes it amenable to greater frequency of visits and hence greater chances of developing knowledge and understanding of the latent or blunt end factors that impact on care. Patient and carers being able to understand, recognise and provide feedback about these more latent factors may be useful for primary-care staff and policy makers, and can help to develop a 'systems approach' to practice improvement.

The range of contributing factors identified by patients and carers in this study reflects some of the available patient safety taxonomies in primary care[23, 26, 300, 301] and the quality of care literature.[291-294] While the issues identified by patients may seem like commonly reported aspects of patient satisfaction or quality of care, these concerns were described by patients as contributing factors to safety incidents that they themselves had experienced or perceived as threats to safety in primary care. The frequent appearance of these traditional risks in the evidence base demonstrates that they continue to be problematic for patients from a safety perspective,[302] and not effectively resolved in primary care. Using the YCFF to import these patient concerns into a safety perspective is unique and grounded in the patient stories themselves. The fact that eight of the contributing factors to safety incidents appear in the YCFF confirms that the findings do apply to a conceptualisation of patient safety. Furthermore, as there has been no theoretical exploration of how patient perceptions contribute to established models of patient safety,[303] this study goes some way to addressing this knowledge gap. Including the patient view is a starting point to bridge the mismatch between patients and health professionals' conceptions of safety, and allows for partnership and further development in this area.[93]

The findings from this study strengthen the idea that patients can observe and comment on what happens to them and what goes on around them through the whole course of their care.[304, 305] Partnering with patients and using their feedback to improve safety currently occurs in hospital settings,[111, 114, 189] and could be applied to primary care. Patient safety reporting mechanisms and tools, such as significant event audits and root cause analysis, are important, but they are retrospective, not often used correctly, poorly designed or have had little value in improving safety.[54, 306] Furthermore, the learnings from such audits are not frequently shared across organisations.[307] A prospective approach that identifies the latent and error-producing conditions in primary care from the patient perspective can assist with addressing these organisational factors before a serious event occurs.[1, 167]

We recommend that tools be developed to capture patients and carers' feedback on the contributory factors to safety incidents in primary care organisations. Primary care organisations could use such a tool to systematically identify areas of strength and weakness, address patient concerns to reduce potential harm and create a culture of safety within the practice. Questionnaires that elicit patients' views on these contributing factors align with the growing evidence that patients can make a substantial contribution to improving safety.[114, 308] An innovative example of this type of patient feedback is the 'Patient Measure of Safety' that has been successfully trialled in hospital settings.[111, 114] A next step would be to develop such a questionnaire for the primary-care setting.

9.5.1 Strengths and limitations

There has been some research conducted, which elicits patients' views on a single type of contributory factor. These include investigating patient typologies of medical errors and harms in primary care,[244] categorising some factors contributing to safety in the medical home,[251] examining patient experiences of care transition between primary and secondary[253] and describing patient issues with handling of laboratory test results in general practice.[246] These findings add to the evidence base in this area, but no study has actively identified a wide range of latent or error-producing factors to safety incidents in primary care from the patient perspective. Although this is a major strength of this study, there still may be some contributing factors to patient safety incidents that were not present in the data. Further research, including a systematic review, is needed to ensure that a comprehensive list of contributing factors to safety in primary care is established. This patient and carer sample may not represent all the views of primary-care patients and carers despite the high degree of complement between the findings and the international literature.[102] More work needs to be undertaken to confirm if these factors or other factors are able to be identified by an international primary-care patient population.

9.6 Conclusion

Patients and carers were able to identify a comprehensive range of contributing factors to patient safety incidents in primary care. We recommend that tools be developed to systematically capture the multiple contributing factors to patient safety incidents from the patient and carer perspective. Patient and carer feedback of this type could help primary-care professionals better understand and identify potential safety concerns and make appropriate service improvements.

9.7 Acknowledgements

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9.8 Competing interests

None declared.

9.9 Contributors

ALH conceived and designed the study. ALH and SJG were responsible for the data analysis and wrote the first draft of the manuscript. JF, JKJ, CW and JAD contributed to specific sections of the manuscript. All authors read and approved the final version of the manuscript.

9.10 Overview of Phase 2 and link to Phase 3

The main finding from Phase 2 was the wide range of factors contributing to safety incidents in primary care that patients and carers could identify. To the best part of my knowledge this is one of the first studies to obtain this kind of information for a primary care setting. The results from Phase 1 showed that patients and carers had limited perception of risk and generally had an assumed sense of safety in primary care but in Phase 2 they could identify a range of error producing and latent factors that contribute to safety incidents. Given the potential for patient involvement in safety, and that little activity is currently occurring in primary care, it is necessary to find ways patients and carers can contribute to improving safety.

Surveys capturing patients' views of contributing factors to safety incidents have been used and validated successfully in hospital settings as a safety improvement tool.[111, 114] The aim of such a tool is to provide patient feedback back to ward staff for them to plan for improvements in safety. The effectiveness of this patient measure of safety tool on safety outcomes has been assessed in a large randomised trial in the UK with mixed results.[189-192]

A similar tool could be developed using the findings from Phases 1 and 2 to create a patient measure of safety for primary care. There are currently no such tools available that prospectively capture this kind of information from patients. Existing patient feedback in primary care consists of satisfaction surveys on quality of care, patient complaints or reporting systems; all of which have several limitations in terms of effects on safety improvement. This gap between evidence and practice provided the direction for the research undertaken in Phase 3.

Chapter 10 will describe the development of a Primary Care Patient Measure of Safety tool, present the domains and items contained within the tool, and discuss the potential implications for practice.

CHAPTER 10 – PHASE 3: DEVELOPING A PRIMARY CARE PATIENT MEASURE OF SAFETY (PC PMOS): A MODIFIED DELPHI PROCESS AND FACE VALIDITY TESTING

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Co-author declarations confirming the nature of my involvement in this publication are detailed in Appendix 2.

10.1 Abstract

Background: Patients are a valuable source of information about ways to prevent harm in primary care and are in a unique position to provide feedback about the factors that contribute to safety incidents. Unlike in the hospital setting, there are currently no tools that allow the systematic capture of this information from patients. The aim of this study was to develop a quantitative primary care patient measure of safety (PC PMOS).

Methods: A two-stage approach was undertaken to develop questionnaire domains and items. Stage 1 involved a modified Delphi process. An expert panel reached consensus on domains and items based on three sources of information (validated hospital PMOS, previous research conducted by our study team and literature on threats to patient safety). Stage 2 involved testing the face validity of the questionnaire developed during stage 1 with patients and primary care staff using the 'think aloud' method. Following this process, the questionnaire was revised accordingly.

Results: The PC PMOS was received positively by both patients and staff during face validity testing. Barriers to completion included the length, relevance and clarity of questions. The final PC PMOS consisted of 50 items across 15 domains. The contributory factors to safety incidents centred on communication, access to care, patient-related factors, organisation and care planning, task performance and information flow.

Discussion: This is the first tool specifically designed for primary care settings, which allows patients to provide feedback about factors contributing to potential safety incidents. The PC PMOS provides a way for primary care organisations to learn about safety from the patient perspective and make service improvements with the aim of reducing harm in this setting. Future research will explore the reliability and construct validity of the PC PMOS.

10.2 Introduction

Internationally, primary care is the first point of contact with the health care system for the majority of patients. There is a misconception that primary care is a low technology environment where safety is not considered to be problematic. A growing body of evidence suggests that this is not the case. For example, patient safety incidents have been predicted to occur in approximately 2% of consultations[310] with other reports suggesting that it is more likely to be around 10%.[311] There has been a range of error types identified with the majority of errors in primary care falling within the categories of medication errors,[32] diagnostic errors,[288] and communication errors.[27, 55]

Few studies are available to help us understand how to improve safety in primary care.[312] One of the ways to address this gap is to involve patients. Indeed, there is an emergent consensus that patients are able to identify potential errors in secondary care,[86] and we are beginning to learn more about this in primary care.[102, 272, 287] Patients have a different perspective on safety and can provide insights to prevent errors that health professionals may not have known about.[313, 314]

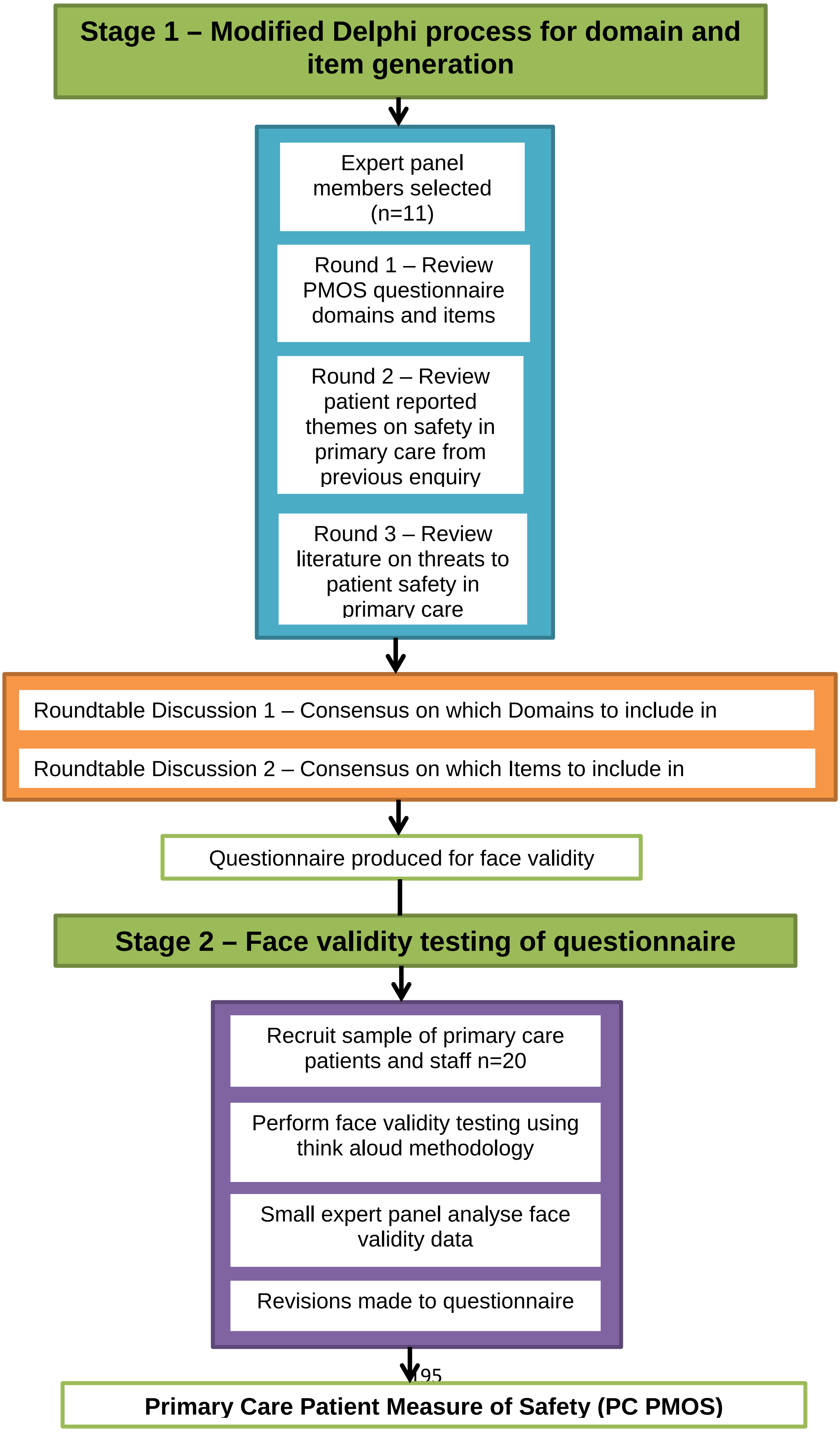
Not only can patients directly comment on error and patient harm, they can also identify factors that contribute to patient safety incidents.[111, 287] A tool to collect patient feedback on the factors contributing to safety incidents has been developed in secondary care.[111, 114] This tool is one element of an intervention currently being assessed in a large trial investigating patient involvement in patient safety in hospitals.[189] The Patient Measure of Safety (PMOS) is a theory and evidence-based tool[111, 114] derived from James Reason's Swiss Cheese model of accident causation[167], and also from a systematic review of the literature which resulted in the Yorkshire Contributing Factors Framework (YCFF).[188] The YCFF outlines twenty factors contributing to safety incidents which range from active failures to latent external factors in hospital settings. Some of the domains of the framework include communication systems, patient factors, physical environment, external policy context, and equipment and supplies.[188]

Patient feedback in primary care tends to focus on experience and satisfaction,[64] or on after event reporting and incident disclosure.[259] Systematic reviews have shown that there are some existing patient reported instruments to measure patient safety in primary care,[61, 66] but no tool has been explicitly developed which comprehensively measures factors contributing to patient safety incidents. Furthermore, only a minority of these tools have an underlying theoretical foundation to support their development and use. Primary care health professionals could use patient feedback to improve safety in the same way health professionals are doing within hospital settings.[189] In addition, evidence has shown that general practitioners are willing to embrace patient feedback but are unsure about how to use this information effectively.[315] A theory driven, evidence-based tool is needed to capture information about the potential ‘latent’ weaknesses in primary care which could contribute to future patient safety incidents. Therefore the aim of this study was to develop a primary care patient measure of safety that can be used as a basis for proactively managing safety and service improvement.

