Unlocking the Potential for Quality Improvement of Healthcare Complaints made about General Practice in Ireland

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Thesis submitted in partial fulfilment of the requirements for the Degree of Doctor of Philosophy (PhD) in Population Health and Health Services Research

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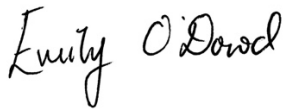
Declarations

I certify that this thesis is all my own work and I have not obtained a degree in this University, or elsewhere, on the basis of this work. My contributions to chapters that were conducted as part of a group project are delineated at the beginning of each of these chapters. No other theses were submitted to this or any other third level institution on the basis of this work.

Emily O'Dowd



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Publications and conference presentations arising from this thesis

Publications

1. O'Dowd E, Lydon S, Madden C, O'Connor P. A systematic review of patient complaints about general practice. Fam Pract 2020;37:3, 297-305 https://doi.org/10.1093/fampra/cmz082
2. O'Dowd E, Lydon S, O'Connor P. Adaptation of the "Healthcare Complaints Analysis Tool" for use in general practice. *Fam Pract* 2021; https://doi.org/10.1093/fampra/cmab040
3. O'Dowd E, Lydon S, Lambe K, Rudland C, Hilton A, O'Connor P. Identifying hot spots for harm and blind spots across the care pathway from patient complaints about general practice. *Fam Pract* 2021; https://doi.org/10.1093/fampra/cmab109
4. O'Dowd E, Lydon S, O'Connor P. A multi-perspective exploration of the understanding of patient complaints and their potential for patient safety improvement in general practice, *Eur J Gen Pract* 2021;27: 1, 35-44 https://doi.org/10.1080/13814788.2021.1900109

Conference presentations

1. ***Limerick Postgraduate Research Conference 2019.***
   Poster presentation: "A systematic review of patient complaints in general practice"
2. ***National Patient Safety Office conference, Dublin, November 2019.***
   Poster presentation: "A systematic review of patient complaints in general practice"
3. ***International Forum on Quality and Safety in Healthcare, Copenhagen, November 2020.***
   Virtual poster presentation: "The impact, motivation for, and learning from patient complaints in general practice; an interview study"
4. ***Trinity Health and Education International Research Conference, March 2021.***

Virtual oral presentation: “Adaptation of the “Healthcare Complaints Analysis Tool” for General Practice Complaints”

5. ***Association of University Departments of General Practice in Ireland (AUDGPI) Joint Scientific Meeting March 2021.***
   Virtual oral presentation: “Adaptation of the Healthcare Complaints Analysis Tool for General Practice Complaints”
6. ***Association of University Departments of General Practice in Ireland (AUDGPI) Joint Scientific Meeting March 2021.***
   Virtual oral presentation: “Using patient complaints to identify the hotspots and blind spots for quality and safety in general practice”

List of abbreviations

AMSTAR: Assessing the methodological quality of systematic reviews

CHOs: Community Healthcare Organisations

CI: Confidence Interval

CINAHL: Cumulative Index of Nursing and Allied Health Literature

CMS: Complaints Management System

CORE-Q: Consolidated Criteria for Reporting Qualitative Research

COVID-19: Coronavirus Disease

GDPR: General Data Protection Regulation

GP: General Practice/ General Practitioner

GMS: General Medical Scheme

GRC: Graduate Research Committee

HCAT: Healthcare Complaints Analysis Tool

HCAT(GP): Healthcare Complaints Analysis Tool (General Practice)

HSE: Health Service Executive

ICAPSS: Irish Centre for Applied Patient Safety and Simulation

IOM: Institute of Medicine

MBI: Maslach Burnout Inventory

NCGLT: National Complaints Governance and Learning Team

NHS: National Health Service

NUIG: National University of Ireland Galway

OR: Odds Ratio

PC PMOS: Primary Care Patient Measure of Safety

PMOS: Patient Measure of Safety

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

PROSPERO: The International Prospective Register of Systematic Reviews

PSI: Patient Safety Incident

QATSDD: The Quality Assessment Tool for Studies with Diverse Designs

UK: United Kingdom

USA: United States of America

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Thesis summary

Healthcare complaints are an underutilised resource for quality and safety improvement. Previous research on healthcare complaints has focused on secondary care. However, there is also a need to consider quality of care in general practice. This PhD thesis aimed to ascertain the potential for healthcare complaints to support quality improvement in general practice.

Four empirical studies were completed. In the first study, a systematic review of 21 studies was carried out to synthesise the extant research on complaints in general practice. This review highlighted the high proportion of clinical complaints in general practice, and the positive and negative impacts that complaints can have on health care systems. In the second study, the Healthcare Complaints Analysis Tool (HCAT), used in secondary care, was adapted for general practice. The adapted tool, HCAT(General Practice) [HCAT(GP)] was tested for reliability with 18 stakeholders using 20 fictionalised complaints. The HCAT(GP) was found to be reliable and valid. In the third study, the HCAT(GP) was used to analyse 230 general practice complaints to identify areas for quality improvement. This analysis identified both hot spots for harm (areas in care where harm occurred frequently) and blind spots (areas that are difficult for staff to observe) in care. In the final study, 29 stakeholders were interviewed in order to explore their perspectives on complaints in general practice. This study revealed an understanding by stakeholders of the potential benefits of complaints, but also highlighted a gap in knowledge between policymakers and practitioners on complaints systems, and a need to further support practitioners who receive complaints.

Complaints made by patients expose issues around quality of care in general practice. Areas where harm occurs to patients in general practice need to be targeted for quality improvement, and future work needs to explore the implementation of the HCAT(GP) in practice.

Chapter 1. Introduction

1.1 General introduction

Modern healthcare systems strive to deliver high quality care to patients. Traditionally, this drive to improve quality of care has been centred on the insights of healthcare professionals. However, recently, the value of patient insights and feedback on their own care has been recognised as a key source of data. This thesis will consider a particularly underutilised source of quality information — healthcare complaints. Complaints are one way through which patients can make their voice heard in healthcare and contribute to quality improvement, but until now their use has been minimally considered or explored. Instead, until recently, the focus has been on addressing complaints on an individual basis rather than on developing learning through their collective analysis. Therefore, complaints are a valuable, but under-exploited, source of information for quality improvement. This thesis will explore the potential of complaints as a form of patient insight into healthcare quality. It will focus particularly on general practice, which is often under-researched compared to the acute services.

1.2 Chapter overview

The purpose of this chapter is to provide the relevant background and context for this PhD thesis. This chapter will first outline the meaning, and domains, of quality in healthcare. A deeper exploration of healthcare quality in general practice will follow. Subsequently, the importance, and value, of patient perspectives on care will be explored, and the potential for the use of healthcare complaints to glean patient insights into quality will be discussed. Next, an analysis of existing research on patient complaints in other healthcare contexts will be outlined. This chapter will then offer an overview of the Irish healthcare system, and specifically Irish general practice, to support contextualisation of the studies that follow and the resulting data. Finally, this chapter will outline the aims of this PhD thesis.

1.3 Definitions

There are several terms which will be used throughout this chapter, and indeed the thesis, which have the potential to cause confusion and

should therefore be clarified at the outset. First, for the purposes of this thesis, "healthcare complaints" refer to expressions of dissatisfaction made by patients about care received within the healthcare system (1). These have also been referred to as "patient complaints" or simply "complaints" in the literature.

Second, the terms "general practice" and "primary care" are also referred to throughout the thesis. These terms are used interchangeably. The WHO defines primary care as first contact, accessible, continued and comprehensive care of patients (2). In the context of this thesis the term "primary care" refers specifically to general practice (i.e., care provided by a team including general practitioner (GP), practice nurse, or admin staff working in a general practice surgery), and does not encompass other fields such as dentistry which are traditionally included in the umbrella term of primary care.

Third, in this thesis, "general practice" and "primary care" are often compared to "secondary care" which refers to the acute services provided within a hospital context. This is defined as healthcare provided which typically requires different specialised skills and equipment than is available in general practice or primary care, and patients are typically referred from primary care to these acute services (3).

Finally, the terms "Ireland" and "Republic of Ireland" are used interchangeably in this thesis, with both referring to the Republic of Ireland only, and not encompassing the healthcare system in Northern Ireland. This is specified as there are two separate healthcare systems on the island of Ireland, with the system in Northern Ireland forming part of the National Health Service (NHS) of the United Kingdom. The Health Service Executive (HSE) is the system in the Republic of Ireland, and the research in this thesis has been conducted in this context.

1.4 Theoretical approaches considered

For the purposes of this thesis, there were two possible directions to take. The first was a patient safety approach, exploring different aspects of safety and how complaints fit into these. Patient safety is a relatively new and burgeoning area within health services research. It has its foundations in

human factors and reliability engineering, and incorporates aspects of psychology and sociology (4). In the latter half of the 20th century, patient safety became an increasing focus of healthcare systems and organisations, when it became clear that experiencing healthcare was a risky ordeal for many patients, and that harm could occur to patients as a result of contact with the healthcare system (5). To this day, it is understood that some level of harm is inevitable within the healthcare system, with estimates ranging from one third to one half of harm being preventable (6,7). It is not however fully understood what exactly is preventable and unpreventable harm (6). Patient harm can be subjective, and harm that was historically considered inevitable or unpreventable can, thanks to medical advances, become preventable (6). With new medical technologies, improvements in training, and increased awareness of risk for patient safety issues, patient care has improved to the point that incidents which would have been considered inevitable in previous decades are now entirely preventable (6). Even if harm does not occur, risk of harm due to system or individual errors are still likely to make up a large part of the healthcare experience(8). All clinicians will make some form of error during their career, some of which will have serious consequences (9). The discipline of patient safety research aims to reduce the amount of harm, and the risk of harm, and a number of theories have been proposed over the decades to attempt to achieve this. The prevailing theories around patient safety have typically fallen in to what are now considered “Safety I” and “Safety II” perspectives.

Safety I and Safety II

Safety I and Safety II are contrasting views and theoretical standings as to how patient safety in healthcare can be theorised and improved. Traditionally, “find and fix” methods of approaching safety issues were focused upon, which is considered the “Safety I” approach (4). This involved identifying errors, patient safety incidents, and harm within healthcare, and exploring how to reduce the likelihood of this event happening again (4). However, due to the complex interactions between different components in patient safety, this kind of cause-and-effect approach of conceptualising safety has been increasingly criticised (10).

This has resulted in a paradigmatic shift in patient safety research towards "Safety II" (11). This section will compare the two approaches and the influences they have had on patient safety research.

As humans, we infer causality, particularly linear causality, everywhere (4). Safety I approaches to patient safety reflect this inference, and attempt to identify the root cause of an issue or even (4). Safety I is focused on what went wrong in a system or event, and aims to eliminate these errors and events to improve patient safety, and prevent the incident from recurring (12). Searching for a root cause of patient safety issues (PSIs) is often seen as efficient in that it will fix the immediate issue, but it is not thorough nor all-encompassing (4). This is especially true in complex sociotechnical systems such as healthcare, in which events do not necessarily have linear causality (13). Interestingly, safety has traditionally been defined in terms of its opposite – when something goes wrong, it described as having been unsafe (4). A system is considered 'safe' when the number of problems is acceptably low as opposed to when the number of things that are going right are acceptably high (4). This conceptualisation of safety can lead to a level of complacency within a system. Hollnagel discusses that, often, when an enterprise is deemed to have reduced risk, there are no longer such stringent safety checks (4). However, with this understanding of safety, it is impossible to observe things that have the potential for going wrong, and to anticipate issues or errors that may arise (5). This proves an issue in complex systems such as healthcare, and as safety research progressed, the problems inherent in "Safety I" thinking became more apparent.

One significant issue with Safety 1 is that it appears to suggest that there are only two states in which a system can exist – safe or unsafe (4). This disregards the fact that people working within a complex system can drift slowly towards unsafe care, into a grey area of safety (8). An assumption of safety I is that a system is predictable, however a complex system such as healthcare is far from that (14). There is performance variability within tasks in healthcare, as something that usually goes right can sometimes go wrong, even if this is a task that has been completed without incident hundreds of times (10). The need to be flexible and

resilient is central to healthcare, which is a dynamic, ever changing environment (14). There is always some influence from the environment or the context, that makes a system too complex to be simply assessed as a linear event which followed a set course (10). Healthcare systems are consistently stretched to their capacity, therefore variability in performance is inevitable and indispensable (14). Individuals within the healthcare system need to make adjustments in order to effectively carry out the work required of them to care for patients (10). In order to manage these issues with patient safety theory, and consider how this variability in work contributes to safety, researchers turned to other industries for ideas on where to go next (4).

Learning from other industries to improve patient safety

Healthcare is one of many high-risk industries, however, many of the other fields have managed risk more effectively than healthcare (e.g. nuclear energy, aviation, oil rigs). Such industries are referred to as High-Reliability Organisations (HROs) (15). They are focused on safety at a systems level, and prioritise it highly within their operations. There is increased awareness that healthcare needs to restructure its views on safety in a similar manner to these industries (4). Several conceptual approaches have been considered as means through which we can understand how these organisations can conduct their business in such a safe manner, despite the associated risk. This section will explore how healthcare is taking the learning from risk management in HROs and applying it to patient safety improvement.

One theory of HROs and their effective risk management is that of organisational mindfulness. Weick and Sutcliffe proposed the idea of organisational mindfulness as a key factor in the inherent safety of HROs (15). These HROs achieve mindfulness through their preoccupation with failure, reluctance to simplify interactions, sensitivity to operations, commitment to resilience, and deference to expertise (15). These processes in combination allow organisations to anticipate the unexpected, rather than attempting the "find and fix" approach that healthcare has traditionally followed. Recent thinking in patient safety proposes a move towards this

idea of mindfulness and resilience, in order to understand how healthcare organisations can adapt and pivot towards the unexpected and minimise patient safety incidents, while still providing quality healthcare to their patients.

Differences also emerge in the conceptualisation of human error between healthcare and other HROs. Hollnagel captures the central 'myth' in healthcare regarding human error; "It is a truth universally acknowledged that the overwhelming majority of accidents are due to 'human error' (4). This idea of human error as a root cause of safety issues has historically been pervasive in the understanding of safety in healthcare (12). Hollnagel however argues that it disregards research on the role of the system in patient safety, and oversimplifies the causal role of humans within such a system. The converse of this statement implies that, if the accidents are due to human error, so too are the times that the process occurs correctly, i.e. when things go right 90% of the time, it is also due to humans (4). It is therefore being increasingly understood that system-level factors in healthcare such as a busy environment, pressure from management to reach targets, and staffing issues, need to be considered. If these are disregarded, and the focus is solely on the role of the healthcare provider in the error, safety is unlikely to improve for patients (5).

Safety II

Learning from other high-risk industries, and from safety science in general (16) on improving safety has led to the development of safety II thinking in healthcare. While safety I is focused on the absence of error, safety II is focused on how and why things typically go right (11), even when the conditions are less than the ideal ones imagined when developing the guidelines or rules in the first place. In safety II, the understanding that there is a difference between the "ideal" work and the "real" work, taking into account the variability that may emerge in practice (17), and managing risk accordingly. Healthcare systems are complex and often adaptive. They tend to be resilient to emerging issues that cause harm, and may resort to practices that are not technically "ideal" or "safe" in order to continue to provide care despite external pressures. Therefore, focusing on when things

go right in healthcare, and on understanding the everyday work that ensures things go right despite threats to safety (16), can give us increased insight into how to make patient care safer. This approach acknowledges the sub-standard conditions and limited resources that healthcare providers are subject to in their workplace, and highlights the role played in patient safety by the many levels of the sociotechnical system (13). Safety II rejects the idea that care can always be the absolute best that it should be, and instead explores how individuals and systems adapt to difficult scenarios (14). Novel work in patient safety and quality improvement has recommended moving away from a singular focus on safety I methods of investigation such as Root Cause Analysis (RCA), and instead incorporating other systems-level approaches (16). It was found in one study that when one incident was examined from both an RCA perspective and a more dynamic Systems-Theoretic Accident Model and Processes (STAMP) perspective, different causal factors were implicated in the error (16), with the systems level or safety II perspective implicating individual factors less than the traditional safety I RCA.

As patient safety research shifts to the proactive, prospective safety II model, there are a number of theoretical frameworks that can help organise and translate theory to practice. The Yorkshire contributory factors framework (18), and the sociotechnical model of healthcare (13), both incorporate what we have learned from safety science research about the role of multiple levels of the healthcare system in patient safety. The sociotechnical model of healthcare considers non-linear and iterative geneses of patient safety issues, and highlights that attention needs to be paid to multiple aspects of the system simultaneously (13). These aspects can include individual behavioural and relational factors, cultural issues, and financial and structural factors. The Yorkshire contributory factors framework (18) is a similar conceptualisation of the various contributory factors to patient safety issues. This framework, developed by Lawton and colleagues (18), encapsulates the various levels at which an error might be sourced, and how these play a role in patient safety issues.

These various patient safety models and frameworks are a useful context to the work of this thesis, however they do not fully capture the role

of complaints within healthcare. Healthcare complaints can occur even when a patient safety issue has not occurred, or indeed harm has not occurred to patients. For this reason, it was decided to consider healthcare quality as the guiding theoretical framework for this thesis.

1.5 Healthcare quality

There has been a continuous drive to improve the quality of healthcare internationally over the past century (19, 20). In modern day healthcare, quality of care is a core concept, and is intrinsically linked to funding provided to organisations (21). However, while it is widely accepted that quality is a necessity in healthcare, organisations can often fall short of providing high quality care (21). This may be attributable to the fact that quality is a somewhat nebulous concept, and different attempts to form a comprehensive definition have emerged over the years (22). Early definitions of quality focused quite narrowly on the aim of delivering medical care in such a way that risk is minimised, and the benefits to health are maximised (23). This is a somewhat one-dimensional perspective on quality, and is more equivalent to what would now be defined as safety in healthcare (17). Over time, there has been more of an emphasis on broadening the definition of quality, with safety representing only one aspect of quality care (22). There is now an understanding of the broad scope of quality healthcare, recognising that it can be subjective and context-dependent (24). Quality healthcare can be defined differently by different stakeholders (24), and the understanding of what is quality healthcare also varies greatly based on the context (i.e., secondary versus primary care). This pluralistic view of quality in healthcare has been increasingly recognised, and is now considered to more accurately reflect the disparate, complex healthcare system, in comparison to earlier, more rigid perspectives (25). In recent years, the Institute of Medicine (IOM) definition of quality, which embraces this plurality, has become the standard definition, used as a framework for research into quality improvement across various healthcare specialties (26, 27).

IOM Domains of healthcare quality

The IOM defines high quality healthcare as being safe, effective, patient centred, efficient, timely, and equitable (28). The IOM definition emerged from a series of roundtable discussions which recognised the urgent need to improve healthcare quality, and to do so in a systematic manner (29). The six domains of quality reflect different essential aspects of high quality care, and build upon each other, interact, and compete for resources as institutions and systems strive to provide a high standard of care to their patients (30). Quality in healthcare is complex, but can be better understood, and improvement efforts are likely to be more effective, when these six domains are considered in combination (31). The IOM report has, since its release, spurred a intensive drive to improve quality in healthcare along each of the domains (21). It has also provided a framework for researchers and policymakers alike to follow when attempting to improve quality of care within their own systems and organisations (32). A wide range of improvement efforts have since been based on these domains, and the need for a redesign of the healthcare service based on these core principles has been recognised (33, 34). The IOM report, when defining each of the domains of healthcare quality, underlined the importance of understanding performance on each of the domains, in isolation and combination, to support effective quality improvement. It is therefore necessary to explore and understand each of these domains.

Safe. The first of the IOM domains of quality healthcare is safe care. Patient safety is defined as the absence of preventable harm to patients during healthcare provision, and the reduction of risk of unnecessary harm (35). A focus on safety as a vital aspect of quality care has developed over the past century, and it is now an established priority of healthcare systems and organisations (8). It is understood that some level of harm is inevitable within the healthcare system, with estimates ranging from only about one third to one half of harm being preventable (6, 7). Rates of harm and the safety of a healthcare setting are measured by looking at adverse events,

patient safety incidents, and levels of iatrogenic disease (36). In secondary care it is estimated that between 4% and 17% of hospital admissions are associated with a patient safety incident (PSI; defined as any unintended or unexpected incident(s) that could have or were judged to have led to patient harm) (37), with 7% resulting in death (38). In primary care, population-based record review studies have found two to three PSIs per 100 consultations, with around 4% of these PSIs associated with severe harm (39). Although safe care as a domain of quality typically works synergistically with the other domains, it can be challenged and threatened by the competing demands of the other IOM domains of quality, for example providing timely and cost-efficient care (32).

Timely. A second domain from the IOM framework is the provision of timely healthcare. Timely care avoids harmful delays in providing services to patients in need (28). Patients who receive healthcare in a timely manner can also benefit in terms of their clinical outcomes, have reduced costs of care, and experience more effective management of their symptoms (40). The provision of timely healthcare therefore is intrinsically linked to several of the other IOM domains of quality (e.g., effectiveness). Unfortunately, providing healthcare in a timely manner is a challenge within under-resourced, and over-subscribed healthcare services globally (41). This can be seen at various junctures within the health service, with patients in emergency departments often highlighting unacceptably long waiting times as poor quality care, or those at the boundaries of care struggling to access a service (42, 43). Delays across services are a significant challenge to timely healthcare, and many quality improvement interventions have focused on reconfiguring this aspect of healthcare (44). The need to provide timely care, while complementing many of the domains of quality such as efficiency and patient-centred care, can also conflict with the need to provide safe and effective care. Safety checks and striving to deliver the most effective, evidence-based treatment may involve necessary delays, thereby limiting the timeliness of care (25). Deciding how to prioritise these domains of quality healthcare within a resource-limited system is often a

difficult calculation and ethical consideration for management, policymakers, and regulators (45). This conflict is a central tension in the provision of quality healthcare, and one on which researchers and decision makers in healthcare continue to focus. It demonstrates the need to continue to consider each of these domains of quality care when designing quality improvement interventions.

Effective. Effective care is defined by the IOM as the provision of interventions that are founded on scientific knowledge to all those who need them (28). Essentially, effective care is providing evidence-based care to patients, and avoiding treatments which are not supported by evidence, or are unlikely to improve health outcomes. This need for effective care is understood by patients, as they state that high quality care should improve patient health status (22). While it is a central domain to quality healthcare, it can be difficult to tread the ethical line of deciding what is effective care. Effective care must refrain from providing interventions to individuals who would not benefit (28). This is challenging in a healthcare system which increasingly cares for patients who have multiple complex needs in general practice, the wider community, or secondary care settings (46). It is also difficult to ensure only effective care is provided as patient expectations for healthcare are often high, sometimes unrealistically so (47). Effective care is threatened by these expectations, as poor quality or ineffective care involves over-treatment and exposing patients to risks from interventions that are not likely to be effective (22). There is a need to look more at the effectiveness of care, with a clear gap between implementing research evidence in practice (48), and the continued use of treatments that have limited effectiveness (49). This gap between research and practice must be bridged, and ensuring the effectiveness of care must remain a central focus of quality improvement efforts.

Efficient. The fourth domain of quality healthcare is that it is efficient. This can be considered in terms of either clinical or financial efficiency. It involves avoiding waste of supplies, equipment, ideas, and energy (28). In recent years, when considering efficiency, there has been a

move away from solely examining the financial cost of processes and products, and towards an emphasis on performance measurement to determine whether care is efficient (31). The efficiency domain of quality healthcare works in tandem with effective care, as ensuring patients are not overtreated with care that is not likely to improve health outcomes, will also ensure that resources are not being wasted (31). Ineffective care is therefore fundamentally linked to inefficient care (31). However there is also a need to balance effectiveness and efficiency to ensure the highest possible quality care can be delivered (23). Increasingly, technology is being utilised to improve healthcare efficiency. For example, one study explored the added benefits to healthcare quality of technology for dementia care (50). As no cure currently exists for this condition, healthcare has turned to technology to efficiently improve health outcomes and quality of life (50). Innovative solutions such as this can help health services across the world improve the efficiency of their care, and in turn improve quality. Similarly to timely care, for care to be efficient, it can be in conflict with the safety domain, as financial efficiency must sometimes suffer in order to provide the safest possible care to patients (25). Once again, the interaction of the different quality domains requires disentanglement, and careful consideration by decision makers.

Equitable. For healthcare to be of high quality, it must be equitable, that is, not varying based on individual characteristics such as gender, ethnicity or socio-economic status (28). Equitable care is best considered in terms of population level healthcare delivery, rather than on an individual patient level, as it can be difficult to examine an individual's experience of equity without considering the broader societal context (31). This domain of quality is particularly relevant for privatised healthcare systems such as that of the USA, or even in the semi-private health service in Ireland. Health equity was flagged as a key priority by the IOM moving forward, with exorbitant costs for healthcare insurance in the USA precluding many from accessing even basic healthcare (28). However, even within the UK, with its extensive public health system, patients with a higher socioeconomic status have greater access to the private health care system, which can circumvent

some of the accessibility and resource issues of the public system (51). If healthcare cannot be accessed by all those who require it, it cannot be considered to be of high quality (28). Healthcare accessibility must be based solely on need, and not be influenced by individual or societal constraints, with inequitable care closely related to poor health outcomes in marginalised groups (31). For example, Traveller communities in Ireland and Great Britain report poorer experiences of healthcare than the general population, and have separately been found to suffer a greater burden of ill health than the general population (52, 53). Equity is often considered in terms of access to care, however it can also be examined in terms of the effectiveness domain of quality care. Campbell and colleagues argue that particular interventions may be more effective in certain aspects of the population, and that equity of effectiveness should consider specific needs of population sub-groups (31). Careful consideration of patient needs is required to ensure this difference is taken into account when deciding whether care is equitable, effective and of high quality.

Patient-centred. Finally, the sixth requisite domain of quality healthcare is that it is patient-centred. Patient-centred care is respectful of and responsive to the needs of patients, and ensures that patient values guide clinical decisions (28). When care is patient-centred, it sees the patient as a person, rather than a problem or an illness, and brings patients on board as collaborators within their own care. This domain of quality healthcare is central to this PhD thesis, which will explore the added value of utilising an under used form of patient insight to improve care. As awareness grew of the need for care to be patient-centred, it was first theorised in terms of individual interactions between patient and provider (54). In recent years this understanding has expanded to encompass how the healthcare system as a whole interacts with the patient, groups of patients, and the population as a whole (54). Recent research has explored the understanding across healthcare systems as to what patient-centred care actually is, and has found an almost universal perception of the concept (55). Since the landmark IOM report (28), healthcare providers have been striving to ensure the patient is prioritised and centred when designing and delivering care. These efforts

can take the form of respecting patient wishes and dignity while receiving care, and link closely to the other domains of healthcare (55, 56). These are just a selection of the ways through which healthcare services and providers have modified their care in order to centre patients. This final domain of quality care as defined by the IOM is a vital aspect of improving healthcare provision.

Healthcare quality in general practice

Primary care is the first point of contact, along with the primary mode of healthcare delivery, for the majority of patients, with most interactions with the healthcare service beginning and ending with the general practitioner (GP) (57). Each year, there are an estimated 29.1 million patient contacts within Irish general practice alone (58). It is therefore crucial to understand, explore, and improve care delivery in this setting, however the quality of care in general practice has been considered far less frequently than the care provided within hospitals within research (59). In recent years, general practice has also become more complex, with a movement towards increased provision of care in the community for conditions that would previously have required hospitalisation, and a rise in multimorbidity in patients (8, 60). Patients may also interact with multiple points of the healthcare service, and it can often fall to the GP to coordinate their care across these (35). GPs must deal with a broad variety of issues and illnesses, manage the transitions between primary and secondary care, and monitor the health of their patients across a long time frame (58). Each of these features of general practice can complicate patient care. Despite these challenges, general practice is often considered to be of lower risk than secondary care (61), and has therefore been less of a research focus when examining quality in healthcare. As general practice changes, our understanding of what quality healthcare is in this context must reflect this change, and quality research in a hospital context may not be universally applicable, therefore research is needed into the primary care and general practice context.

The importance of understanding quality in general practice is evident. However, to date, there have been challenges in measuring quality in general practice, with no singular established metric of quality in this context. Research into quality measurement and improvement in general practice utilises multiple measures, with outcomes for patients with chronic illnesses, access to care for patients, and staff reporting of team climate within a practice all used as indicators of quality in general practice (62-65). Performance indicators for key chronic illnesses, such as measuring admission rates to hospital for asthma, diabetes and chronic heart disease, are frequently used as a proxy for general practice quality (66). However, there is no one clear measure of quality in primary care, with measurement complicated by the expansive nature of quality (25). The existing proxy measures of quality are mostly based on the staff perspective (67). Staff skill and their desire to care for patients is central to a functioning health service, and their insights into and monitoring of quality indicators are a traditional means through which we establish whether high quality care is being provided (59). Given the disparate nature of general practice, it is vital that any and all existing methods are used to capture and highlight issues in general practice both pre-emptively and retrospectively, in order to capture the most comprehensive picture of quality possible.

Despite the dominant focus on staff insights into quality of care, it is increasingly understood that different methods of identifying quality issues can complement each other, with one tool or individual identifying issues that another might not (68). One study in general practice explored the benefits of different sources of quality improvement data, looking at physician and pharmacist reported adverse events, patient experiences of adverse events, assessment of medical records, and assessment of all deceased patients. Almost no overlap was found in the findings that emerged from each of these methods (69). It is therefore evident that incorporating multiple methods of measuring quality is beneficial. Moving forward, alternative methods of reporting incidents and assessing quality need to be explored to complement and "scaffold" the systems in place (70). One means of achieving this could be incorporating insights from stakeholders in primary care other than the staff who work within the

organisation, in particular the patients themselves (70). Quality measurement needs to move away from the singular focus on staff measures of quality, and incorporate patient perspectives into general practice quality improvement. The complexity of general practice as a healthcare setting requires these alternative perspective to ensure the delivery of high quality care (71). Moving forward, greater emphasis must be placed on the patient perspective on quality improvement.

1.6 Patient perspectives on quality in healthcare

The focus on engaging with healthcare workers to elucidate the quality and safety of care is not unique to general practice. The patient perspective has in the past been largely overlooked (72), with the patient voice largely absent from investigations into healthcare quality (73). However, in recent years, researchers have begun to explore the potential of patient perspectives for establishing, and supporting the improvement of, healthcare quality. Patients can be key players in patient safety improvement both individually and as a group at large (74), and can identify different factors of care quality compared to healthcare staff (73).

Recently, the patient perspective on healthcare is increasingly recognised as a valuable source of information on quality. Patients are not only capable of identifying issues within care, but have also been found to be willing to provide feedback on this, even when they would not be comfortable directly challenging healthcare professionals (75, 76). Patients and their family members have a unique perspective, as they are present throughout the entire patient care pathway, and are also external to the influences and pressures of the healthcare system (77). As a result of this, they can see issues around accessing care, and following discharge, that are not necessarily visible to staff within a healthcare setting (78). Patients have also been found to have their own ideas of what comprises quality care, and they emphasise the importance of accessible, quick care with good communication, relief of symptoms, and avoidance of injury (77). Understanding how patients prioritise aspects of quality healthcare is beneficial when considering future quality improvement, to ensure the needs

of patients are met (77). It is clear that there is great potential for utilising patients as stakeholders in care (70). With increasing understanding of the benefits of patient insights to quality improvement in healthcare, organisations in western and developed countries are starting to require the measurement of patient experiences of healthcare (79).

Methods of gathering patient perspectives into quality of care include patient satisfaction surveys (80), feedback websites (81), and mixed-method consultations (82). Patient experience surveys can provide insight into the IOM domain of patient-centred care, among other domains (83). Patient experience measures may also have direct benefits to understanding and improving outcomes in care, with recent evidence supporting a link between patient reported experiences of high quality care, higher levels of patient safety within a healthcare setting or unit (84), and increased adherence to treatment plans (83). The 'National Inpatient Experience Survey' is now run annually in Ireland, gathering insights into patients hospitalised on one particular day of the year (85), with nationwide initiatives such as this demonstrating the emphasis and value now being placed on patient insights. The Patient Measure of Safety (PMOS) (76) is another example of a tool being used to reliably capture patient insights into safety and quality of care. Patients are more informed than ever, and can play an important role in their own care, which is being recognised in the healthcare system by decision makers, researchers, and practitioners alike (70).

The use of patient feedback to explore quality of care, and to support quality improvement, while being recognised by many as beneficial, has also been criticised by some. It has been suggested that patients can often have unrealistic expectations of care, and therefore their insights may reflect these high expectations rather than the true quality of care (86). Other studies have demonstrated that patients have a certain level of assumed sense of safety when in contact with the healthcare system, again casting into doubt the usefulness of their insights (57). The trusting relationship between healthcare providers and patients can mitigate and obfuscate any sense of risk on the part of the patient (57). Some findings suggested that only patients who experienced harm or a poor outcome from care were able

to identify safety issues (87). However, recent research in general practice has found that when provided with a checklist of contributing factors to errors, patients could identify latent patient safety issues within their care, indicating that despite concerns around their input, the patient perspective remains valuable (57). It is therefore important to establish opportunities for patients to identify and report unsafe and poor quality care.

Patient perspectives in general practice

Research into patient insights has traditionally been focused on secondary care, with many of the methods of ascertaining patient insights emerging within hospital contexts (75). However, there is increased awareness of need for work in other healthcare settings (57). Patients have helped to identify medication safety issues in general practice (73), latent safety issues within mental health services (88), and barriers to patient contributions to quality improvement within these settings (89). The traditionally secondary care based methods of gathering patient perspectives (80-82) are progressively being established in general practice. Tools developed initially for secondary care such as the Patient Measure of Safety (PMOS) are now being adapted for use in a general practice context, as the need for quality improvement in primary care is recognised (90). The Primary Care Patient Measure of Safety (PC PMOS) has been widely applied in general practice to identify patient-reported safety issues, and in turn improve patient safety and quality of care (82). The use of tools such as the PC PMOS highlight the benefit of the patient insights in settings other than secondary care. In conjunction with metrics such as patient record review (91), clinical audits (92), and staff safety climate surveys (93), patient perspectives are beginning to be explored more as potential avenues for quality and safety in general practice. However, there is one avenue of patient insight which is as of yet under explored, that may also provide important overview of quality issues in healthcare. Unsolicited feedback from patients in the form of complaints or compliments is an untapped resource for quality improvement.

1.7 Patient complaints about healthcare

The patient voice is evidently a useful means of improving quality and safety in general practice and healthcare more broadly (70). One of the means through which patient perspectives on care can be accessed is through healthcare complaints (94). A patient complaint is defined as an expression of dissatisfaction about care received, which is often written and formal (94). Patient complaints, unlike many other forms of patient insight into care, are typically unsolicited. They could therefore be considered a particularly valuable additional account of services provided by the healthcare system, as there may be some inherent differences between solicited and unsolicited feedback due to either courtesy bias or patient fear of impacting their own care negatively when responding to surveys (94-96). However, complaints about healthcare remain an underutilised source of data about quality and safety in healthcare (94). They are typically seen in terms of risk management and litigation, as opposed to being examined through a quality improvement lens (97). Healthcare organisations tend to deal with complaints in an individual manner, and aim to resolve issues quickly, which is seen as important for patient satisfaction and to avoid escalation of issues (97). However, complaints are rarely examined collectively at a systems level and this is a clear failure to capitalise on the learning that they can offer (94). Recent research has begun to explore the potential of complaints for patient safety improvement, through such collective analysis.

Use of complaints in the healthcare system

Complaints, while having evident benefit for safety improvement, are frequently not considered by healthcare providers or services to be adverse events, and so tend not to be examined as a source of patient safety data (97). The primary goal of mollifying patients and resolving complaints individually misses the opportunity to have quality improvement as a major outcome of complaints (97). Similarly, when complaints are made on wards in tertiary hospitals, they have been found to lead to changes within that ward, however not to translate to similar changes across the entire hospital

(98). In many cases, the goal was to let the patient vent without making efforts to make improvement based on their feedback (98). If public relations departments in hospitals are the only ones who hear patient complaints, very little will come from them in terms of improving quality of care (98).

Often, complaints are attributed to the patient characteristics, rather than wider system level issues in care, with patients seen as being unreasonable or as having malicious intent (99). Complaints are a rare event in the context of patient interaction with the health service, and many patients do not complain, even when they experience poor care (100, 101). The fact that the majority of complaints are not upheld also leads to a sense on the part of the providers that they are often unjustified, and this perception may impede their use as quality and safety improvement data (89). While patients have a privileged viewpoint into their care, they are also external to the workings of the healthcare system, and do not always know what factors are at play in the disruption of their care (8). There is a great deal of dismissal of patient complaints as they are seen as not taking into account the pressures the doctors are under, and as coming from non-experts (102). As a result, the insight of patients is not always valued by healthcare providers.

However, despite these issues around the reliability of healthcare complaints, researchers into complaints as a form of quality improvement data emphasise that the fact that a patient has perceived poor care, and made the complaint, demonstrates that something needs to be explored within the system (78). Further, the Berwick report (72) found that at the moment, healthcare organisations have very little capacity to learn from any safety or quality data that they receive, which is something that needs to be addressed moving forward in order to make care safer. It is argued therefore that it is vital to move towards a quality and safety perspective on complaints (97). Complaints are an existing data source that are already available to healthcare organisations, and would take few extra resources to utilise effectively (97). Institutions need to treat patient complaints as another tool to complement their safety improvement toolbox, and learn from them accordingly.

When considering the potential of healthcare complaints, there are pertinent theories relating both to why people complain, and how complaints are received and handled. Understanding these theories might, in turn, help us understand and utilise complaints more effectively. In terms of why people complain, the idea of complaints as the apex of a pyramid has been proffered (100). This pyramid model of complaints maps the trajectory of a complaint through the healthcare system as having a wide base of dissatisfied users, and a peak of complaints that is much smaller (see Figure 1.1) (100). Complaints are different to dissatisfaction, and involve initiative and the means to complain (100). Voiced grievances, or complaints, are the top of this pyramid, and only a small minority of dissatisfied healthcare users will move from the base of this pyramid to the apex and actually make a complaint (100). In some cases patients may be reluctant to call their expression of dissatisfaction a complaint, with more work needed on why some individuals will complain and others do not (100). The effort involved in making a complaint can also often dissuade patients from complaining, and the poor systems involved frustrate those who do complain, particularly when no changes are apparent from their efforts (78). There are a multitude of barriers to the use of complaints for quality improvement in healthcare, at the individual provider and patient levels, and at the systems level depending on how complaints are viewed by the organisation (i.e., as a threat or an opportunity) (77). The pyramid theory of complaints highlights the need to consider complaints from the perspective of both patients and providers to ensure that these barriers are minimised, and that complaints are used for quality improvement. The degree to which complaints may be useful to hospitals and other healthcare contexts is still speculative therefore, though there is growing evidence that complaints correlate with other indicators of quality of care and safety (103).

As well as understanding why complaints come about, theory has examined the ways in which they are handled and managed. Researchers have theorised patient complaints in the context of "Game theory" from economics, in order to understand how positive outcomes can come from the conflict that arises between a patient and the healthcare provider they are complaining about (104). It is argued that complaints can be responded to

by healthcare providers in either a productive or a defensive manner, and that if responses are productive, there will be a more positive outcome for all involved (104). This ties in with the competing views of complaints as a public relations issue or as a useful insight into quality of patient care (97). Unfortunately, in many instances, practitioners see complaints as a threat to their professional identity (105) and in turn can respond defensively to complaints rather than examining the learning that can come from the data. This theory emphasises that more work needs to be done to ensure the personal and professional wellbeing of individuals who receive complaints, and to support them to see complaints as a positive, constructive occurrence (106). This is particularly relevant in highly litigious societies such as the United States of America (USA), where the culture around error in medicine is commercialised, and individual healthcare providers are frequently targeted in law suits (107). A shift away from this combative attitude, towards a more holistic, systems-level approach to responsibility for errors, will benefit both patients and healthcare providers, as individual healthcare providers would be less afraid to openly disclose errors if they knew they would be supported by their employers (108). Complaints can act as an early warning system (109), if they are theorised and considered in this manner, rather than solely as punishment. Healthcare complaints have the potential to be a valuable, independent source of data on healthcare quality, and need to be considered as such by the management and staff involved in their handling and analysis.

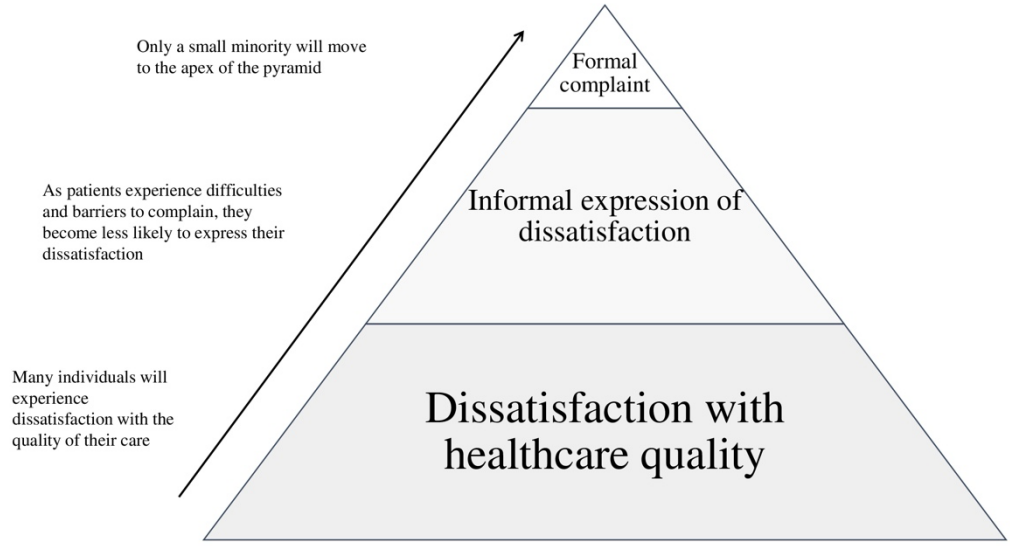

Figure 1.1 Pyramid of individuals who experience dissatisfaction compared to those who complain. Adapted from Mulcahy and Tritter (1998) (100)

An increasing focus on complaints in healthcare services

The reframing of complaints as an early warning system for issues, and an opportunity for healthcare quality improvement began to build momentum following the 2013 Report on the Mid-Staffordshire Trust in the National Health Service (NHS) England, by Robert Francis (110). The Francis report emerged following an investigation into a series of failings in multiple care settings in the region, which led to the unnecessary suffering and death of many patients (110). It identified a wide range of systemic failings in the trust, and highlighted many areas of poor patient safety due to organisational culture, tolerance of risky behaviour, and a lack of consultation with the patients who were under the care of the trust (110). The report described the deaths of over 1,200 patients, and highlighted that these deaths may have been prevented had complaints from patients and family members been considered and heeded (110). This report was a shocking insight into how systemic issues within a service can lead to catastrophic harm to patients, but also highlighted the potential benefit of accessing patient complaints data which already exists in the system for

identifying these high-level issues (110). Currently, many patients and families complain in order to improve the healthcare system, however their efforts are often in vain, when the system to which they are complaining is primarily designed for handling complaints on a case-by-case basis (111).

Analysing complaints for quality improvement

Following the publication of the Francis report, researchers began to focus more closely on the potential of complaints and explore how they could be employed for quality and safety improvement purposes (94). Complaints are not just a sign that something has gone wrong, but can identify what might have gone wrong, but didn't due to a patient's oversight, and therefore can be used to identify how care can be more resilient (111). A negative outcome in care is increasingly conceptualised as an opportunity to gain a better understanding of complex systems and the different factors within these systems that contribute to the quality of care (112). One review identified a lack of a standard taxonomy with which to analyse complaints with the aim of safety and quality improvement (94) and noted that this was inhibiting the extraction of potential data on safety incidents from complaints. They found that while there was a steady increase in research on complaints, there was little aggregation of complaints data in a standardised manner (94). Building on the findings of this review, the authors went on to develop a standardised tool to analyse patient complaints about hospital care (113).

Complaints in general practice

Perhaps unsurprisingly, complaints about care in general practice have not received as much attention as those in hospital settings. Indeed, while the Healthcare Complaints Analysis Tool (HCAT) (113) provides a means through which acute services can capture and utilise the insights provided by patients in a reliable fashion, it was developed and validated for use in secondary care only. However, there is a clear need to consider complaints in general practice. GPs have been found to be the subject of up to 47% of complaints made against doctors (114). One study found that as many as

17% of GPs were the subject of at least one complaint between 2012 and 2016 (115). With 29.1 million consultations annually in Ireland (58), and approximately one in 2000 resulting in a complaint (116), this is a massive untapped data source. As quality and safety research turns increasingly towards primary care (117), it is vital to establish what, if anything, complaints research could contribute to our understanding of what goes wrong in general practice.

Although there are data to evidence relatively high rates of complaints in general practice, it is not currently known what domains of quality patients are typically complaining about, or how complaints are received by individuals in this context. Hospital complaints have been found to vary from clinical safety issues (i.e., the IOM safe care domain), to problems with management (IOM domain of timely care) and communication and listening (IOM domain of patient-centred care) (94). General practice has unique contextual factors that may play a role in poor quality care (118), and therefore could influence what complainants may raise in their letters. The long duration of the care relationship can obfuscate the harm, both physical and psychological, that patients in general practice can experience, and complaints may play a role in highlighting this (59). The co-operation between general practice and the secondary care system is a blind-spot in which patients can often access information on their care not available to their physicians (119). Each of these unique factors in general practice settings can link back to different domains of quality, that the complaints may help to reveal to staff. The severity of the issues and the harm that can emerge from patient interactions with the general practice setting are also not well understood and conceptualised. The diverse and segmented nature of general practice, makes it very difficult to ascertain the true extent of issues within the system (119). As a result, it is also difficult to identify how doctors who receive complaints may need to be supported to manage these complaints effectively, and to engage in quality improvement based on complaints data, instead of being threatened and traumatised by the experience of receiving a complaint (106). There is therefore an evident need for supports that facilitate the systematic analysis of complaints to

highlight commonly occurring issues that require improvement, and to protect the wellbeing of staff in general practice.

1.8 Irish healthcare system

Before concluding this chapter, it is important that the context of this thesis, within the Irish healthcare system, is outlined. The Irish healthcare system comprises a diverse and multi-level structure, with divides between hospital and community care, and also between public and private care. Increasingly, it is moving from a mixed public/private system to a system of universal, integrated healthcare (60, 120). The Health Service Executive (HSE) is the public national health service in Republic of Ireland. The HSE comprises both public hospitals and community care services. Within public community care, there are nine "Community healthcare organisations" (CHOs) which are divided geographically (121) (see Figure 1.2 below). These CHOs encompass general practice, dentistry, and other forms of community care such as public health, mental health services and services for older people (121).

Figure 1.2 Map of CHOs and hospital groups in Ireland, adapted from a Health Service Executive publication (121).

General practice in Ireland

General practice in the Republic of Ireland falls on the boundary between the public and private systems. Primary care practices in Ireland operate as autonomous, private businesses (123). However, up to half of their patients, due to a number of personal circumstances (e.g., advanced age, unemployment, household income), are "public" patients in possession of a Medical card. This allows them to attend the GP free of charge, and the

GPs are reimbursed for these patients by the HSE under the general medical scheme (GMS) (58). Approximately 42% of patients in Ireland are under this scheme (123).

General practitioners in the Republic of Ireland typically work in small practices, with an estimated 18-25% of practices operating as single-handed units (i.e. only one GP working there) (58), in which they have little to no medical support or second opinions (58). The policies and procedures within individual general practices are diverse, presenting a barrier to implementing national-level policies on these autonomous businesses (124). There is also a large variation in connections to hospitals depending on the GP practice location, i.e. whether it is urban or rural (123). There are an estimated 1,635 general practices in Ireland (125), which are under severe pressure due to funding and recruitment issues (126). The most recent figures suggest that there are an estimated 21.4 million GP consultations and 7.7 million practice nurse consultations per year in Ireland (58). While there are no definitive figures available for general practice complaints in Ireland, with an error rate of between 2-3% in general practice (61), this is a large absolute number of potential patient safety incidents in general practice. GPs at single-handed practices report an average of 32 consultations daily (58), with the average consultations per GP at a group practice per day standing at 29 (58). This is a high number, and reflects the shortage of GPs in Ireland, as it is anticipated that by 2025 an additional 1,380 GPs will be required to meet demands (126). The shortage of GPs means that a large number of medical card patients are forced to see a locum (i.e., substitute/temporary) GP at each of their visits, or to travel large distances to access their own GP (126). With increased pressure on the system at large, and individuals often not getting to see the same doctor with each visit, there is a reduction in continuity of care, and shorter appointments, which have been previously flagged as increased risk of error or misdiagnosis in primary care (124). Another aspect of the general practice service in the Republic of Ireland is the out-of-hours services, which also experience issues with continuity of care. GPs in out-of-hours centres see unfamiliar patients who were not able to attend their own GP, or in acute situations in the evenings or weekends (127).

The Irish complaints system

Complaints in the Irish healthcare system, and particularly in the context of general practice, are impacted by the disparate nature of the system. Within the public system, CHOs have a number of designated "Complaints officers" and "Complaints managers" who have oversight on the complaints about services within that area (121). However, across the CHO regions, there is little sharing of data, and complaints frequently do not move beyond an individual regional complaints manager. There are also limited avenues for patients to make complaints about their GP care (128) (See Figure 1.3). Public, medical card patients, can complain to the HSE complaints officers about their GP. However, private patients with that same GP, cannot complain to the HSE (128). There are limited options for a private patient when it comes to complaining. They can complain to the Irish Medical Council if the issue relates to the professional conduct of the doctor, or to the practice if there are other issues such as communication or management problems (128). Public patients also have these options, along with the pathway to complain to the HSE. Out-of-hours co-operatives typically have well organised complaints systems, in contrast, but again, this is dependent on local organisation (127). These differences, and structures, likely contribute to complaints not being utilised effectively within the Irish general practice system, as practices may manage complaints very differently, and complaints may never move beyond the practice setting. Indeed, even those complaints that are made to the medical council are often only resolved individually, rather than being explored and examined at a broader systemic level. There is little to no standardisation of the complaints process, analysis of the complaints in terms of safety, or aggregation of the issues that emerge from the complaints across the national system.

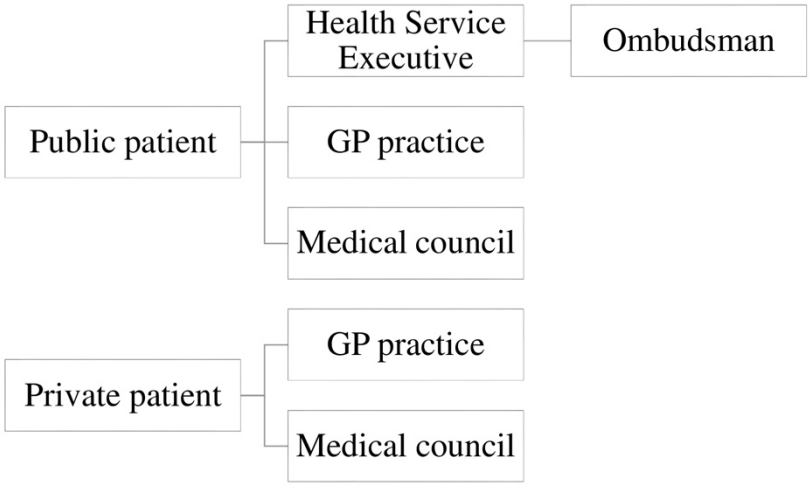

Figure 1.3 Flow chart of complaints process for private and public general practice patients

The culture of error disclosure and transparency within the Irish healthcare system has also been under scrutiny in recent years, with transitions of care between general practice, hospital care, and screening services particularly highlighted (129). The Cervical Check scandal in 2018 (130), during which it came to light that a substantial number of Irish women had not been informed about false negative results of their cervical smears, despite an audit of the results, emphasised the importance of open disclosure in healthcare (131). This scandal also laid bare a culture of defensiveness and lack of transparency in medicine in the Republic of Ireland (131). Complaints already form part of this healthcare system, and as the culture moves away from this lack of transparency towards a more open and just culture, the need for engagement with complaints about general practice in Ireland is becoming more apparent. A just culture (i.e., an atmosphere of trust which promotes the disclosure of crucial safety information, that de-emphasises blame (132)) within healthcare in Ireland would encourage further conversations around the benefits of complaints made about general practice. In turn, this could help to identify areas in which patient insights could improve patient safety and quality of care.

However, the current lack of structure around general practice complaints, and the disparate nature of general practice in Ireland, is impeding this use of complaints. It is clear that there are a number of contextual factors playing a role in the use of complaints in general practice in Ireland, and the added value of systematically utilising these complaints for improvement in such a disparate system needs to be explored.

1.9 Patient and Public Involvement in this thesis

The concept of the patient voice is central to this thesis. The studies throughout focus on unlocking the potential of patient complaints to improve quality of care, and highlight the additional benefit to care of considering this insight as a useful source of data. Increasingly, researchers in healthcare are turning to patients and the wider public to strengthen and support their work from the design stage onwards. Public and Patient Involvement (PPI) is recognised as a strength of research studies, and is defined as a dynamic partnership between researchers and the public, with research being conducted with or by the public, rather than "on" them (133). Involving patients and the public from the design and conception stage of research can ensure that the priorities of the wider public are centred and that their needs are met (133). Networks across Ireland and internationally are being developed to support the involvement of patients and the public in health research. For example, the HRB Clinical Trials Network, expanded in 2021, provides a structured support to researchers who wish to incorporate PPI into their work (134), as does PPI Ignite in NUIG (135). It is increasingly being required by funders, with many researchers including PPI groups in the writing of grants and development of studies from the very start. This thesis unfortunately did not include a PPI group or input from the public from the start, as will be discussed further in the limitation section in Chapter 6. At the time of planning the PhD studies, PPI was a key objective of many researchers, however its value was not fully appreciated for studies by postgraduate students and PhD candidates. It is clear that patient and public involvement would have been beneficial to this thesis, which centres itself on the voices of patients, and future PhD students would benefit greatly from considering this from their design

stages of their studies. It has also highlighted to this researcher the benefits of including PPI from the beginning, and this will be taken into consideration in future work, throughout my career.

1.10 Thesis aim and research questions

Complaints made by patients have undeniable potential for quality improvement in secondary care. They are increasingly being seen as a new way to access patient insights into their own care, and to identify issues of quality and safety. However, the work on healthcare complaints has yet to reach fruition in the general practice setting. There is a clear, and pressing, need to both explore perceptions of complaints, and the readiness of systems and staff to engage with these, and to develop supports to facilitate the systematic review and analysis of complaints submitted. Therefore, the overarching aim of this thesis is to:

> *ascertain the potential for healthcare complaints to support quality improvement in general practice.*

In order to achieve this aim, it first must be considered whether complaints about general practice can identify issues of quality and safety, and whether there is existing research on tools for reliable complaints analysis in general practice. The HCAT, while appearing to be a useful tool for the analysis of complaints, was not designed for use in primary care contexts. It is possible that this tool may be applicable to such contexts, and indeed this was considered likely prior to the beginning of this PhD, however this will have to be considered throughout the thesis. There may also be existing tools which were designed explicitly for the analysis of general practice complaints in a systematic manner that are not as well known. If none are found following a systematic search of the literature, the HCAT will be considered the most appropriate tool to move forward with when considering GP complaints. Therefore, the first research question is:

1. *What is currently known about the nature of healthcare complaints about general practice, and is there an tool such as the hospital-based "Healthcare Complaints Analysis Tool" that facilitates the valid and reliable analysis of complaints in this context?*

Tools which reliably analyse hospital complaints have provided a means of tapping in to a source of data within the health service that has yet to be exploited to its full potential. However, it is not yet clear if such a tool can be used in the context of general practice. Therefore, the second research question is:

2. *Can the HCAT be used to facilitate the valid and reliable analysis of complaints about general practice in the Republic of Ireland, or can this tool or similar be adapted for this use?*

Assuming a tool is found, or adapted, to reliably analyse complaints made about general practice, the third research question is:

3. *Can the content of healthcare complaints made about general practice in the Republic of Ireland be reliably analysed and used to identify areas for quality improvement?*

Finally, in addition to having a tool to facilitate the review and analysis of complaints about general practice, there is also a need to consider the barriers and facilitators to learning from healthcare complaints, specifically in the Irish context. Contextual and cultural factors determine the success of any intervention, and as such it is necessary to understand how stakeholders perceive general practice complaints, and what needs to be done to facilitate the use of complaints for identifying quality issues. Therefore, the final research question is:

4. *How do stakeholders in general practice in the Republic of Ireland perceive healthcare complaints, and what does this tell us about the*

context in which a complaints analysis tool for quality improvement will be received?

1.11 Conclusion

Improving quality in healthcare is a central aim of health services research. As care expands into the community, it is vital that research into quality improvement in general practice is pursued to the same extent as that in secondary care contexts. This will involve utilising a multitude of quality improvement methods, including those that incorporate the patient insight into care. Complaints are an existing data source, however they have not yet been utilised fully with this goal in mind. This thesis aims to explore the benefits of analysing healthcare complaints about general practice.

1.12 Thesis structure

The thesis that follows presents a series of publications and studies which were designed and conducted to answer the above research questions. As is typical within a PhD programme, this thesis incorporates studies with a broad variety of methodologies. The methods described within the following chapters are reflected in Figure X below, which highlights how each study and method used informed the next. The first study, Chapter 2, is a systematic review of literature on general practice complaints, and will focus on answering the first research question *(What is currently known about the nature of healthcare complaints about general practice, and is there an tool such as the hospital-based "Healthcare Complaints Analysis Tool" that facilitates the valid and reliable analysis of complaints in this context?)* by reviewing the literature on general practice complaints to determine the existing knowledge on the content of complaints. This method was chosen in order to give a rigorous overview of the literature on complaints, and to identify if there was a complaints analysis tool as of yet unknown that could be used for general practice contexts. Prior to conducting the review, it was known that there was a reliable tool for the analysis of hospital complaints (the HCAT) however it was not clear whether a similar tool existed for general practice. Following the review, it

became clear that there was no complaints analysis tool specifically for general practice, however that the HCAT had potential for use in this context. The second study, Chapter 3, led directly from this review, and focuses on the second research question (*Can the HCAT be used to facilitate the valid and reliable analysis of complaints about general practice in the Republic of Ireland, or can this tool or similar be adapted for this use?)* and describes the process of determining whether a tool can be applied to general practice complaints, or be adapted for this purpose. Through applying an iterative, six-stage process that reflected the development of the original HCAT, followed by a survey of stakeholders in general practice complaints, it was possible to adapt a reliable version of the HCAT for use in general practice. Chapter 4 followed from this, and reports on the analysis of complaints made about general practice, addressing the third research question (*Can the content of healthcare complaints made about general practice in the Republic of Ireland be reliably analysed and used to identify areas for quality improvement?*). Again, in methods similar to those used by the developers of the original HCAT, the new tool was applied to a sample of complaints, and inter-rater reliability was tested. Chapter 5 is the penultimate chapter, and final study conducted for the PhD, and reports on a series of interviews with stakeholders to determine how they perceive complaints, thereby answering the fourth research question (*How do stakeholders in general practice in the Republic of Ireland perceive healthcare complaints, and what does this tell us about the context in which a complaints analysis tool for quality improvement will be received?*). While diverging somewhat from the path of the other studies, Chapter 5 was informed by a lack of understanding of the context of general practice complaints in Ireland. It was known that there was little use of complaints as a safety or quality improvement tool, however it was not known why exactly this was. In order for future researchers and practitioners to be able to successfully implement the findings of this thesis, it was necessary to understand the context into which this work would be placed. The final chapter (Chapter 6) is a general discussion of the research, which will summarise the findings of the thesis, and explore the implications and limitations of this body of research.

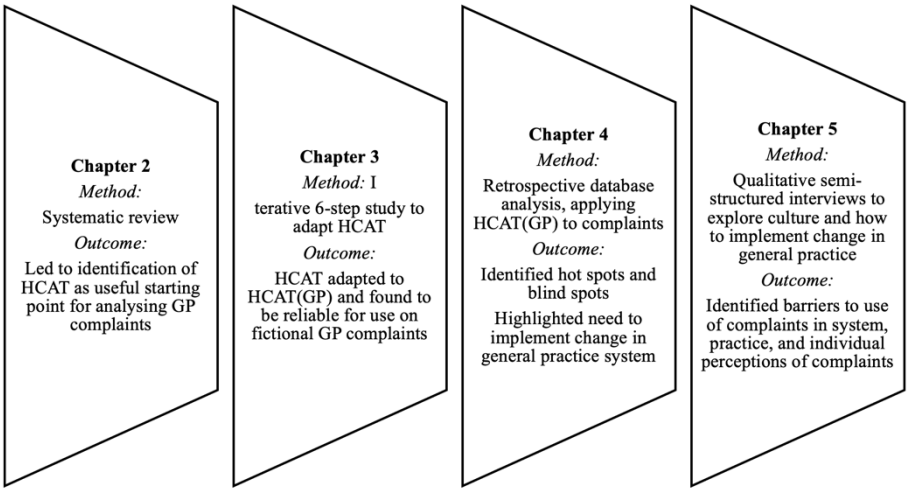

Figure 1.4 How the studies within this thesis fit together.

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Chapter 2. A systematic review of patient complaints about general practice[1]

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Author contributions

This study was led by EOD. EOD, POC and SL were involved in the design and planning of the study. EOD conducted searches and screening of databases. EOD and CM carried out data extraction and quality appraisal of included studies. EOD drafted the initial manuscript, and made extensive revisions. All authors assisted with redrafting the manuscript and reviewed and approved all drafts of the manuscript prior to publication.

Contribution of this chapter to the thesis

There is little known about patient complaints made about general practice. This chapter provides an overview of the current state of the general practice complaints literature and synthesises the issues which emerge from the complaints, the frequency with which people complain, and what are patients motivations for submitting complaints. This is necessary in order to establish an understanding of prior work, identify research gaps to be addressed by later studies in the thesis, and to establish an international benchmark for the analysis of complaints in general practice contexts. The purpose of this review was to identify the issues within general practice complaints and provide a foundation for the thesis. The review was also intended to serve as a comprehensive background to complaints research in general practice, and addresses research question one of the thesis:

What is currently known about the nature of healthcare complaints about general practice, and is there an tool such as the hospital-based "Healthcare Complaints Analysis Tool" that facilitates the valid and reliable analysis of complaints in this context?

Abstract

Background: Healthcare complaints are an underutilised resource for quality and safety improvement. Most research on healthcare complaints is focused on secondary care. However, there is also a need to consider patient safety in general practice, and complaints could inform quality and safety improvement.

Objective: This review aimed to synthesise the extant research on complaints in general practice.