10.3 Methods

The questionnaire was developed in two stages. Stage one comprised domain and item generation of the questionnaire and stage two involved testing the face validity with patients and primary care staff (Figure 10.3 illustrates the methods).

Figure 10.3 Flow diagram outlining questionnaire development



10.3.1 Stage 1 – Consensus process for domain and item generation

10.3.1.1 Procedure

A modified Delphi technique[316] was used to reach consensus on the domains and items to include in the questionnaire. This technique was chosen as it has been shown to be an effective method for gaining consensus and has been used successfully to develop quality indicators in primary care.[267] Modification included the addition of two round table discussions with panel members after rating and review rounds were completed. The round table discussions applied a Nominal Group Technique (NGT)[269] approach to agree on the final domains and items to be included in the draft version of the questionnaire. NGT is a group process that usually involves sharing and discussion of reasons for the choices made by each group member.

The modified Delphi process consisted of three rounds of rating and review over a three week period and the addition of two discussion round tables with panel members. The discussions were held two weeks apart. They were used to elicit any further contributions from the panel members, and to facilitate final consensus on the questionnaire domains and items prior to face validity testing. Modification of the Delphi technique was incorporated into the study design as discussion among panel members was required to generate different ideas about the subject matter and reduce group conformity which can influence the quality of findings. The social interaction during the round table discussions was thought to facilitate group acceptance and ownership of the results.[268] The combination of two consensus methods has been advocated by contrast with a Delphi process that has preceded NGT for initial item generation.[270, 271]

The multidisciplinary expert panel contained members with extensive experience and knowledge in the field of patient safety in primary care from Australia, the US, and the UK.

Panel members' backgrounds included general practice academics (n=4); a consumer representative who is the CEO of an organisation that embodies more than 50 Australian consumer and advocacy organisations for people with chronic illness (n=1); nursing, sociology, health systems and safety researchers (n=4); and a representative from the Australian Commission on Safety and Quality in Health Care (n=1).

Three sources of information were provided to the expert panel members over a three week period. These included the domains and items from the PMOS questionnaire for hospital use,[111, 114] a brief description of the themes and sub-themes from previous enquiry of the research team investigating patients' views of safety in general practice,[272, 287] and a brief description of the themes from the literature about threats to patient safety in primary care.[21, 23, 25, 26, 29, 32, 57, 300, 301, 303]

The three sources of information were presented electronically to panel members in Excel spreadsheets. Modification to the Delphi rating scale has been used successfully in previous research.[270] For each source of information, panel members were asked to simply answer 'yes', 'no' or 'unsure' as to whether they considered the domain or item to be a contributory factor to patient safety in primary care. For each response, panel members were also asked to provide comments or justification at a level they felt necessary for their response. The categorical response options were a further modification from the traditional Delphi rating scale of 0-9. This modification was made to give panel members more discrete and clearer categories to choose from. It was thought to assist with or prompt discussion about the 'unsure' domains or items during the round tables with panel members. A measure of dispersion or median score was not required for feedback to panel members as each domain and item was discussed at length during the round tables where consensus was reached.

Modification to the Delphi rating scale has been used successfully in previous research.[270] All panel members were instructed to provide responses anonymously via email to the facilitator (AH). Anonymous reporting aimed to allow panel members to freely express their opinions and avoided the potential dominance by eminent or highly opinionated panel members.

10.3.1.2 Analysis

Responses were analysed by the facilitator and presented back to the panel during the first round table discussion. During the round table, panel members examined the results and reached consensus about which domains to include in the questionnaire. The facilitator used these results to generate example items for each domain where there was not already an existing PMOS questionnaire item.[111, 114] During the second round table discussion, panel members considered the example questionnaire items and refined these until consensus was reached.

10.3.2 Stage 2 – Face validity testing

10.3.2.1 Sample

There were two participant groups for this stage of the study: i) patients; and ii) healthcare professionals, managers and administrators from primary care settings within Australia and UK. Primary care patients and staff were purposively sampled from networks known to the research team. The network from which the sample was selected included participants with past experience and knowledge of the research area and who had formal established partnerships with the relevant universities undertaking the study. These patients and staff were selected from various patient demographics and different professional groups with the aim of increasing diversity of the sample and to ensure that the questionnaire would be valid and usable across countries.

10.3.2.2 Procedure

A ‘think aloud’ methodology was employed to test the face validity of the draft version of the questionnaire.[265] Twenty ‘think aloud’ interviews were conducted with patients (n=11) and staff (n=9). ‘Think alouds’ were arranged at a time and place convenient for the participants. Staff included general practitioners, practice nurses, community pharmacists, practice manager and administration staff. As staff and patients are potential users of the survey it was important to gain both their views.

The ‘think aloud’ method involved asking participants to talk aloud about their thoughts and feelings as they read and decided how to respond to each question in the draft version of the questionnaire.[264, 265] Participants were also asked questions following the ‘think aloud’ process which included the perceived barriers to questionnaire completion, time taken to answer the questionnaire and questionnaire format.

All interviews were digitally recorded and transcribed verbatim. Interviews were between 20 minutes and 1 hour in length.

Participants were also asked to complete a demographic questionnaire as part of the consent process.

10.3.2.3 Analysis

Revisions were made to the questionnaire following the ‘think aloud’ procedure. A smaller working group (AH, SG, JOH, JF, JJ, JD) considered the findings from the interviews to reach consensus on the items to be included in the final version.

Two researchers (AH and SG) independently reviewed all the transcripts. Patient transcripts were analysed to identify when participants were able to understand and respond to the questions on the draft questionnaire. This was a dichotomous assessment consisting of ‘yes’ or ‘no’ for ability to understand and, or respond to the question. Staff transcripts were analysed to identify the relevance and importance of each item for practice. Any particular issues with questions from both patients and staff were also considered during the analysis.

Responses to questions following the interviews were collated and reviewed. These together with the interview transcripts were used to make revisions to the draft questionnaire.

The final version of the questionnaire was assessed for readability using the Flesch Reading Ease and Flesch-Kincaid Grade level.[317]

10.3.3 Ethics

Ethics approval was granted for this study by the Flinders University Social and Behavioural Research Ethics Committee (project no. 5667), and the University of Manchester (project no. 14339). Participants from Stage 2 provided informed written consent and received a shopping voucher for their time and travel expenses.

10.4 Results

10.4.1 Stage 1

Three rounds of rating and review and two discussion meetings with expert panel members resulted in a draft questionnaire with 24 domains and 77 questionnaire items. The domains and items are listed in Appendix 6.

10.4.2 Stage 2

10.4.2.1 Understanding and responding

Results from the interviews with patients are presented in Appendix 7. This table shows the number of patients who could understand (comprehension of the statement) or respond (experience of the statement), and both understand and respond (both comprehend and experience) to the questionnaire items. Generally, patients could understand and respond to most items. Demographics of patients and general practice staff are provided in Table 10.4.2.1.

Table 10.4.2.1 Demographic information of participants (patients n=11 and staff n=9)

Patients	**n (%)**	
Female	9 (82%)	
University education	7 (64%)	
Repeat prescriptions	8 (73%)	
Common health conditions:		
Arthritis	5 (45.5%)	
	Mean (SE)	**Range**
Age (years)	53 (4.51)	33-74
Number of health conditions (level of morbidity)	2 (0.51)	0-5
Number of GP visits per year	15 (5.11)	1-52
Staff	**n (%)**	
Female	9 (100%)	
Profession type:		
General Practitioner	3 (33%)	
Practice Nurse	2 (22%)	
Practice Manager/Office Administrator	2 (22%)	
Pharmacist	2 (22%)	
	Mean (SE)	**Range**
Age	40 (4.03)	24-57
Years of experience	6.2 (3.15)	0.16-30

SE: Standard Error

10.4.2.2 Time to complete the questionnaire

On average participants took 15 minutes to complete the questionnaire, apart from one participant with low literacy level who took longer (40 minutes).

10.4.2.3 Strengths of questionnaire and barriers to completion

Participants felt that patients would be willing and able to complete the questionnaire. Staff also agreed that this type of tool would be useful for improving safety in primary care. Both patients and staff identified some potential barriers to completing the questionnaire, mostly concerning the length of the questionnaire and the level of attention required to remain engaged for a long period of time. Patients were specifically apprehensive about their responses being attributed to them individually. Other patients thought that elderly people and those with low literacy levels would need external facilitation to complete the questionnaire. Some participants used the ‘neither agree or disagree’ option when the statement was not applicable to them or they did not know how to respond. Negatively worded items were also problematic for some patients but not staff. Some patient participants were unfamiliar with the terminology used in items, for example, ‘adherence’ and ‘after hours’. Responses were similar between participants from different cultural groups.

10.4.2.4 Questionnaire format and implementation

Participants thought that providing a range of formats of the questionnaire would be beneficial. Participants believed that younger people would prefer the questionnaire to be online or electronic and older people would prefer a paper-based questionnaire or require external facilitation. There were various responses about where and when to complete the questionnaire. Many believed the time in the waiting room prior to their consultation would be an ideal time. Others felt it would be better to complete the questionnaire at home because they would be more comfortable and have more time in a neutral setting. They acknowledged that getting these questionnaires back would be problematic. The intended time for patients to complete the questionnaire would be just after a recent primary care visit.

10.4.2.5 Developing the final version of the questionnaire

Based on the findings of the interviews described above the draft questionnaire was revised. The expert panel (AH, SG, JOH, JF, JD) discussed each of the 77 items with the aim of strengthening the questionnaire and reducing the length.

In total 50 items were retained from the draft questionnaire. The wording was changed for 13 items to improve clarity, based on patient and staff feedback from the interviews (see Appendix 6). Questions related to a specific primary care professional were also grouped together in the final version for ease of completion. The remaining questions were randomly ordered to remain true to the original format of the PMOS questionnaire for hospital settings where there was little effect of question order shown in participant responses.[111] The random order of items was also thought to reduce participant fatigue or confusion when similarly grouped items appear together on the questionnaire. A mix of both positive and negatively worded items was also included in the questionnaire to minimise the possibility of acquiescent response bias and assist with future reliability and construct validity testing.[318]

In the draft questionnaire there were 24 domains. Some of these were collapsed into existing domains or renamed to be consistent with PMOS domains identified from hospital settings15, and from the YCFF on which the PMOS is based.[188] This resulted in 15 domains. The ‘Access to resources’ domain was collapsed into ‘Access’; ‘Coordination of care’ and ‘Provider performance’ domains were collapsed into a renamed domain ‘Task Performance’; ‘Medicare system and structure’ was renamed ‘External policy context’; ‘Staff training’ was renamed ‘Training and education’; ‘Team-work’ was renamed ‘Team factors’; and ‘Type and layout of practice’ was renamed ‘Physical environment’ (Appendix 8).

10.4.2.6 Readability of the questionnaire

The Flesch Reading Ease of the final version of the questionnaire was 59.0. This means that the questionnaire is easily understandable by 13–15-year-old students. Readability of the questionnaire using the Flesch-Kincaid Grade level was 7.8. This means that the text is expected to be understandable by an average student in the 7th grade (ages 12 to 13).