Methods: Five electronic databases were searched; Medline, Web of Science, CINAHL, PsycINFO, and Academic Search Complete. Peer-reviewed studies describing the content, impact of, and motivation for complaints were included, and data extracted. Framework synthesis was conducted using the Healthcare Complaints Analysis Tool (HCAT) as an organising framework. Methodological quality was appraised using the Quality Assessment Tool for Studies with Diverse Designs (QATSDD).

Results: The search identified 2,960 records, with 21 studies meeting inclusion criteria. Methodological quality was found to be variable. The contents of complaints were classified using the HCAT, with 126 complaints (54%) classified in the Clinical domain, 55 (23%) classified as Management, and 54 (23%) classified as Relationships. Motivations identified for making complaints included quality improvement for other patients, and monetary compensation. Complaints had both positive and negative impacts on individuals and systems involved.

Conclusion: This review highlighted the high proportion of clinical complaints in general practice compared to secondary care, patients' motivations for making complaints, and the positive and negative impacts that complaints can have on healthcare systems. Future research focused on the reliable coding of complaints, and their use to improve quality and safety in general practice, is required.

2.1 Background

Healthcare complaints are formal expressions of dissatisfaction regarding any action or care by the health service or a healthcare provider that is perceived to be sub-optimal and to have an adverse impact on patients and their families (1). The submission of a complaint indicates that a threshold of dissatisfaction has been crossed during the process of care (2).

Healthcare complaints are recognised as an underutilised resource for quality and safety improvement (3). Complaints are traditionally addressed on an individual basis, typically by responding to the patient and resolving the issue identified in that specific complaint (4). However, there is recognised value to analysing complaints at the systems level by aggregating the data from multiple complaints and utilising the learning from this process (5,6). Patients often have insight into issues and problems that providers themselves do not recognise or are not exposed to (e.g., problems prior to admission and following discharge) (7). The knowledge gained from patient complaints could be particularly important when a culture exists in a system whereby staff are unwilling or unable to raise quality and safety issues themselves (8).

Most research on healthcare complaints is focused on care delivered in the hospital setting (6). This is unsurprising, given that the study of safety and quality in general practice lags far behind that in hospital settings (9). Typically, general practice has been considered relatively low-risk (10). However, as services are increasingly being diverted from a hospital setting to the community (11,12), there is a greater need to consider quality and safety in this domain of healthcare. Patients interact more frequently with their General Practitioner (GP) than hospital doctors (13,14), and with this increase in volume of interaction, the risk of errors occurring also rises (15). Adverse events have been found to occur in 2-3% of general practice appointments (16). However, despite the recognition of the growing complexity and potential for error in general practice, GPs report that they find it difficult to know where to start with implementing quality and safety improvement practices (17).

Healthcare complaints could serve as one source of data for informing quality and safety improvement in general practice. Serious issues occur in general practice which patient complaints could identify, such as treatment delays, difficulty accessing treatment, or delays in diagnosis (18). Using complaints to access patient insights into safety and quality issues in general practice could provide valuable learning, given the frequency of contact and the privileged viewpoint that patients have within the healthcare system (7).

This systematic review aimed to synthesise the extant research on healthcare complaints and medicolegal claims in general practice. Medicolegal claims are defined as a written demand for compensation for medical injury (19), and complaints are formal expressions of dissatisfaction with healthcare (1). For the purpose of this review, both will be hereafter referred to using the umbrella term "complaints". Specifically, we examined the following: a) the content of complaints described in included studies; b) what motivated the individual to make the complaint; c) the impact of the complaints on the healthcare providers and systems involved, and; d) the harm experienced by the patients in the incident which led to the complaint. It was intended that this review would offer an understanding of the nature and impact of healthcare complaints in general practice, and facilitate comparison between the content of healthcare complaints in primary and secondary care. The review also considers the potential for adapting existing complaints taxonomies to make these more readily applicable to general practice.

2.2 Method

This systematic review was conducted with reference to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (20). In accordance with best practice in systematic reviews (21), a protocol for the review was registered on the Prospective Register of Systematic Reviews (PROSPERO; registration number CRD42019123245).

Search strategy

Five electronic databases were screened to identify relevant papers for inclusion in this review: Medline, Web of Science, Academic Search Complete, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and PsycINFO, between October and November 2018, and updated in March 2019. The search strategy was developed with the assistance of a research support librarian, and was based on the strategy used by Reader and colleagues (6). The search comprised of Medical Subject Headings (MeSH terms) and other keywords relating to patient safety or experience (e.g., "patient satisfaction", "safe*"), complaints (e.g., "malpractice", "complain*"), and primary care (e.g., "general practice", "primary care"). The full electronic search strategy used for Medline can be found in Appendix 1. This search strategy was adapted as necessary for the other electronic databases. The search strategy included terms relating to healthcare practitioners and services other than general practice (e.g., dentistry, physiotherapy, pharmacy), as this review was part of a larger community care-focused project. However, for the purposes of this review, the authors only included studies that focused on general practice. In each database, search returns were limited to English language results only. There was no limit placed upon publication year. Following the electronic searches, the reference lists of studies which were identified as suitable for inclusion, and those of related review papers (6,22), were screened to identify any additional relevant studies. This search strategy complied with best practice for systematic reviews, as laid out in the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) checklist (23).

Study selection

Inclusion criteria. To be eligible for inclusion, studies were required to be peer-reviewed and to present original, empirical data on healthcare complaints that related to poor care experiences in general practice. Studies were required to have a focus on one or more of the following: 1) patients' motivation for making the complaint; 2) the content or nature of complaints; 3) the impact of the complaint on the patient,

healthcare provider or system, or: 4) the harm experienced by patients in the event leading to the complaint. For the purposes of this review, it was considered necessary that the complaints described within studies were instigated by the patient/service user, or someone acting on their behalf, rather than being solicited by researchers through surveys, interviews, or otherwise.

Exclusion criteria. Studies that were focused on healthcare complaints relating to secondary care settings were excluded along with studies which provided no original, empirical data on healthcare complaints (e.g., review papers, editorials, or commentaries). Studies were also excluded if: 1) they were focused on the analysis of incident reports from healthcare professionals; 2) complaints were solicited using a survey or qualitative methodology, and; 3) they focused on community health services other than general practice.

Screening process

The title and abstract of all search returns in each of the five databases were screened by the first author (EOD). The full-text of any study that appeared relevant was screened in order to confirm its suitability for inclusion. Further, if it was unclear from examination of the title and the abstract whether or not the study fit the inclusion criteria, the full text of the article was also screened. A second author (SL) reviewed any article for which there remained uncertainty.

Data extraction and synthesis

Data extraction was conducted independently by two authors (EOD and CM). Any disagreements were resolved through discussion until consensus was achieved. Agreement was calculated as an average of 95% across all studies, ranging from 89% to 100% for individual studies. A third author (SL) was consulted in the event that consensus could not be achieved. A standardised form was used by the two authors to extract data from studies which fit the inclusion criteria. Extracted information included

general characteristics of studies (e.g., year of publication, country of study, individual making the complaint, methods used), along with the data under the headings below.

Methodological quality. The Quality Assessment Tool for Studies with Diverse designs (QATSDD) (24), was used to assess the methodological rigour of the included studies. This tool was considered appropriate as the studies included in this review were heterogeneous in design. The QATSDD is a 16-item scale developed for use by health service researchers, which has been used successfully in other systematic reviews (25-27). Each QATSDD item is scored on a scale ranging from 0 (e.g., 'no mention at all') to 3 (e.g., 'detailed description of each stage of the data collection procedure'), with a maximum possible score of 42 for qualitative or quantitative studies, and 48 for mixed method studies. Two authors (EOD and CM) applied the QATSDD to included studies, and disagreements were resolved through discussion until consensus was achieved.

Content and categorisation of complaints. Data on the content of complaints (i.e., the issue(s) described) were extracted from the studies. These data took the form of raw complaints extracted from either text or tables within the included studies, and/or the interpretations of complaints made by the authors of individual studies. These data were synthesised by four authors (EOD, SL, POC, CM) using the Healthcare Complaints Analysis Tool (HCAT) (28). The HCAT is a tool which allows for the systematic coding and categorisation of healthcare complaints in a hospital setting (28). The HCAT has been found to be statistically reliable and valid, and there is no suitable tool designed specifically for use in general practice. A framework synthesis approach was taken to coding the complaints with the HCAT. Framework synthesis is a structured, deductive approach to collating data, often used when there is an existing theory (29). Data were coded into the HCAT framework using an iterative process. This allowed for the researchers to determine how the general practice complaints can fit under the HCAT tool, which was developed for hospital complaints. Complaints were categorised using domains ('Clinical', 'Management',

'Relationships') and categories within those domains such as "Quality", "Safety", "Listening" and "Environment".

Motive for making complaint. If available, information on the reason(s) why the patient was motivated to make a complaint was extracted.

Impact of complaint. Where possible, the impact of the complaint on the patient, providers, or healthcare service was extracted from studies.

Harm to patient in the events leading to complaint. When available, the harm caused to patient in the event leading to the complaint was extracted.

2.3 Results

A total of 2,960 records were identified from the databases screened, with further papers identified from hand searches of reference lists. Figure 2.1 presents the PRISMA flow diagram. A total of 21 papers (19,30-49), published between 1986 and 2018, were deemed eligible for inclusion in the review.

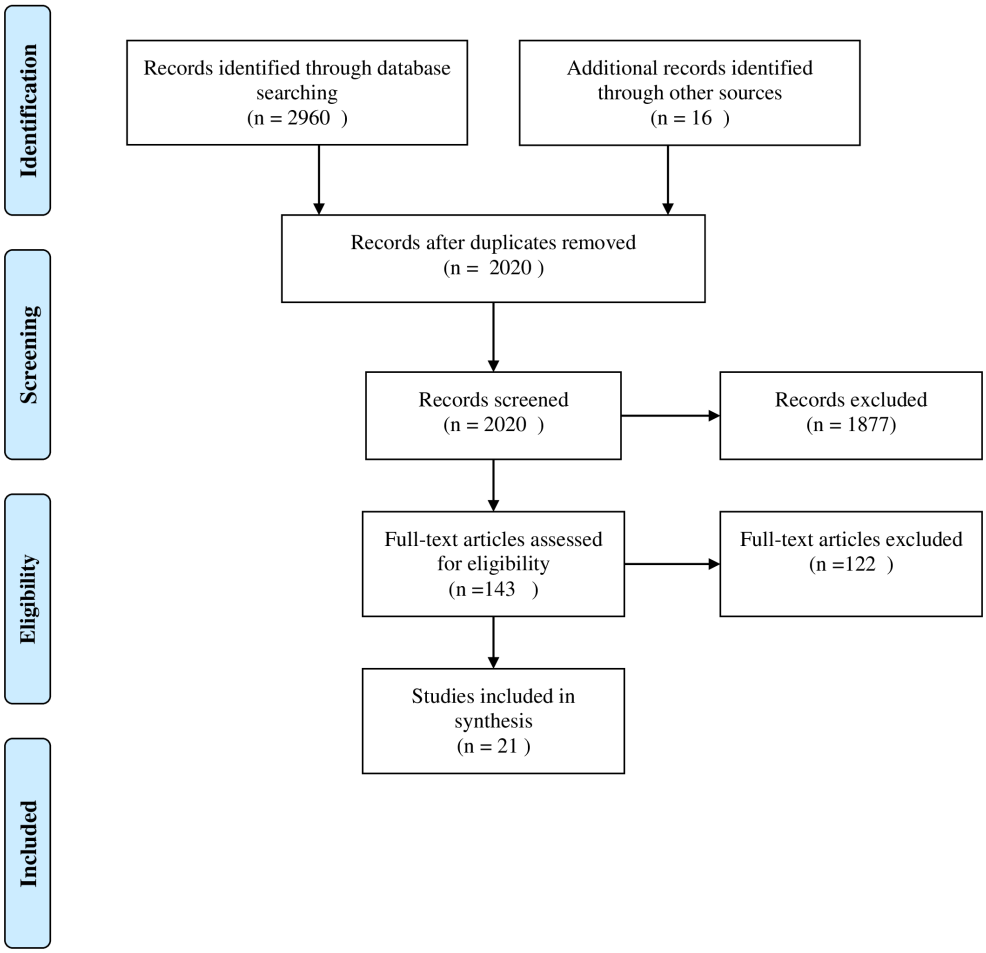

Figure 2.1 PRISMA Flow Diagram

Methodological quality (n=21)

Overall, the quality of included studies was found to be variable, with 14 studies scoring 50% or less (raw score of 24 or less) on the QATSDD (mean raw score =19.8, range of scores =8-29). One study was qualitative only, six were quantitative only, and 14 were mixed methods. Studies scored well on items including "Fit between stated research question and method of data collection", "Clear description of research setting", and "Statement of aims/objectives in main body of report". Studies received low scores on items including "Evidence of sample size considered in terms of analysis", "Rationale for choice of data collection tool(s)", and "Good justification for analytical method selected".

Characteristics of included studies (n=21)

Table 2.1 presents a summary of the characteristics of studies that were included in this review. The majority were conducted in the USA (*n*=8, 38%). Studies were also conducted in countries including the UK (*n*=6, 29 %), Ireland (*n*=2, 10%) and Denmark (*n*=2, 10%). All studies took place in general practice settings, but varying terminology was used to describe these. As can be seen in Table 2.1, "General Practice" was the most commonly used term (*n*=14, 67%), amongst others (e.g., "ambulatory care" (*n*=2, 10%) and "family medicine" (*n*=1, 5%)). There was some variation in the characteristics of individuals who made the complaints or claims. However, in the majority of the included studies, the complaints were made either by the patient themselves (*n*=12, 57%), or by a family member (*n*=10, 48%). Finally, studies utilised different methods to examine the complaints, including reviews of complaints databases (*n*=15, 71%), observational studies with before/after designs (*n*=1, 5%), and audits of informal complaints procedures (*n*=1, 5%). Further information regarding the characteristics of included studies can be found in Appendix 2.

Table 2.1. Characteristics of included studies (dated 1986-2018)

Characteristics	**n, %**
Country	
- USA	8, 38%
- UK	6, 29%
- Ireland	2, 10%
- Denmark	2, 10%
- Netherlands	1, 5%
- Israel	1, 5%
- Singapore	1, 5%
Setting	
- General practice	14, 67%
- Out of hours general practice	2, 10%
- Ambulatory care	2, 10%
- Outpatient chronic pain management	1, 5%
- Family medicine	1, 5%
- Outpatient general medicine	1, 5%
*Individual making complaint**	
- Patient	12, 57%
- Family members (including parent, son/daughter)	10, 48%
- Non-family members	4, 19%
- Partner of patient	3, 14%
- Professional colleague	3, 14%
- Solicitors/advocates	1, 5%
- Healthcare inspector	1, 5%
- Social worker	1, 5%
- Warden of sheltered housing	1, 5%
- Other	3, 14%
- Not specified	8, 38%
Method used	
- Review of claims/complaints database	15, 71%
- Analytic observational study with before/after design	1, 5%
- Audit of medical records	1, 5%

- Description of experience of handling complaints	1, 5%
- Analysis of informal complaints made to a family health service authority	1, 5%
- Audit of an informal complaints procedure	1, 5%
- Retrospective cohort study of patient complaints to an out of hours service provider	1, 5%
Motive for making complaint	
- Wish for explanation	1, 5%
- Wish for placement of responsibility	1, 5%
- Wish for quality improvement for future patients	2, 10%
- Review of GPs competence	1, 5%
- Economic compensation	1, 5%
- Better level of general service	1, 5%
- Professional discipline	1, 5%
- Feeling devalued	1, 5%
- Other sanction	1, 5%

*Column does not sum to 100% as some studies had more than one type of complainant.

Content of complaints (n=18)

The content of complaints was synthesised using the HCAT framework. The existing HCAT framework did not require adaptations in order to code and synthesise the content of complaints in included studies. Figure 2.2 presents how the complaints (*n*=235) were organised into different categories using the HCAT framework. Of the total number of complaints, 54% (*n*=126) were categorised as Clinical, 23% (*n*=55) were categorised as Management, and 23% (*n*=54) were categorised as Relationships. Exemplar complaints that were synthesised using the HCAT framework can be found in Table 2.2.

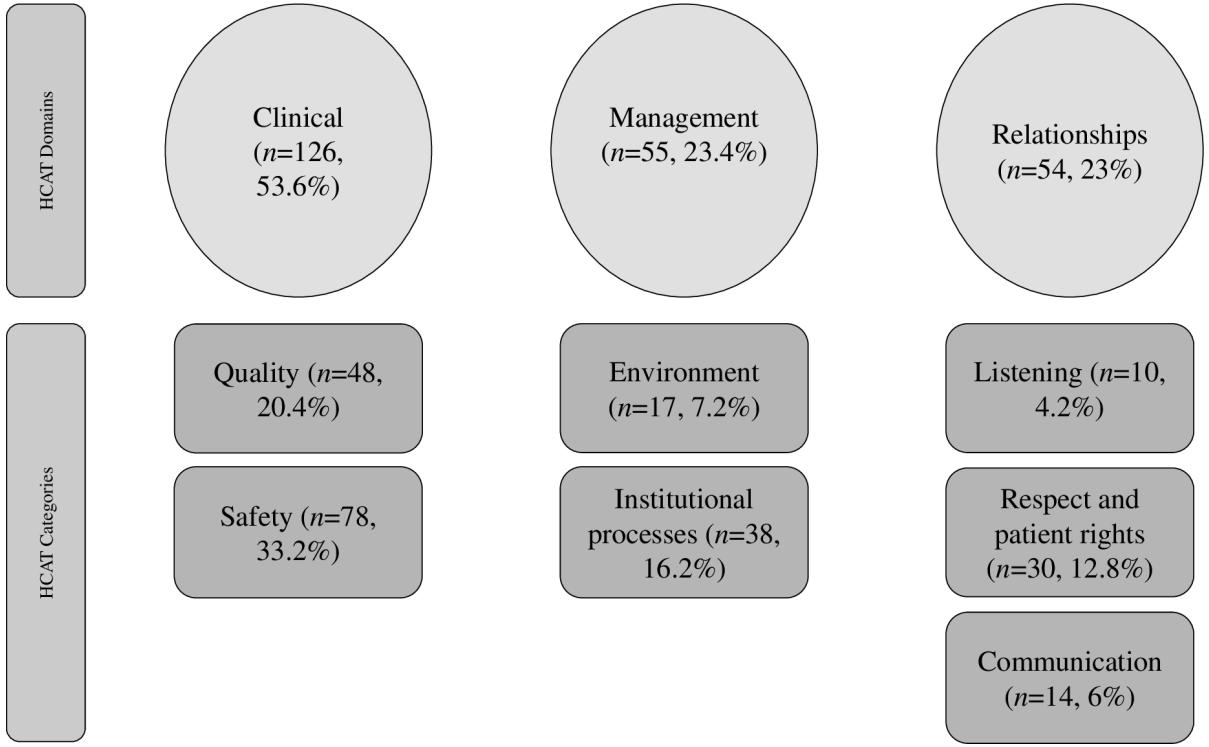

Figure 2.2. Number of complaints in included studies as classified into HCAT domains and categories (Total complaints *n*=235)

Table 2.2 Exemplar complaints from included studies (dated 1986-2018) categorised under Healthcare Complaints Analysis Tool

HCAT Domain *HCAT Category*	**Exemplar complaints from included studies**
Clinical Problems	
Quality	Inadequate patient assessment (29) Failure to supervise or monitor care (36) Unsatisfactory treatment (43) Problems with records (45)
Safety	Wrong patient or body part (45) Misdiagnosis (43) Drug allergy missed (41) Incorrect interpretation of diagnostic or laboratory tests (38)
Management	
Environment	Physical environment (41) Telephone system (46) Poor administration (44) Inadequate disposal of drugs (43)
Institutional processes/Health system processes	Length of NHS waiting lists for treatment (46) Surgery cancelling appointments (43) Patient access to care (39) Cost (30)
Relationship	
Respect and patient rights	Alleged assault (40) Impolite behaviour (37) Breach of confidentiality (36) Discrimination (49)
Listening	Not taken seriously (43) Unmet patient expectations/requests (41) Doctor not investigating symptoms as much as the patient wanted (40)
Communication	Inadequate explanation (41) Poor explanation of illness and of prescription (30) Inadequate explanation of diagnosis or management plan (49) Poor spoken English (43)

Motives for making complaint (n=2)

Two of the included papers (33,44) described patients' motives for making a complaint. Motivations included a desire for placement of responsibility, economic compensation, and professional disciplining of the practitioner involved. In both studies, "preventing the same thing happening to other people" or "quality improvement for future patients" also emerged.

Impact of the complaints (n=16)

Studies described a number of outcomes of healthcare complaints for the patient, providers, and wider health service. At an individual patient level, the award of monetary compensation was described in four papers (19%). Other outcomes included an apology or explanation being provided to the patient (*n*=4, 19%), or the patient changing doctors (*n*=3, 14%).

A number of outcomes were described for healthcare providers in included studies, such as the disciplining of doctors (*n*=5, 24%), or complaints against them being dropped (*n*=9, 43%). Disciplinary measures included reprimands, fines, or removal from performers list.

System level outcomes such as an investigation by an external body (e.g., committee, ombudsman, governmental department), (*n*=4, 19%) and the implementation of an intervention or audit (*n*=2, 10%) were also described in some of the included studies. Further detail of the impact of complaints can be found in the data extraction table in Appendix 2.

Harm to patients in events leading to complaints (n=14)

Of the included studies, 14 (67%) made some attempt to classify the harm to the patients in the event leading to the complaint. There was heterogeneity in the classification of harm across the included studies, however it typically ranged from "minor temporary harm", "insignificant injury", through to "grave injury" or death of a patient, depending on the scale that was used for classification. The National Association of Insurance commissioners severity scale (ranging from 1 'Emotional only', to 9 'Death') (50) was utilised in four papers (19%). Other studies developed severity scales (42), or adopted other systems (49) to measure level of harm.

2.4 Discussion

There is an increasing recognition of the importance of assessing, and improving, quality and safety in general practice. Healthcare complaints are an underutilised data source for informing such efforts. This review examined the content of complaints in included studies, the motive and harm which led to making these complaints, and the impact of the complaints on patients, providers, and the wider system. Key findings included the fact that there was a higher proportion of clinical complaints compared to relationship or management issues, that patients can be motivated to complain with the intent of making service improvements, and that complaints had positive and negative impacts for all those involved in the process.

A large proportion of complaints in the included studies were found to focus on quality and safety issues. In the past, issues around error and safety in primary care and general practice have been somewhat neglected, with the focus being on quality and safety in secondary care (9). However, the data from this review emphasise that greater attention must be given to addressing safety in general practice. Many of the complaints in this review related directly to clinical issues, which included errors, poor care, and safety incidents (e.g., 'Drug allergy missed' (41), 'Failure to supervise or monitor care' (37)). Patient expectations could have some role to play in these findings, particularly with regards to quality complaints, as healthcare has moved to a more consumer-based model (51-54). However, patient expectations aside, it is evident from this synthesis that safety issues must be considered more seriously in general practice research.

The proportion of general practice complaints in the included studies which related to quality and safety was greater than has been found in a review of secondary care complaints (53.6% in general practice as compared to 33.7% in secondary care (6)). This somewhat surprising result could be because patients have more frequent contact with GPs than hospital doctors, and are increasingly seeing multiple GPs (55). Lack of continuity in GP care has been flagged by practitioners as a factor leading to error (55). It is evident, therefore, that there should be increased focus on complaints relating to safety issues in general practice research. Currently,

complaints data in general practice is severely underutilised as a means of identifying issues (3). Using this aggregated data, rather than addressing individual complaints, could allow researchers to develop a broader understanding of what patients are complaining about, and enable these to be addressed at a higher level, contributing to system-level organisational learning (56). GPs are competent in developing solutions to address problems around safety and quality in their own practice (15,57), and should be encouraged to examine these problems using their complaints data. However, the large body of complaints data could also be used to move beyond that, placing more emphasis on changing the system wide problems as well as individual practices (6).

Only two papers discussed the motives that led to patients making a complaint, and as such, there are limits to the conclusions that can be drawn. However, the fact that one of these motives was to improve the healthcare experience for other patients warrants further discussion. Motives including "wish for quality improvement for future patients" (33) and "to prevent the same thing happening to other people" (44) were identified in the two studies that examined this aspect of complaints. While complaints are often viewed by practitioners as negative, and individuals who made these complaints are sometimes distrusted in their motives (58,59), this review indicates that patients can desire to be agents for change. Complaints are one way through which patients and family members can feel they are contributing to service improvement (7). It has previously been identified that patients have a privileged viewpoint within the health system, which could help increase understanding on systemic issues that occur during the process of care (56). For example, in this synthesis, complaints around institutional processes were often regarding 'blind spots' that only patients could identify, such as not being able to access appointments (43), or the cost of an appointment being a barrier to accessing healthcare (31). Future research should focus on exploring patients' motivations for complaining, and engage with their wish to contribute through using complaints data, and other tools such as patient surveys.

The focus of this review was on complaints made by patients. However, there is also likely a proportion of patients who may be

dissatisfied with their GP care, but do not complain. Previous research has found that people might not complain for reasons including power imbalances, lack of understanding of the complaint channels, and a lack of responsiveness on the part of the provider (60). It is important therefore for GPs to proactively engage with patients who already complain, and remove the barriers which may prevent others from complaining. For example, practitioners could ensure patients receive clear information on where to complain (60). The availability of this information would be an effective way of improving patient experience, quality, and safety, and could ensure that the viewpoints of all patients are represented (56, 61, 62).

The data synthesised in this review on the impact of complaints highlighted how complaints can have positive and negative impacts on the system as a whole, not just on individuals. Only two of the included studies reported practices making changes following the analysis of complaints (31, 34). Included studies more often described the impact of complaints on the patient themselves, for example "payment to patient" (37), or "changing doctor" (43), and on the provider involved in the events leading to complaints such as "disciplinary action" (33), or "complaint successfully defended" (49). This focus on the negative impacts of complaints on individuals is reflected in how complaints are often framed as punitive, causing stress, anger, and even depression for the providers (58). However, potentially more important is how complaints can impact positively on the system, as a learning tool for safety improvement (e.g., 'engaging in risk reduction' (31)). Reframing complaints as learning opportunities, and analysing them collectively, could benefit practices, and also the healthcare system as a whole, by moving away from complaints as a negative experience targeting individual providers (6, 63).

Limitations

There are a number of limitations to the current review. First, the studies included were heterogeneous in nature. They used different methods (e.g., review of database, audit of medical records, retrospective cohort study), categorised complaints in a variety of ways (e.g., HCAT, systems

developed by the authors), and focused on different outcome variables (e.g., impact, motive, content). This heterogeneity is both a limitation and a strength. The heterogeneity increased the complexity of synthesising the data, and, as a result, it was challenging to derive learning from the data. On the other hand, this variation served to clarify the need for a reliable and standardised system for analysing GP complaints moving forward. Inclusion of a wide range of studies allowed for a broad overview of the existing research on complaints about GP. By highlighting the heterogeneity within the canon of knowledge on complaints, this review has set the stage for future work to focus on more specific research questions. There was also considerable variation in the methodological quality of the included studies.

Secondly, raw complaints from the included studies were unavailable. Therefore, the synthesis of complaints is based upon the study authors' interpretations of the complaints rather than on the actual patient complaints. However, in most cases, the authors of included studies did provide examples of the raw data, which facilitated the synthesis.

Thirdly, it was initially intended to examine the frequency of GP complaints. This intention was included in the PROSPERO protocol. However, during the data extraction it became apparent that it was not possible to synthesise the data on frequency given the different methods authors used to calculate and present this data. As a result, it was necessary to amend the PROSPERO protocol. It is therefore recommended that some consistency is established for calculating and presenting frequency data in future studies, at which point this could be reviewed.

Finally, this review only included studies which were peer-reviewed and published in English. There is a lack of best-practice guidelines for searching grey literature, and it is often difficult to interpret data included in grey literature due to poor reporting (64). There is also some evidence to demonstrate that limiting the language does not negatively impact a review (65).

Future research and application to practice

This review has highlighted areas for future research and changes to practice. First, the use of the HCAT as an organising framework for synthesis has indicated that it can be successfully used to classify general practice complaints. However, future work is necessary to validate the tool in primary care. The use of a standardised tool that is reliable and valid would reduce the heterogeneity of data available on complaints, and facilitate quality and safety improvements in general practice (28). Standardisation in the analysis of complaints would also facilitate comparisons between the different aspects of healthcare (such as primary and secondary care) regarding quality and safety (56). Utilising a standardised, reliable tool such as the HCAT could enable future research to apply the rigour of secondary care to the analysis of general practice complaints.

Secondly, there is a relative lack of research on complaints in general practice, as compared to secondary care. Moreover, the existing research is predominately limited to the UK and USA, and more research into GP complaints internationally is required to allow for further comparisons. This review of general practice complaints included 21 papers, compared to the 59 included in the hospital care review by Reader and colleagues (6). This finding is at odds with the high volume of contact that patients experience with general practice, indicating a need for more research on general practice complaints.

Thirdly, more research is required on how patients can contribute to improving safety and quality in general practice. It is evident from this review that patients are motivated to improve the healthcare system at large, and therefore, integrating patients' experiences must be prioritised in patient safety research moving forward.

Finally, there is a need for the learning from this systematic review to be applied by GPs to their work. The small number of practices utilising the complaints data to make system improvements indicate that this is an area to be further explored. By collating complaints and framing them as learning opportunities, GPs could use them to identify improvements and reduce the number of complaints they receive (15, 57).

Conclusion

The data which emerged from this review highlighted the high proportion of quality and safety related complaints in general practice, patients' motivations to improve the healthcare system, and the various positive and negative impacts that complaints can have on individuals and systems involved. Future research focused on the reliable coding of complaints, and their use to improve quality and safety in general practice would be of much interest.

How this study influenced the work which follows

This chapter has outlined the existing research on healthcare complaints in general practice. In doing so, it has answered the first research question of the thesis on the nature of healthcare complaints in general practice. It identified that there is no existing tool for the systematic analysis of general practice complaints, however that the HCAT has potential for application to this context. It identified a large proportion of quality and safety complaints in general practice, and established that while there is no existing tool for analysis of general practice complaints, the HCAT has potential for application to this context. This, in turn, leads directly to the second research question of the thesis on whether a tool can be used, or adapted, to facilitate the reliable analysis of general practice complaints. In the next chapter, the HCAT, used in this chapter to synthesise author classifications of general practice complaints, will be explored as a potential tool for the systematic, valid and reliable analysis of complaints about general practice.

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Chapter 3. The adaptation of the 'Healthcare Complaints Analysis Tool' for general practice[2]

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Author contributions

This study was led by EOD. EOD, SL and POC designed and conceptualised the study. EOD conducted the steps in stage one, testing the HCAT on general practice complaints, consulting throughout with SL and POC on adaptations to the HCAT. EOD designed the survey and analysed the results. EOD drafted the manuscript, and all authors reviewed and redrafted this manuscript prior to submission for publication.

Contribution of this chapter to the thesis

There is currently no consistent or reliable means for the categorisation of the content of general practice healthcare complaints. There is a need to establish whether a tool can be used, in a similar manner to the HCAT in secondary care, to reliably categorise complaints. This would facilitate the use of complaints to identify areas for potential quality improvement in general practice. The purpose of this study was to establish whether the HCAT could be used as a tool to reliably analyse complaints about general practice, and if not, whether it could be successfully adapted for this purpose. It also aims to establish whether an adapted version of the HCAT is reliable and valid. This contributes to the overall aim to understand the potential added benefit of patient insights for quality improvement in general practice by providing a psychometrically sound tool to facilitate the analysis and understanding of complaints. This chapter will therefore examine the second research question of the thesis:

Can the HCAT be used to facilitate the valid and reliable analysis of complaints about general practice in the Republic of Ireland, or can this tool or similar be adapted for this use?

Abstract

Background: Patient complaints about care in general practice are underutilised as a source of safety improvement data.

Objective: This study aimed to adapt a secondary care complaints analysis tool for use in general practice contexts and assess the validity, reliability and usability of the adapted tool.

Methods: The study was conducted in two phases. *Phase A:* The Healthcare Complaints Analysis Tool (HCAT) designed for use in secondary care was adapted for use in general practice using an iterative six-stage process. *Phase B:* Participants from key stakeholder groups [General practitioners (n=5), complaints managers (n=9), health service researchers (n=4)]. Participants completed an online survey and analysed 20 fictionalised patient complaints using the adapted tool. Inter-rater reliability and agreement with a referent standard were analysed using Gwet's AC1 statistic.

Results: *Phase A:* The HCAT was adapted to the Healthcare Complaints Analysis Tool (General Practice) [HCAT(GP)]. The HCAT(GP) tool consists of three domains (clinical, management and relationship problems), and seven categories. The HCAT(GP) had both content and face validity. *Phase B:* Inter-rater reliability was substantial for the HCAT(GP) categories (Gwet's AC1 = 0.65). Within-group agreement on the seven HCAT(GP) categories was substantial to perfect (AC1 0.61-0.85). Participants had substantial to perfect agreement with the referent standard across the survey with a mean AC1 of 0.899 (Range 0.76-0.97).

Conclusion: This study reports the adaptation of the HCAT(GP) and has established that the tool has sufficient validity, reliability and usability. This adapted tool can be applied to general practice complaints to identify areas for improvement.

3.1 Background

Healthcare complaints made by patients are an important source of data to inform quality and safety improvement (1). Complaints offer privileged insights into the patient journey, and help identify issues in safety and quality of care, that may not be visible to healthcare workers (2). Analysis of complaints can therefore identify issues in care that otherwise might have been missed (3).

While research on complaints is advancing in secondary care (4-6), there is a lack of research and understanding pertaining to the benefits of analysing complaints in general practice (7). The Healthcare Complaints Analysis Tool(HCAT) (8), developed for the analysis of hospital complaints, has been vital in efforts to tap into the potential of patient complaints as a data source. The HCAT allows researchers and practitioners alike to categorise complaints based on their content, severity, and harm caused to patients (8). This reliable and valid tool has been used to identify hot spots (an area of high risk within care) and blind spots (an area of care that is either unobservable or incorrectly observed) in hospital care, and suggest areas for safety improvement (3). While the HCAT has been applied to out-of-hours general practice complaints (9), the tool was specifically designed for use in secondary care. Therefore, it is unclear whether the HCAT is reliable and appropriate for use in general practice contexts. Some aspects of the HCAT in particular may not be appropriate for use in analysing complaints about general practice as they refer to parts of the patient journey exclusively present in secondary care (e.g., discharge, admissions, care on ward) (8). This paper aims to explore this across two phases by: a) adapting and testing the validity of a version of HCAT specific to general practice; and b) examining the reliability and usability of this adapted tool.

3.2 Design

This is a cross-sectional study, with two phases: a) the adaptation and validity assessment of a version of the HCAT designed to classify complaints about general practice, and b) an online survey of key stakeholders to evaluate the reliability and usability of the adapted tool.

3.3 Phase A: Adaptation and validation of the HCAT for general practice.

Phase A Method

The adaption of HCAT for general practice was carried out in six stages.

Stage 1: Reviewing the original HCAT. The starting framework for this study was the original HCAT (8). The HCAT consists of several parts, which are applied sequentially to a complaint:

- Firstly, the content of the complaint is classified using one of the seven HCAT problem categories (quality, safety, environment, institutional processes, listening, communication, and respect and patient rights).
- Next, the severity of the complaint is identified, ranging from 1 (Low) to 3 (High).
- Third, the stage of care at which an issue occurred is recorded (admissions, examination and diagnosis, care on the ward, operation and procedures, or discharge and transfer).
- Finally, the overall harm to the patient reported in the complaint is identified from 1 (minimal harm) to 5 (catastrophic harm).

In order to assess content validity (10) of the HCAT in general practice contexts, the seven HCAT problem categories were used to synthesise data in a systematic review of 21 studies on patient complaints about general practice (7) (Chapter 2). The categories were found to be appropriate for capturing all of the issues emerging from the complaints in

the included studies, which gave initial indications that the HCAT could be used to categorise complaints made about general practice (7). As a result of this, researchers decided to focus on the HCAT for classifying general practice complaints.

Stage 2: Testing HCAT categories. The HCAT problem categories were used to analyse a sample of 30 real general practice complaints by the authors (two experienced PhD level patient safety researchers, and a doctoral student undertaking a PhD in patient complaints). The HCAT categories were found to suitably classify all issues occurring in this sample of general practice complaints, thus providing evidence of face validity.

Stage 3: Testing HCAT severity classification. The HCAT severity classification was applied by the authors to the same sample of complaints as in stage two. It proved difficult to apply the HCAT examples for ascertaining severity of an issue to general practice complaints. Following discussion, the hospital-specific severity examples were replaced with general practice-appropriate examples. The revised severity scales were applied to a different sample of 30 complaints by the authors and found to appropriately capture complaint severity in general practice.

Stage 4: Testing HCAT stages of care. The sample of complaints used in stage two was analysed in terms of stages of care by the authors. It was found that the HCAT stages of care required adaptation for general practice. The authors decided to align the stages of care to the patient journey in general practice: accessing care, while in the practice, during the consultation, referral/follow-up, and other/unspecified. These categories were tested these on the second sample of complaints used in stage three.

Stage 5: Testing HCAT harm ratings. The definitions used for the harm ratings in the original HCAT were not entirely clear when applied to general practice. Therefore, following a review of the original risk matrix used to develop the HCAT harm ratings (11), the wording of the harm ratings were changed slightly to reflect general practice settings. The revised

harm levels were then applied by the authors to the second sample of complaints used in stage three and found to be appropriate.

Stage 6: Expert consultation. Following the minor changes made to the HCAT, the adapted version of the tool was designated the Healthcare Complaints Analysis Tool(General Practice) [HCAT(GP)], and shown to three members of the Irish National Complaints Governance and Learning Team. These experts work directly with healthcare complaints daily, and have oversight on the complaints process within the Irish health service. They were satisfied that the adapted tool would be suitable for use with general practice complaints. This expert review also indicated that the tool had content validity (10).

Phase A Results

A summarised version of HCAT(GP) domains and categories, with sample severity ratings, is provided in Figure 3.1. The complete HCAT(GP), including stages of care, severity ratings, and harm, is shown in Appendix 3.

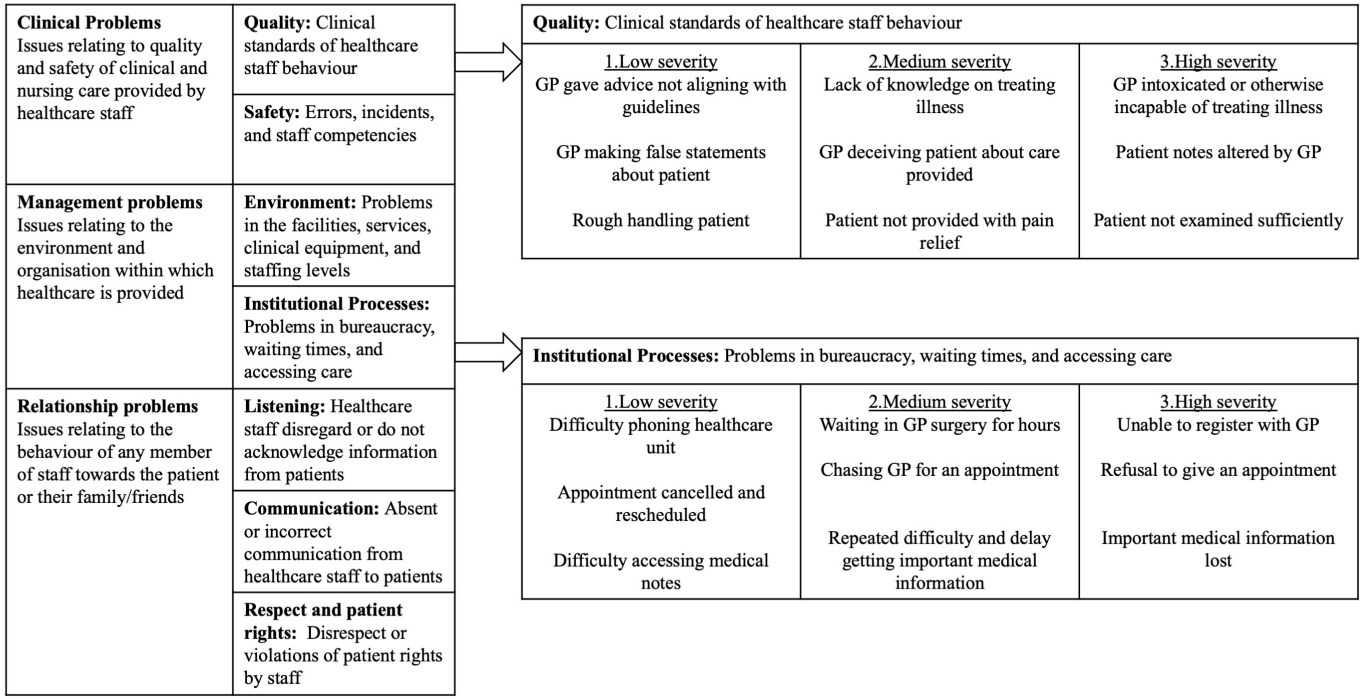

Figure 3.1 Domains and categories of adapted HCAT(GP) with example severity indicators for the "Quality" and "Institutional Processes" categories. Figure adapted from Gillespie and Reader (8).

3.4 Phase B: Reliability and usability testing

Phase B Method

Participants. Eligible participants were General Practitioners (GPs), healthcare policymakers/complaints managers, and health service researchers in Ireland. Participants were recruited using purposive sampling (12), between September and December 2020, with one author (EOD) emailing stakeholders directly. Efforts were made to ensure stakeholder groups were proportionally represented.

Development of survey. An online survey was developed (see Appendix 4). This survey included 20 fictionalised complaints, which were created by the researchers based on real general practice complaints. Real complaints were not used due to ethical concerns. Researchers ensured that issues within the complaints spanned the range of the HCAT(GP) problem categories, severity ratings, stages of care, and harm. Of the complaints, 14 contained only one issue, and 6 contained multiple issues (*n* issues per complaint: 2-4). For each of the complaints, researchers set a 'correct' response based on their experience of using the HCAT, and set this as a referent standard against which the participants would be compared. Following the analysis of the fictionalised complaints, participants were asked to rate the tool on usability, defined as whether they found it easy to use, easy to learn, user-friendly, and whether they would recommend it to a colleague. These questions can be found in Appendix 4, and were based on literature on technology acceptance (13-15). Usability is important to ascertain, as technology is more likely to be accepted if it fulfils the above criteria, and this is true also of complaints analysis tools (13-15).

Online training. Participants were sent a link to the HCAT(GP) survey which can be found in Appendix 4. Prior to the survey, the participants watched a 13 minute video explaining the purpose of the HCAT(GP), with worked examples of the application of the tool. The video can be found at this link https://youtu.be/vo8ckQ8Gh48.

Analysis. Responses were analysed by: 1) assessing the inter-rater reliability between the participants both within their stakeholder groups and across the sample at large; and 2) comparing participants' responses to the referent standard. Inter-rater reliability is defined as multiple coders observing the same issues within a complaint, and this is important for complaints analysis to ensure confidence in the tool's findings (8). Gwet's AC1 was used to calculate both the inter-rater reliability and the comparison of coder responses to the referent standard (8, 16). Agreement data from Gwet's AC1 were interpreted as: 0.01-0.2 = poor/slight, 0.21-0.4 = fair, 0.41-0.6 = moderate, 0.61-0.8 substantial, 0.81-1 = perfect (17). Descriptive statistics on participants' ratings of the usability of the tool were also analysed. The analysis was conducted using R statistical software (18).

Phase B Results

Demographics. A total of 18 individuals participated in Phase B of the study - four were health service researchers, nine were experts working in complaints analysis, and five were GPs. A further 10 GPs were contacted and declined to participate due to other commitments.

Inter-rater reliability. There were no missing data for the variables of interest. Inter-rater reliability was substantial for HCAT(GP) categories across all complaints (Gwet's AC1 = 0.65). Reliability on categories was greater for single issue complaints than multiple issue complaints (See Table 3.1). Agreement across different aspects of the HCAT(GP) was also calculated, and these results are presented in Table 3.1. Within-group agreement on HCAT(GP) categories was substantial to perfect (Gwet's AC1 0.61-0.85), indicating that the adapted tool can be used reliably by individuals across professions to classify complaints made about general practice.

Table 3.1 Inter-rater reliability of participants using HCAT(GP) from stakeholder survey, 2020

Agreement type	Gwet's AC1	CI
HCAT(GP) categories		
All complaints	0.65	0.61-0.69
Single issue	0.65	0.54-0.75
Multiple issue	0.35	0.26-0.44
HCAT(GP) categories classified within professional groups		
GPs	0.61	0.54-0.67
Complaints managers	0.61	0.55-0.66
Researchers	0.85	0.78-0.92
HCAT(GP) stages of care		
All complaints	0.48	0.43-0.54
Single issue	0.59	0.47-0.72
Multiple issue	0.45	0.38-0.51
HCAT(GP) severity		
All complaints	0.49	0.38-0.61
Single issue	0.35	0.15-0.56
Multiple issues	0.51	0.36-0.66
HCAT(GP) harm		
All complaints	0.50	0.39-0.62
Single issue	0.59	0.45-0.73
Multiple issue	0.51	0.34-0.68
Average agreement of participants with referent standard (Range)	0.899 (0.76-0.97)	

*All calculations were significant at the p<.05 level

Comparison to referent standard. Participants had substantial to perfect agreement with the referent standard across the survey with a mean Gwet's AC1 of 0.899 (Range 0.76-0.97).

Usability. Participants indicated that they found the HCAT(GP) to be useful, user friendly, and that they would recommend it to their colleagues (see Table 3.2). However, one participant did not find the HCAT-GP easy to learn, and this should be considered when rolling out training to wider audiences.

Table 3.2 Participant responses to usability questions on HCAT(GP) from survey, 2020

Prompt	Strongly disagree/Disagree n(%)	Neither agree nor disagree n(%)	Agree/Strongly agree n(%)
The HCAT(GP) was easy to use	0 (0%)	0 (0%)	14 (100%)
The HCAT(GP) was useful	0 (0%)	2 (14%)	12 (86%)
The HCAT(GP) does everything I would expect it to	0 (0%)	1 (7%)	13 (93%)
The HCAT(GP) was user friendly	0 (0%)	0 (0%)	14 (100%)
I learned to use the HCAT(GP) quickly	1 (7%)	1 (7%)	12 (86%)
I would recommend the HCAT(GP) to colleagues	0 (0%)	1 (7%)	13 (93%)

3.5 Discussion

This paper described the adaptation of the HCAT for use in general practice, and established content and face validity, inter-rater reliability, and usability. General practice complaints are underutilised as a source of data on patient experiences, and lacking a tool for their systematic analysis (7). The HCAT(GP) has great potential to support the use of patient complaints for safety and quality improvement.

The HCAT(GP) provides a reliable means through which general practitioners, health researchers, and complaints managers alike can analyse patient complaints about general practice. The reliability of this tool was comparable to that of the original HCAT, with participants achieving substantial to perfect scores against a referent standard (8). Across all problem categories the overall reliability of the HCAT(GP) was found to be sufficient. The reliability testing in our study also indicated that participants with different professional backgrounds were able to successfully apply the tool to general practice complaints. GP participants and complaints managers both achieved substantial reliability when rating the complaints categories, while researchers had perfect reliability. It is particularly important that the HCAT(GP) can be used reliably by all stakeholders as general practice is a disjointed system, with lots of boundaries between different aspects of the patient journey (19-21).

Participants considered the HCAT(GP) to be a useful and usable tool. This is an important aspect of this study, as acceptance by stakeholders is vital for a tool or intervention to be successfully introduced (22). This is particularly the case in a context as busy and complex as general practice, and GPs indicating that the HCAT(GP) was useful and usable bodes well for its introduction in the "real world". With general practitioners often working in silos (23), having the ability to conduct complaints analysis at a local level and feeding up to national level in a standardised manner will be of huge benefit (24). Individual care teams can learn from complaints within their own practice and others, and can apply this learning to in-house processes in order to prevent future harm to patients. Moreover, using the HCAT(GP), in conjunction with the HCAT for hospital care, healthcare systems can ensure that the entire patient journey is represented and

captured for safety and quality improvement at both national and local levels.

Limitations

There are a number of limitations inherent in our study. First, the tool was not applied to real complaints, but to fictionalised complaints based on real-life general practice complaints. This was necessary to address ethical concerns with using real patient data for research without their consent (25). Second, the tool was adapted and tested on complaints based on one healthcare system, which differs in structure and funding to other countries (26). This may have limited the generalisability of the tool to international systems. Third, the HCAT(GP) was not tested for criterion or construct validity. Future work should explore construct validity by conducting a factor analysis of the HCAT(GP) (10). Finally, there were only a small number of GP participants in this study, which may limit our understanding of how acceptable and reliable this tool may be when used by this population.

Implications for research and practice

The HCAT(GP) should be used to analyse a larger sample of real general practice complaints, in order to explore the benefits to practice of analysing general practice complaints using a reliable tool. The original HCAT has been applied in a similar manner to secondary care contexts internationally (3, 27-29), with the data from the HCAT categorisations and further analysis of these showing promise for contributing to safety improvement (3, 28, 29). Extending this systematic analysis of patient complaints to general practice will complement the work being done in secondary care, and capture more learning from patient complaints across the healthcare system. The HCAT(GP) allows researchers, practitioners, and policymakers to identify issues that are occurring most frequently within general practice settings, and provide an evidence base for the implementation of quality and safety improvement measures. It can also be used across different levels of the healthcare system, as while there may

only be a small number of complaints at the individual practice level, the tool could be used to first categorise complaints at a local level and the categorised data could be shared regionally or nationally in order to conduct higher-level analysis of complaints trends. The standardisation of complaints categorisation through using this tool would support this higher-level analysis. It therefore has potential both as a tool for categorisation, and as a first step in the analysis of trends in healthcare complaints.

Future research should also explore the reliability of certain aspects of the tool, in particular the 'harm' and 'severity' ratings. The HCAT(GP) also does not include subcategories, in contrast to the original HCAT. This decision was made as the subcategories in the original HCAT were not tested for reliability (8). Future research should explore the reliability of subcategories for the HCAT, and explore the potential of subcategories for the HCAT(GP). Multiple-issue complaints were also less reliably analysed than single-issue complaints, which should be interrogated by future research as complaints often have more than one key issue within them (8). It is possible that since the participants were presented with the multiple issue complaints towards the end of the survey that fatigue played a role in the loss of reliability (30). One means of improvement could be the organisation of stakeholder consultations or think-aloud sessions, which would afford the opportunity to stakeholders in GP complaints to determine how they can be aided in utilising the tool for safety improvement.

Finally, the HCAT(GP) was found to be mostly moderately to substantially reliable with minimal training. This is an important finding as extensive training would be a barrier to the widespread adoption and use of the tool. The survey used in Phase B of this study to train the participants could be used in a similar manner to the IT-based training of the original HCAT (8) and allow for feedback to be provided to participants on their performance. Further work could also explore any improvements to reliability or usability through the delivery of face-to-face training.

Conclusion

Patient complaints about general practice are underutilised for safety improvement. The HCAT(GP) has the potential for use as a reliable tool for analysing healthcare complaints about general practice. This has implications for the systematic analysis of these complaints, and could provide a means through which patient safety in general practice can be improved.

How this study influenced the work which follows

This chapter outlined the process of testing and adapting the HCAT for use in general practice contexts. As a result, an adapted tool, the HCAT(GP) was produced, and found to have acceptable reliability when tested on fictionalised complaints. A number of changes were made to the original HCAT for hospital care. These changes included modifications to the stages of care, new examples to illustrate severity ratings in a general practice context, and new definitions of the levels of harm. The adapted HCAT(GP) was tested by a sample of stakeholders, who analysed fictionalised complaints following a short training video. This indicated that the tool was reliable, and usability questions highlighted that participants considered the tool acceptable for use in a general practice context. This highlights the potential of this tool for the categorisation of complaints to identify areas for quality improvement, thereby successfully answering research question two. However, as this chapter used fictionalised complaints with the HCAT(GP), it remains to be seen whether the HCAT(GP) can be used to categorise real general practice complaints. The following chapter will apply the HCAT(GP) to a sample of complaints in an effort to answer the third research question on the content and severity of healthcare complaints made about general practice, and determine whether they can be used to identify areas for quality improvement.

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Chapter 4. Identifying hot spots for harm and blind spots across the care pathway from patient complaints about general practice[3]

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Author contributions

This study was led by EOD. EOD, POC, SL, CR and AH were responsible for designing and conceptualising the study. CR and AH supported access to complaints data. EOD and KL conducted the coding and agreement of the complaints for inter-rater reliability. EOD conducted statistical analysis on the coded data. EOD drafted the initial manuscript, and all authors redrafted and reviewed the manuscript prior to submission for publication.

Contribution to thesis

This chapter follows directly from the adaptation of the HCAT for use in general practice complaints. The HCAT(GP) was found to be reliable when used by stakeholders to analyse fictionalised complaints. However, it has not yet been applied to real general practice complaints. This chapter utilises the newly adapted HCAT(GP) tool to analyse a sample of real general practice healthcare complaints, with the aim of identifying and understanding the content of the complaints made about general practice in Ireland. In turn, it will support the identification of areas in general practice in Ireland to be prioritised for quality improvement. This chapter extends and complements the previous chapters by adding knowledge on what people complain about in Irish general practice, what hot spots and blind spots for quality issues exist in general practice care, and the levels of harm that are reported in these complaints. In doing so, it addresses research question three:

"Can the content of healthcare complaints made about general practice in the Republic of Ireland be reliably analysed and used to identify areas for quality improvement?"

Abstract

Background: Healthcare complaints are underutilised for quality and safety improvement in general practice. Systematic analysis of complaints has identified hot spots (where harm occurs) and blind spots (that cannot be observed) in secondary care, and the Healthcare Complaints Analysis Tool (HCAT) has been adapted to the HCAT(GP) for the general practice context.

Objective: This study aimed to: (1) assess whether the HCAT(GP) can be used for the systematic analysis of patient complaints about general practice; and (2) identify the hot spots and blind spots in general practice to be prioritised for quality and safety improvement.

Methods: A sample of GP complaints was collected. Complaints were coded with the HCAT(GP), classified by category, stage of care, severity, and harm. Descriptive statistics were run to identify issues within the data. A Chi Square test of independence identified hot spots, and a logistic regression was used to explore blind spots.

Results: A total of 230 complaints, encompassing 432 problems, were categorised. Relationship issues emerged most frequently. Hot spots were identified in the consultation and the referral/follow-up stages ($\chi^2(5, n=432) = 17.931, p<.05$). A blind spot for multiple issues occurring across the patient care pathway was identified, with the likelihood of harm increasing with number of issues (OR = 2.02, CI= 1.27-3.23, $p<.05$).

Conclusion: Healthcare complaints are a valuable data source for improving general practice. This study demonstrated the utility of the HCAT(GP) to support the systematic analysis of general practice complaints, and to identify hot spots and blind spots that need improvement.

4.1 Background

Healthcare complaints are expressions of dissatisfaction with care provided (1). While complaints have typically been considered in terms of risk management, they can also be an opportunity to gain valuable insight into patient perceptions of safety in healthcare (2, 3). Patients are in a position to identify areas of risk within healthcare that are not discernible by staff (4). Therefore, incorporating patient insights into quality and safety improvement can complement other measurement and monitoring tools (3). Healthcare complaints are increasingly being considered as one means through which patient insights on quality and safety in care can be utilised (1). When using complaints for insight into quality and safety, the description of events within a complaint is taken at face value, without further scrutiny. Many complaints are not upheld following individual investigations (5), and therefore there is an argument that they can be considered an unreliable data source. However, as other researchers have discussed extensively, whether or not the complaint is upheld in investigations is inconsequential (3), as the complainant saw a need to make a complaint, and that in itself is relevant to quality improvement. Healthcare complaints are therefore a burgeoning avenue for researchers looking to improve patient care.

When systematically analysed, and considered through a quality improvement rather than a risk management lens (6), healthcare complaints have the potential for identifying hot spots (i.e. points in care with a high prevalence of harm or near-misses) and blind spots (i.e. points in care that cannot be observed by staff members) (2). The Healthcare Complaints Analysis Tool (General Practice), or HCAT(GP), provides a reliable approach to analysing complaints about general practice (Chapter 3) (7). This tool was adapted directly from the HCAT, which was developed to analyse complaints about secondary care (8). The HCAT(GP) supports the classification of issues within complaints, the stages of care in which these issues occurred, the severity of the issues, and the level of harm experienced by the patient (7). HCAT(GP) has acceptable levels of validity, reliability and usability when used by GPs, healthcare complaints analysts and health services researchers to evaluate fictitious patient complaints (7). However,

the use of the tool to analyse a database of real complaints about general practice has not been assessed. Therefore, the aims of this paper are to:

(1) assess whether the HCAT(GP) can be used to support the systematic analysis of actual patient complaints about general practice; and
(2) identify the hot spots and blind spots in general practice that should be prioritised for quality and safety improvement.

4.2 Method

Design

This study used a retrospective analysis of databases to sample and categorise healthcare complaints about general practice in Ireland.

Sample

Two samples of complaints were analysed for this study. The first sample (*n*=69) was all the 2019 general practice complaints received by the Irish Health Service Executive. The second sample of complaints (*n*=161) was received from an Irish medical indemnity company and constituted all complaints made to the Irish Medical Council about insured GPs from 2017-2019 (inclusive). In order to ensure compliance with General Data Protection Regulations (GDPR), any identifiable information was redacted by the data controllers prior to sharing with the research team.

Ethical approval

This study received ethical approval from the NUI Galway Research Ethics committee (REC), reference number 18-Sept-17.

HCAT(GP)

All the complaints were analysed using the HCAT(GP) (7). It can be seen from Figure 4.1 that the HCAT(GP) supports the classification of the content of the complaint, the stage of care at which the issue occurred, the severity of the issue, and the overall level of harm reported by the complainant.

HCAT(GP)				
Domain	**Category**	**Severity**	**Stages of care**	**Harm**
Clinical Problems: Issues relating to quality and safety of clinical and nursing care provided by healthcare staff (i.e., doctors, nurses, radiologists, and allied health professionals)	Quality: clinical standards of healthcare staff behaviour	0: Not present	1.Accessing care	0. N/A: No information on harm is reported, or no harm came to the patient
	Safety: Errors, incidents and staff competencies	1: Low	2.While in the practice	1. Minimal intervention or treatment required, upset caused to patient
Management Problems: Issues relating to the environment and organisation within which healthcare is provided (for which administrative, technical, facilities and management staff are usually responsible)	Environment: Problems in the facilities, services, clinical equipment and staffing levels	2: Medium	3.During the consultation	2. Minor physical or mental harm caused to patient, intervention from GP or other primary care provider required to ameliorate harm
	Institutional Processes: problems in bureaucracy, waiting times, and accessing care	3: High	4.Referral/Follow up	3. Significant mental or physical harm, secondary care intervention required to ameliorate harm
Relationship problems: Issues relating to the behaviour of any specific member of staff towards the patient or their family/friends	Listening: Healthcare staff disregard or do not acknowledge information from patients		5.Unspecified/Other	4. Patient experienced or faces long term incapacity, either physical or mental
	Communication: absent or incorrect communication from healthcare staff to patients			5. Death or multiple/permanent injuries, or chronic mental health problems.
	Respect and patient rights: Disrespect or violations of patient rights by staff			

Figure 4.1. Healthcare Complaints Analysis Tool (General Practice) [HCAT(GP)]

Procedure

The redacted complaints were collated into an Excel database. Each complaint was carefully read by the primary researcher (EOD), and then the HCAT(GP) was used to categorise the issue(s), the stage(s) of care, the severity of the issue(s) and the harm reported within each complaint. In order to ascertain inter-rater reliability, a second researcher (KL) independently double-coded 33% of the sample using the HCAT(GP). Disagreements were resolved through discussion and consensus.

Analysis

There were four stages to the analysis.

1. *Data preparation*. Data from the finalised Excel database were cleaned and exported into R statistical software (9) for analysis. The "Harm" variable was recoded into a binomial variable (i.e., a harm score of 0 on the HCAT(GP) was recoded to "No harm" (0), and scores from 1-5 were recoded as "Harm" (1)). Analysis was then conducted on the cleaned data.
2. *Descriptive analysis*. Descriptive statistics were computed to determine what issues were emerging frequently from the complaints. This was followed by the assessment of inter-rater reliability of the two researchers' analysis across all of the HCAT(GP) using Gwet's AC1 (a measure of agreement between raters (10)).
3. *Identification of hot spots*. This analysis was based on R code developed by Gillespie and Reader (2). Hot spots were defined as points in care where harm or near-misses for harm were prevalent. It was intended to analyse the near-miss hotspot in this study by examining the complaints which had high severity but no reported harm. However, this was not possible due to small sample size of the present study. We therefore only assessed for the harm hot spot. A Chi Square test of independence was used to establish whether there was an association between the stage of care of an issue, and harm to the patient, and to identify where in the patient care pathway harm

was likely to occur. A matrix plot was designed to visually represent these data.

4. *Identification of blind spots*. Blind spots were defined as areas within care that are unobservable or difficult to observe. There are three main types of blind spot that can be captured by HCAT(GP). The first is the "entry/exit" blind spot, which captures issues that occur at the boundaries of care or outside of the general practice setting. The "errors of omission" blind spot, when an action is not done is implicit within the HCAT(GP). These errors of omission are rarely captured in other patient safety measures but have been found using analysis of hospital complaints (2). We assessed for the entry/exit and the errors of omission blind spots using descriptive statistics. The final blind spot examined was the "systemic problems" blind spot, where issues occur across multiple stages of the patient care pathway. The systemic problems blind spot is indicated by an increased likelihood of harm if more than one stage of care or issue is present within a complaint. This was analysed using a logistic regression with harm as the outcome variable, predicted by number of issues per complaint and number of stages of care within a complaint.

4.3 Results

Inter-rater reliability

Substantial inter-rater reliability across the HCAT(GP) was achieved between the two researchers (Gwet's AC1 = 0.79, CI= 0.77-0.82).

Descriptive statistics

A total of 230 redacted complaints about general practice were analysed. Details of the descriptive statistics are shown in Table 4.1.

Table 4.1 Descriptive statistics of complaints

Descriptive Statistics	N (%) (Total *n*=230)
Data source	
Medical indemnity company	161 (70%)
HSE community healthcare organisations	69 (30%)
Complainant	
Patient	131 (57%)
Parent	34 (15%)
Child of patient	21 (9%)
Other family members	23 (10%)
Other	11 (5%)
No information	10(4%)
Gender of staff member(s) complained against	
Female	52(23%)
Male	101(44%)
Female and male staff	11(5%)
No information	66 (28%)

Table 4.2 provides an overview of the analysis of the complaints using HCAT(GP). There were a total of 432 individual issues within the 230 complaints, with a mean of 1.88 problems per complaint (SD = 0.98). When analysed, each of the three domains from the HCAT(GP) were represented in the complaints. Complaints issues occurred most frequently at the "Consultation" stage of care (*n*=208, 48%). Half of the complaints reported some level of harm, and the majority of the issues were judged to have either medium (n=178, 41%) or high (n=165, 38%) severity (see Table 4.2).