The final version of the questionnaire is the Primary Care Patient Measure of Safety (PC PMOS) (Figure 10.4.2.1).

Figure 10.4.2.1 The Primary Care Patient Measure of Safety (PC PMOS) questionnaire

Please indicate your level of agreement with the following statements

	Strongly Disagree	**Disagree**	**Neither agree or disagree**	**Agree**	**Strongly Agree**	**Not Applicable**	**Don't know**	Additional Comments
1. I was always treated with dignity and respect	**1**	**2**	**3**	**4**	**5**	**N/A**		
2. The doctor… a. Always considered what I want for my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
b. Did not have the skills, experience or knowledge to correctly manage my health condition	**1**	**2**	**3**	**4**	**5**	**N/A**		
c. Always listened to what I had to say about my illness / symptoms / treatment	**1**	**2**	**3**	**4**	**5**	**N/A**		
d. Always seemed to have the right information after I received treatment elsewhere	**1**	**2**	**3**	**4**	**5**	**N/A**		
e. Was interrupted during my consultation	**1**	**2**	**3**	**4**	**5**	**N/A**		
f. Interacted with me in a manner I found acceptable	**1**	**2**	**3**	**4**	**5**	**N/A**		
3. The nurse… a. Always considered what I want for my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
b. Did not have the skills, experience or knowledge to correctly manage my health condition	**1**	**2**	**3**	**4**	**5**	**N/A**		
c. Interacted with me in a manner I found acceptable	**1**	**2**	**3**	**4**	**5**	**N/A**		
d. Always listened to what I had to say about my illness / symptoms / treatment	**1**	**2**	**3**	**4**	**5**	**N/A**		
4. Other health professionals… (For example, pharmacist, physiotherapist etc.) a. Always considered what I want for my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
b. Did not have the skills, experience or knowledge to correctly manage my health condition	**1**	**2**	**3**	**4**	**5**	**N/A**		
c. Always listened to what I had to say about my illness / symptoms / treatment	**1**	**2**	**3**	**4**	**5**	**N/A**		

	Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree	Not Applicable	Don't know	Additional Comments
5. I got answers to all the questions I had regarding my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
6. I was able to make an appointment with a health professional of my choice	**1**	**2**	**3**	**4**	**5**	**N/A**		
7. Staff didn't seem to know what they were meant to be doing	**1**	**2**	**3**	**4**	**5**	**N/A**		
8. I understood what staff were explaining to me about my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
9. Information about me that my health care team needed was always available e.g. discharge summary, referral letters, test results	**1**	**2**	**3**	**4**	**5**	**N/A**		
10. Staff always knew everything they needed to know to care for me. e.g. allergies, other conditions, medical history, medications	**1**	**2**	**3**	**4**	**5**	**N/A**		
11. The cost of medications prevented me from filling a script when I needed medication	**1**	**2**	**3**	**4**	**5**	**N/A**		
12. I have not always followed the recommended treatment	**1**	**2**	**3**	**4**	**5**	**N/A**		
13. I was able to access the after hours service when needed	**1**	**2**	**3**	**4**	**5**	**N/A**		
14. When I accessed the after hours service it was useful	**1**	**2**	**3**	**4**	**5**	**N/A**		
15. The diagnosis or treatment plan recommended by my doctor, nurse or other health professional was right for me	**1**	**2**	**3**	**4**	**5**	**N/A**		
16. I could not remember what my doctor, nurse or other health professional recommended about my treatment	**1**	**2**	**3**	**4**	**5**	**N/A**		
17. On at least one occasion a member of staff was not able to use the necessary equipment	**1**	**2**	**3**	**4**	**5**	**N/A**		

	Strongly Disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree	Not Applicable	Don't know	Additional Comments
18. I had enough time during the consultation with a health care professional	**1**	**2**	**3**	**4**	**5**	**N/A**		
19. I knew who to go to in the practice if I needed to ask a question	**1**	**2**	**3**	**4**	**5**	**N/A**		
20. If I was referred important information about my care was passed on / made available	**1**	**2**	**3**	**4**	**5**	**N/A**		
21. Equipment needed for my care was always working properly	**1**	**2**	**3**	**4**	**5**	**N/A**		
22. Staff were always able to get help from other staff when they asked for it	**1**	**2**	**3**	**4**	**5**	**N/A**		
23. I see my doctor as the person who coordinate all my care with specialists and hospitals	**1**	**2**	**3**	**4**	**5**	**N/A**		
24. I was involved in all the decisions about my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
25. The practice was very clean	**1**	**2**	**3**	**4**	**5**	**N/A**		
26. Once I had been referred there was a delay	**1**	**2**	**3**	**4**	**5**	**N/A**		
27. The cost of seeing a doctor, nurse or other health professional at the practice prevented me from seeking care when I needed it	**1**	**2**	**3**	**4**	**5**	**N/A**		
28. I was able to make an appointment at a time that suited me	**1**	**2**	**3**	**4**	**5**	**N/A**		
29. My test results were always available when required e.g. scans, blood tests, x-rays	**1**	**2**	**3**	**4**	**5**	**N/A**		
30. My care changed and other health professionals outside the practice did not know about it	**1**	**2**	**3**	**4**	**5**	**N/A**		
31. Staff gave me conflicting information about my treatment/care	**1**	**2**	**3**	**4**	**5**	**N/A**		

	Strongly Disagree	**Disagree**	**Neither agree or disagree**	**Agree**	**Strongly Agree**	**Not Applicable**	**Don't know**	Additional Comments
32. When necessary staff undertook a thorough examination of me during the consultation	**1**	**2**	**3**	**4**	**5**	**N/A**		
33. I always felt that staff listened to me about my concerns	**1**	**2**	**3**	**4**	**5**	**N/A**		
34. Where necessary my doctor, nurse or other health professional regularly monitors/reviews my health condition	**1**	**2**	**3**	**4**	**5**	**N/A**		
35. Seeing the same doctor, nurse or other health professional is important to me	**1**	**2**	**3**	**4**	**5**	**N/A**		
36. Administration staff interacted with me in a manner I found acceptable	**1**	**2**	**3**	**4**	**5**	**N/A**		
37. I feel I cannot speak up about certain things with health professionals at the practice	**1**	**2**	**3**	**4**	**5**	**N/A**		
38. My referrals have always been appropriate	**1**	**2**	**3**	**4**	**5**	**N/A**		
39. Sometimes there was no-one available to deal with aspects of my care	**1**	**2**	**3**	**4**	**5**	**N/A**		
40. I was always given enough information that I could understand about my care and treatment	**1**	**2**	**3**	**4**	**5**	**N/A**		

10.5 Discussion

Patient safety in primary care is a growing field and patients are emerging as a potential source of information about safety in this setting but no evidence-based or theory driven tool currently exists that captures this information from patients.

This paper describes the development of the first patients' questionnaire measuring factors contributing to safety that has been developed for the primary care setting. The PC PMOS could be a tool to provide feedback on patients' understanding of the factors contributory to safety incidents in primary care. This tool is a resource to further the involvement of patients in safety in primary care.[85] The development of this tool meets a gap in the body of evidence which suggests that only 3% of all patient safety in primary care tools use the patients' perspective.[61]

The PC PMOS is innovative as patients have traditionally had limited opportunity to participate in prevention of harm other than in more formal ways of identifying risk, such as incident reporting.[86, 102, 272] This tool goes one step beyond current practice which at best limits or ignores the patients' potential for involvement in safety in primary care.

There were four unique primary care domains which were additional to the original PMOS questionnaire for secondary care settings. The unique domains were continuity of care, external policy context, primary-secondary interface and referrals. These domains reflect the structural diversity and broader scope of primary care,[55] and hence the contributing factors to safety incidents and the errors that occur are likely to be different from hospitals.[319] Given these differences there is clearly a need to develop tools that are specific for the primary care context.

The PC PMOS contains a balance of domains which are considered to be both error producing and latent contributory factors to safety incidents, unlike its secondary care counterpart.[111, 114, 167] The PMOS for hospital settings contains domains that are mainly centred on local working conditions (error producing) factors, with the exception of the cross cutting 'communication' domain.[111, 114] These latent domains are important because it demonstrates that patients are aware and have understanding of a wide range of safety factors which contribute to their care.

As measurement and monitoring of patient safety is a current challenge in healthcare,[35] the PC PMOS tool may be diagnostic, useful and practical for primary care staff to undertake safety improvement work, as well as a means of monitoring changes over time. We anticipate that primary care practices will use the survey results from the PC PMOS to identify areas of weakness and to plan continuous quality improvements, much like they do in quality improvement Collaboratives[320] and hospital applications of the tool which utilise action planning cycles of activity.[189] Patient feedback collected on the PC PMOS may be regarded as the extra piece of the patient safety intelligence 'jigsaw'.[86, 321]This tool could enhance or complement current data collection methods used in primary care to identify and prevent safety incidents such as significant event or root cause analysis already required for accreditation.[133] Patient and staff feedback, and other data sources such as complaints, will together provide a more comprehensive picture of patient safety.

Primary care staff report that they struggle to make changes based on patient survey feedback alone,[322] and qualitative data can provide important contextual information that is in some cases a more preferable option for staff.[323, 324] The PC PMOS was intentionally designed with free text space for patients to provide qualitative responses to further elaborate each item when necessary. The PC PMOS alleviates some of these challenges identified by primary care staff who use patient experience surveys,[322] as this tool specifically focuses on areas of safety that are not only important to patients, but the contributory factors are derived from theory and the literature, and can therefore impact on practice.

There are a number of potential barriers to implementation of the PC PMOS. Recruitment of patients is always a major barrier to data collection. Our findings suggested that patients preferred to receive the tool in a variety of different formats which may increase response rates. Particularly vulnerable patient groups may experience difficulties completing the questionnaire. For example, those with low literacy, a visual impairment, physical or other disabilities, and the elderly or very young people may experience problems when voicing concerns about the safety of their care. This may impact the use and usefulness of the tool as feedback from these vulnerable groups is important because they are considered the most at risk groups for safety incidents.[42] In those cases we recommend external facilitation, although we recognise the challenges of how to operationalise this in practice. Patient peers and volunteers have been used successfully for patient data collection in hospitals and may be an avenue for exploration in primary care.[325] We addressed participants' concerns about the length of the questionnaire which was reduced during expert panel meetings but we were still able to retain sufficient domains and items required for further validation and testing. Specific items on the PC PMOS relating to cost of services or access may not be relevant to all primary care contexts and we recommend the removal or adaption of these items where necessary.

10.5.1 Strengths and Limitations

The major strength of this study is that both inductive and deductive approaches were undertaken to be as inclusive as possible when developing the questionnaire domain and items. Three sources of information were used to create the content of the tool. We recognise that not all factors contributing to patient safety incidents are included in the tool. Practitioners should use the PC PMOS in conjunction with other safety measurement tools such as significant event analysis or patient complaints. Furthermore, while the face validity testing was conducted on a small number of participants these were from two countries. The sample was predominantly female, which is a direct result of the purposive sampling methodology employed. There are greater proportions of females working in the healthcare industry,[326] and women are more likely to attend primary care[327] and respond to surveys than men.[328] Further work will test the reliability and validity of the questionnaire on a larger scale with a more representative sample of the general population. The implications for using a modified Delphi process for the development of the PC PMOS was considered to be beneficial to the study overall and produced a strong tool that is based in both the evidence and expert opinion. The inclusion of panel members in round table discussions was particularly useful for achieving consensus on the domains and items. We recognise that the sample size and composition of the expert panel members are different from the traditional Delphi processes which usually comprise large randomly sampled populations. This may have influenced the potential range and scope of ideas generated and the level of agreement reached. We attempted to mitigate this by including a diverse range of experts who provided anonymous feedback during the rating and review rounds, and who had a high response rate between rounds and attendance at discussion meetings. The sample size also followed the ideal group size as specified by the NGT approach, and was pragmatic to implement.[268]

10.6 Conclusion

This work presents the first tool to allow the systematic collection of patient feedback on the safety of care, within a primary care setting. The PC PMOS is theory-based, and evidence-based, with data gathered both inductively (interviews with patients) and deductively (literature review and use of a theoretical framework). The PC PMOS provides a way for patients to identify various factors contributing to safety incidents. Patients are potentially a valuable source of information to help prevent harm. Patient feedback would not be used exclusively to improve patient safety but this tool should form part of a comprehensive approach to safety management in primary care. Future research will explore the reliability and validity of the PC PMOS with a larger sample of patients in order to develop an intervention that improves patient safety in primary care.

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10.8 Competing interests

None declared.

10.9 Contributors

ALH conceived and designed the study. ALH and SJG were responsible for the data collection and analysis, and also for creating the first draft of the manuscript. ALH, SJG and JOH developed the first draft of the PC PMOS and all the authors contributed to the final version. JOH, JF, JKJ, and JAD contributed to specific sections of the manuscript. All authors read and approved the final version of the manuscript.

CHAPTER 11 - CONCLUSION

The research question established at the beginning of this thesis was *How can patients be involved in improving safety in Australian primary care?* The specific objectives to address this question were to understand patients' and carers' views of safety in Australian primary care; to investigate whether patients and carers can identify factors that contribute to safety incidents in Australian primary care; and to develop a tool for patients to provide feedback about contributing factors to safety incidents in primary care. The research question and specific objectives have been addressed through the three studies conducted in Chapters 8, 9 and 10.

There were three main conclusions resulting from the studies in this thesis. Firstly, patients had an assumed sense of safety in the primary care setting. This perception was mitigated by feelings of trust and the doctor–patient relationship and limited patients' risk awareness and ability to comment directly on potential safety issues. Secondly, patients were considered as a valuable source of information about contributing factors to safety incidents in primary care. Their insights and experiences helped to identify both error-producing and latent conditions in the primary care setting which may not have been identified through other methods of investigation. Thirdly, a patient involvement in safety tool was developed which could serve two purposes; 1) to engage patients as safety partners during their care and, 2) to provide feedback to primary care practices that can then be used to undertake safety improvement work.

As mentioned in previous chapters, there is a dearth of information that adequately describes patients' perceptions of safety in primary care, or evidence that shows the effectiveness of using such feedback to improve practice. At the time of writing this thesis is the first Australian research enquiry to provide a comprehensive description of various patient-identified contributory factors to safety incidents in primary care, as well as to develop a tool to use this patient feedback in safety improvement activities.

The main outcome of this thesis was the development of the Primary Care Patient Measure of Safety tool. This tool was developed using both inductive and deductive methods, and has direct lineage from the validated hospital PMOS tool.[111, 114] The PC PMOS is comprised of 50 items that cover 15 latent conditions in the primary care environment influencing safety incidents. The PC PMOS provides a way for primary care organisations to learn about safety from the patient perspective, and to then make service improvements with the aim of reducing safety incidents in this setting. The tool could enhance or complement current data collection methods used in primary care to identify and prevent safety incidents, and is also a practical response to the growing need to find appropriate and effective ways of involving patients in improving patient safety.

One of the main strengths of this thesis is the use of both a theory- and evidence-based approach to investigation. Use of James Reason's accident causation model and the subsequent theoretical adaptations for the health care context,[167, 170, 188] as well as patient involvement in health care theory, provided a necessary foundation for the research aims, method, interpretation and application of the thesis findings. The successful use of these models in hospital setting research also provided encouraging results that support the approaches used in this thesis.[189-192]

The thesis findings further support the need for the patient view to be included when considering the development of a framework or theory of contributing factors to safety incidents in primary care. The patient-identified contributory factors to safety incidents resulting from this thesis enquiry were unique and differed from what has already been ascertained through other research methods that do not include the patient, such as retrospective record review or physician incident reporting. A framework or theory that includes the patient view would allow diverse error-producing and latent conditions in the primary care environment to be recognised broadly throughout the academic and health care communities and enable targeted, valued and effective safety incident prevention work to occur. Such a framework is currently being created by researchers from the Greater Manchester Primary Care Patient Safety Translational Research.[34]

At the time of writing, two studies were published that further validate the findings from this thesis. A paper published in 2016 by Ricci-Cabello et al. investigated patients' perceptions and experiences of patient safety in primary care in England.[329] Qualitative interviews with n=27 patients revealed four main factors that could affect patient safety. These included 1) patient-related factors (attitude, behaviour, and literacy levels), 2) health professional factors (attitudes and competence), 3) patient-provider relationship (communication and trust), and 4) the primary care system (workload, resources, care coordination, accessibility, teamwork and information accuracy).[329] These contributory factors to safety incidents are equivalent to what the patients from Phase 1 and 2 of this thesis identified in 2014 and 2015. This validates the shared perceptions of patients across different contexts and settings and contributes to the knowledge gap in this area of patient safety research.

Ricci-Cabello et al. published another paper in 2017 that detailed the results of their study using the Patient Reported Experiences and Outcomes of Safety in Primary Care (PREOS-PC) questionnaire to collect data about patient experiences and outcomes of safety in primary care.[330] This questionnaire is described in Chapter 1 and focusses mainly on safety incidents after they occur rather than capturing information about contributory factors to a safety incident prior to it occurring, but it does contain ten questions about some contributory factors to safety incidents in the primary care environment. The results were generally positive with more than two thirds of patients reporting that providers took adequate measures to ensure safe healthcare delivery (contributory factors to safety incidents included in this scale were availability, time, communication, coordination of care, information management and teamwork).[330] The findings from this study confirm that patients have the capacity to report on contributory factors to safety and indicates the potential usefulness of patient responses to a more comprehensive measure of patient safety such as the PC PMOS.

11.1 Limitations

The strengths and weaknesses of individual studies have been discussed within the chapters, as have their implications. When considering the thesis as a body of work, there are some additional limitations to acknowledge. Firstly, transferability of the findings is unknown. The sampling of participants for the inductive enquiry (Chapters 4 and 5) comprised one rural and regional area in south-east Australia. The experiences of rural and regional participants from one area may have limited the types of contributory factors for safety incidents identified and the importance placed on them. Metropolitan participants or participants from other areas in Australia or other countries may identify new or different contributory factors or place different levels of importance to those already acknowledged. Some of these concerns are mitigated by the concordance with the findings in the primary care literature,[102, 103, 254] the hospital literature,[86, 111, 321] and the theoretical framework.[188] Face validity testing of the PC PMOS was conducted with primary care patients and staff from

Australia and the UK, and showed little variability between these two groups. Further research studies are needed to establish the validity and reliability of the tool with other primary care populations.

Secondly, when considering the PC PMOS tool as a patient engagement in safety activity, it does sit at the lower end of the patient engagement spectrum.[110, 161] Patient feedback through surveys is said to suffer from various limitations. Examples of such limitations include the control of the feedback process. Often the provider or organisation regulates the processes and mechanisms of patient feedback and patients are discouraged from being involved in designing or implementing patient feedback strategies.[110] Another limitation of collecting feedback through surveys is that patients are doubtful about feedback being acted upon by the organisation.[110] Patients consider surveys to be a compliance-driven exercise, rather than an improvement tool. In conjunction with this last point, practitioners or organisations are seldom able to make changes to practice based on patient feedback for many reasons (i.e. insufficient time and resources, ambiguous patient feedback, lack of knowledge or skills in safety improvement). Surveys are also less likely than other more interactive or participatory forms of patient feedback to result in changes to patient safety, unless there is a team committed to actively using this information and moving forward with improvements.[110]

While surveys are a passive form of patient engagement, they have been proven useful for identifying problems that can generate more active forms of involvement. Furthermore, carefully designed, validated and evidence-based instruments that capture what is deemed important to patients have been correlated with clinical indicators of quality of care,[331] such as communication and care coordination.[332] Carmen et al. (2013) have also stated that patient feedback through surveys is appropriate when implementing interventions across multiple levels of engagement.[161] The PC PMOS is intended to be used in conjunction with other patient safety measures and activities in primary care so it meets some of these limitations described above. Given the absence of any other available tools specifically capturing patient views of the contributing factors to safety incidents in primary care, it provides a starting point for further exploration of its effectiveness as a patient engagement in safety strategy.

Thirdly, a recent editorial by Iedema and Angell in *BMJ Quality & Safety* (2015) made some criticisms about the PMOS tool and its application.[63] This has implications for the PC PMOS, which has direct lineage from the PMOS. Their criticisms were related to the difficulties with the measurability of patient experience, the translation of measurement into practice improvement, and current approaches and experiences of service responses to patient feedback.

Measuring patient experience accurately is challenging no matter what method is used. The appropriateness of methods for various patient demographics and population profiles is important when capturing patient feedback. Different population groups may respond differently to questionnaire scales, items and formats. Additionally, when designing tools for patient feedback, the inclusion of vulnerable groups—such as those with low English proficiency, from diverse cultural backgrounds, the elderly, or patients with high levels of disability—is necessary to ensure the composition of items and results are comparable across the population. The PC PMOS was designed from inductive enquiry of a diverse patient profile whose demographics included vulnerable groups, predominantly those from rural areas, but also patients with low socioeconomic status, the elderly, patients with multiple chronic conditions, and those with low levels of educational attainment. The face validity testing of the PC PMOS was also undertaken with a diverse patient profile from both Australia and the UK. This was performed to ensure an international relevance and applicability of the tool. Additionally, the PC PMOS is currently being translated for use in a research project to improve patient safety culture in the French primary care system. If successful, the PC PMOS could be translated into several other languages.

Translating patient feedback into practice improvement was also noted as a concern by Iedema and Angell (2015).[63] The contextual information necessary for making changes to practice was assumed to be absent from the PMOS. The PMOS is implemented through external facilitation and each item has a comments section where qualitative (contextual) information is collected. Experiences of safety concerns, harms or positive incidents are also captured through qualitative questioning at the end of the PMOS. This information is provided back to staff for them to undertake action planning. When I attended and observed staff action planning meetings the effectiveness of the qualitative comments provided by patients was revealed. This process helped staff to understand their local working conditions and the contexts in which these patient experiences took place. It was the qualitative comments that often contributed to the development of action plans and implementation of change. The PC PMOS has been designed with the same opportunity for qualitative comments as the PMOS to ensure that contextual information needed for effective learning, action planning and behaviour change is collected. The PC PMOS was designed to be self-completed by patients, rather than through external facilitation by a researcher or peer like the PMOS. This difference between the two tools was intended to reduce the labour and resources required to upscale and implement the PC PMOS in primary care setting which is time-poor and potentially hesitant to change. Ease of use by patients and practices was thought to facilitate acceptability and sustainability of the PC PMOS in practice.

Much of the research emerging from the patient safety literature asserts that patients are expert ‘eyewitnesses’ of their care and are willing and able to provide feedback to service providers on their experiences.[42, 111, 333] Conversely, there is research that demonstrates the reluctance of patients to challenge health care professionals directly, and that providers and organisations do not systematically encourage or welcome patient feedback.[258, 259] Furthermore, patients are often dissatisfied with the process of providing feedback and find it challenging to discuss experiences of harm.[259] These issues may affect the uptake, implementation and effectiveness of the PC PMOS in primary care. Current governance structures, organisational culture, and absence of policy or processes could prevent practices seeking patient feedback on safety. As mentioned in Chapter 2, these are broader problems at the policy or organisational level that require greater attention and investment into patient safety improvement more generally. Until these challenges are resolved at a national level there still remain some existing opportunities to introduce the PC PMOS into primary care. These are discussed at the end of this chapter.

11.2 Recommendations for future research

The PC PMOS will need to undergo psychometric testing to confirm the tool’s construct validity and reliability. A large validation study will need to be undertaken to determine the:

- factor structure and internal reliability of the scale (test–retest reliability)

- extent to which the scale discriminates among general practices (discriminant validity)
- extent to which the scale predicts safety incidents (predictive validity), and
- extent to which the scale converges with staff measures of patient safety (convergent validity).