Table 4.2 Complaints issues analysed by HCAT(GP)

HCAT(GP) sections	**N(%) issues (Total *n*=432)**	
Stages of Care		
1 – Accessing Care	72 (17%)	
2 – In the practice	25 (6%)	
3 – During the consultation	208 (48%)	
4 – Follow-up/Referral	59 (14%)	
5 – Other	45 (10%)	
Multiple stages	23 (5%)	
Severity		
1 – Low	89 (21%)	
2 – Medium	178 (41%)	
3 - High	165 (38%)	
Domains *Categories*		*Example issues within categories*
Clinical Domain	**139 (32%)**	
Quality	89 (21%)	*Not conducting assessment of patient*
Safety	50 (12%)	*Misdiagnosis of appendicitis*
Relationship Domain	**174 (40%)**	
Listening	45 (10%)	*Parent input on child illness ignored*
Communication	27 (6%)	*Blood test results not received by patient*
Respect and patient rights	102 (24%)	*Verbal assault of patient*
Management Domain	**119 (28%)**	
Environment	14 (3%)	*Surgery not accessible by wheelchair user*
Institutional Processes	105 (24%)	*Patient not able to register with GP*
Harm	**N(%) (Total *n*=230)**	*Example harm*

0 – No harm reported	115 (50%)	-
1 – Minimal	57 (25%)	*Complainant upset*
2 – Minor	22 (10%)	*Patient experienced stress and anxiety*
3 – Moderate	14 (6%)	*Short term recovery impacted*
4 – Major	6 (2%)	*Patient developed PTSD*
5 – Catastrophic	16 (7%)	*Patient died*

Hot spots

The Chi Square test of independence found a significant relationship between stage of care and whether or not harm was present in a complaint ($\chi^2(5, n=432) = 17.931, p<.05$). This indicated that certain stages of care could be considered "hot spots" for harm. Figure 4.2 presents a matrix plot of the distribution of the issues within the complaints across the stages of care. There are a number of things to consider when looking at this plot. The size of the boxes on the plot reflects the proportion of complaints issues occurring at that stage, and a solid outline indicates that the proportion is more than would be expected based on the chi-square test. From this figure, it is clear that there are hot spots in both the consultation and referral/follow up stages, as well as when a complaint occurs across multiple stages. Fewer than expected complaints resulted in harm at the "Accessing Care" stage of the patient pathway.

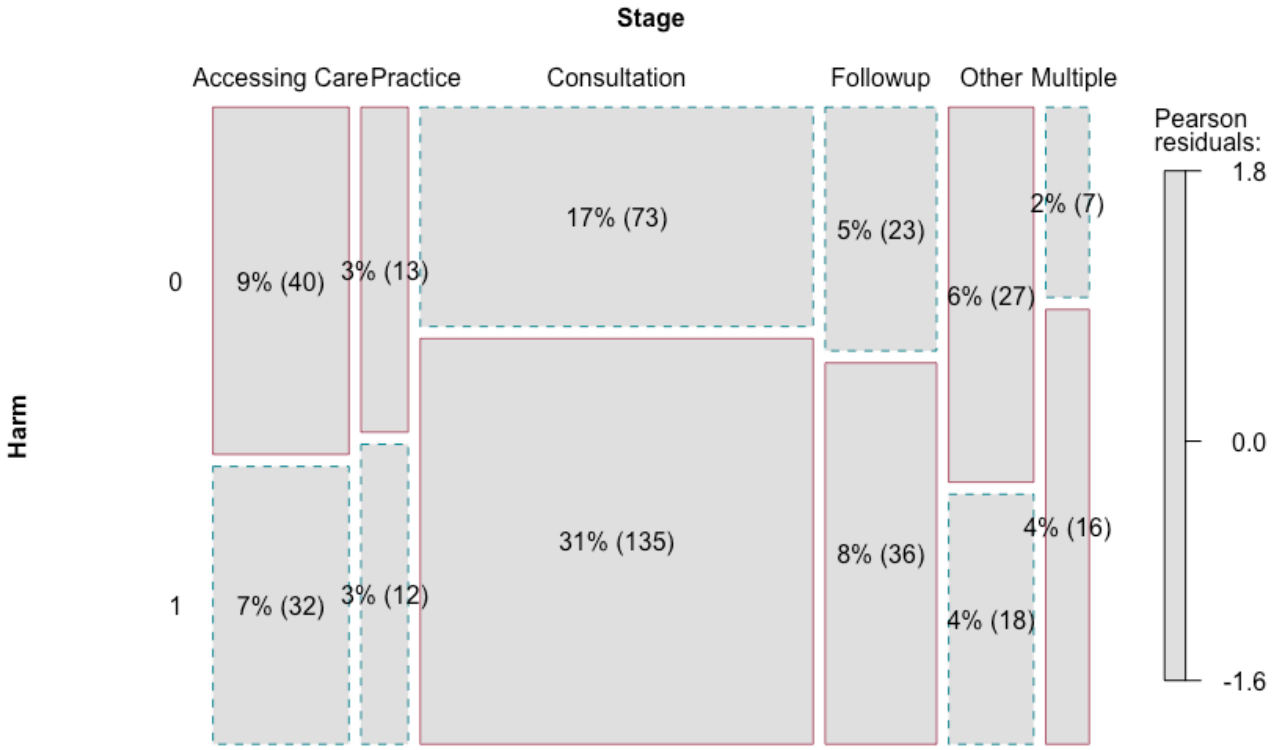

Figure 4.2 Matrix Plot of Harm by Stages of Care. (Harm 0 = no Harm present, Harm 1 = Harm present)

Blind spots

Three types of blind spots were identified.

1. *"Entry/Exit" blind spot.* Of the issues within the complaints presented in Table 4.2, almost one third (n=131, 30%) occurred at the boundaries of care, that is, stages 1 (Accessing Care) and 4 (Referral/Follow-up). Issues included not being able to make an appointment with the GP, not being referred for specialist care, and not being scheduled for follow-up tests.
2. *"Errors of omission" blind spot*. Issues assigned to the "Quality", "Communication" and "Listening" categories are considered to be "Errors of omission". Therefore, over one third of issues in this sample were classified as being "Errors of omission" (n=161, 37%). Examples of these issues within the complaints included not listening to parents regarding a child's allergies, failure to conduct a thorough examination, and not sending test results.
3. *"Systemic problems" blind spot.* Following the logistic regression, it was found that there was indeed a systemic problems blind spot. Complaints with more issues were associated with an increased likelihood of harm (OR = 2.02, CI= 1.27-3.23, $p<.05$).

4.4 Discussion

Patient complaints are an underutilised source of data that have the potential to identify where improvements can be made to patient safety in general practice. The HCAT(GP) is a valid, reliable and useable framework to support the analysis of patient complaints. The aims of this paper were to assess whether the HCAT(GP) can be used to support the systematic analysis of actual patient complaints about general practice, and to identify the hot spots and blind spots in general practice that should be prioritised for quality and safety improvement.

The application of the HCAT(GP) enabled the systematic categorisation of complaints made about general practice in Ireland, and allowed for further analysis of the trends across these complaints. Overall, issues emerged in each of the categories and domains of the HCAT(GP). In

contrast to analyses of hospital complaints, where clinical issues dominated the findings (2), relationship issues emerged most frequently from the GP complaints. This emphasised the particular importance of the doctor-patient relationship and the inherent trust between GPs and their patients (11). This is arguably more important in general practice as compared to secondary care as patients have relationships with their GPs that last for many years (11). Communication skills training, an emphasis on patient-centred care, and rapport building could all be utilised to help address relationship issues faced by patients when receiving care (12).

Clinical and management issues also were prevalent in the analysis, with 24%(*n*=105) of issues pertaining to institutional processes, and 21% (*n*=89) to problems with quality of care. Complaints often incorporated issues from across several categories. This phenomenon also occurred in hospital complaints (2). The wide scope of issues from this complaints analysis suggests that there is a need to take a holistic view of quality and safety improvement in general practice. A previous systematic review highlighted the prevalence of clinical issues in general practice complaints (13) (Chapter 2). However, this present study also indicates that it is vital that relationship and management issues are tackled to improve quality of care. It is important these trends are explored further in other contexts, outside of Ireland, and with larger samples, to establish whether they persist.

Several hot spots and blind spots in care emerged from the analysis of the patient complaints. A harm hot spot was identified in the consultation stage of the patient care pathway. Patient safety research in secondary care is often centred on identifying error and clinical issues (14), however this is less of a focus in general practice research (15). The harm hotspot emerging at the consultation stage in this study indicates that errors do occur within the general practice context, and this reflects recent research on the prevalence of patient safety issues within general practice (16). Another harm hot spot identified was “follow-up/referral”. This is an important finding, as continuation and transition of care was also identified as a blind spot (the “entry/exit” blind spot), which other methods of monitoring patient safety may miss (2). Safety issues and harm emerging at the boundaries of care is indicative of the recognised gap and potential issues faced by

patients when transitioning between different aspects of the health service (17). GPs tend to work independently, and lack the administrative and clinical support afforded to their hospital colleagues (18). In Ireland, a quarter of GPs work in single-handed practices, which could contribute to issues at the boundaries of care, along with a perceived lack of support on referrals from hospital departments and consultants (19, 20). Future research should further explore the complaints qualitatively in order to understand the full extent of the phenomena occurring at these stages (2). Interventions could in turn be developed based on these findings to improve patient safety and quality of care at these points of the patient care pathway. There is also a need to examine other hot spots of care in general practice. With a larger sample of complaints, "near miss" hot spots where there are a lot of high-severity issues that don't result in harm, could be identified (2). Similarly hot spots for catastrophic harm could be analysed in order to prioritise areas for improvement.

Several blind spots in general practice were identified in the analysis. These included the "entry/exit", "systemic problems", and "errors of omission" blind spots. The identification of a systemic problems blind spot was particularly interesting, as if a patient experienced poor care at multiple stages during their interaction with their general practice, they were then more likely to experience harm and report it in their complaint. It is vital to have improved insight into the entire patient care pathway and the multiple issues which may emerge throughout it, as patients are often the only people who are witness to their own care across the entire system (2). This is an aspect of care that cannot be accessed using other forms of patient safety monitoring tools, and therefore highlights the potential for complaints to be used in tandem with these other tools (e.g., patient record review, global trigger tools, safety climate questionnaires (3, 21, 22). Similarly, errors of omission are rarely identified through other means, as they are rarely observed, or when they are, responsibility is rarely taken (23). However, errors of omission are prevalent in healthcare, and these findings reiterate the importance of healthcare complaints for identifying errors of omission (2). Safety and quality improvement in general practice must incorporate the learning on these various blind spots to ensure issues that

patients experience are dealt with, even when they are not directly witnessed by the healthcare provider. Utilising the data on blind spots that emerge from complaints in this manner could help identify issues as they emerge, and prevent harm from occurring to patients (2).

Implications for research and practice

A number of important implications for future research and practice have emerged from this study. First, this study has highlighted the difficulties experienced by patients at the transitional points of general practice care. This emphasises the importance of systematic and centralised analysis of complaints across an entire healthcare system. The HCAT(GP) (7) could be used in conjunction with the HCAT for hospital complaints (8) to give a broader overview of the transition from primary to secondary care, and identify which areas that require improvement. Complaints that incorporate elements from both primary and secondary care can now be analysed comprehensively across the entire patient care pathway. Future research could ascertain the benefits of having a tool which can identify issues at these transitions of care in both hospital and GP settings, and enable learning from complaints to move from local level to a system wide view of issues. Future research could also explore collaborating with stakeholders in general practice to consider interventions to address the key findings from the analysis. The study has uncovered areas in GP care which are potentially harmful to patients and must be addressed. Finally, this study examined trends across an entire dataset of complaints. Qualitative research on the specific issues that arise within each of the domains and categories of the HCAT(GP) would help to target improvement initiatives. An in-depth, qualitative understanding of the issues that emerge, as well as insight into the higher level issues across the system, would facilitate improvement initiatives which both tackle issues on the ground and transfer the learning to the wider system, as has been done in other contexts (2, 24). Multi-method analysis would improve our understanding of the issues experienced by patients.

Limitations

This study had several limitations that should be noted. First, the sample size was limited. There is no single, centralised database of GP complaints in Ireland. As such, it is challenging to obtain a large sample of complaints. In addition, due to the requirement to redact the complaints, there was a large burden on the data controllers, limiting the feasibility of gathering a large number of complaints. As a result of this limited sample size, more detailed analyses on hot spots and blind spots could not be run. A second limitation is that the complaints were all collected prior to the beginning of the COVID-19 pandemic, within one healthcare system. Future research must determine whether the HCAT(GP) can reliably analyse and classify complaints made in other healthcare systems, and in light of the changes to general practice that may result from a pandemic (e.g., increase in online consultations).

Conclusion

Healthcare complaints are a valuable, but underutilised, source of data to improve the quality and safety of general practice. This study has demonstrated the utility of the HCAT(GP) tool to support the systematic analysis of patient complaints about general practice, and to identify hot spots and blind spots in care that are in need of prioritisation. This information is of great value in supporting an evidence-based approach to service improvement.

How this study influenced the work which follows

This chapter has outlined the ability of the HCAT(GP) to successfully analyse complaints made in Irish general practice contexts, and identified areas for quality improvement within general practice. The identification of hot spots and blind spots, which indicate issues in the consultation stage and at the transitional points of care, has the potential to contribute greatly to evidence-based quality improvement in this setting. This chapter has therefore answered the third research question of the thesis, indicating that the HCAT(GP) can reliably analyse real complaints about general practice settings.

The next chapter will explore the wider context of complaints in general practice in Ireland, through the lens of stakeholders who manage and receive complaints. This will address the final research question on how stakeholders in Irish general practice perceive healthcare complaints. Understanding the context and culture of complaints in general practice in Ireland will be key for the implementation of quality improvement initiatives developed from collective analysis of complaints. It is therefore vital that we understand people's perceptions of, and attitudes towards, complaints, in order to structure the implementation of quality improvement initiatives appropriately.

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Chapter 5. A multi-perspective exploration of the understanding of patient complaints and their potential for patient safety improvement in general practice[4]

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Author contributions

EOD led this study. EOD, POC and SL were involved in the design and planning of the study. EOD recruited participants, conducted interviews, and transcribed the interview data. All authors were involved in iterative coding of the data and arranging it into its final themes. EOD drafted the manuscript. All authors reviewed and edited drafts of the manuscript prior to submission for publication at a peer reviewed journal.

Contribution to thesis

This chapter follows on from the previous studies, which established that the HCAT(GP) can be used to analyse healthcare complaints about general practice care in Ireland, and that the analysis of complaints using this tool can identify areas in general practice to prioritise for quality improvement. While the data presented heretofore address the overall aim of the thesis, a broader contextual piece of work is absent. It is vital to gain insight into the wider culture of complaints in general practice, and understand provider, management and policy perspectives in relation to this, in order to support implementation of systems or processes relating to the analysis and use of general practice complaints for quality improvement. The findings from previous chapters can only have value and potential for implementation if there is buy-in and support from stakeholders and the system at large. This chapter therefore aims to answer the final research question of the thesis:

"How do stakeholders in general practice in the Republic of Ireland perceive healthcare complaints, and what does this tell us about the context in which a complaints analysis tool for quality improvement will be received?"

Abstract

Background: Healthcare complaints are an underutilised source of information for safety improvement, particularly in general practice settings. Within general practice in Ireland, complaints management is dependent on individual practice policies, with little standardisation nationally, impeding their use for safety improvement. There is a need to understand factors that contribute to unlocking the potential of complaints for safety improvement in general practice in Ireland and internationally.

Objective: To explore perceptions of healthcare complaints of general practitioners, practice nurses and managers, medico-legal professionals, and policymakers.

Method: Participants were recruited using convenience sampling. Interviews were conducted from November 2019-May 2020, based on a semi-structured interview guide. Data were then transcribed and analysed using content analysis. An iterative process was applied to identify emerging themes from the interviews.

Results: A total of 29 participants (19 female, 10 male) were interviewed. Three themes emerged from the analysis, 'why patients submit complaints', 'management of complaints', and 'impact of complaints'. Subthemes included 'barriers and facilitators to complaining', 'practice processes' for complaints management, and 'impacts on staff' of complaints, among others.

Conclusion: There is a lot to be learned about how individuals experience complaints, however this study adds to existing knowledge. The findings from this study can be used to tackle challenges facing complaints management in general practice, including the barriers to complaining for patients and the negative impacts of complaints on the staff, and can also help to build on positive aspects of complaints such as the desire for systemic change among interested parties.

5.1 Background

Healthcare complaints are typically defined as expressions of dissatisfaction, usually in a formal letter, regarding care provided by the health service or a healthcare provider (1). Recent research has shown that patients have a privileged insight in the healthcare system, and can identify issues that staff or members of the organization cannot (2). A patient complaint is an indicator of a certain level of dissatisfaction which requires attention from healthcare providers (3). Patient complaints about healthcare experiences are increasingly being seen as learning opportunities to improve patient safety and quality of care (4,5).

Although relatively common, complaints are an underutilised source of information for safety improvement (6). One recent study examined complaints made about an Irish out-of-hours service and found a total of 298 complaints out of 303,085 consultations (3). It is evident therefore that healthcare complaints in general practice settings could be exploited further for patient safety improvement, in a similar manner to what is beginning to occur in secondary care (5).

A recent systematic review of studies examining complaints in general practice indicated a need for greater understanding of the variables that are crucial to unlocking the potential of patient complaints for safety and quality improvement (Chapter 2) (7). These variables include the motivation of patients in making complaints, the potential positive and negative impacts of complaints in general practice, and how open general practitioners and other healthcare providers are to receiving and engaging with complaints (7). Therefore the purpose of this study is to engage with stakeholders to explore the attitudes towards, and perceptions of, these aspects of complaints in general practice. It is intended that this will support the use of healthcare complaints in quality and safety improvement in the general practice context. This study used a qualitative approach to address the following research questions:

1. How do stakeholders in general practice perceive, experience and manage patient complaints?
2. What impacts do complaints have in general practice?

3. What are the perceived patient motivations for submitting complaints?

5.2 Method

Design

This is a qualitative, semi-structured interview study. The study is presented in accordance with the CORE-Q guidelines for qualitative research (8).

Context

This study was conducted in general practice in the Republic of Ireland. In Ireland, General Practitioners (GPs) work in single-handed practices, group practices, or primary care centres. Patients typically pay privately to attend a GP but some patients with special circumstances (e.g., chronic health conditions, advanced age, low income) attend their GP without paying a fee, on the public system. When making complaints about their GP, private patients must complain to the practice or co-operative, and/or to the Irish Medical Council. Public patients may also complain to the practice or co-operative and/or the national Health Service Executive (HSE).

Participants and recruitment

GPs and people with roles in the complaints process (i.e. medico-legal professionals, complaints policymakers, practice managers and practice nurses) were recruited using a combination of convenience and snowball sampling. In the context of this study, medico-legal professionals are lawyers working at a company that provides GPs with medical indemnity cover, and practice managers are responsible for the daily operations of a GP office including staffing, scheduling, and patient complaints. Recruitment involved advertisements circulated via social media (e.g. Twitter), recruitment emails sent to staff in the national complaints team in the HSE, and emails sent to general practitioners in the local area. Participants were recruited throughout the duration of the

research study until each of the target groups were represented. Everyone who was approached for participation from these groups took part in the study. Efforts were made to recruit patients who have made complaints about general practice, with 6 patient advocacy groups contacted, however no responses were received.

Procedure

Participants were interviewed by a female masters-level researcher (EOD), who was a PhD candidate at the time, with previous experience in conducting semi-structured interviews. The researcher was acquainted professionally with 13 of the participants, and had no prior relationship with the other 16 participants. The researcher had existing knowledge and assumptions about general practice complaints, having conducted other related research. Interviews were conducted either one-to-one in person or via telephone, between November 2019 and May 2020. Due to the onset of the COVID-19 pandemic, any interviews from March 2020 onwards were conducted over the telephone. Participants completed a consent form prior to taking part in the research, and knew the aims of the researcher in conducting this study.

A semi-structured interview guide (Appendix 5) was used to structure the interviews. The guide was developed based on findings from a recent systematic review on complaints which identified patient motivations for complaining, the process of managing complaints, and the impact of complaints for learning as key priorities for research (Chapter 2) (7).

The interviews were audio recorded and subsequently transcribed by one author (EOD) who ensured that all identifying information was removed. Recordings were deleted following transcription. The transcripts were stored on a secure computer and hard drive within the researcher's locked office on the National University of Ireland Galway (NUIG) campus. Where possible, transcripts were returned to participants for comment and/or correction.

Analysis

Deductive qualitative content analysis (9) was used to make meaning of the interviews. This process involved familiarisation with the data, line-by-line coding, grouping of codes into hierarchical themes and subthemes, and reporting (10). The coding scheme was based loosely on the interview guide, while also allowing for new themes to emerge from the data (9). A sample of interviews (*n*=7, 24%) was initially coded individually by the three authors (EOD, SL, and POC). Following this, the codes were grouped and synthesised into themes and subthemes through discussion, and by consensus, between the authors. Following this process, one author (EOD) analysed a further sample of interviews (*n*=7, 24%). The three coders then deliberated again on the coding framework, and any new themes or subthemes which had emerged from the second round of coding were included. At this stage, NVivo 12 was used to manage the data. The remaining interviews were coded by one author (EOD), and no new themes emerged from the data at this point, indicating that a final framework had been reached. This final framework was discussed by the three authors, and following this process, the data were written up and reported by one author (EOD).

Ethics

Ethical approval was obtained from the National University of Ireland Galway (NUIG) Research Ethics Committee (*19-Aug-15; Amend 2002*).

5.3 Results

Participant demographics

A total of 29 participants (19 female, 10 male) were interviewed. Participants included GPs (*n*=13), practice nurses (*n*=3), practice managers (*n*=2), medico-legal experts (*n*=4), and health service policymakers (*n*=7). The interviews ranged from seven to 36 minutes in duration (mean= 19.3 minutes)

Coding framework

The framework which emerged from the analysis consisted of three overarching themes, each with a number of related subthemes. The final themes are presented in Figure 5.1 below. The themes which emerged from the data analysis were: "why patients submit complaints", "management of complaints", and "impact of complaints".

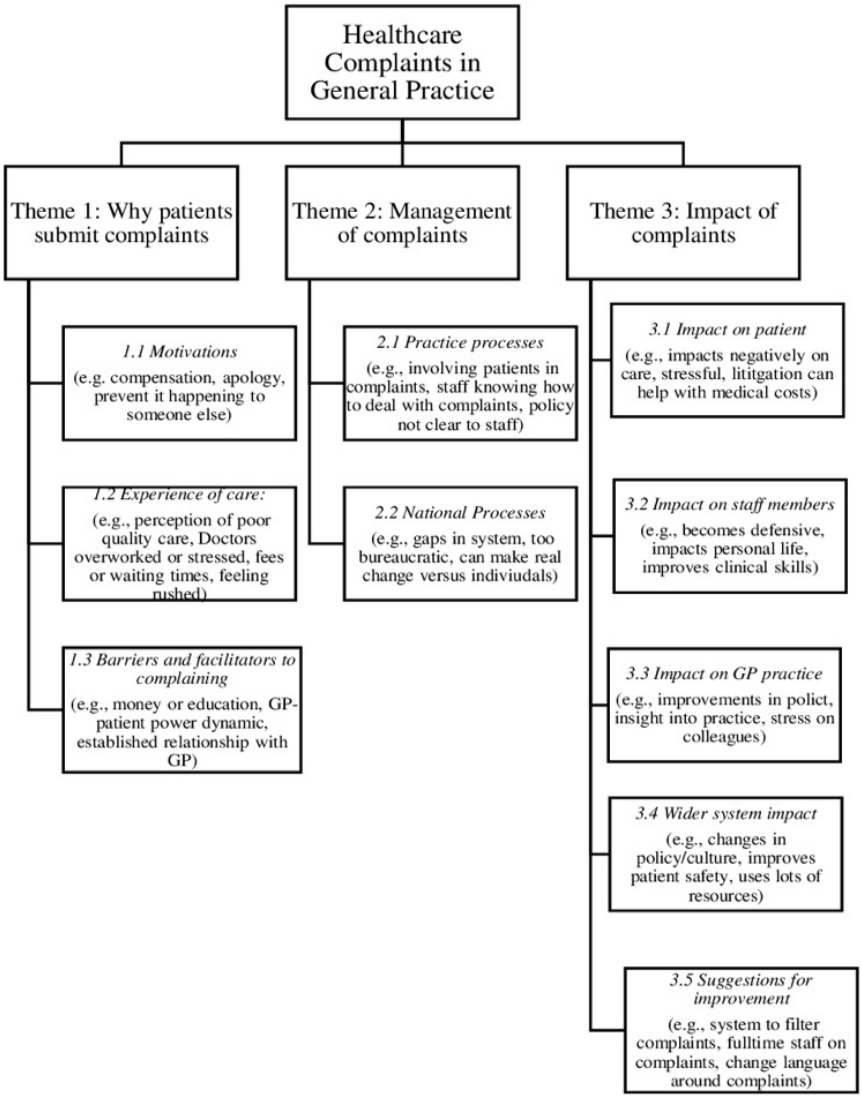

Figure 5.1 Breakdown of themes and subthemes

Theme 1: Why patients submit complaints

The first theme which emerged from the interviews was ‘why patients submit complaints’. Participants from different professional backgrounds discussed their experiences of the factors contributing to patient complaints. Three subthemes were explicated: ‘motivations’, ‘experience of care”, and ‘barriers and facilitators to complaining”. Exemplar quotes illustrating this theme and its subthemes can be found in Table 5.1.

Table 5.1 Exemplar quotes from Theme 1 "Why patients submit complaints" and subthemes.

Theme *Subtheme*	No(%) of participants	Exemplar quotes
1. Why patients submit complaints		
1.1 Motivations	13(45%)	*'I think it is an exercise in sounding out whether they have a case for litigation or not'* (Medico-legal expert 3) *'certainly some* [patients] *want the money back that they spent on the medication say, and you know sometimes people have very limited incomes'* (GP 1). *'most people don't really want to take you to court… they just want to make sure it doesn't happen again to other people'* (GP 12).
1.2 Experience of care	23(79%)	*'perhaps they might feel that they weren't treated well… you know in terms of what the treatment should have been or was'* (GP 3). '*I felt the doctor was rude to me, dismissive of me, the nurse was dismissive of me, rude to me'* (GP 6). *'I touched on lack of resources and I think that's a huge driver in complaints.'* (Policymaker 1).
1.3 Barriers and facilitators	18(62%)	*'more likely to complain, middle class people more than the poorer strata of society'* (GP 5). *'because I suppose of the power differentials between health professionals and patients, they don't tell you if*

	something's going wrong' (Practice nurse 1). *'I think as time has gone on there's more empowerment of patients'* (GP 6). *'you're talking about small communities, people actually know who their GP is, and you know and you're likely to meet them at mass or in a social context as well'* (Practice nurse 1). *'that disappointment that might not have been complained about in-hours will be complained about in out-of-hours because it's a strange clinician in a faceless institution.'* (GP 5).

Subtheme 1.1 Motivations: Patient motivations for complaining were discussed by a number of the interviewees (n=13, 45%). In some cases, patients were perceived as looking for financial compensation when they complain, or as having a desire to vent or express their annoyance at the individual. In some instances, participants acknowledged that the personal circumstances may require patients to be motivated by money. However, others considered patient complaints to be made for the good of others (see Table 5.1).

Subtheme 1.2 Experience of care: Patient perceptions of quality of care, along with miscommunications and misunderstandings around patient expectations, often resulted in complaints, and were discussed by 23 participants (79%).

Other issues in this subtheme related to respect and patient rights, with participants describing patients who say the doctor and other staff members were rude to them, and institutional processes, where factors such as cost, waiting times, or limited resources were seen as having contributed to a complaint (see Table 5.1).

Subtheme 1.3 Barriers and facilitators to complaining: Some participants (*n*=18, 62%) described how certain contextual and systemic factors can either facilitate or impede patient complaints. Affluent, highly educated patients were considered more likely to complain than those from lower socioeconomic backgrounds.

GP and practice nurse participants frequently brought up the imbalance of power between patients and GPs as something which can serve as a barrier to complaints. Historically, patients may have hesitated to challenge the judgement of GPs because of the power differential between patients and physicians. It was interesting that this power imbalance was raised by a practice nurse, whose position as an intermediary between GPs and patients may contribute to their understanding of the challenges faced by patients in complaining.

However, participants also described a cultural shift away from this, with increased empowerment of patients in contemporary general practice. This cultural shift away from an imbalance of power, and towards empowering patients, was considered a facilitator of patient complaints.

Another factor implicated was the personal relationship between patients and their GP, particularly in rural or small communities. Where the GP is well known to the patient they may be less likely to complain. Accordingly, where the GP is not known to the patient they were seen as being more likely to complain (see Table 5.1).

Theme 2: Management of complaints

The second theme which emerged from the interviews explored participants' experiences of how complaints are managed in the system. This theme consisted of two subthemes: 'practice processes' and 'national processes', and can be seen in Table 5.2 below.

Table 5.2 Exemplar quotes from Theme 2 "Management of complaints" and subthemes.

Theme *Subtheme*	No(%) of participants	Exemplar quotes
2.Management of complaints		
2.1 Practice processes	28(97%)	*'It's about talking to them in the first instance I suppose and trying to alleviate it without it escalating'* (Practice nurse 3). *'In the place where I work currently I haven't come across a general standard reporting procedure for complaints'* (Practice nurse 2). *'I would love to see a specific policy, SOP* [standard operating procedure] *on complaints'* (Practice nurse 2).
2.2. National Processes	29(100%)	*'like I don't know how it's managed nationally, or broadly'* (Practice manager 1). *'I think it's too weighted against the doctor, the doctor has absolutely no recourse to complain about a patient.'* (GP 1). *'I suppose I think it's functioning better than it has been in the past. There's definitely renewed focus on complaints and learning from complaints'* (Policymaker 3).

Subtheme 2.1 Practice processes: This subtheme was discussed by almost all participants (*n*=28, 97%). Interviewees who work or have worked in general practice settings tended to focus on the importance of having

defined, explicit practice processes for managing and resolving patient complaints, and recognised the need to resolve complaints quickly and locally. However, a number of participants believed that a quick resolution was hampered by a lack of a defined protocol at a practice level. It became clear from the analysis that there is often no standardised procedure for handling complaints within individual practices, or indeed across practices nationally, despite the fact that the need for one was recognised by participants (see Table 5.2).

Subtheme 2.2 National processes: All participants interviewed discussed this subtheme. However, participants had contrasting opinions on the functionality and efficacy of the national process in place for managing complaints. Practice managers in particular were unaware of the national process, with their knowledge often limited to their practice processes.

Any patient complaints that were escalated beyond the practice were then handled by the doctors themselves and their legal teams, not the administrative staff within the practice. There was a clear disconnect between those working in management and policy settings, and those working in general practice. GPs and their representatives felt that the national management process was not set up to support the healthcare practitioner, and that it was weighted against the doctor.

However, those participants with a role in the national complaints process had a more positive view of the system. They mainly discussed the variation in following the national process within the country, and how it has improved from previous iterations (see Table 5.2).