Using the PMOS validation study as an example, approximately 500 patients across 10 primary care practices would need to complete the PC PMOS. This predicted sample size is based on the principle of needing 10 participants per questionnaire item, and the PC PMOS is comprised of 50 items. A small subsample of patients (approximately 10% of the total sample) would need to complete the PC PMOS again for test–retest reliability purposes.[334, 335] Practice staff would also need to complete a safety measure, such as staff perceptions on safety culture, to determine the convergent validity. Predictive validity is problematic due to frequency of safety incidents reported in primary care, and the lack of adequate clinical risk management systems that contain sufficient data on the types of incidents that occur. A potential option to overcome this issue would be to collect self-reported incident data from patients at the time of data collection for the PC PMOS.

A validation study would determine the robustness of the PC PMOS tool and verify the final factor and item structure. Further confirmatory factor analysis with another patient population will be needed to corroborate the factor and item structure validity. Ideally, this population would be from somewhere other than Australia to strengthen the tool's relevance and applicability on an international scale.[vi]

Once the PC PMOS has undergone psychometric testing, an evaluative trial to assess the tool's effect on safety outcomes will be needed. A trial similar to that undertaken to assess the effectiveness of the PMOS in hospital settings[189-192] could be used as a model for undertaking a comparable study in primary care. A process evaluation would also be needed to occur alongside the evaluative trial to determine the acceptability, adoption, appropriateness, fidelity of the PC PMOS as a patient involvement in safety intervention.

11.3 Potential practical application of the PC PMOS

There is a plethora of surveys available to measure a variety of patient experiences and outcomes. Nonetheless, many of these tools are never applied and utilised in regular practice because they are either too burdensome on patients or practice staff or these data collected are not perceived as useful by people at the sharp end of practice.[336]

The sharp end of care in the primary care clinical setting is the frontline activity where the patient directly interacts with the health care team, and where safety and quality is created. This setting within the system of care is "the key to implementing effective strategy, information technology, and other key aspects of intelligent enterprise" (Mohr, Batalden & Barach, 2004 p.ii34).[337] Safety measurement from the patient's perspective within the

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[vi] At the time of writing the PC PMOS has undergone preliminary validation testing with a sample of patients in Manchester, UK. The initial confirmatory factor analysis results are promising with 22 items being removed to devise a 9 factor model consisting of 28 items. This 28 item PC PMOS demonstrated good internal reliability with average inter-item correlations ranging from 0.20 to 0.70. The 28 item PC PMOS also demonstrated good discriminant validity between primary care practices ($F = 2.64$, $df = 72$, $p < .001$). But, it did not demonstrate good convergent validity with practice staff patient safety scores; failing to reach statistical significance ($r = -0.64$, $k = 9$, $p = .06$). Further analysis is currently being undertaken (July 2017) and publication of the full validation results are expected in late 2017 / early 2018.

primary care clinic, like the PC PMOS, needs to be of value to the people contained within that system. In addition to being of value to the primary care clinic, the introduction and sustainability of the PC PMOS is also important when considering its application in practice.

Existing approaches to patient safety in Australian primary care that were described in Chapter 2 could be used to test the value of the PC PMOS when embedded in practice. This could consist of trialling and promoting the PC PMOS through the Australian Primary Care Collaboratives (APCC) program at the primary health network level or systematically introducing the tool into the 5th edition of the RACGP Standards[338] and accreditation process.

Although the APCC are now unfunded, a meso- level primary care organisation like the APCC or Primary Health Networks (PHNs) could trial the PC PMOS as an improvement wave in primary care practices. The APCC have shown great interest in developing and running a patient safety wave, and were leading partners when designing a manual for patient safety in primary care.[339] A further extension of this wave's focus on accurate patient health summaries, clinical audit, automated trigger tools, event logs, significant event analysis and medication reviews, could include patient feedback on safety using the PC PMOS. Including patient feedback on safety in this way complements the proposed strategies to improve safety.

The Plan Do Study Act (PDSA) method of the Collaboratives would be appropriate for the introduction and assessment of the PC PMOS. The PDSA method is familiar to many primary care practices and is used to test the effectiveness of change in practice. Practice teams develop a plan to test the change (Plan), carry out the test (Do), observe and learn from the consequences (Study), and determine what modifications should be made to the test

(Act).[340] The change, in this instance, would be to decide to use patient feedback to improve safety (Plan). The Do part would entail obtaining patient feedback through administration of the PC PMOS. The Study part would involve analysing the patient data, and then developing an action plan (Act) to make changes to practice based on these data. The cycle could be repeated over various time points to assess if improvements in safety are being achieved at the practice level. These data collected at the wave level could then be used to determine if the PC PMOS tool was effective in a larger cohort of practices. The Collaboratives approach to improvement is similar to how the PMOS is being implemented and evaluated in hospital settings in the UK.[189-192]

PHNs could help to facilitate promotion of the PC PMOS as a safety improvement Collaborative at the practice level. As one of the four priorities for the PHNs is to focus on quality and safety of care, this type of Collaborative would connect practices to safety improvement activities occurring locally. Alternatively, PHNs could promote the PC PMOS through their internal networks and assist with facilitation and implementation at the practice level.

The 5th edition of the RACGP Standards require that practices seek feedback from patients once every three years.[338] They have options about how they seek this feedback but this usually takes the form of a questionnaire. This can be either a validated and recommended patient experience questionnaire or they can develop and use a practice-specific method (either a self-derived questionnaire or patient focus group or interviews). The 5th edition of the RACGP Standards also require that practices regularly monitor, identify and report near misses and mistakes in clinical care and identify deviations from standard clinical practice that may result in patient harm.[338] Once validated, the PC PMOS could be used as a tool to meet both RACGP standard of care requirements during the accreditation process. This could be achieved through applying to RACGP to have the PC PMOS considered as an approved validated questionnaire. Approval at this level would allow the systematic introduction and use of the tool in practice. One of the accreditation agencies (AGPAL) has shown interest in the PC PMOS tool through an invitation to present the research from this thesis at a workshop during their conference in 2016. Participants in this workshop consisted of general practitioners, practice nurses, researchers, and patients. Participants were able to trial the PC PMOS in small groups using patient case studies, identify the contributory factors to safety, and brainstorm types of safety improvement interventions based on the PC PMOS feedback. Workshop participants found the tool useful and were positive about its potential application in practice.

Recognition of the potential importance of the patient voice and contribution to safety improvement is something recommended by all those involved in safety improvement including clinicians, organisations, policymakers, and the patients themselves.[42, 95] The findings from investigations in this thesis go some way to attending to this unmet need, and building a contribution to new knowledge in the field of patient safety in primary care.

APPENDICES

Appendix 1. Definitions of terms used in patient safety literature

Term	**Definition**[341]
Harm	Occurs if a patient's health or quality of life is negatively affected by any aspect of his or her interaction with health care.
Error	Often used to include slips and lapses, mistakes, close calls and near misses.
Slips and lapses	Occur when people know what they want to do, but actions do not turn out as they intended or according to plan. Slips are often associated with a lack of attention because, for example, of a distraction, while lapses are associated with failure of memory.
Mistakes	Occur when the plan itself is wrong and failure is associated with faulty judgement, decision making, knowledge or problem solving.
Adverse events	Imply harm and result in unintended injury caused by medical management.
Patient safety incidents	Defined by the National Patient Safety Agency (NPSA) (2004) as 'unintended or unexpected incidents that could have led, or did lead, to harm for one or more patients'.[342]
Near miss	Defined by the NPSA (2004) as a 'prevented patient safety incident',[342] in other words, an event or circumstance with the potential to cause harm, but which in this case was avoided.
Never events	Serious, largely preventable, patient safety incidents that should not have occurred if the available preventive measures were implemented, for example wrong site surgery.

Reproduced from: McCaughan D, Kaufman G. Patient safety: threats and solutions. Nursing Standard 2013;27(44):48-55

Appendix 2. Co-author declarations

Co-author Declaration: Prof James Dunbar

Declaration by Andrea Hernan ('the candidate') regarding their contribution to the manuscripts presented in this thesis:

Manuscript details	Candidate involvement
Hernan A, Walker C, Fuller J, Johnson J, Elnour A, Dunbar J. Patients' and carers' perceptions of safety in rural general practice. Med J Aust. 2014; 201: S60-S3.	I led all aspects of this manuscript including: • Concept and study design • Data collection and analysis • Writing of the manuscript • Submission of manuscript and responsibility for coordinating and drafting revisions My overall contribution to the manuscript was about 75%. Data analysis was undertaken jointly with Dr Christine Walker. Remaining authors contributed to specific sections of writing the manuscript. I was not responsible for grant writing or acquisition of funding for this research project.
Hernan A, Giles S, Fuller J, Johnson J, Walker C, Dunbar J. Patient and carer identified factors which contribute to safety incidents in primary care: a qualitative study. BMJ Qual Saf. 2015; Published Online First: 13th May 2015, doi:10.1136/bmjqs-2015-004049	I led all aspects of this manuscript including: • Concept and study design • Data collection and analysis • Writing of the manuscript • Submission of manuscript and responsibility for coordinating and drafting revisions My overall contribution to the manuscript was about 75%. Data analysis was undertaken jointly with Dr Sally Giles. Remaining authors contributed to specific sections of writing the manuscript. I was not responsible for grant writing or acquisition of funding for this research project.
Hernan A, Giles S, O'Hara J, Fuller J, Johnson J, Dunbar J. Developing a primary care patient measure of safety (PC PMOS): a modified Delphi process and face validity testing. BMJ Qual Saf.	I led all aspects of this manuscript including: • Concept and study design • Data collection and analysis

2015; Published Online First: 4th July 2015, doi:10.1136/bmjqs-2015-004268	• Writing of the manuscript • Submission of manuscript and responsibility for coordinating and drafting revisions My overall contribution to the manuscript was about 70%. Data collection and analysis was undertaken jointly with Dr Sally Giles. Data analysis was undertaken jointly with Dr Jane O'Hara. Remaining authors contributed to specific sections of writing the manuscript. I was not responsible for grant writing or acquisition of funding for this research project.

Declaration by the co-author

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to the this manuscript, and the nature of the contribution of each of the co-authors;

2. They meet the criteria for authorship in that they have participated in the conception, execution or interpretation of the data, or writing of the manuscript that reflect their field of expertise;

3. They will take public responsibility for their role in the manuscript, except for the first author (the candidate) who accepts overall responsibility for the publication;

4. There are no other authors of the publication according to these criteria; and

5. Potential conflicts of interest have been disclosed to the editor or publisher of journals, and appear in the end matter of each manuscript.

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Co-author Declaration: Dr Amr Abou Elnour

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Manuscript details	Candidate involvement
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5. Potential conflicts of interest have been disclosed to the editor or publisher of journals, and appear in the end matter of each manuscript.

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Date: 26/06/2015

Co-author Declaration: Prof Jeffrey Fuller

Declaration by Andrea Hernan ('the candidate') regarding their contribution to the manuscripts presented in this thesis:

Manuscript details	**Candidate involvement**
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5. Potential conflicts of interest have been disclosed to the editor or publisher of journals, and appear in the end matter of each manuscript.

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Jeffrey Fuller Date:

7 July 2015

Co-author Declaration: Dr Sally Giles

Declaration by Andrea Hernan ('the candidate') regarding their contribution to the manuscripts presented in this thesis:

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Hernan A, Giles S, Fuller J, Johnson J, Walker C, Dunbar J. Patient and carer identified factors which contribute to safety incidents in primary care: a qualitative study. BMJ Qual Saf. 2015; Published Online First: 13th May 2015, doi:10.1136/bmjqs-2015004049	I led all aspects of this manuscript including: • Concept and study design • Data collection and analysis • Writing of the manuscript • Submission of manuscript and responsibility for coordinating and drafting revisions My overall contribution to the manuscript was about 75%. Data analysis was undertaken jointly with Dr Sally Giles. Remaining authors contributed to specific sections of writing the manuscript. I was not responsible for grant writing or acquisition of funding for this research project.
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Hernan A, Walker C, Fuller J, Johnson J, Elnour A, Dunbar J. Patients' and carers' perceptions of safety in rural general practice. Med J Aust. 2014; 201: S60-S3.	I led all aspects of this manuscript including: • Concept and study design • Data collection and analysis • Writing of the manuscript • Submission of manuscript and responsibility for coordinating and drafting revisions My overall contribution to the manuscript was about 75%. Data analysis was undertaken jointly with Dr Christine Walker. Remaining authors contributed to specific sections of writing the manuscript. I was not responsible for grant writing or acquisition of funding for this research project.
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3. They will take public responsibility for their role in the manuscript, except for the first author (the candidate) who accepts overall responsibility for the publication;
4. There are no other authors of the publication according to these criteria; and
5. Potential conflicts of interest have been disclosed to the editor or publisher of journals, and appear in the end matter of each manuscript.