Theme 3: Impacts of complaints

The final theme explores the impacts of complaints, both positive and negative, on individuals and systems within general practice. This theme was divided into four subthemes based upon who or what was impacted by the complaint, all of which are presented in Table 5.3.

Table 5.3 Exemplar quotes from Theme 3 "Impact of complaints" and subthemes.

Theme *Subtheme*	No(%) of participants	Exemplar quotes
3.Impact of complaints		
3.1 Impact on patient	17(59%)	*'if that* [the complaint] *goes all the way, the patient is going to be up on a stand as well as the doctor, getting cross-examined, and I think patients don't essentially realise that'* (Medico-legal expert 2). *'…the impact on the patient obviously is that if they feel particularly aggrieved about something, at least they have a process in place to bring it through'* (GP 12). *'it perhaps makes you feel negative about that patient or their family.'* (GP 5).
3.2 Impact on staff member	23(79%)	*'no doctor remembers any good things done, but he remembers all the bad things done, all the mistakes, and the complaints, and they're the things that stick out in the memory, because they can be very personally very difficult, very stressful, very traumatic'* (GP 9). '*I know that I have heard doctors saying, well after this happened we do something differently. So there are definitely learnings that are there'* (Medico-legal expert 3) *'It would make you practice more defensively, if you had someone complain about a missed test result before then you'll end up testing everybody for that thing and*

		that's probably not the right way of doing it either' (GP 10).
3.3 Impact on GP practice	15(52%)	*'because of that incident we have completely changed our practice protocols on repeat prescribing.'* (GP 9). *'You've staff who are already sort of under siege in terms of the workload, media focus, you know simply trying to work in overcrowded, difficult situations, and then on top of that you have very understandable complaints…So you have a morale issue'* (Policymaker 5).
3.4 Impact on wider system	17(59%)	*'for every [complaint] …we do highlight to the powers that be and say listen there is additional resources required here… it is put on a list for when and if we do get money.*'(Policymaker 1). *'it really identifies key learnings across the system but it's coming from… the voices of our patients… and how do we turn that into action how do we turn that into change'* (Policymaker 2).

Subtheme 3.1 Impact on patient: Some participants (*n*=17, 59%) mentioned the impact that they perceived complaints to have on patients. These impacts were both positive and negative, with some acknowledging it a stressful experience for patients, for example when they are asked to take to the stand in front of the medical council.

However, others highlighted that it can be a positive experience for patients when a complaints process works well, as they have a process in place to deal with something that aggrieved them.

A negative impact on patient care as a result of making a complaint was discussed by some participants. Some GPs acknowledged that while they would go to all lengths to avoid treating patients differently following a complaint, that different treatment might be given to patients seen as being prone to complaining

Subtheme 3.2 Impact on staff members: A total of 23 participants (*n*=79%) believed that complaints can have both positive and negative impacts on those on the receiving end, whether that is personally or professionally. Doctors and staff members mentioned feeling stressed, upset, angry, and burned out as a result of experiencing a complaint, and that the experience can be 'very *difficult, very stressful, very traumatic'* (GP 9).

In terms of their professional life, while some touched on the possibility of complaints to make improvements in a doctors' practice, with one noting '*I know that I have heard doctors saying, well after this happened we do something differently. So there are definitely learnings that are there'* (Medico-legal expert 3), many others discussed the increased defensiveness of GPs practice following complaints, such as over-testing patients.

Subtheme 3.3 Impact on GP practice: Complaints were often described by participants (*n*=15, 52%) as having a direct, positive impact on the policies and procedures within specific practices. For instance, one GP

noted that *'because of that incident we have completely changed our practice protocols on repeat prescribing.'* (GP 9).

On the other hand, for some, complaints had a negative impact on the atmosphere in the practice, with staff morale depleted by a combination of the complaints and understaffed working conditions.

Subtheme 3.4 Impact on wider system: While GP, practice nurse, and practice manager participants often discussed the impact of the complaints on the GP practice itself, the legal advisors and individuals working for larger organisations tended to focus on the impacts on the system as a whole, with 17(59%) of participants addressing this. One participant reported that: *'for every [complaint] …we do highlight to the powers that be and say listen there is additional resources required here… it is put on a list for when and if we do get money.*'(Policymaker 1).

The importance of using the patient voice to learn and improve as a national system was emphasised, particularly by people working in policy development. However, there was a recognised gap between engagement with complaints and subsequent action. For instance, one policymaker commented that: *'it really identifies key learnings across the system but it's coming from… the voices of our patients… and how do we turn that into action how do we turn that into change'* (Policymaker 2).

5.4 Discussion

Main findings

Engagement with participants in this study regarding healthcare complaints has offered insights into why patients complain, how complaints are managed, and the impacts of complaints on staff, GP practices, and the healthcare system. There is a recognised lack of knowledge and understanding to facilitate the effective use of healthcare complaints for quality and safety improvement in general practice. This understanding may be used to support changing attitudes towards healthcare complaints, to

enable the utilisation of complaints for quality and safety improvement, and to facilitate patient contributions to improving their care.

Why do patients complain?

One interesting aspect of how participants experienced complaints was their perception of why patients complain. In our study, participants were most likely to attribute altruistic motivations to patients who submitted healthcare complaints. This is a positive finding, and reflective of patients' self-reported motivations (11). However, some participants had negative perceptions of patient motivations for submitting healthcare complaints, and further awareness-raising that patients can often have altruistic motivations is therefore required. This would help to highlight the value of these complaints, by emphasising that not all complaints are made by patients for personal gain or to spite healthcare providers. It is vital that the healthcare service capitalises on the desire from patients to contribute to safety improvement through, for example, complaints, patient experience surveys, and informal comments (12-14). Capturing and utilising patient feedback while being cognisant of the altruistic motivations that patients can have for providing this feedback, could help improve patient care and outcomes in a participatory, inclusive manner (15).

Local and national complaints processes

It was clear from this study that there is a need to establish continuity between practice-level and national complaints processes. There was a clear tension between local and national processes, which is potentially inhibiting the learning from complaints. Resolution of this tension would ensure that the potential of healthcare complaints to improve quality of care is realised. GPs and practice staff emphasised that they aim to resolve complaints locally before they escalate to external, formal processes. This local resolution may be beneficial to the practice involved in the complaint because issues would be dealt with swiftly, without the involvement of external bodies (16). However, the focus on local resolution without any sharing of knowledge at a wider systems level may be

detrimental to patient safety as the learning is not disseminated to others (16). Also, the low number of complaints received by individual practices would preclude learning on broader issues. Thus, national processes need to be implemented and streamlined to ensure local complaints can effectively feed into systems-level learning from complaints (5). Policymakers could for example provide nationally standardised guidelines for local practices to follow when building a complaints process, and also introduce the use of a framework to analyse complaints at all levels and a centralised system to facilitate knowledge exchange. The difference in perception of how the complaints process is functioning between frontline workers and policymakers is also a barrier to the effective use of healthcare complaints, and this finding echoes international research on the difference between 'work-as done' on the sharp end of healthcare, and 'work-as-imagined' (17). This gap in understanding must be reduced, and the system transformed into one that is unified and streamlined, in order to effectively learn from experiences (18).

The impact of complaints

The impact of complaints was discussed in a nuanced manner by participants in this study, and has built understanding of how complaints can impact upon different levels of the health service, from the individual to the system at large. Participants' often negative perception of the impact of complaints reflects what has previously been explored in the research (19). Currently, the complaints system is combative, with an emphasis on blame rather than on improvement (11). Doctors have been found to face extreme stress when they receive a complaint, with GPs reporting anger, lack of confidence in practice, and even depression in the wake of a complaint (19,20). It is clear that work is needed on reframing complaints, and restructuring the complaints process, particularly through acknowledging the potential negative impact of complaints, supporting providers who receive a complaint, and on shifting the emphasis towards a system that fosters learning rather than seeking to punish. The opportunity could also be provided to doctors themselves to respond to complaints, which in turn

could reduce their negative experiences and feelings of powerlessness when they receive a complaint. This could be particularly beneficial in the instances where their clinical judgement is that the complaint is not justified.

Learning from complaints

Despite the fact that opinions on complaints seem to be more focused on blame than learning, participants did discuss the learning opportunities that complaints offer. There is therefore clear potential for complaints to impact positively on healthcare providers and systems (5). Complaints can improve patient safety and experiences of care (5), and can in turn be viewed positively by healthcare providers who value this insight into the care they provide. This positive view could also contribute to maintaining therapeutic relationships following complaints by reducing emphasis on the negative aspects of complaints, and helping practitioners experience complaints as constructive instead of combative, and means of achieving these should be explored in future work. As such, there is a need to further consider how complaints can be better used as a mechanism for improving care in general practice, and how healthcare providers and managers within the health system can be supported to identify the positive impacts of healthcare complaints on practice and policy.

Limitations

This study has a number of limitations. First, patients are not represented as participants. It was initially intended to include patients or patient advocates as participants in the study, however it proved difficult to access this group. Every effort was made to recruit patients who had made complaints, with the researchers contacting patient advocacy groups, however no response was received. Despite this, the study provides an otherwise broad sample of stakeholders in general practice, and as one review highlights, many complaints studies have tended to focus on the patient experience alone (7). This study provides a key insight into an

alternative perspective, that of individuals on the receiving end of complaints.

Second, the breadth of the research questions may be considered a limitation of the study. Each of the themes encapsulated a wealth of data, and may have benefited from a deeper exploration. The paper was exploratory by design, and intended to capture the general experiences of a wide range of people, which it achieved, however future work could take a closer look at the individual themes to see what else could emerge from their deeper study.

Third, the representation of different professional groups within the participants for this study was not equally distributed, with more GPs interviewed than other individuals. There is the potential for bias of results here, with the GP voice over-represented in comparison to practice nurses, for example. This was a necessary result of the structure of the networks for different professional groups, as practice nurses and managers for example are often more isolated within a practice than GPs in Ireland. Future work should attempt to recruit more of these under-represented groups to ensure a balanced understanding of their experiences of complaints.

Finally, the study is limited to the experiences of individuals working within the context of general practice in Ireland. Therefore, some of the findings may be specific to this context, particularly those relating to the management of complaints within the national and local systems. Nonetheless, our findings on complaints are largely aligned with those of related studies conducted in other countries (7).

Implications

This study has illuminated some areas which warrant focus within future research and practice contexts. First, there is no standardised way of capturing the learning from complaints at both local and national levels at the moment, with some practices or areas achieving this more successfully than others. A standardised system such as a version of the Healthcare Complaints Analysis Tool (HCAT) (21) could be applied at both a local and national level to ensure consistency in complaints analysis. This in turn

could capture the learning from complaints at all levels of the health service. The HCAT is a validated, reliable tool for analysing healthcare complaints about secondary care, used to identify system level trends within the data and in turn has the potential to improve patient safety through identifying hotspots and blind-spots in care (21). A similar tool, adapted for a general practice setting, could improve the experience of receiving complaints by structuring and standardising their analysis, and could identify similar hotspots and blind-spots.

Secondly, research is needed to change the overall culture surrounding complaints in the healthcare system. Future research could work on interventions to change the attitudes towards complaints in general practice, or run awareness-raising campaigns to elucidate the benefits of patient complaints for all. Finally, further research could explore in greater depth how to support healthcare providers who are the subject of a complaint, to reduce the negative impact of complaints on individuals and the system at large. This in turn would benefit patient safety, by ensuring the wellbeing of healthcare providers and by emphasising the benefits over the drawbacks of healthcare complaints.

Conclusion

Stakeholders in general practice are very aware of the potential for complaints to be used as a tool for patient safety improvement. However, work needs to be done to increase awareness of patients' desire to contribute to safety improvement through feedback, to improve the experience of receiving a complaint for individual healthcare providers by moving from a focus on blame to a focus on learning from complaints, and to ensure the learning from complaints is standardised and shared at a national level.

How this study influenced the work which follows

This chapter, the final study of the PhD thesis, has provided greater understanding of the context of healthcare complaints made about general practice, and the healthcare complaints system, in the Republic of Ireland. In doing so, it has answered the final research question of the thesis on the perceptions of stakeholders regarding complaints. It was found that while individuals who receive complaints often experience them negatively, and find them stressful, they can also appreciate the potential for learning from this feedback. It highlighted the gap between individuals on the front line of general practice and those who are making policy and management decisions. It also identified areas for improved communication between practitioners and policymakers around complaints, and will be a useful point of reference when considering the implementation of complaints analysis for quality improvement in general practice in the future. The final chapter of this thesis will summarise and collate the findings of each of the studies, and contextualise them in terms of existing literature. The discussion will summarise how the aims of the thesis have been met, give an overview of key learning that has resulted, appraise the strengths and limitations of the PhD research, and outline suggestions for future work on complaints in terms of research, policy and practice.

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Chapter 6. Discussion

6.1 Chapter overview

The overall aim of this thesis was to '*ascertain the potential for healthcare complaints to support quality improvement in general practice*'. The four studies presented in this thesis have described; a systematic review of studies examining complaints about general practice (Chapter 2); the adaptation of the HCAT to support the analysis of complaints about general practice (Chapter 3); the application of the HCAT(GP) to complaints about Irish general practice (Chapter 4), and; interviews with stakeholders in general practice to establish how complaints about general practice could be used for quality improvement (Chapter 5). This final chapter will outline how the four research questions outlined in Chapter 1 have been answered, make recommendations for research, policy and practice relating to patient complaints about general practice, and identify the strengths and weaknesses of the research studies described in this thesis.

6.2 Research question one

What is currently known about the nature of healthcare complaints about general practice, and is there an tool such as the hospital-based "Healthcare Complaints Analysis Tool" that facilitates the valid and reliable analysis of complaints in this context?

Prior to the completion of this thesis, there was little understanding of the nature of healthcare complaints about general practice, or their analysis. It is increasingly recognised that complaints made about other healthcare contexts provide an insight into potential areas for quality improvement (1). With an increasing focus on understanding and improving quality and safety in general practice (2-5), exploring the potential of complaints in a general practice context was seen as an opportunity to build on this momentum. Complaints are an underutilised source of information on patient perspectives about their care (6), and have been found to provide a unique insight into hot spots (i.e. areas of care with high incidence of harm or near misses) and blind spots (i.e. areas of care which are unobservable or incorrectly observed by staff) about hospital care (1). General Practitioners

have previously reported difficulties in accessing information on how to improve care (7), and complaints may be a new avenue through which they could access the data and insights necessary for this. Answering the first research question of this thesis was important in order to understand the state of the literature on general practice complaints, and to establish if there was an existing tool for their categorisation and analysis (8).

This first research question was answered in Chapter 2 of the thesis through a systematic review of studies that have examined complaints about general practice. This review collated the findings of 21 studies of general practice complaints. The contents of complaints as reported in the included studies were classified using the HCAT (8), with 126 complaints (54%) classified in the Clinical domain, 55 (23%) classified as Management problems, and 54 (23%) classified as Relationship issues. The predominance of clinical complaints within this synthesis indicated the potential of complaints for accessing information about general practice quality. The safe care domain of quality (9) is often considered in terms of secondary care, however this review highlighted the importance of examining safety in general practice, with the largest proportion of the complaints (*n*=78, 33.2%) reflecting this domain. The systematic review in Chapter 2 of this thesis supports existing research in this context, and demonstrated how we can learn about safety in general practice from patient complaints. The other two HCAT domains, Management and Relationship problems, were also represented. Management issues included difficulty accessing care, capturing the IOM quality domains of timeliness and equity (9), and the Relationship problems within the review often reflected a lack of patient-centredness, also a key IOM domain (9). This review contributed significantly to understanding of the nature of patient complaints, and highlighted the potential for complaints to identify quality issues across the IOM domains. The studies which examined motivations for complaining also highlighted that patients are willing to contribute to quality improvement, and typically had benevolent intentions when making a complaint. Complaints therefore not only reflect an dissatisfaction with care, but also a desire and willingness on the part of patients to improve care quality. This desire to contribute to change has been recognised in the health

services research literature (10-12), and highlights the potential benefit of complaints as a new source of data on quality.

The systematic review (Chapter 2) also addressed the second part of the research question. Following the search, no tool to support the analysis of patient complaints about general practice was identified. Included studies analysed complaints using a variety of methods. These included author-developed taxonomies, qualitative coding, or the HCAT for secondary care (8). The analysis of complaints about general practice was not standardised across the studies, and validity or reliability of the coding methods were not assessed. While the HCAT (8) successfully synthesised the contents of complaints included in this review, it was not possible to conduct a full meta-analysis of the included studies due to the heterogeneity of studies. Heterogeneity of methods and measures is often an issue identified within health services research and healthcare quality improvement (13, 14), and contributes to inconsistency among findings (15). It is possible therefore that similar inconsistency in complaints analysis would be rectified through standardising the various methods of complaints categorisation. This could also facilitate higher-level trend analysis from complaints. While some advocate for the importance of considering heterogeneity when examining complex social systems such as healthcare (16), the standardisation of approaches has previously been found to facilitate thinking around quality and safety improvement (14). With the demonstrated need for a cohesive approach to complaints analysis to prevent safety issues in hospital care (17), it is clear that a standardised approach would also be of benefit to general practice. This study highlighted the need for a systematic, reliable tool, such as the HCAT (8), for specific use in a general practice context. It was apparent from the synthesis that patient complaints can identify issues in general practice care, however it was not clear if these issues could be reliably identified, with included studies not providing an assessment of the reliability of the analysis methods (Chapter 2). It became clear from this study that a psychometrically sound tool would facilitate the full exploitation of the potential of healthcare complaints for quality improvement in general practice.

6.3 Research question two

Can the HCAT be used to facilitate the valid and reliable analysis of complaints about general practice in the Republic of Ireland, or can this tool or similar be adapted for this use?

The second research question of this thesis follows directly from the findings of the first study, and the lack of a suitable tool for analysing complaints about primary care. One of the main recommendations from the systematic review was to identify a tool for the systematic analysis and categorisation of general practice complaints. Similarly to other tools and classifications, standardisation of the analysis of complaints would allow an assessment of changing trends in complaints across time (18), and support national and international comparisons (19-21). Until recently, there was also a lack of a valid and reliable tool to analyse complaints about secondary care. However, a tool, the HCAT (8), has been developed that has been shown to have good psychometric properties. The HCAT, having been successfully used in Chapter 2 to categorise and synthesise the data from studies included in the review, was considered potentially suitable for use in the categorisation of general practice complaints. Therefore, rather than developing a completely new complaints analysis tool for primary care, the HCAT was adapted for use in primary care settings. It is a common criticism of work in the social sciences that new tools are continually developed rather than existing tools being refined and strengthened (22-24). However, in health services research there are several examples of the successful adaptation of methods and tools for measuring and monitoring safety in secondary care to primary care settings (e.g. safety climate surveys, patient record review, PMOS to PC PMOS) (25-28). Therefore, it was decided to adapt the reliable, valid HCAT (8) for use in general practice, the process of which is described in Chapter 3.

Chapter 3 answered the second research question through an iterative process of testing the HCAT on general practice complaints, and, when it was found that an adaptation was required to facilitate comprehensive and useful coding of general practice complaints, developing an adapted version of the HCAT (8). The HCAT stages of care

and definitions of the different harm and severity ratings in particular required adaptation to suit the general practice setting. This was achieved through an iterative process of testing each of the sections of the HCAT (8) against complaints, and subsequent discussion and consensus building. The domains and categories of the original HCAT, which were reliable in the analysis of hospital complaints (8), were also capable of analysing general practice complaints, and were tested first. Next, the stages of care were adapted to reflect the patient journey through general practice. Following this, the harm ratings were modified in their definitions to suit the general practice context. For example, the definition of 'Moderate harm' was adjusted from *'Significant intervention required to ameliorate harm (e.g., from a grade 2-3 pressure ulcer, healthcare acquired infection)'* to *'Significant mental or physical harm, secondary care intervention required to ameliorate harm'*. Subcategories were not included in the adapted version, as there was no reliability data on these from the original HCAT (8). As per best practice (29), stakeholders were involved in the modification of the HCAT. At the end of this phase, an adapted version of the HCAT was finalised, and named the HCAT(GP).

Following the adaptation, the tool was tested for inter-rater reliability. Establishing the reliability of the adapted HCAT(GP) was vital to achieve the aims of the study. High inter-rater reliability will ensure that the tool can be used by different individuals across the healthcare service, and yet provide a standardised assessment of the issues within complaints, independent of the individual who categorises them. This is crucial for generalisability of findings (30, 31). Other tools within health services research have also emphasised the importance of inter-rater reliability (32, 33). To ascertain the reliability of this tool, a sample of stakeholders were trained on its use, and asked to apply the tool to fictionalised general practice complaints via an online survey. Overall, the HCAT(GP) was found to be substantially reliable, with a Gwet's AC1 across all categories of 0.65 (CI = 0.61-0.69) (Chapter 3). Stakeholders within different professional groups (i.e., complaints managers, health service researchers, general practitioners) had substantial agreement scores with their colleagues (range 0.61-0.85), indicating the reliability of the HCAT(GP) when applied to

complaints by individuals from different professions. Some aspects of the tool, such as the harm and severity, only obtained moderate reliability (Harm range 0.50-0.59, severity range 0.35-0.51), which echoed the findings on reliability of the original HCAT (8), and must be considered further. The participants were also asked to rate the tool on its usability and acceptability. The HCAT(GP) was found to be acceptable and usable by those who tested it, with most individuals indicating they thought it would be useful for their own work (n=12, 86%), and that it was easy to learn (n=12, 86%). The buy-in from different stakeholders for this adapted tool is very promising for the future of complaints analysis within the Irish healthcare system, with previous work on new technology adoption indicating the importance of broad stakeholder support (29). The adaptation of the HCAT(GP) successfully answers research question two, as while no existing tool was found to be suitable for general practice complaints categorisation, the subsequently adapted tool was found to be reliable and useful for this purpose. The HCAT(GP) therefore has demonstrated potential to be a valid and reliable method for analysing complaints about general practice in the Republic of Ireland.

6.4 Research question three

"Can the content of healthcare complaints made about general practice in the Republic of Ireland be reliably analysed and used to identify areas for quality improvement?"

Following the adaptation of the HCAT(GP) described in Chapter 3, the next step was to evaluate the utility of the tool for the categorisation and analysis of real healthcare complaints made about general practice. Therefore, Chapter 4 described a study using HCAT(GP) to analyse a sample of general practice complaints. This study was conducted with the aim of identifying areas for quality improvement, and in particular hot spots and blind spots in general practice care. As previous research has indicated, the ability of complaints to identify hot spots and blind spots in healthcare is of particular use for quality improvement, as blind spots in particular are

difficult to accurately capture using other methods (1). Within general practice, researchers had yet to identify hot spots and blind spots in a similar manner to hospital complaints, which the newly adapted HCAT(GP) has the potential to explore.

In this study, the HCAT(GP) was used to analyse a sample of 230 complaints about general practice in the Republic of Ireland, in order to answer the third research question of the thesis. There were two parts to the research question, namely whether the tool could reliably analyse real complaints, and whether this analysis would identify areas for quality improvement in general practice. Regarding the reliability of classification of complaints within this study, a subsample of the complaints was double coded by a second researcher, and inter-rater reliability was used to ascertain whether the tool was reliable for use in this sample. The reliability in this study was calculated across the entire tool, and the resulting data were similar to those reported in the previous study in Chapter 3 (in this study, Gwet's AC1 = 0.79, CI= 0.77-0.82), and of the original HCAT (categories' reliability calculated using Gwet's AC1 ranged from 0.69-0.91) (8). This indicated that the adapted HCAT(GP) was as reliable with real complaints as it was with fictionalised complaints, and that it had comparative reliability to the original HCAT (8).

The contents of the 230 complaints were categorised with the HCAT(GP) and then analysed. The analysis identified hot spots for harm (i.e., areas in care where there are high instances of harm to patients) (1) within Irish general practice at both the consultation stage of care, and at the follow-up/referral stage of care. These were important findings considering the historical conceptualisation in the literature of general practice as safer than secondary care, with harm typically considered difficult to link directly to a specific patient safety incident, as it can often occur incrementally over long periods of time in general practice (34). This in turn led to a lack of focus on safety in primary care compared to secondary care (35, 36). Recent work has however highlighted the potential for harm and safety issues to occur within general practice, and subsequently explored means of identifying and addressing adverse events (26, 37). The harm identified through the use of the HCAT(GP) therefore indicates that this tool could be

used in conjunction with other measurement tools and interventions to improve patient safety in general practice (2, 26). The analysis also identified a blind spot (i.e., area in care which cannot be observed by staff, or that is poorly observed) (1) for system-level issues, where patients were more likely to experience harm when they reported issues at multiple stages of care. Blind spots for errors of omission and at the boundaries of care were also identified. Errors of omission were defined as the subset of issues that involved something not being done when it should have been (i.e., the quality, communication, and listening categories within the tool) (1). The blind spot at the boundaries of care was defined as complaints occurring at transitional stages of care (i.e., accessing care, and referral/follow-up in the HCAT(GP), and admissions and discharge in the HCAT) (1). These findings point to areas within general practice which have previously been highlighted as areas of concern within the safety literature (2, 38, 39) and support the need to focus quality improvement efforts on these problems moving forward. The blind spots in particular support the idea that there are additional benefits to analysing patient complaints as a form of insight into quality of care in general practice, as it is known that GPs struggle to assess how to measure or improve safety (7), and the complaints blind spot analysis would provide them with a new perspective on these issues. Blind spots are also not areas of care that can be easily observed using other forms of soliciting patient insights such as structured questionnaires (26, 40, 41), or indeed through commonly used staff measures of quality of care (42, 43).

6.5 Research question four

How do stakeholders in general practice in the Republic of Ireland perceive healthcare complaints, and what does this tell us about the context in which a complaints analysis tool for quality improvement will be received

In the final study, described in Chapter 5, insights were gained into the broader context of complaints in Irish general practice. It is vital when considering new quality measurement tools to examine the context of the broader system, as leadership from management, physician involvement,

and resourcing can all influence the success of a quality improvement initiative (44, 45). This exploration of context and culture around improvement initiatives can ensure any potential barriers to new tools are pre-empted and considered prior to implementation, and provide insight into how the tool should be targeted at stakeholders to maximise the success of the initiative (44-46). Understanding how complaints are perceived by those who receive and manage them, from this PhD, will ensure any future quality improvement measures are not only founded on evidence from complaints analysis, but that they will be acceptable for stakeholders working within the broader system. There are many examples of the implementation of initiatives struggling to succeed due to the context in which they were introduced (47, 48), or stakeholders feeling inadequately consulted prior to implementation (49), and it was important for this PhD research to attempt to avoid this. It is also necessary to ensure stakeholders are supported to make quality improvements based on complaints analysis, and for this to occur, it is important to understand their perspective. Interviews were carried out with 29 stakeholders (GPs, practice nurses and managers, medicolegal professionals and complaints experts) in order to gain insights on how they: (a) perceive healthcare complaints; and (b) believe complaints can be used for quality improvement. It was found that, in general, the stakeholders were cognisant of the benefits of complaints as a learning tool. However, they also highlighted some challenges and negative aspects of complaints.

Typically, GPs and practice nurses perceived complaints as being stressful experiences, even if they also identified them as useful for learning purposes. They highlighted the personal and professional strain that they face following a complaint, which was similar to previous findings in other healthcare contexts (50). While these stakeholders recognised that complaints had the potential for use as learning tools, healthcare providers were often primarily focused on the negative aspect of the complaints, and the personal and professional difficulties they faced within the existing system of complaints management. They emphasised the fear that patients may make complaints that are not founded on genuine issues, and that there is an increased culture of litigation and malicious complaints. This echoes

previous findings, with a trend in increased complaints and litigation emerging globally (51-53), and a general lack of trust in patient insights (54). However, despite this, practitioners also recognised that many patients do not have these malicious intentions when making complaints, reflecting the findings of the systematic review that indicated that patients are often motivated to complain for quality improvement purposes (Chapter 2). Understanding this conflict between what stakeholders believe the potential of complaints to be, and the stressful aspects of complaints, is vital, and this study highlighted that further support must be provided to individuals who are the subject of a complaint. Addressing the potential negative impact of complaints on healthcare professionals through mentorship programs, support from professional bodies and managers, and wellbeing programs within workplaces (55, 56), will help ensure that these patient insights are used as a learning tool for quality improvement, while simultaneously limiting the negative impacts on individuals of receiving a complaint. Healthcare providers are at risk of serious mental, physical, and professional suffering if they are not supported when they experience incidents, including complaints (50, 57-59), and this must be recognised and counteracted.

This chapter also provided a greater understanding of how complaints analysis in Irish general practice needs to move forward with the collective collaboration of all individuals and groups involved in the process. This study specifically identified how in order for the potential of complaints to be unlocked, there is a need for increased coordination and co-operation between management, policymakers, and individuals on the front line. Without the coordination of individuals working in practice and policy, interventions are unlikely to be successfully adopted (44, 49). This has been evident in other countries in hospital care regarding translation of learning from complaints to practice (60), and must be explored further to ensure the HCAT(GP) can be successfully integrated into the system to enable quality improvement. The interviews in Chapter 5 identified a gap in the understanding of the complaints process between stakeholders working in local practices, and those working on a national level, and underlined the fact that there is currently little to no sharing of findings from complaints at

a higher level. This study also highlighted the need for management and policymakers to ensure the systems are set up in such a way that the learning is shared locally, regionally and nationally, particularly in the context of general practice, where many physicians work in single-handed practices (61). There are existing networks in healthcare that could be tapped into to ensure knowledge sharing (62), and the identification of these challenges within the interview study provides essential context to the thesis, as successfully dealing with these challenges, and exploiting such existing networks, will ensure complaints are utilised to their full potential.

6.6 Strengths

There are a number of strengths of the research described in this PhD thesis.

Foundation on a systematic review

First, the use of a systematic review to provide an overview of the existing research on general practice complaints is a particular strength of this thesis, as it facilitates the contextualisation of the findings of the other studies. Systematic reviews are considered to be excellent sources of data in the hierarchy of evidence (63, 64), and provide a structured look at existing work, in a way that is effective, appropriate, and feasible, and can help researchers make well informed decisions about the direction of their work (63, 65). They are also increasingly recognised as beneficial to postgraduate research students to replace or complement the traditional literature review at the beginning of a PhD (66, 67). Utilising a systematic review ensured that all the relevant literature in the field was captured, establishing the state of the literature to date, and provided a solid foundation for the ensuing work on adapting the HCAT (8). This made certain that the studies which followed addressed clear research gaps, built on literature that came before, and advanced research in the area of general practice complaints.

Adaptation of an existing complaints analysis tool

Another particular strength of this research is that the HCAT(GP) is an adapted version of an existing, psychometrically sound taxonomy, the

HCAT (8). Adapting tools from secondary care to primary care contexts has been successfully utilised previously (25). The PMOS and PC PMOS are a particularly relevant example of the successful adaptation of a tool from secondary to primary care contexts (26-28). Adapting the HCAT for use in general practice contexts also avoided the critique often levelled at social science research that new tools are always being developed, rather than resources being directed into improving upon existing tools (22, 24). One example of this is the concept of burnout, which although typically measured by the Maslach Burnout Inventory (MBI) (68), is often also measured using new tools such as the Copenhagen Burnout Inventory (69) or indeed single item measures (70), rather than working on refining the original tool to resolve its issues. Benefits of refining an existing tool for complaints analysis in this PhD were both the time saved, and the implications for reliability. The reliability of the HCAT(GP) echoed that of the HCAT (8), highlighting the benefits of using this original tool as a launch point for general practice complaints analysis, rather than starting from scratch.