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Name: Julie K Johnson

Date: 7 July 2015

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Declaration by Andrea Hernan (‘the candidate’) regarding their contribution to the manuscripts presented in this thesis:

Manuscript details	Candidate involvement
Hernan A, Giles S, O’Hara J, Fuller J, Johnson J, Dunbar J. Developing a primary care patient measure of safety (PC PMOS): a modified Delphi process and face validity testing. BMJ Qual Saf. 2015; Published Online First: 4th July 2015, doi:10.1136/bmjqs-2015-004268	I led all aspects of this manuscript including: • Concept and study design • Data collection and analysis • Writing of the manuscript • Submission of manuscript and responsibility for coordinating and drafting revisions My overall contribution to the manuscript was about 70%. Data collection and analysis was undertaken jointly with Dr Sally Giles. Data analysis was undertaken jointly with Dr Jane O’Hara. Remaining authors contributed to specific sections of writing the manuscript. I was not responsible for grant writing or acquisition of funding for this research project.

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4. There are no other authors of the publication according to these criteria; and

5. Potential conflicts of interest have been disclosed to the editor or publisher of journals, and appear in the end matter of each manuscript.

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Co-author Declaration: Dr Christine Walker

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4. There are no other authors of the publication according to these criteria; and
5. Potential conflicts of interest have been disclosed to the editor or publisher of journals, and appear in the end matter of each manuscript.

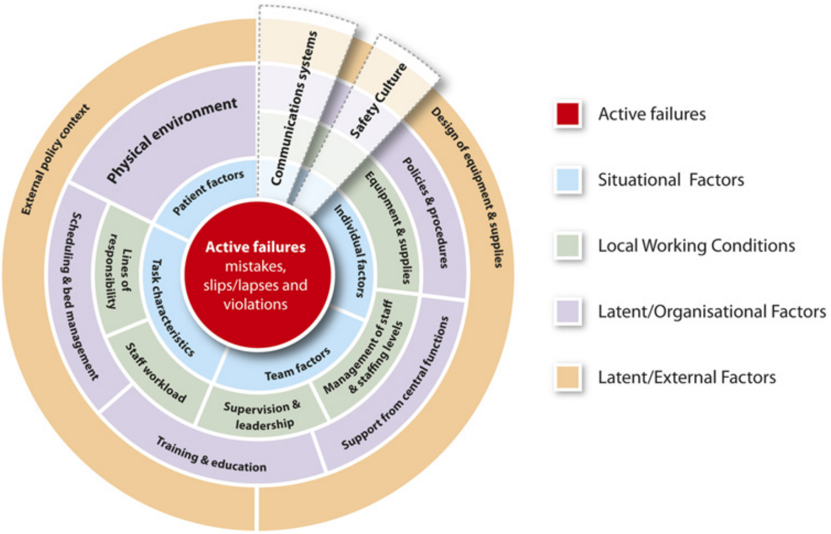
Signature: Christine Walker.

Name:

CHRISTINE WALKER.

Date: 8/7/2015

Appendix 3. The Yorkshire Contributory Factors Framework



Factor	Definition
Active failures	Any failure in performance or behaviour (eg, error, mistake, violation) of the person at the 'sharp-end' (the health professional)
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services. This includes both written (eg, documentation) and verbal (eg, handover) communication systems
Equipment and supplies	Availability and functioning of equipment and supplies
External policy context	Nationally driven policies / directives that impact on the level and quality of resources available to hospitals
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations
Individual factors	Characteristics of the person delivering care that may contribute in some way to active failures. Examples of such factors include inexperience, stress, personality, attitudes.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing levels for the volume of work
Patient factors	Those features of the patient that make caring for them more difficult and therefore more prone to error. These might include abnormal physiology, language difficulties, personality characteristics (eg, aggressive attitude).
Physical environment	Features of the physical environment that help or hinder safe practice. This refers to the layout of the unit, the fixtures and fittings and the level of noise, lighting, temperature etc.
Policy and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality
Safety culture	Organisational values, beliefs, and practices surrounding the management of safety and learning from error
Scheduling and bed management	Adequate scheduling to manage patient throughput minimising delays and excessive workload
Staff workload	Level of activity and pressures on time during a shift
Supervision and leadership	The availability and quality of direct and local supervision and leadership
Support from central functions	Availability and adequacy of central services in support the functioning of wards/ units. This might include support from Information Technology and Human Resources, portering services, estates or clinically related services such as radiology, phlebotomy, pharmacy.
Task characteristics	Factors related to specific patient related tasks which may make individuals vulnerable to error
Team factors	Any factor related to the working of different professionals within a group which they may be able to change to improve patient safety
Training and education	Access to correct, timely and appropriate training both specific (eg, Task related) and general (eg, Organisation related)

Reproduced from: Lawton R, McEachan RRC, Giles SJ, Sirriyeh R, Watt IS, Wright J. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. BMJ Qual Saf 2012;21:369-80[188]

Appendix 4. Summary of the strengths and weakness of the literature review studies

Schoen C, Osborn R, Doty MM, Bishop M, Peugh J, Murukutla N. Toward Higher-Performance Health Systems: Adults' Health Care Experiences In Seven Countries, 2007. *Health Affairs* 2007;26(6):717-34.[239]

The major strength of this study was the ability to perform international comparisons of patient-reported primary care experiences of safety within a large sample size. The questions asked of adults were specific and presented as combined and separated rates of error per country. The additional participant responses investigated in the survey provide supporting evidence for promotion of medical homes; however, this is a US-centric conclusion and not necessarily generalisable to all primary care systems internationally. Furthermore, the definition of a primary care medical home was devised from four indirect questions about accessing regular doctors, medical history location, care coordination and ease of contact. A direct question regarding what the patient or country defines as a medical home would enable more clarity and trust in the survey responses. The findings are briefly explained in the discussion with little reference to the literature to corroborate or contest the results.

Panagioti M, Blakeman T, Hann M, Bower P. Patient-reported safety incidents in older patients with long-term conditions: a large cross-sectional study. BMJ Open 2017;7(5).[240]

The main strength of this study is the investigation of self-reported safety incidents with a population at high risk of experiencing errors in care; older patients with chronic health conditions. The findings from this study fill a gap in an under researched area with a population group that is often excluded from research. The large sample size of the population is another study strength. The associations of patient characteristics and self-reported safety incidents were conducted using robust statistical analysis methods and increase the reliability of the findings. The limitations of this study is the use of dichotomous variables to determine the type of errors patients' experience. This limits the potential of other error types to be specified by patients and prevents wider understanding of all types of errors prevalent in primary care. The error rate may also be subject to under or over-reporting bias as it was self-reported by patients and not compared to another object measure of error.

Mira JJ, Nebot C, Lorenzo S, Pérez-Jover V. Patient report on information given, consultation time and safety in primary care. *Quality and Safety in Health Care* 2010;19(5):1-4[241]

The findings regarding continuity of care were not elaborated in the discussion section of the paper and the self-reported methods used means that objective validation was not performed to determine the legitimacy of patient accounts.

Kistler CE, Walter LC, Mitchell C, Sloane PD. Patient perceptions of mistakes in ambulatory care. *Archives of internal medicine* 2010;170(16):1480-87.[242]

The strengths of the study by Kistler et al. (2010)[242] were that sampling of survey participants was employed across a large and diverse sample of primary care patients, and the findings were consistent with the literature regarding patient perceptions of error in primary care. There were some limitations of this study. Sampling bias may have occurred in primary care practices through the use of opportunistic participant recruitment. Frequent users of primary care are more likely to have chronic conditions or poor health that impacts on the likelihood of experiencing and perceiving a medical mistake. These findings may therefore be an overestimation of the true rate of error in primary care. The high level of self-reported harm resulting from a wrong diagnosis or wrong treatment is not consistent with the literature that states error in primary care may be frequent, but harm resulting from the error is much lower than in secondary care settings. This unexpected result was attributed to patients having a broader definition of harm compared with practitioner or academic definitions of harm. The Likert scale used to assess the level of harm may not be an effective scale to capture patient views of harm for this patient population. While the sample was large and generally representative of the population studied, the findings may not be generalisable to other patient populations elsewhere in the US or other countries. Like most of the patient-reported studies, no review of medical records was performed to determine the actual level of harm and compare similarities and differences between patient and objective review. The authors suggested that the findings were related to frequent attendance by patients with chronic back pain and poor physical health. Frequent attendance is a predisposing factor for patients to be at increased risk of adverse events. This conclusion is supported by the literature, however, the finding of patients with high levels of education having higher likelihood of perceiving mistakes and African-Americans being less likely to perceive mistakes contrasts with the literature. The authors suggest that low educational attainment and minority status are related to increased satisfaction with care, lower rates of complaints, and lower expectations of care. These characteristics were then thought to translate into less likelihood of perceiving a mistake. This explanation for the results is somewhat of an exaggeration and lacks a clear relationship. The limitations of this study (noted above, including sampling bias and data collection methods) could contribute to these unexpected results.

Solberg LI, Asche SE, Averbeck BM, Hayek AM, Schmitt KG, Lindquist TC, et al. Can patient safety be measured by surveys of patient experiences? *Joint Commission Journal on Quality and Patient Safety* 2008;34(5):266-74.[243]

This study by Solberg et al. (2008) demonstrates the difference between patient reports of error and what practitioners consider to be an error.[243] Interpretation of the term 'error' by patients may be an explanation for the difference observed between patient reports of safety incidents and practitioner categorisation or error. Study methods that incorporate an objective view to corroborate or dispel patient self-reported safety incidents strengthen the credibility of the findings. The chart review indicating that 2% of patient-reported incidents were considered as error corresponds to findings obtained in other record review studies in primary care. While the inclusion of an objective view is a study strength there were some limitations to this process. Firstly, the schema used for the categorisation of error was self-derived and not based on any evidence-based framework or taxonomy. Secondly, single screening of error reports in the first instance by one nurse may have missed potential errors, and the report may not have gone on for subsequent categorisation of error by the physicians. This may have resulted in an underestimation of patient-reported errors. Thirdly, response bias may have been prevalent in the physician reviewers who were all physicians or had association with the practice where the data were collected. This may have been particularly evident in their judgement regarding classification of 'misunderstandings' of care. Other limitations of the study concerned the questions used to elicit patient reports of error. The question used in this study asked about any errors in the participant's family, therefore the actual rate reported in this study is likely to be much lower due to the increase in sample size.

Kuzel AJ, Woolf SH, Gilchrist VJ, Engel JD, LaVeist TA, Vincent C, et al. Patient reports of preventable problems and harms in primary health care. ***Annals of Family Medicine*** **2004;2(4):333-40.[244]**

Although quantifying the qualitative data may be seen as a weakness of the study design, given the aim of the study was to create a taxonomy of errors, the design can be considered appropriate in this case. Other limitations of this study are that the patient experiences may not be transferable to other US communities or international population. Random sampling of patients with general experiences of primary care, rather than sampling patients with specific safety incidents, may yield different types of errors or harms and influence the taxonomy produced. Recall bias may also influence the results as patients were asked to describe problematic issues with primary care from their entire past experience. The authors detail at length the mistakes perceived by patients and associated effects for the normal diagnostic/treatment challenges, and possible adverse events/near misses categories – but not the communication/relationship issues category. This makes it difficult to draw conclusions about this finding. The authors also combine communication and relationship issues together in one category when they are commonly thought of as two distinct contributory factors to safety in primary care.

Buetow S, Kiata L, Liew T, Kenealy T, Dovey S, Elwyn G. Approaches to reducing the most important patient errors in primary health-care: patient and professional perspectives. *Health & Social Care in the Community* 2010;18(3):296-303.[245]

The limitation of this study is the types of patient errors identified are not unique when compared with the literature, and are directly related to the specific characteristics of each group. The strength of this study, however, is that it provides a ranking of importance for patient-related errors and hence helps to delineate areas of potential action that matter most to patients. Furthermore, patient sampling and recruitment methods of the study may bias some of the findings as marginalised patients may have different views from other patient groups.

Cunningham DE, McNab D, Bowie P. Quality and safety issues highlighted by patients in the handling of laboratory test results by general practices-a qualitative study. *BMC Health Services Research* 2014;14(1):206.[246]

The authors described the results adequately and compared and contrasted the results with other studies in the literature. There were a few limitations, namely around patient sampling, which may have biased some of the findings as patients were recruited directly by the practice manager, they were all located from one NHS board, and all were over 45 years of age. Younger patients and a random sample may have yielded different results. Furthermore, analysis of the data was not adequately described in the methods section. There was no mention of an analysis framework or theory, just that it was performed in a thematic approach. There was no information provided about how codes were generated.

Litchfield IJ, Bentham LM, Lilford RJ, McManus RJ, Greenfield SM. Patient perspectives on test result communication in primary care: a qualitative study. *British Journal of General Practice* 2015;65(632):e133-e40.[247]

One of the limitations of this study is the focus group methodology and number of patients within each group. Three out of the six focus groups had three or less patients who were also relatively homogenous in terms of age, gender and socio-economic status limiting the transferability of the results to other communities or countries. It is also unclear exactly how many focus groups were conducted. This paper may have benefited from adhering to the reporting of qualitative research guidelines like the COREQ.

Brown M, Frost R, Ko Y, Woosley R. Diagramming patients' views of root causes of adverse drug events in ambulatory care: An online tool for planning education and research. *Patient Education and Counseling* 2006;62(3):302-15.[248]

The major strength of this study was the use of an evidence-based model for data collection and analysis, and the resulting diagram for use in practice. The composition of the patient sample is a study limitation as it contained more women than men who were of higher socio-economic status than the general population. Therefore their views may not be representative of the wider population.

Serper M, McCarthy DM, Patzer RE, King JP, Bailey SC, Smith SG, et al. What patients think doctors know: Beliefs about provider knowledge as barriers to safe medication use. *Patient Education and Counseling* 2013;93(2):306-11.[249]

The strength of this study was that it included a large sample of patients and employed random recruitment of adults who were capable of completing the structured interview. This enhances the generalisability of the results to other communities. As in the Brown et al. (2006) study,[248] miscommunication between the patient and the practitioner was expected to impact on the occurrence of ADEs; however, both studies did not investigate the actual occurrence of ADEs.[248, 249] An objective and external source of data is needed to validate the self-reported data. Furthermore, much of the contextual information about patient and practitioner interaction was not captured in the study, which may help to explain some of the findings.

Rhodes P, Campbell S, Sanders C. Trust, temporality and systems: how do patients understand patient safety in primary care? A qualitative study. *Health Expectations* 2016;19(2):253-63.[102]

Rhodes P, Sanders C, Campbell S. Relationship continuity: when and why do primary care patients think it is safer? *British Journal of General Practice.* 2014;64(629):e758-e64.[103]

The major strength of this study was the in-depth exploration of a relatively under-reported topic. Their findings and interpretation go beyond most of the qualitative studies obtained in this literature review. Themes and subthemes are verified with patient quotes and the results are substantiated alongside the sociological literature on doctor–patient relationships and safety in primary care. The limitation of this study concerns transferability of findings. As the primary care system and structure in the UK is different from other countries some of the findings regarding access to care and choice of provider are limited to this sample only.

Dowell D, Manwell LB, Maguire A, An PG, Paluch L, Felix K, et al. Urban outpatient views on quality and safety in primary care. *Longwood Review*. 2005;3:2-8.[250]

While the list of the patient and practitioner interpersonal characteristics is valuable, the study only briefly touches on this contributory factor to safety, without going into much depth about ways practitioners could enhance communication or the potential safety benefits or consequences of patient–practitioner communication. The analysis was said to be conducted using grounded theory but the authors then went on to count and present the frequencies of themes and subthemes. This technique implies a confusion of methodologies. The small number of participants from one area in the US also reduces the transferability of the findings. The system-level issues such as insurance and funding may not be applicable to other primary care contexts internationally where primary care is available at no or little cost.

Scobie A, MacKinnon NJ, Higgins S, Eichegary H, Church R. The medical home in Canada: Patient perceptions of quality and safety. *Health Management Forum* 2009;22(1):47-51.[251]

Like the Schoen et al. (2007) study,[239] which utilised the Commonwealth Fund survey data, this study used the same method for devising a definition of a medical home using four indirect questions about accessing regular doctors, medical history location, care coordination and ease of contact. A direct question regarding what the patient defines as a medical home would enable more clarity and trust in the associations presented. Nonetheless, the findings from this study are in keeping with the literature on continuity of care and its influence on safety in primary care. The Commonwealth Fund surveys employ standardised sampling and weighting rules to enhance generalisability of results to the wider Canadian population.

Clark R, Australian *Patient Safety Survey*, PhD thesis, School of Health Sciences, Deakin University 2002.[132]

Although this study provides valuable information regarding the thesis aims and objectives, there are some limitations. The data are now over 10 years old and the sample was primarily from metropolitan areas. Moreover, many of the predictors of adverse events lack detail regarding patients' views of latent and error-producing conditions in primary care that make it susceptible to safety incidents. They were mainly attributed to error producing conditions in the environment and not latent or system-level factors,[132] which is contrary to the evidence from hospital settings that suggests patients can identify a range of error-producing and latent factors contributing to safety incidents.[111, 114] Furthermore, the self-reported nature of the survey means that the results could be an over or under report of the actual occurrence of adverse events.

Flink M, Öhlén G, Hansagi H, Barach P, Olsson M. Beliefs and experiences can influence patient participation in handover between primary and secondary care—a qualitative study of patient perspectives. *BMJ Quality & Safety* 2012;21(Suppl 1):i76-i83250[252]

This study employed a theory-driven coding framework to analysis constructed within a clear and relevant study aim. The results are detailed and the themes are presented with associated patient accounts. The discussion explained the findings with reference to the literature and provided recommendations for improving the handover process. The limitations of this study include the sample characteristics. Patients with chronic diseases may have different handover experiences from patients without a chronic disease. These patients may have disabilities that prevent them from participating in the handover process and therefore the conclusions about participation may not be transferable to all patient populations. The primary and secondary care context in Sweden may not be applicable to other health care contexts internationally.

Flink M, Hesselink G, Pijnenborg L, Wollersheim H, Vernooij-Dassen M, Dudzik-Urbaniak E, et al. The key actor: a qualitative study of patient participation in the handover process in Europe. *BMJ Quality & Safety* 2012;21(Suppl 1):i89-i96.251[253]

Similar to the first study, recommendations for future studies and practice implications are made and comparison of the findings with the literature is carried out. There are some study limitations, however, including lack of detail about the study population demographic characteristics. There is no indication of patient age, gender, or type of chronic condition. This lack of information makes it difficult to determine the patient context and connection to the findings. The methods for data analysis also have some limitations. Secondary analysis of data prevents validity checks with the original source and can bias the findings to the researcher's interpretation, rather than the true patient account. Patient stories, the interviews and focus groups were also not translated from the native language in which they were conducted into English or back translated by a second team of professional translators, but rather by the research team. This may have resulted in linguistic misinterpretation and discredits the results. Furthermore, analysis was not performed within or between countries. This type of analysis may have identified deviant cases or divergent findings that would provide information on which types of patients and what kinds of health care contexts enable patient participation in the handover process to be successful. These sampling and analysis limitations constrain the integrity of the results.

Rhodes P, McDonald R, Campbell S, Daker-White G, Sanders C. Sensemaking and the co-production of safety: a qualitative study of primary medical care patients. *Sociology of Health & Illness* 2016;38(2):270-85.[254]

This study used various theories and frameworks (such as Weick's concept of sensemaking[343] and Gidden's theory of trust and risk[344]) to position the research question and perform the analysis. Conceptualising the data with use of such frameworks enables a greater depth of inquiry and advanced understanding of patient involvement in primary care safety. Patient accounts supported the results and conclusions. Although there are many strengths in this study the limitations are confined to the transferability of findings to other populations and countries. Different patients without chronic disease or less experience with primary care may have different views on safety and, as such, the results would be altered.

Appendix 5. Reflexive documentation of research process

My own reflexive process

Aligning with an interpretivist framework was a natural way of thinking about my position in the research framework. My own personal beliefs, values and experiences of undertaking research matched the accepted philosophical underpinnings of viewing the world as existing of multiple realities. My previous research experience and interests somewhat shaped my approach to this study as well as framing my perspectives and ideas. My knowledge base and subsequent literature review refined what I wanted to explore in this study and provided a vantage point to start with. During the analysis I tried to be open and receptive to different or diverging outcomes that were not supported by my original preconceptions; this is especially evident in the themes surrounding the rural context and luck associated with healthcare. I also felt the research process was an intuitive and creative journey where themes emerged naturally from the data without forcing preconceived ideas onto it.

I am a patient and consumer of healthcare myself, as well as a human being and a researcher. Negotiating these simultaneous roles during and after the data collection was moderated through constant awareness and reflection on how and why I was drawn to particular points in the data and how I explored and explained the derived conclusions. I was particularly able to empathise and understand participants' accounts of errors or harms in their care; either because of my own status of being a rural person or because of my family's history of experiences errors in their medical care. This empathy motivated my actions to get to the bottom of the truths, probe and ask supplementary questions as needed to gain a clear and comprehensive understanding of the context that allowed such events to unfold. I was also conscious of creating an environment that allowed participants to honestly share their feelings and thoughts with me, as we were likely to be discussing sensitive issues about health, illness and care. I was strategic to place myself in the centred of the table or area where the focus groups took place to avoid a meeting style or authoritarian interaction. I also clearly described before beginning the discussion about my role as a researcher (particularly regarding my independence from the medical clinic, allied health or community health centre, or hospital), the aims of the study, funding sources, outcomes of participants contribution, and privacy and confidentiality of data.

In addition to the mindfulness described above, the approaches I undertook to assist me with practising reflexivity throughout the data collection and analysis process was the use of note taking during the focus groups as well as afterwards. I often had participants speak with me after the focus group was closed and the audio recorder was turned off so these accounts were written down and added to the data collected. I also kept a journal to record any spontaneous thoughts or ideas which assisted with interpreting the data. This journal was also used post focus group to de-brief with myself about the stories participants shared during the focus groups. It was helpful in reflect on particular points of interest, things to be mindful of when analysing the data, where things could be improved for future groups and potential follow up questions for the next group.