Use of multiple methods

The use of a variety of methodologies throughout the studies included in this thesis is another strength of the programme of research. The statistical techniques used within the thesis were robust, and reflected the techniques used in the analysis of hot spots and blind spots emerging from hospital complaints (1). However, the interview study, through its use of qualitative content analysis (71, 72), allowed the researchers to explore the perspectives of stakeholders in more depth than is possible within a survey framework, and also allowed for novel insights to emerge, compensating for the rigidity of quantitative, researcher-designed questionnaires (73, 74). The qualitative methodology supported an insight into the context of complaints within the health service, with culture often best understood through an incorporation of qualitative engagement rather than solely through quantitative analysis (75, 76). The complaints were also qualitative in nature, and moving from the qualitative to quantitative through the

application of the HCAT(GP) and analysis of findings, ensured that the research capitalised on the strength of each of these methodological approaches (73). The combination of findings from each of these methodologies within this PhD therefore strengthens the argument for complaints as a potential source of data on quality improvement, and provides a holistic view of the research topic. Finally, the suitability and rigour of the methods employed in each chapter likely contributed to the studies being accepted for publication in peer reviewed journals. The work completed in each of these studies has already undergone peer review, and was found to stand up to the requirements of these scientific journals.

Involvement of multiple stakeholders in supporting and planning the research

The involvement of stakeholders and policymakers as collaborators from inception to completion is also a strength of this research. Involving collaborators in research from different backgrounds is consistent with best practice, and can produce better and more relevant interventions (29, 77, 78), particularly in a field as disparate as health services research (79). The HSE National Complaints Governance and Learning Team (NCGLT) were essential collaborators from the beginning of the project, as they agreed to redact and share their complaints data, without which this PhD would not have been possible. The NCGLT were also central to recruitment for the studies in Chapters 3 and 5, using their connections within the HSE to engage complaints managers and officers in the research. They facilitated the presentation of this project at their quarterly complaints managers forum, which promoted the work among stakeholders and allowed for the input of other individuals working with complaints in Ireland. This involvement was key to delivering a useful tool for the analysis of complaints, and will support its implementation moving forward (78). The support from the HSE also indicated the willingness of management and decisionmakers to engage with complaints research, and to encourage the culture of complaints as one of learning rather than punishment, which will

be of benefit for the translation of the findings of this research into practice and policy (80).

The PhD was also directly supported by the involvement of the researchers from Drs Reader and Gillespie (The London School of Economics) who developed the HCAT (8). They provided training on the original tool, and attended meetings for progress updates and discussions. Having the original authors of the HCAT involved was incredibly beneficial for the PhD research, as it ensured the adapted tool aligned with their work in secondary care, and involving experts from the field of study has been found to have far reaching benefits for projects, particularly when conducted by early career researchers (81). Dr Reader was also a member of the Graduate Research Committee (GRC) for the project, a group which provides independent support to PhD candidates in NUIG. Along with Dr Reader, Professor Andrew Murphy (a GP Professor of General Practice in NUIG) and Professor Dara Byrne, Director of the Irish Centre for Applied Patient Safety and Simulation (ICAPSS) (who is also a doctor with a role in medical and intern education) held positions on the committee. The involvement of individuals with such varying backgrounds provided the essential experience of working with multidisciplinary teams, something which is a vital skill for health service researchers to develop, particularly when examining healthcare quality (82). It also ensured that perspectives on the project, throughout the duration of the research programme, reflected a broad range of potential users of the tool (83). The studies included in this PhD were also presented at several general practice conferences over the course of the three years, which allowed for input from other GPs and stakeholders. This feedback in turn led to the development of the final study, as it became clear that their insights were vital for the implementation of a new tool such as the HCAT(GP). Implementing the PhD findings, and ensuring that complaints will be effectively utilised for quality improvement, will be greatly assisted by the direct involvement of these groups.

Involvement of multiple stakeholders as participants in the research

This research was strengthened by the inclusion of stakeholders from multiple backgrounds as participants. The studies in Chapters 3 and 5 included individuals from different backgrounds such as general practitioners, policymakers, medicolegal professionals, and health service researchers, who would have varying perspectives on complaints in general practice. These varying perspectives are of benefit to the research, with past work indicating the utility of broad insights into healthcare quality (29). Involving users of diverse backgrounds as participants is being increasingly touted as important for health services research (84), as it can alter the prioritisation of research objectives, make research and outputs more user-focused, and restructure the power imbalance between different stakeholders in care (78, 85). The inclusion of general practitioners is particularly beneficial, as they are at whom the tool is ultimately aimed, and also the individuals who are typically the most negatively impacted by complaints. Their insights into complaints in the interview study in Chapter 5, and their ease of use of the HCAT(GP) in Chapter 3, will support the use of the tool moving forward, and also highlighted the gap between policy and those on the ground in general practice around complaints perception. Other stakeholders who were involved as participants included medicolegal professionals working with general practice complaints, health services researchers, and complaints managers, all of whom contributed a unique perspective into the state of complaints in Irish general practice. Engaging different groups as participants allowed for differences in opinion and knowledge to be showcased and considered, and moving forward these different perspectives will need to be negotiated and resolved for effective implementation of the findings of this thesis (84, 86).

Development of a valid and reliable tool that can be used to analyse complaints in general practice.

A final strength of this PhD research is the development of a tool that can be used to reliably analyse complaints in general practice. The HCAT(GP) is the first reliable framework for the analysis of general

practice complaints, and has the potential to be used to support quality improvement based on the findings of complaints analysis, in a similar manner to the HCAT for hospital care (8). This tool is a valuable addition to the literature on complaints analysis for the purpose of general practice quality improvement, and will be used beyond the completion of this thesis, having a practical impact on the health service. The unique benefit of health services research emerges when translated to practice and policy, with efforts being made internationally to reduce the transitional period from research to practice, and to implement new knowledge as quickly as possible (87, 88). It is intended that this PhD will have a timely, direct impact on policy and practice. A user guide, similar to that of the original HCAT (8), is currently being developed for the continued use of the HCAT(GP), and the training video and survey that were used in Chapter 3 will continue to be made available to those who wish to apply the HCAT(GP) to their complaints. The HCAT(GP) has already informed some changes to the HSE Complaints Management System (CMS), used by complaints officers to register a complaint, and it is intended that over time it will be fully integrated into the system. Several GP participants in the adaptation study in Chapter 3 also requested a link to the training to implement the HCAT(GP) within their own practices. This rapid adoption of the tool by key stakeholders is encouraging for the translation of this research into practice and policy. It is hoped that the HCAT(GP) will be applied across the Irish healthcare system and beyond, and thus enable the systematic analysis of complaints made about general practice and improvements in the quality and safety of care received by patients in this setting on a national scale.

6.7 Limitations

Although there were several strengths to this PhD, it is also important to acknowledge some of its key limitations.

Limited number of complaints

The number of complaints accessed for the analysis using the HCAT(GP) was smaller than anticipated. As a result of the small sample size, in Chapter 4 it was necessary to dichotomise the "Harm" variable in order to meaningfully assess hot spots for harm, which was not originally intended. Whether or not harm was present in the complaint was therefore measured, rather than the difference between the levels of harm as had been explored using the original HCAT (8). This reduced the detail that could be gleaned from the hot spot analysis on the spectrum of harm patients experience at these points of care. Future research should examine the different levels of harm experienced by patients within the stages of care. The original HCAT analysis in hospital care was completed on complaints that were accessed using freedom-of-information requests, facilitating the collection of a large sample of complaints (8). In contrast, the HCAT(GP) analysis was conducted with the tacit agreement and co-operation of the HSE, who contributed a sample of complaints about general practice settings. The sample from the HSE was a small number of their yearly complaints about CHOs, however since only few of the CHO complaints tend to relate to general practice, the limited numbers were expected. Medisec, a medical insurance firm for the protection of GPs, also provided a sample of complaints. These were all of the complaints that Medisec received over a three year period (2017-2019), an entire population of complaints.

The COVID-19 pandemic also played a role in limiting the sample size of the included studies, with disruption caused to this PhD in a similar manner to many other research projects globally, as research pivoted to focus on the public health crisis (89, 90). The health system in Ireland, as in many other countries, has faced significant disruption across its services due to the pandemic (91, 92), the full consequences of which will likely not be understood for many years (90). Prior to the pandemic, data for this project were collected and analysed in person in the NCGLT office, with the key involvement of NCGLT team members. However, from March 2020, working in person in the NCGLT office was not possible due to lockdowns (93), and the data sharing agreements in place for this PhD had to be

renegotiated. This renegotiation was in turn delayed due to the redeployment of the NCGLT staff to urgent pandemic-related services (94). Despite the limited number of complaints, the studies in this PhD reflect the sample sizes used in other studies, with the number of complaints across all studies included in the systematic review (Chapter 2) totalling only 235 (mean = 13 complaints). The HSE only receives a small number of complaints about general practice annually, with the majority of GP complaints being made either in the practices themselves, or to the medical council. Efforts were made to contact individual practices and out-of-hours co-operatives for further samples of complaints, however this was unsuccessful, and given the disparate nature of the system and low incidence of complaints in individual practices, would likely have provided minimal extra data.

General Data Protection Regulation (GDPR) limiting complaints analysis

Data protection laws, and GDPR, were also a factor in the limited sample size of the thesis. As per the interpretation of GDPR in Ireland, for data to be used for the purposes of research, having not been collected for that reason, and without the explicit consent of the individuals who provided the data, it must be redacted (95, 96). This requirement for explicit consent is unique to Ireland when applying the EU GDPR legislation (95). Redacting the complaints was a time-intensive process, as the data controllers, in this instance the NCGLT and Medisec, were required to fully anonymise all identifiable information from the complaints prior to sharing the data with the researchers. Analyses have found the new GDPR and health research regulations to have had a negative impact on health research in Ireland, and this is something which must be considered in future (96). The COVID-19 pandemic also contributed to issues around GDPR when analysing complaints from the HSE. Agreements made with local data controllers regarding the sharing of complaints had to be renegotiated, and some were not comfortable sharing their data outside of the internal HSE offices.

Reliability of HCAT (GP)

The reliability of the HCAT(GP) was satisfactory, however for some subsections of the tool, it was less robust, achieving only moderate reliability. This echoes the findings of the original HCAT (8), however further exploration on why it is that certain aspects of the tool are less reliable than others is required. For example, the severity ratings of the HCAT(GP) were less reliably classified than either the categories or the domains. While efforts were made to strengthen reliability of severity scales by rewording the examples to suit general practice contexts, it was clear that these examples could not comprehensively cover each possible scenario. As a result, coders were often forced to rely on their own judgement of the severity of the issue. Consideration must be given in the future as to how the reliability of this key aspect of the HCAT(GP) can be improved, perhaps by simplifying the rubric (97) by removing the "Medium" severity classification and instead dichotomising the severity variable into simply "Low" and "High". There is some suggestion that further training can improve inter-rater reliability (98, 99), which could also be explored.

Lack of patient involvement

The lack of involvement of patients in this research is also a major limitation. It proved difficult to sample and recruit patients for involvement in the interview study in Chapter 5. The underlying aim of this thesis was to explore how patient insights in the form of complaints can add to quality improvement, and it was hoped to have patient involvement throughout the project, not just through the analysis of their complaints. In particular, it was hoped to gain insight into what prompted patients to make complaints, and how they experienced the process of making a complaint, by involving them in the interview study. The importance of including patients in research relevant to their care has been emphasised throughout the literature (10, 11, 84), with their perspective on healthcare being increasingly valued and respected (10, 12, 100). Patients can identify issues with care and systems that are not visible to individuals working in these settings (1, 101). Patient advocacy groups were contacted in an effort to access patient insights into

their experiences of complaints and the complaints process. Unfortunately, none of these groups responded to requests for participation.

There are a number of reasons why patients may have been difficult to involve in this research. First, recruiting complainants through general practitioners was not feasible, as asking GPs to identify patients who made complaints about them would be a sensitive issue, and could negatively impact the physicians involved who experienced stress around complaints (50, 58). Second, there was also no specific group to target through an organisation, as complainants are a diverse group, who experience different issues (102, 103). Third, the advocacy groups that do help patients in these instances are often tailored specifically towards secondary or residential care, and possibly were not interested in the primary care context (e.g. the Patient Advocacy Service which specifically handles concerns around hospital care). Finally, at the beginning of the PhD project, there were few established supports for Public and Patient Involvement (PPI). However, in the intervening period, an increase has been seen in funding PPI centres in institutions across Ireland and the creation of a new network to encourage, co-ordinate, and support PPI in health research (104). Moving forward, research into patient complaints should engage more with these networks to involve patients in research. Setting up a representative patient group specifically for primary care that would be willing to work with researchers on issues such as complaints and dissatisfaction may also be useful for future patient involvement.

Limited generalisability

The research was conducted within one health service only, in the context of Irish general practice. This limits the generalisability of the findings to other health systems, internationally, which may be organised differently in terms of primary and secondary care (105-107). However, each of the studies included in the review in Chapter 2 were also conducted within a specific healthcare setting, and it was possible to synthesise their findings on complaints using the HCAT (8) with no apparent inconsistencies. This indicated that despite the different healthcare systems,

similar issues are emerging internationally in general practice complaints, and that a reliable framework such as the HCAT(GP) could be used to classify complaints across these contexts. The HCAT(GP) must be applied to complaints in other general practice contexts, and the reliability within those contexts assessed and refined, which has been suggested as a useful way to ensure generalisability within health research (108). The HCAT (8) has also been tested for reliability with Danish complaints and found to retain acceptable levels of reliability (109), therefore it is anticipated that similar findings would emerge for the HCAT(GP). This would then enable international comparisons of complaints issues. Within the Irish context, there was also limited involvement of the out-of-hours general practices, which may have encompassed different complaints issues, as they operate in a different manner to daytime general practice, with acutely ill patients that are typically unfamiliar with the doctor (110, 111). Future research should apply the HCAT(GP) to other health service contexts to ensure that reliability of the tool remains acceptable.

6.8 Overall implications and recommendations

The findings of this thesis have implications for research, policy, and practice. Healthcare complaints are an available, underutilised resource of data on quality of care (101). This is particularly the case in a general practice context, which is being increasingly recognised as a vital aspect of the healthcare system (61), and one which requires more attention from researchers into quality and patient safety (36). The global population is ageing, particularly in developed countries (112), and with this comes an increase in complex care and multimorbidity of patients (113). As the needs of the population changes, so too does the provision of care, with more and more treatments being moved into community and general practice settings (35). The new Sláintecare policy, a cross-party 10-year plan for the reorganisation of the Irish healthcare system, seeks to reorientate care from hospitals into the community, which again highlights the increasing importance of high quality primary care (114). There are already over 29.1 million GP consultations in Ireland per annum (61), with an estimated 2-3%

resulting in errors or PSIs (115). Complaints made about general practice could therefore be an increasingly useful source of data over the next number of years, if exploited effectively with a tool such as the HCAT(GP). This thesis has provided a new insight into quality in general practice, and has implications for improvement of care provision across the general practice context, and for research into these improvements.

Implications and recommendations for research

The research carried out as part of this PhD extends work on complaints analysis in hospital care, has introduced a tool for the reliable categorisation of complaints made about general practice, and has offered important insights into the 'culture' and processes around complaints management in general practice which will be required to support further work and change in this area.

Provides a standardised tool for analysing complaints. This thesis has adapted a reliable tool for the analysis of general practice complaints. This will have major implications for quality improvement in general practice. To date, there was no one tool for the standardised analysis of complaints in general practice, as discussed in Chapter 2. A standardised tool that is reliable will facilitate the systematic utilisation of general practice complaints as quality improvement data (1, 8). Standardisation of tools and language in healthcare is useful for quality improvement and measurement across different contexts (116-118). Despite the adaptations made in Chapter 3, the HCAT(GP) is also similar to that of the original HCAT, and very few changes were made to the structure of the tool apart from making it relevant to a general practice setting. As a result, it could be possible for future research to explore the benefits of using the two tools in conjunction. Utilising these two reliable tools could provide a comprehensive overview of the issues within a particular healthcare system, especially across the boundaries of care, an area that emerged as a blind spot within this research (see Chapter 4). This analysis and overview could in turn lead to a consolidated approach to quality improvement across primary

and secondary care, the integration of which will be more and more important as care moves into the community (119-121). Now that these two tools are available for use, researchers should build on these, rather than developing new frameworks. The results from complaints analyses internationally of the HCAT for hospital complaints have been very promising, with the systematic identification of issues heralded as having substantive potential for quality improvement (1, 122). It is hoped that the HCAT(GP) will be similarly adopted, and the two tools could be used to comprehensively capture the quality issues across multiple healthcare contexts nationally and/or internationally.

Supports the identification of what primary care patients complain about in order to foster learning. The findings of the complaints analysis in Chapter 4 also have implications for research into healthcare quality. There is a tendency within healthcare to collect data, and then not utilise it to its full potential, which has negative implications for patient care (6). This may be particularly evident when considering patient complaints, as found by the Francis report which highlighted over 1,200 deaths that could have been prevented had healthcare complaints been used effectively for improvement purposes (17). Capturing complaints and resolving them on an individual basis is not enough, as they must also be actioned to make recommendations for quality improvement (6). The study in Chapter 4 identified hot spots and blind spots in general practice care, which must be further explored. The findings from this study that healthcare complaints within the general practice context are often of high severity, and indeed that they report high levels of harm to patients, particularly within the consultation stage, are very interesting. The potential for harm in the consultation stage of general practice is concerning considering the large number of patient contacts with general practice that occur each year (over 29.1 million consultations in general practice in Ireland per annum) (61). It also echoes findings of errors within the consultation stage of care from other safety measurement initiatives (2). As this hot spot has been identified, further research must now be conducted to examine what improvements are required for general practice consultations. Combining

the findings from the high-level HCAT(GP) analysis with qualitative analysis of issues within specific complaints, and with other patient safety measurement tools, could help researchers to identify what exactly is going wrong during the general practice consultation, and to identify interventions to make care safer and of higher quality, in a similar manner to the HCAT in secondary care (122). The hot spot for harm in the consultation stage was just one example of what the HCAT(GP) revealed about general practice care. Future research could focus on the other hot spots and blind spots in care identified with the tool to develop interventions for quality improvement.

Allows for the consideration of complaints within a broader quality assessment framework. The HCAT(GP) adapted for this thesis has implications for research into healthcare quality, particularly in general practice. The complex, multifaceted nature of healthcare quality has been discussed extensively in the literature (9, 123-126), and in Chapter 1. Many tools focus solely on one of the IOM domains of quality (9), with a particular emphasis on measures of safety. Medical record reviews, trigger tools, and clinical audits of practice policies and procedures, are some of the safety-oriented quality improvement measures that have been introduced in general practice to date (25, 26, 37). However, the HCAT(GP) can identify issues pertaining to several of the IOM domains (9) when analysing complaints, and is not focused on safety alone. For example, issues classified as management by the HCAT(GP) could relate to either the timely care or equitable care domains of healthcare quality. Equally, relationship issues could reflect poor quality care in terms of the person-centeredness domain. Future research should explore the benefits for healthcare quality of examining these many domains through the HCAT(GP) analysis, as it is well recognised that the domains other than safety and effectiveness have received considerably less attention (127, 128). This new tool may spawn or encourage useful research within the other IOM domains. This newly adapted tool should now be used in conjunction with other measurement and monitoring tools to identify various quality issues within general

practice. The multi-pronged approach will ensure that more of the issues that occur in general practice are captured, explicated, and utilised in future research and interventions.

Supports the consideration of the role of the patient voice in quality in primary care. This thesis has underlined the importance of patient insights into quality of care. Researchers recognise the potential of patient perspectives, and have made efforts to access this potential through different tools, surveys, and patient involvement in research (10, 12, 129). Patients provide an insight into the difficult-to-access areas of the healthcare system, that cannot be accessed by staff-centric methods and tools (10). Complaints, as a form of patient insight, were under-exploited, particularly in general practice (111). This thesis addressed this gap, and has highlighted the potential added benefits of patient complaints as a new form of patient insight into healthcare quality. Measurement and collection of data in healthcare is common, however there is a lack of utilisation of these existing data for improvement purposes (130). It is intended that the HCAT(GP) will bridge this gap between collection and utilisation. Categorising and analysing complaints, an existing data source, also means that we can access patient insight without additional burden to patients, maximise individuals contribution to research, and place minimal strain on resources (131-133). The HCAT(GP) will allow for a systematic means of accessing this insight within complaints, and research should examine the added benefit of these insights when developing interventions. However, the interview study also highlighted the concern that is held by many policymakers and practitioners regarding complaints – whether complaints are actually legitimate or valid. As patients are not privy to the inner workings of an organisation and their expectations can be contrary to good quality care (134, 135), it is probable that a proportion of complaints do not reflect poor quality care on the part of the staff member. Future research could explore the proportion of complaints that are resolved in favour of the staff member in receipt of the complaint, and learn more about why patients may make complaints that are not justified. Other work could determine whether the characteristics of complaints can predict the outcome. For example, it could be possible that

complaints with high levels of harm are more likely to be resolved in favour of the complainant. Research into improving patient-provider communication and managing the expectations of patients is also required moving forward. General practitioners discussed patient expectations during the interview study, and the pressure that these expectations can place on them to provide care that is not best practice (such as inappropriate prescribing (136)), or face a complaint. This gap between what patients complain about, and what "really" went wrong, needs to be further explored, in order to ensure the patient insight is valued for its merits, while also considering the potential fallacies surrounding this form of data (54).

Highlights need to examine why patients do not complain. This thesis examined the complaints that were made about general practice, however it is also well established that not everyone who experiences dissatisfaction will make a complaint about poor quality care (137). The pyramid model of complaints emphasises this, with only a small proportion of individuals making formal complaints (138). The interview study in Chapter 5 illuminated this further, as complaints were considered an unusual event by practitioners, despite the high number of patient contacts across general practice in Ireland (61). Participants in the interview study also outlined barriers to individuals making complaints about their general practice care, such as concern about a breakdown of the provider-patient relationship. However, the perspective of the patient was missing in this study, and there would be benefits to working with a cohort of patients who have experienced poor care, and either did or did not make a complaint as a result (137). The participants in the interview study, while acknowledging the potential for learning from complaints, were more focused on the negative aspects of receiving a complaint, and it is possible that patients too are more focused on the negative connotations of making a complaint (54, 137). This thesis therefore has implications for the study of complaints in general. Further work must explore and dismantle the specific contextual barriers to making complaints about general practice, in Ireland and internationally. This is not to encourage complaints as such, but rather to understand why patients do not complain in order to facilitate equitable

access to sharing insights into healthcare quality for all patients (102, 139, 140). These insights could be in the form of comments, complaints, or even compliments, with recent work looking at utilising the HCAT for these forms of data to identify high quality care (141).

Implications and recommendations for practice and policy

This thesis has implications not only for research into complaints and healthcare quality, but also for both practice and policy. In the context of practice, the findings of this PhD can be used to improve the quality of care delivered to patients, and to improve the management of complaints at practice level. For policy, it highlights the need to have a standardised tool within a healthcare system for the analysis of general practice complaints, and for the culture around complaints to be reconsidered or addressed.

Need for improved complaints management in practices. The interview study in Chapter 5 of this thesis highlighted the lack of continuity within practices and across the system regarding complaints analysis. Many GPs and practice nurses were unaware of their own practice's policy regarding complaints, and while they did identify that complaints could be used for improvement at a local level, this was not translated to a systematic process within their practice. This echoes what is known about complaints management within hospital contexts, with complaints mostly seen through a risk management rather than a quality improvement lens, and little systematic sharing of learning from complaints across hospital units (60, 142). The HCAT(GP) developed in this thesis could therefore be used to provide a structuring framework around which GPs and practices can centre their analysis of complaints and improve care delivery. By introducing a tool such as the HCAT(GP), practices could be empowered to learn from their own complaints locally, in a systematic manner, and also share the findings regionally and nationally. The user guide for the HCAT(GP) currently under development, along with the existing online training survey and video (Chapter 3), could possibly function as a form of toolkit to support practice, and in turn help facilitate local implementation of the

HCAT(GP). Action research in implementing other toolkits for improvement in healthcare settings highlights however that care must be taken not to overburden local staff (143), and there may be need for facilitators to help staff at practice level to integrate this tool into their practice (143).

Need for support and training for recipients of complaints. The prevalence of relationship and management issues within the complaints highlights the need for increased resourcing and support for over-worked GPs. Relationship problems were a massive source of strain within the complaints, with patients feeling upset and hurt from the perceived rudeness or lack of communication or listening from a clinician or other GP staff. On one hand, at a practice level, GPs and other practice staff could be encouraged to develop their communication skills, which can be easily and cheaply implemented, and has previously been found to be effective in improving patient-provider relationships (144). However, these relationship problems likely also link to a difficulty with resourcing within the wider system, with pressure on GPs leading to a deterioration in practitioner wellbeing, and in turn the patient-practitioner relationship (145, 146). Subsequently, relationship problems may in fact be better resolved in a similar manner to the management issues, by taking a top-down approach to supporting practitioners and patients, and providing increased resources to practices under pressure (147). The COVID-19 pandemic has emphasised the existing pressures faced by general practitioners (148). They are neglected and underfunded, and yet a large body of work and pressure from the health service rests on them (61). There is also a requirement for GPs to manage the running of a practice as well as their clinical work, in comparison to the employee status of their hospital colleagues (149), although there is an increase in the number of practices with specific practice managers (149), which could benefit the implementation of structured complaints analysis. A restructuring of the system to aid GPs in managing work pressures and complaints is necessary.

Need for a culture change around complaints. The interviews in Chapter 5 showed that despite a high level commitment to learning from complaints among management, there is still the sense within the Irish healthcare system, particularly amongst frontline staff, that a complaint is a solely negative experience, reflecting other research on the negative impact of complaints on physician wellbeing (50). This is something which needs to be addressed moving forward, as what has been shown previously is that when there is a solely punitive response to errors within the system, the issues are not resolved and indeed physicians are negatively impacted, and less likely to report incidents (150). The participants in the interview study highlighted the stressful nature of receiving a complaint, also seen in other contexts (50), which must be examined by policymakers with the intention of improving the culture around complaints. The issue of physicians as second victims of medical errors and patient safety incidents is receiving growing attention (58, 59), as physician wellbeing and patient outcomes have been found to be inextricably linked (50, 151). Ensuring that practitioners are supported to facilitate learning from the complaints process, while also supporting their wellbeing, needs to be a central focus of any intervention involving complaints moving forward. Amongst the policymakers themselves, the positive aspects of complaints were highlighted, however this must be extended and communicated to individuals who are in direct receipt of complaints. Changing the culture around complaints at both policy and practice levels to this supportive model is vital for quality improvement, and any changes must be supported by all users of the tool, as context plays a key role in the success of implementation programmes (44, 45, 101). A just culture around complaints (whereby system-level factors are considered and individuals are held accountable when necessary, but not indiscriminately blamed (101)) would ensure high quality care, and support learning from insights into care from complaints. It is acknowledged that culture change within an organisation, particularly one as expansive as healthcare, is a lengthy process, and can be difficult to instigate and sustain (152), however the enthusiasm from stakeholder collaborators and participants during this PhD research indicates

that this process of shifting the culture of complaints in Irish general practice may already be underway.

Need for improved complaints pathways in the Irish healthcare system. A major finding that emerged from this research is the lack of pathways through which patients can make complaints about their care. This is limiting the impact of complaints as a learning tool by causing a barrier to complaints being made in the first place, and must be considered by stakeholders and policymakers moving forward. Efforts need to be made to encourage patients to participate in quality improvement through making complaints. The HSE, with the launch of their "Your service, your say" policy (153) appear to recognise this, however more work needs to be done. Currently, for GP care, only public patients can make a complaint through this service. Private patients who are unhappy with their care are only able to complain to either their practice directly, or to the medical council (154), with GPs indicating in interviews in Chapter 5 that patients will often just move practice rather than complain. The Irish Medical Council only has a remit to investigate complaints about the professional practice and competencies of GPs, and it does not make adjudications on complaints about relationship or management issues (155). Unfortunately, this is not widely realised by patients, and complaints relating to these issues are made to the medical council, and ultimately rejected, thereby costing resources and time, with little results, to the frustration of the patient. On the other hand, if a patient complains to their GP directly, they risk jeopardising their relationship with their doctor, and they may not get a response that they are satisfied with. The HCAT(GP) is a useful, reliable tool for the analysis of large numbers of complaints and the identification of issues, however this lack of complaints pathways greatly limits the potential of complaints as a tool for quality improvement, as there is no centralised database of all general practice complaints. A third-party, independent body, with a centralised database of complaints would likely improve the complaints experience for patients, practitioners, and policymakers, and would facilitate the increased use of complaints as a quality measure. Policymakers and

researchers need to further explore the potential of introducing such a service for general practice.

Conclusions

There are over 29.1 million annual patient contacts with general practice care in Ireland (61), with most patients visiting their GP on average 4.34 times per year (61). This creates a clear need to ensure that good quality, safe care is being provided in this context. However, to date there have been difficulties in understanding quality and safety in general practice, and making related changes. Healthcare complaints are a promising source of data on quality of care, with a recent shift towards understanding the need to utilise these to support and scaffold other measures of quality. Patient insights into care expand upon and support the learning that can be accessed through engagement with healthcare staff, and ensuring that these are thoroughly interrogated as a learning opportunity is being increasingly prioritised within quality research. This thesis has highlighted the potential for patient insights about general practice quality to be accessed through their complaints, in a similar manner to recent work in secondary care. This thesis aimed to *"ascertain the potential for healthcare complaints to support quality improvement in general practice"* and through a series of research studies, has answered this question comprehensively and convincingly. The newly adapted HCAT(GP) is a reliable, useful tool, which has been tested with a variety of stakeholders, and can identify issues within general practice care that are not necessarily visible through other measurement methods. The systematic review in Chapter 2 and the interview study in Chapter 5 have also contextualised the issue of complaints in general practice, and identified areas which need further exploration. This thesis has therefore demonstrated the potential for healthcare complaints to support quality improvement in general practice, and provided a means through which this potential can be reliably realised.

Along with developing the HCAT(GP), this thesis has identified areas within general practice complaints and the Irish healthcare system that require improvement to further support the use of complaints as a learning

opportunity. There is a clear need for the culture around complaints to change in the Irish healthcare system, to greater support both those who make complaints, and those who are on the receiving end of them. A positive outlook on complaints as a potential for learning, rather than construing them solely as a means of punishing healthcare workers, along with a more cohesive system for the registration and analysis of complaints, will benefit the quality of general practice at both a national and local level. The HCAT(GP) should be applied to more general practice complaints in Ireland and internationally moving forward, and interventions based on the findings of hot spots and blind spots in care from the analysis need to be developed and their utility assessed. Patients are the centre of our healthcare system, and their voice is a valuable one for quality improvement. In order to ensure the care provided to patients is of the best possible quality, tools such as the HCAT(GP) need to be integrated into existing systems, while supporting providers, as we continue to move towards a patient-centred, democratic healthcare service, and aim to learn from our mistakes.