Appendix 6. PC PMOS domains and items in the face validity testing version and reasons why items were discarded

Reason for discarding item key

1. The item was considered not to be a direct contributing factor to patient safety
2. The item was considered difficult for primary care organisations to respond to or take action towards
3. Patients had no knowledge or experience of the particular item. For example, communication that occurred outside a consultation that the patient was not privy to.
4. The item was considered to be repetitive, or clearly phrased elsewhere in another item

*question wording changed after think aloud process

Domain	***PC PMOS item***	***Item source***	***Item retained for final version Yes (Y)/No (N)***	***Reason for discarding item***
Patient related factors	1. The diagnosis or treatment plan recommended by my doctor, nurse or other health professional was right for me*	Self-derived question (Delphi addition)	Y	
Desire for an explanation and apology	2. I did not receive an apology when something went wrong	Self-derived question (Delphi addition)	N	1
Patient related factors	3. The doctor, nurse or other health professional always considered what I want for my care	Self-derived question (Delphi addition)	Y	
Staff training	4. On at least one occasion a member of staff was not able to use the necessary equipment	PMOS	Y	
Dignity and respect	5. I was always treated with dignity and respect	PMOS	Y	
Patient related factors	6. I am responsible for my health	Self-derived question (Delphi addition)	N	2
Provider performance	7. The doctor, nurse or other health professional did not have the skills, experience or knowledge to correctly manage my health condition	Self-derived question (Delphi addition)	Y	

Organisation and Care Planning	8. I have needed urgent treatment and there was no-one available to do it	PMOS	N	2
Team-work	9. Staff didn’t seem to know what they were meant to be doing	PMOS	Y	
Coordination of care	10. I see my doctor as the person who coordinate all my care with specialists and hospitals*	Self-derived question (Delphi addition)	Y	
Staff training	11. Inexperienced staff seemed to find it hard when they were left to do things on their own	PMOS	N	3
Patient related factors	12. I could not remember what my doctor, nurse or other health professional recommended about my treatment	Self-derived question (Delphi addition)	Y	
Communication	13. I always felt that staff listened to me about my concerns	PMOS	Y	
Continuity of care	14. I have an ongoing relationship with this practice	Self-derived question (Delphi addition)	N	1
Communication	15. I was involved in all the decisions about my care	Self-derived question (Delphi addition)	Y	
Communication	16. When staff talked about my care with others the information they shared was correct	PMOS	N	3
Staff roles and responsibilities	17. I knew what the different roles of the people caring for me were	PMOS	N	4
Organisation and Care Planning	18. My care changed and other health professionals outside the practice did not know about it*	PMOS	Y	
Information flow	19. My test results were always available when required e.g. scans, blood tests, x-rays	PMOS	Y	
Communication	20. Nurses interacted with me in a manner I found acceptable	Self-derived question (Delphi addition)	Y	
Communication	21. I always felt that other health professionals listened to what I had to say about my illness / symptoms / treatment	PMOS	Y	

Communication	22. I got answers to all the questions I had regarding my care	PMOS	Y	
Referrals	23. If I was referred important information about my care was passed on / made available*	PMOS	Y	
Communication	24. I always felt that doctors listened to what I had to say about my illness / symptoms / treatment	PMOS	Y	
Communication	25. I was always given enough information that I could understand about my care and treatment	PMOS	Y	
Desire for an explanation and apology	26. I did not receive an explanation when something went wrong	Self-derived question (Delphi addition)	N	1
Provider performance	27. When necessary staff undertook a thorough examination of me during the consultation*	Self-derived question (Delphi addition)	Y	
Access to resources	28. The doctor or nurse had to leave the room to get equipment / supplies that should have been available	PMOS	N	4
Vulnerability	29. I feel I cannot speak up about certain things with health professionals at the practice	Self-derived question (Delphi addition)	Y	
Access	30. My treatment/ procedure did not always happen on time	PMOS	N	4
Access	31. I was able to access the after hours service when needed*	Self-derived question (Delphi addition)	Y	
Information flow	32. Staff always knew everything they needed to know to care for me. e.g. allergies, other conditions, medical history, medications	PMOS	Y	
Continuity of care	33. I have an ongoing relationship with health care professionals	Self-derived question (Delphi addition)	N	1
Referrals	34. My referrals have always been appropriate*	PMOS	Y	

Communication	35. My carer or family member was involved in making decisions about my care where appropriate	Self-derived question (Delphi addition)	N	3
Type and layout of practice	36. The practice was very clean	PMOS	Y	
Communication	37. My carer or family member was provided with enough information that they could understand about my treatment/care plan where appropriate	Self-derived question (Delphi addition)	N	3
Referrals	38. I found the process of getting referred to a specialist/hospital/other health professional difficult	Self-derived question (Delphi addition)	N	3
Risk awareness	39. I think there are safety risks are at the practice	Self-derived question (Delphi addition)	N	3
Organisation and Care Planning	40. Staff gave me conflicting information about my treatment/care	PMOS	Y	
Communication	41. I understood what staff were explaining to me about my care	Self-derived question (Delphi addition)	Y	
Team-work	42. Staff were always able to get help from other staff when they asked for it	PMOS	Y	
Patient related factors	43. I have not always followed the recommended treatment*	Self-derived question (Delphi addition)	Y	
Organisation and Care Planning	44. A doctor or nurse changed my treatment and other doctors or nurses in the practice did not know about it	PMOS	N	4
Information flow	45. Information about me that my health care team needed was always available e.g. discharge summary, referral letters, test results*	PMOS	Y	
Vulnerability	46. I was given the opportunity to voice my concerns	Self-derived question (Delphi addition)	N	4

Patient involvement in safety	47. I knew where to go at the practice if I had a complaint	Self-derived question (Delphi addition)	N	4
Staff roles and responsibilities	48. I have always known which doctor and nurse are responsible for my treatment	PMOS	N	3
Continuity of care	49. Seeing the same doctor, nurse or other health professional is important to me	Self-derived question (Delphi addition)	Y	
Team-work	50. Staff did not work together as a team here	PMOS	N	3
Primary – Secondary Care Interface	51. My doctor always seemed to have the right information after I received treatment elsewhere*	Self-derived question (Delphi addition)	Y	
Equipment (design and function)	52. Equipment needed for my care was always working properly	PMOS	Y	
Team-work	53. Doctors and nurses were always able to get advice from within the practice when needed	PMOS	N	4
Access	54. I was able to make an appointment with a health professional of my choice	Self-derived question (Delphi addition)	Y	
Access to resources	55. The doctor was interrupted during my consultation	Self-derived question (Delphi addition)	Y	
Patient related factors	56. I know about the health conditions I have	Self-derived question (Delphi addition)	N	1
Organisation and Care Planning	57. I knew who to go to in the practice if I needed to ask a question	PMOS	Y	
Primary – Secondary Care Interface	58. Once I had been referred there was a delay*	Self-derived question (Delphi addition)	Y	
Staff training	59. I noticed that staff had different ways of doing the same thing e.g. performing tasks, prescribing medication, following care plans	PMOS	N	2

Time during consultation	60. I had enough time during the consultation with a health care professional	Self-derived question (Delphi addition)	Y	
Organisation and Care Planning	61. Where necessary my doctor, nurse or other health professional regularly monitors/reviews my health condition*	Self-derived question (Delphi addition)	Y	
Communication	62. I always felt that nurses listened to what I had to say about my illness / symptoms / treatment	PMOS	Y	
Type and layout of practice	63. The physical environment made it difficult for staff to do their jobs e.g. poor lighting, consulting room layout, examination equipment, clutter and untidiness	PMOS	N	1
Medicare system and structure	64. The cost of seeing a specialist or other health professional prevented me from accessing these services when it was recommended by my doctor	Self-derived question (Delphi addition)	N	2
Patient involvement in safety	65. The practice has opportunities for patients to be involved in improving safety e.g. patient representatives on committees, complaint systems	Self-derived question (previous research by study team	N	3
Access	66. When I accessed the after hours service it was useful*	Self-derived question (Delphi addition)	Y	
Communication	67. Administration staff interacted with me in a manner I found acceptable	Self-derived question (previous research by study team	Y	
Trust	68. I trust staff at the practice	Self-derived question (previous research by study team	N	1
Organisation and Care Planning	69. There were enough staff at the practice to get things related to my care and treatment done	PMOS	N	3
Medicare system and structure	70. The cost of seeing a doctor, nurse or other health professional at the practice prevented me from seeking care when I needed it	Self-derived question (previous research by study team	Y	

Access	71. I was able to make an appointment at a time that suited me	Self-derived question (previous research by study team	Y	
Patient involvement in safety	72. The practice has opportunities for me to be involved in my own safety	Self-derived question (previous research by study team	N	3
Access	73. Sometimes there was no-one available to deal with aspects of my care	PMOS	Y	
Communication	74. Doctors interacted with me in a manner I found acceptable	Self-derived question (previous research by study team	Y	
Provider performance	75. The doctor made a mistake prescribing a medication	Self-derived question (Delphi addition)	N	1
Medicare system and structure	76. The cost of medications prevented me from filling a script when I needed medication	Self-derived question (previous research by study team	Y	
Staff training	77. Trainees were supervised appropriately	Self-derived question (Delphi addition)	N	4

Appendix 7. Responses to questionnaire items from the patient face validity testing

Item number	Expressed difficulties with understanding		Expressed difficulties in responding		Were able to both understand and respond		Item number	Expressed difficulties with understanding		Expressed difficulties in responding		Were able to both understand and respond	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**		**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
1	4	7	3	8	10	1	26	2	9	1	10	11	0
2	2	9	3	8	10	1	27	2	9	1	9	10	0
3	1	10	2	9	10	1	28	0	11	1	10	11	0
4	0	11	0	11	11	0	29	0	11	0	11	11	0
5	0	11	0	11	11	0	30	1	10	2	9	10	1
6	0	10	1	9	9	1	31	1	10	3	8	10	1
7	2	9	0	11	11	0	32	0	10	1	9	10	0
8	0	11	0	11	11	0	33	2	8	3	7	9	1
9	1	10	0	11	11	0	34	1	9	0	10	10	0
10	2	9	1	10	10	1	35	0	11	2	9	11	0
11	3	8	6	5	10	1	36	0	10	1	9	10	0
12	1	10	0	11	11	0	37	0	10	1	9	10	0
13	0	11	0	11	11	0	38	0	10	1	9	10	0
14	1	10	0	11	11	0	39	1	10	0	11	11	0
15	0	10	0	10	10	0	40	1	10	1	10	11	0
16	1	10	0	11	11	0	41	0	11	1	10	11	0
17	1	10	0	11	11	0	42	0	11	2	9	11	0
18	2	8	1	9	10	0	43	1	10	1	10	11	0
19	2	8	2	8	9	1	44	0	11	1	10	11	0
20	1	10	0	11	11	0	45	1	10	0	11	11	0
21	2	9	0	11	11	0	46	1	10	1	10	10	1
22	0	10	0	10	10	0	47	0	10	2	8	10	0
23	1	10	2	9	10	1	48	1	9	1	9	9	1
24	0	11	0	11	11	0	49	0	11	2	9	11	0
25	0	11	1	10	11	0	50	0	11	1	10	11	0
Item number	**Expressed difficulties with understanding**		**Expressed difficulties in responding**		**Were able to both understand and respond**		**Item number**	**Expressed difficulties with understanding**		**Expressed difficulties in responding**		**Were able to both understand and respond**	
	Yes	**No**	**Yes**	**No**	**Yes**	**No**		**Yes**	**No**	**Yes**	**No**	**Yes**	**No**
51	1	10	1	10	11	0	77	0	11	1	10	11	0
52	0	11	3	8	11	0							
53	0	11	3	8	11	0							

54	1	10	2	9	10	1
55	1	10	2	9	10	1
56	0	10	1	9	10	0
57	0	11	1	10	11	0
58	0	11	3	8	11	0
59	0	11	1	10	11	0
60	0	11	1	10	11	0
61	0	11	0	11	11	0
62	0	11	1	10	11	0
63	0	10	1	10	11	0
64	0	11	1	10	11	0
65	1	10	2	9	11	0
66	1	10	1	10	11	0
67	1	10	2	9	10	1
68	0	10	1	9	10	0
69	0	11	0	11	11	0
70	1	10	2	9	10	1
71	0	10	1	9	10	0
72	2	8	3	7	8	2
73	1	10	1	10	10	1
74	1	10	3	8	11	0
75	0	11	1	10	11	0
76	0	11	3	8	11	0

Appendix 8. Comparison of domains and number of items between draft and final version of the PC PMOS questionnaire

Domain	Included in draft questionnaire (Y/N)	Number of items contained within domain	Included in final questionnaire (Y/N)	Number of items contained within domain
Access	Y	6	Y	6
Access to resources	Y	2	N	
Communication	Y	14	Y	12
Continuity of care	Y	3	Y	1
Coordination of care	Y	1	N	
Desire for an explanation and apology	Y	2	N	
Dignity and respect	Y	1	Y	1
Equipment (design and function)	Y	1	Y	1
External policy context*	N		Y	2
Information flow	Y	3	Y	3
Medicare system and structure	Y	3	N	
Organisation and Care Planning	Y	7	Y	4
Patient involvement in safety	Y	3	N	
Patient related factors	Y	6	Y	6
Physical Environment*	N		Y	1
Primary – Secondary Care Interface	Y	2	Y	2
Provider performance	Y	3	N	
Referrals	Y	3	Y	2
Risk awareness	Y	1	N	
Staff roles and responsibilities	Y	2	N	
Staff training	Y	4	N	
Task Performance*	N		Y	6
Team-work	Y	4	N	

Team Factors*	N		Y	2
Time during consultation	Y	1	N	
Training and Education*	N		Y	1
Trust	Y	1	N	
Type and layout of practice	Y	2	N	
Vulnerability	Y	2	N	
Total		77		50

*Collapsed or renamed domains

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