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Appendices

Appendix 1. Summary of Medline OVID search strategy

1. Exp Patient Safety/
2. Exp Patient Satisfaction/
3. Exp Professional-Patient Relations/
4. safe*.ti,ab
5. satisf*.ti,ab
6. quality.ti,ab
7. experience*.ti,ab
8. OR/1-7
9. ((claim* or complain* or complim* or litigation or malpractice or letter* or feedback or comment*) adj3 (user* or patient* or resident* or client*)).ti,ab.
10. 8 AND 9
11. Primary Health care/
12. Home Health Nurses/
13. Medicine, Community/
14. Health Services, Outpatient/
15. Health Centres, Ambulatory/
16. Nursing, Community Health/
17. Psychiatry, Community/
18. Neighborhood Health Centers/
19. Dentistry, Community/
20. Nursing, Public Health/
21. Home Health Care Nursing/
22. Dentistry, Public Health/
23. Family adj1 Physician*.ti,ab
24. Family adj1 Pract*.ti,ab
25. Generalist*.ti,ab
26. General adj1 Pract*.ti,ab
27. Primary adj1 Care adj1 Physician*.ti,ab
28. Ambulatory adj1 Care.ti,ab
29. Primary adj1 health*.ti,ab
30. Primary adj1 health adj1 care.ti,ab

31. Primary adj1 care.ti,ab
32. office adj1 visit*.ti,ab
33. house adj1 call*.ti,ab
34. aftercare.ti,ab
35. community adj1 health adj1 nurs*.ti,ab
36. home adj1 treat*.ti,ab
37. community adj1 psychiatrist*.ti,ab
38. community adj1 psychologist*.ti,ab
39. practice adj1 nurs*.ti,ab
40. public adj1 health adj1 nurs*.ti,ab
41. dietician.ti,ab
42. dentist*.ti,ab
43. community adj1 dentist*.ti,ab
44. physiotherapist*.ti,ab
45. occupational adj1 therapist*.ti,ab
46. speech adj2 language adj1 therapist*.ti,ab
47. podiatrist.ti,ab
48. community adj1 pharmacist.ti,ab
49. OR/11-48
50. 10 AND 49

Appendix 2. Data extraction table

(Reference numbers relate to Chapter 2 references)

Author, year, Country	Setting	Individual complained/ claimed against	Individual making complaint	Motive for making complaint	Content of complaint	Method	Impact of complaint/Harm	QATSDD Score
Abrecht et al[30], 2017, USA	Outpatient chronic pain management	Physicians	Not specified	Not specified	Behaviour-related patient factors: - Non-compliance with treatment plan - Failure to complete the scheduled follow-up appointments and tests Behaviour-related provider factors: - Sexual misconduct Clinical judgement factors: - Inadequate patient assessment - Improper selection of therapy and inadequate monitoring Communication factors: - Inadequate communication among providers - Poor rapport with the patient	Review of claims/complaints database	Harm: National Association of insurance commissioners severity scale. - "High severity" scores of 6-9 corresponding to permanent major injury or death (48.6%) - "Medium severity" 3-5 temporary major or permanent minor injuries (16.2%) - "Low severity" 0-2 – temporary minor injury (35.2%) Outcomes of the alleged damaging events included death, emotional trauma,	23

					- Inadequate education of the patient regarding risks of treatment Documentation factors: - Insufficient, inaccurate, or delayed documentation Technical problem factors: - Pharmacy dispensing error - Medication product malfunction Electronic health record factors: - User error with implementation of new system Administrative factors: - Inadequate training of staff Improper medication management Abandonment Failure to diagnose Sexual misconduct Discrimination Other Defamation Wrong procedure		addiction to opioids, vision loss, and other	

Barragry et al[31], 2016, Ireland	Out of hours general practice	Established GP non-established GPs GP registrars	Patient themselves family members (of which 60% were mothers of minors) non-family members	Not specified	Concerns regarding clinical care Cost Communication Process of care Other Communication difficulties - Difficulty seeking information - Perceived rudeness in the consultation - Perceived lack of understanding or concern - Poor explanation of illness and of prescription	Analytic observational study, with before/after design.	Impact: - Co-operative engaged in a process of organised risk reduction. - Two complaints were the subject of a medical council investigation, neither of which were upheld, and a third complaint resulted in the Co-Operative engaging as a co-complainant with the original complainant to the general medical council in the United Kingdom. The registration of the doctor was subsequently endorsed. - In the minority of cases where an adverse medical outcome was evident, the Co-operative engaged closely with the complainant, and was seen to evidently modify case	21

							handling/procedure, to actively feedback to co-operative team members involved in care, and in two instances to forward modest costs (<1500 euro, directly to complainants without prejudice, where adjudged appropriate and necessary in the light of additional expenses and inconvenience to the complainants. - In no instances did complaints relating to care of patients result in civil litigation. Harm: - In 90% of complaints overall, there were no adverse medical outcomes.	
Birkeland, dePont Christensen, Damsbo	General Practice	General Practitioners	Not specified	Not specified	Not specified	Review of claims/complaints database	Impact: - Discipline of GP(s) taken in 114 (27%) of cases.	19

et al[32], 2013 (a), Denmark								
Birkeland, depont Christensen et al[33] 2013(b), Denmark	General Practice	General Practitioners	Not specified	Categorised as: Patient's wish for: **Communication:** Explanation, placement of responsibility, **Correction:** quality-improvement for future patients, review of the GP's competence, **Restoration:** economic compensation, better level of general service, **Sanction:** professional discipline, other sanction.	Not specified	Review of claims/complaints database	Impact: - GP disciplined in 126 (22%) of complaints. - Criticism expressed in 96 decisions (17%), and professional competence disputed in 30 decisions (5%). - 96 decisions resulting in the GP being criticised included eight GPs being disciplined with injunction. One of these GPs was brought before the prosecuting authority, but the charge was later dropped. Harm: - Serious urgent illness? (No/Yes) - Cancer? (No/Yes) - Death of patient? (No/Yes)	22

Cowan & Wilson[34], 2007, UK	Primary care	General practitioners Doctor working for an out-of-hours primary care organisation	Relative of patient Partner of patient Solicitors/advocates Professional Colleague Other	Not specified	Clinical care - Failure/delay/wrong diagnosis - prescription problem or error - inadequate or inappropriate treatment - failure to visit or delay in visit - failure or delay in referral or inappropriate referral Interpersonal skills - Attitude or rudeness of doctor - Attitude or rudeness of nurse or admin staff - General concerns about communication Administrative problems - Record keeping - Failure to follow practice policies/procedures Professional conduct matters - Breach of confidentiality - Chaperoning problems - Consent problems	Review of claims/complaints database	Impact: - Of 116 complaints in the sample, only evidence of three having conducted a significant event audit (SEA). Harm: - 116 complaints after the death of a patient.	21
Cox & Holden[35], 2009, UK	Primary Care trust, 35 GP practices	General Practitioners	Patients	Not specified	Not specified	Review of complaints/claims database	Impact: - Of the 27 GPs, management of seven affected their performers list status,	14

							one GP was removed from the performers list, one was suspended and later removed, one left general practice during the process, one remains on long-term ill-health, two GPs refusing appraisal received 28 days warning of removal from the performers list, and one received a written warning regarding list status and future behaviour. - One local GP referred for health and performance issues was also found not to be on any PCT performers list due to an administrative error. Excluding the first four, the other 23 GPs whose cases were managed by the group are known to be working as GPs today, all of whom in unrestricted practice.	

							- There was outside involvement and support in management of the 37 cases. Remedying work was undertaken solely within the PCT in 14 cases and shared with another body in a further 12 cases. 11 needed remedying or management outside the PCT. Harm: - Cases presented in terms of classification of performance issues according to type and risk to patients: 19/37 classified as red-light risk, and 18/37 as amber.	
Esmail[36], 2010, UK	Primary care	General practitioners	Patients	Not specified	Failure or delay in diagnosis Medication prescription errors Failure or delay in referral Failure to ward off or recognise the side-effects of medication	Review of claims/complaints database	Severity: - The most common recorded outcome of such errors was the death of the patient (21% of cases). - Deterioration in clinical condition (6%)	15

							- unnecessary pain (4%)	
Flannery et al[37], 2010, USA	Family medicine	Family physicians Additional personnel included: -Other physician -consultant -nurse -emergency room physician -Radiologist -Manufacturer of drug or equipment -Physician assistant -Other hospital personnel -Resident or intern -Technician	Not specified	Not specified	Most prevalent medical misadventures - Errors in diagnosis - None noted - Improper performance - Failure to supervise or monitor case - Medication errors - Failure or delay in referral or consultation - Failure to perform - Failure to recognise a complication of treatment - Failure to instruct or communicate with patient - Delay in performance Most prevalent associated medical issues: - Equipment malfunction - Problem with records - Problem with history or examination - Communications between providers - X-ray error - Improper conduct by physician - Premature discharge - Lack of adequate facilities	Review of claims/complaints database	Impact: - 8,797 claims resulted in payment to plaintiff. - Total indemnity paid for family physicians was $1.4 billion Harm: Severity of injury assigned to one of 9 categories as established by the national association of insurance commissioners severity index - Emotional injury only - Insignificant injury - Minor temporary injury - Major temporary injury - Minor permanent injury - Significant permanent injury - Major permanent injury - Grave injury - Death	18

					- Comorbid conditions - Unnecessary treatment Associated legal issues: - Informed consent - Abandonment - Failure to conform with rules, regulations - Breach of confidentiality - Assault and battery - False imprisonment			
Gaal et al[38], 2011, Netherlands	Family practice	Family physicians	Patient Family member Healthcare inspector Not retrieved	Not specified	Wrong diagnosis Insufficient medical care Wrong treatment Too late referral Incorrect statement or declaration Violation of privacy Not showing up or showing up too late at a house visit Provision of insufficient information Impolite behaviour Inappropriate patient contact Billing for treatment Other reasons Impossible to identify type of complaints for 19 cases	Review of claims/complaints database	Impact: - 134 cases (53.6%) were suspended - 18 cases (7.2%) were declared not applicable - 9 cases (3.6%) were withdrawn - 1 case (0.4%) was not further pursued by the plaintiff - In 88 cases (35.2%), the family physician was disciplined - Of the 88 negligence verdicts, 69 resulted in a warning, 11 in a reprimand, and 2 in a temporary suspension from practice	22

							- In 6 cases no disciplinary measure was given. All inappropriate patient contacts (100%), violations of privacy (64.3%), and an incorrect statement of declaration (53.3%) resulted in disciplinary measures Harm: - No health consequences - Small harm - Medium harm - Severe harm - Patient death - Health consequences unknown - Psychological or emotional - Minor physical - Significant physical - Major physical - Death	
Gandhi et al[19], 2006, USA	Ambulatory care	Primary care physicians radiology	Not specified	Not specified	Diagnostic errors. Missed/delayed diagnosis Initial delay by the patient in seeking care	Review of claims/complaints database	Harm:	21

		General surgery Pathology Physician's assistant Registered nurse or nurse practitioner Trainee			Failure to obtain adequate medical history or physical examination Failure to order appropriate diagnostic or laboratory tests Adequate diagnostic or laboratory tests ordered but not performed Diagnostic or laboratory tests performed incorrectly Incorrect interpretation of diagnostic or laboratory tests Responsible provider did not receive diagnostic or laboratory tests results Diagnostic or laboratory tests were not transmitted to patient Inappropriate or inadequate follow-up plan Failure to refer Failure of a requested referral to occur Failure of the referred-to clinician to convey relevant results to the referring clinician Patient nonadherence to the follow-up plan		National Association of Insurance Commissioners 9 point severity scale. - Psychological or emotional - Minor physical - Significant physical - Major physical - Death	
Harris[39], 1995, USA	Primary care	Primary care physicians	Patients	Not specified	Pap smear complaints Quality complaints - Issues of patient service - Technical quality of care - Patient access to care	Audit of medical records	Not specified	24

Hart & Weingarten[40], 1986, Israel	General practice	General practitioners	Not specified	Not specified	Received by local area director - Quality of the medicine - Doctor not investigating symptoms as much as the patient wanted - Refusal to see the patient - Professional style - Could not talk to own doctor about problems related to sex - Doctors attitude and demeanour - Sort of general practitioner he was (family or child/adult) - Clerk transferred them to a new doctor without asking Received by Regional director - Negligence - Refused house calls - Psychogeriatric mismanagement - Certification appeals - Professional misconduct (One concerning alleged assault, and two concerning breaches of misconduct)	Description of experience of handling complaints	Impact: - Management was modified in 44 cases, usually after consultation with the doctor, except in a few special cases involving medical certification. - In 45 cases the problem was solved by referral to an agent which the doctor had not considered. (i.e., patients referred to specialists as a solution to complaints). - In 65 cases, the outcome was a change of doctor for the patient. - 68 complaints were dismissed completely. Of the complaints received by the regional director: - 3 were investigated by a Ministry of Health committee of inquiry, and in one case the doctor was reprimanded.	8

							- In three cases legal proceedings were instituted resulting in a fine for the doctor in one case, and a settlement out of court in another. - Four complaints were heard by the regional complaints committee, seven were received by the ombudsman, and two were given publicity in the national press.	
Lim et al[41], 1998, Singapore	Family health service	Doctors, nurses, registration clerks, to pharmacy staff.	Relatives Patients Friends Others	Not specified	Attitude/conduct - Rude/impolite/discourteous - Uncaring - Other conduct problems - Insensitive - Irresponsible - Arrogant/hostile Professional skills - Inadequate examination - Poor professional skills/incompetent - Inadequate explanation - Dispensing error - Poor professional conduct/attitude/style	Review of claims/complaints database	Impact: - It was found that 43% of complaint cases lodged were justifiable, 38% not justifiable, and 19% inconclusive. - In 47 of the complaint cases, it was difficult to conclude on their justification.	17

					- Wrong diagnosis - Unnecessary medical examination - Drug allergy missed Unmet patient expectations/requests Waiting time Communication - Unnecessary comments - Inadequate explanation - Other communication problems Registration - Registration problems - Medical records problems - Queue problems - Physical environment - Others - Other drug related problems - Social/racial discrimination - Inefficient phone answering system - Too young doctor - Inexperienced doctor - Move from place to place			

Mack et al[42], 2017, USA	Ambulatory care at a large academic cancer centre	Administration Finance Physician Nurse/nurse practitioner Psychosocial provider (e.g., social worker, psychiatrist, psychologist) Pharmacy Medical services (e.g., lab, imaging) Non-medical services (e.g. food, retail) Infrastructure (e.g., parking, security Research Information technology Other	Patients themselves Spouse or partners Other family members Friend Referring provider on behalf of patient Social worker on behalf of patient Parent	Not specified	(Classified using HCAT) Management - Including service issues - Delays - Finance and billing - Access and admission Clinical care - Overall quality of care - The patient journey - Treatment, and examinations - Skills and conduct of staff - Errors in diagnosis - Other safety incidents Relationships - Communication breakdown - Patient-staff dialogue - Incorrect information - Humaneness and caring - Patient rights	Review of claims/complaints database	Impact: - Clarify normal process to patient - Apologise - Improve existing process - Transfer care to other provider or facility - Provide small service (gift card, parking) - Reschedule appointment - Supplement usual care process for patient - Adjust bill - Provide meeting with social worker - No action documented Harm: - 64% of complaints defined by the taxonomy as low severity - The remainder were rated as moderate or high severity	27

Nettleton & Harding [43], 1994, UK	Family health	GPs	patient themselves, relatives, friends, warden of sheltered housing.	Not specified	Inadequate clinical treatment - Inappropriate prescribing - No action or treatment given when required - Misdiagnosis - No medical examination/investigation carried out - Inappropriate treatment - Persists with prescribing - Unsuccessful treatment - Unsatisfactory treatment - Contradictory diagnosis Practitioner not responding or co-operating - Failure to co-operate with services or equipment - Refused to put on list or struck off list - Refusal to visit - Refusal to refer - Refuses to sign certificate - Stops repeat prescription - Lack of information provided with diagnosis - Told to register with another GP - Refusal to prescribe	Analysis of all informal complaints made to a Family Health Service Authority	Impact: - Letters sent from the FHSA to the complainant included: a sympathetic apology; an explanation to the effect that the FHSA is only empowered to investigate complaints that allege that a practitioner has failed to meet an obligation of service. It is pointed out that the matter complained about does not constitute a breach of contract; thanks the complainant for drawing attention to the matter; sometimes advise complainants to take further action. - If breach of contract, administrator would consult a more senior officer. Most were not and, in these cases, a standard letter could be sent. Of the 112 letters received in 1990, there	15

					- Forced to register with practice for a visit as temporary resident - Not taken seriously - Lack of ongoing care and support Personal attributes of the health professional - Manner - Poor spoken English - Will inform other GPs about patient - Disclosure about personal information Organisation of practice and staff - Difficulty making appointments - Manner of receptionists - No GP ever available - GPs administrative incompetence - Lack of surgery facilities - Administration of repeat prescriptions - Surgery cancelling appointments - Surgery not equipped to carry out treatment		were 5 formal investigations.	

					Financial issues - Budget - Charging for a letter - Advised to go private - Charges Mistakes made by practitioner - Mistake on prescription - Mistake when dispensing - Dispensing out of date drugs - Inadequate disposal of drugs			
Owen[44], 1991, UK	General practice	General practitioners	Not specified	26% of letters said that the complainant's purpose in bringing the complaint was to prevent the same thing happening to other people.	Failure to visit Delay in visiting Failure to diagnose Error in prescription Failure to arrange emergency admission Delay in diagnosis Failure to examine Failure to refer for investigation or opinion Poor administration Delay in arranging emergency admission Delay in referral for investigation or opinion Miscellaneous Unsatisfactory attitude of general practitioner	Review of claims/complaints database	Impact: - Not determined Harm: - In 32% of letters the death of the subject patient was an important feature of the complaint	18

Phillips et al[45], 2004, USA	Primary care medicine	GPs, internists, paediatricians	Not specified	Not specified	Diagnosis error Wrong patient or body part Medication errors Improper performance Failure to instruct or communicate with patient Performed when not indicated or contraindicated Delay in performance Not performed Surgical foreign body left in patient after procedure Patient positioning problem Failure to supervise or monitor case Failure to recognise a complication of treatment Not or improperly performing resuscitation Failure/delay in admission to hospital Failure/delay in referral or consultation Improper supervision of resident or other staff personnel Failure to properly respond Surgical/procedural clearance contraindicated No medical misadventure Problems with records Consent issues Breach of contract Premature discharge from institution X-ray error	Review of claims/complaints database	Impact: - Half of closed claims were reported as having been reviewed for negligence - Reviewed claims were more likely to result in an indemnity payment Harm: Severity classification of expert panel reviewed cases: - Low severity - moderate severity - high severity - death	20

					Communication between providers Other			
Pietroni & de Uray-Ura[46], 1994, UK	General practice (experimental primary health care centre)	Doctors, practice staff.	Patients	Not specified	Administrative - Repeat prescriptions - Telephone system - Receptionist - Administrative staff action or inaction - Appointment procedures Doctors or medical care or both - Delay or difficulty in getting prescriptions - Rudeness of doctor - Medical care - Appointments system - Telephone system - Waiting time - Doctor from deputising service Other NHS length of waiting lists for treatment.	Audit of an informal complaints procedure	Impact: - Letter of apology from health centre - Letter of explanation and clarification of health centre procedures - Resolved by meeting with general practitioner, patient, and patient's representative - Explanation from hospital to which complaint was addressed - Not resolved.	15
Quinn et al[47], 2017, USA	Outpatient general medicine	Outpatient general medicine physicians (internal medicine or	Patient	Not specified	Diagnostic error (including failure or delay in ordering a diagnostic test, failure or delay in obtaining a consult or referral, failure to establish a differential diagnosis). Error in clinical judgement	Review of claims/complaints database	Harm: National association of insurance commissioners injury Severity scale:	20

		family medicine)			Error in communication		- 0: Low, legal issue only, e.g., lost medical records, property damage, depositions - 1: Emotional only e.g., mental distress or suffering that is temporary (e.g., HIPAA violations, discrimination, false cancer diagnosis) - 2: Temporary insignificant (lacerations, contusions, minor scars, rashes, no delay in recovery) - 3: medium, Temporary minor (infections, fractures, missed fractures, recovery delayed) - 4: Temporary major (burns, surgical material left in patient, drug side effects, recovery delayed) - 5: Permanent minor (loss of fingers, loss or damage to organs,	

							includes nondisabling injuries) - 6: High, Permanent significant (deafness, loss of limb, loss of eye, loss of one kidney or lung) - 7: Permanent major (paraplegia, blindness, loss of two limbs, brain damage) - 8: Permanent grave (quadriplegia, severe brain damage, lifelong care or fatal prognosis - 9: death Impact: - Cases Filed as suits (vs claim) n=282 (84%) - Cases resulting in indemnity payment n=163 (49%)	
Rodriguez et al[48], 2008, USA	Primary care & other specialties	Primary care physicians	Patients	Not specified	Classified as Access-related, or not.	Review of claims/complaints database		26

Wallace et al[49] (2018), Ireland	Out of hours General practice	GPs triage Nurse administrative staff Multiple healthcare professionals Other	Parent/guardian Patient son/daughter Spouse/partner Other family member Healthcare professional Other	Not specified	Clinical - Diagnosis - Prescribing - Referral - Dissatisfaction with clinical examination - Unmet expectations regarding management - Misdiagnoses Relationship - Perceived rudeness - Abrupt manner - Inadequate explanation of diagnosis - Management plan - Dissatisfaction with the approach of the GP to the consultation Management - Dissatisfaction with payment for review consultations - Refund requests - Waiting time to see the GP - Suitability of infrastructure - Triage processes	Retrospective cohort study of patient complaints to an out of hours service provider	Impact: - 30 complaints against GPs were upheld and resulted in a formal apology to complainant. - Successfully defended to the satisfaction of both parties - Closed without agreement Harm: - No/minimal - Minor - Moderate - Major - Catastrophic	29

Appendix 3: Healthcare Complaints Analysis Tool(General Practice)

HCAT(GP)

Clinical Problems: Issues relating to quality and safety of clinical and nursing care provided by healthcare staff.

Quality: Clinical standards of healthcare staff behaviour **• Keywords: "not provided", "was not done", "did not follow guidelines", "poor standards", "should have", "not completed", "unacceptable quality", "not successful".**		
1. Low Severity	**2. Medium severity**	**3. High severity**
Rough handling patient	Patient not provided with pain relief	Patient not examined sufficiently
Patient not involved in care plan	Aspect of care plan overlooked	Failing to heed warnings in patient notes
GP gave advice not aligning with guidelines	Lack of knowledge on treating illness	GP intoxicated or otherwise incapable of treating illness
GP making false statements about patient	GP deceiving patient about care provided	Patient notes altered by GP
Wound not dressed properly	Seeping wound ignored	Infected wound not tended to
Safety: Errors, incidents, and staff competencies **• Keywords: "incorrect", "medication error", "did not notice", "mistake", "failed to act", "wrong", "poor coordination", "unaware", "missed the signs", "diagnosis".**		
1. Low Severity	**2. Medium severity**	**3. High severity**
Slight delay in making diagnosis	GP failed to diagnose a fracture	GP misdiagnosed critical illness
Slight delay in prescribing medication	Failure to prescribe required medication	Incorrect medication prescribed
Minor error filling out patient notes	GP overlooked information (i.e. previous experience of an illness)	GP overlooked critical information (e.g., serious drug allergy)
Minor misunderstanding among GP and colleagues	Test results not shared with colleagues	Failure to coordinate time-critical decision

Management Problems: Issues relating to the environment and organisation within which healthcare is provided (for which administrative, technical, facilities and management staff are usually responsible).

Environment: Problems in the facilities, services, clinical equipment, and staffing levels **• Keywords: "not available", "shut", "not enough", "dirty", "shortages", "broken", "poor equipment", "soiled", "used before", "poorly signed".**		
1. Low Severity	**2. Medium severity**	**3. High severity**

Noisy reception area	Patient cold in treatment room	Dirty environment, rodents.
Potholes in carpark	Accessible parking not available	Surgery not accessible
Software in surgery not appropriate for best care	Equipment not available to carry out required procedure	Medical equipment not working
GP repeatedly called out of appointment	Cannot access specialist care	Severe staff shortages
Institutional Processes: Problems in bureaucracy, waiting times, and accessing care • Keywords: "delayed", "postponed", "cancelled", "lost", "not admitted", "administrative problems", "not referred", "confused notes", "more paperwork", "unaware of me".		
1. Low Severity	**2. Medium severity**	**3. High severity**
Difficulty phoning healthcare unit	Waiting in GP surgery for hours	Unable to register with GP
Phone calls not returned	Complaint not responded to	Emergency phone call not responded to
Appointment cancelled and rescheduled	Chasing GP for an appointment	Refusal to give an appointment
Short delay in referral	Patient not referred for routine care	Lack of continuity of care between services leading to delay in urgent care
Difficulty accessing medical notes	Repeated difficulty and delay getting important medical information	Important medical information lost

Relationship Problems: Issues relating to the behaviour of any member of staff towards the patient or their family/friends

Listening: Healthcare staff disregard or do not acknowledge information from patients • Keywords: "I said", "I told", "ignored", "disregarded", "battled to be heard", "not acknowledged", "excluded", "uninterested" and "not taken seriously".		
1. Low Severity	**2. Medium severity**	**3. High severity**
Patient question ignored	Mild patient pain ignored	Severe distress ignored
Patient suggestions dismissed	Patient-provided information dismissed	Critical patient-provided information repeatedly dismissed
Question acknowledged, but not responded to	Patient anxieties acknowledged, not addressed	Patient pain acknowledged but not addressed
Communication: Absent or incorrect communication from healthcare staff to patients		

• **Keywords: "no-one said", "I was not informed", "he/she said 'X'", "they told me", "no-one explained", "contradictory", "unanswered questions", "confused", "incorrect".**		
1. Low Severity	**2. Medium severity**	**3. High severity**
Short delay communicating test results	Long delay communicating test results	Urgent test results delayed
Patient received incorrect directions	Patient received conflicting diagnoses	Patient given wrong test results
Unclear communication of care plan	Care plan not communicated	Patient given incorrect information about care
Respect and patient rights: Disrespect or violations of patient rights by staff **• Keywords: "rude", "attitude", "humiliated", "disrespectful", "scared to ask",** **"embarrassed", "inappropriate", "no consent", "abused", "assaulted", "privacy".**		
1. Low Severity	**2. Medium severity**	**3. High severity**
Staff spoke in condescending manner	Rude behaviour	Staff physically lashed out at patient
Private information divulged to receptionist	Private information divulged to family members	Private information shared with members of the public
Staff member made patient feel uncomfortable	Patient intimidated by staff member	Patient discriminated against
Lack of privacy during discussion	Lack of privacy during consultation	Lack of privacy during physical examination

Stages of care

1	Accessing care
2	While in the practice
3	During the consultation
4	Referral/Follow up
5	Unspecified or Other

Patient harm

0. N/A	No information on harm is reported, or no harm came to the patient
1. Minimal harm	Minimal intervention or treatment required, upset caused to patient
2. Minor harm	Minor physical or mental harm caused to patient, intervention from GP or other primary care provider required to ameliorate harm
3. Moderate harm	Significant mental or physical harm, secondary care intervention required to ameliorate harm

4. Major harm	Patient experienced or faces long term incapacity, either physical or mental
5. Catastrophic harm	Death or multiple/permanent injuries, or chronic mental health problems.

Appendix 4. HCAT(GP) online survey

Participant information

You are being invited to take part in a research study to be carried out at NUI Galway by Ms Emily O'Dowd, a PhD candidate in the Discipline of General Practice

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You don't have to take part in this study. If you decide not to take part, it won't affect you negatively in any way.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You don't have to give us a reason. If you do opt out, rest assured it won't affect you negatively in any way.

What does the study involve?

This study will involve completing a short online training session in the use of the HCAT-C. This will involve a short video demonstration, and some opportunities to practice analysing example complaints. After this, you will be asked to analyse a number of general practice complaints, which were made up by the researchers based on real data, and your responses in this analysis will be recorded in an online survey. The entire process is expected to take roughly 30 minutes.

Is this study confidential?

Information gathered about you in this study will be kept private and confidential. No identifying data will be collected when you complete the study. Your contact details will be stored separately from your survey data and will not be linked in any way. The data collected as part of the survey will be kept for five years in the office of the researcher, room G009 in the Anatomy building, NUIG, as per data protection regulations. Only the researcher will have access to this raw data.

Should you wish to receive them, the researcher will send you updates on the progress of the study, and information on the results. The results of this study will be published in an academic journal and could be presented at academic conferences. No information capable of identifying you will appear in any publications or presentations.

Should you consent to it, the researcher will store your contact details in order to invite you to participate in future research studies. This information will be kept confidential and will not be linked to your survey data.

What if something goes wrong when I'm taking part in this study?

If you get upset or distressed at any point of this study, you are free to stop taking the survey or withdraw from the study. You may also contact any of the following organisations should you feel distress as a result of this study.

Samaritans: 116 123; www.samaritans.org

Aware: 1800 80 48 48; www.aware.ie

What are the benefits to taking part?

If you decide to participate in this study, you could benefit indirectly from the changes to the complaints process that may lead from the study. This PhD aims to improve patient safety through utilising data on patient complaints, and as such patients could benefit from your participation in this study. You will also receive a €25 One for All voucher for your time.

Further information:

More detailed information on your data protection can be found at this link: Participant information leaflet

If you have any further questions about the study or if you want to opt out of the study, please contact:

Emily O'Dowd

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Consent form

* 1. I have read and understood the Information leaflet about this research project. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction

Yes

No

* 2. I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect me in any way.

Yes

No

* 3. I am aware of the potential risks, benefits and alternatives of this research study.

Yes

No

* 4. I have been given a copy of the information leaflet and this completed consent form for my records, should I want it.

Yes

No

* 5. I consent to take part in this research study having been fully informed of the risks, benefits and alternatives.

Yes

No

* 6. I give informed explicit consent to have my data processed as part of this research study

Yes

No

* 7. I consent to be contacted by researchers as part of this research study

Yes

No

Please open or download the HCAT-GP at the link below now, and then begin the video:

Please analyse the following complaints using the HCAT-C.

There are 14 complaints in this section, each with one issue for you to analyse

* 8. I was at my GP the other day and I just have to report the awful experience I had when I was there. I have lots of issues with my mental health and wanted to speak with the GP about them because I feel they are really impacting my life in a bad way. I was trying to tell the GP about my problems but he kept looking at his computer and not making eye contact with me, he refused to hear what I was saying. I felt the appointment was a waste of time because I left even more upset about it than before because the GP wasn't paying attention to my problems or taking them seriously even though I was crying all the way through the appointment he didn't take one notice of me even when I said I was suicidal. I never want to see that GP again.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 9. I took my baby to the out of hours service last night because she had a high temperature, wasn't drinking, and had diarrhoea. I was shocked that the doctor did nothing and just checked her ears and throat and said come back the next day if she isn't better. I think it's an absolute disgrace that they just sent a really sick screaming baby home without doing anything.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 10. I am writing to complain about my GP Dr X in Y primary care centre. I went to the doctor 4 years ago and was told by the GP that I had an enlarged prostate, but not to worry because it was benign and to just keep an eye on it. I was in lots of pain and my family have a history of prostate cancer so I was very nervous that that's what it was. I went to get another opinion this year after being on the waiting list for years and it turns out that I have prostate cancer which should have been picked up by the GP four years ago, when he said that I just had an enlarged prostate and that it wasn't prostate cancer, even though he knew about my family history.
This could have seriously impacted my health, is there some way I can be compensated for this.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

*

11. The door at my GP's office has a very high rim at the bottom which makes it very difficult for my elderly mother who is in a wheelchair to enter the surgery. I have also heard that people have tripped there before it is clearly a trip hazard and needs to be fixed as soon as possible before someone hurts themselves.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 12. I went to my GP because I had a sore leg and also a cough. She was typing something up about my cough when I mentioned the sore leg she said "mhmm" but I don't think she really heard me and she never asked me to explain further about it.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 13. I recently went to the student health centre in my college, to see the GP about starting on PrEP. When I attended the appointment, I was very disappointed that the GP had little to no knowledge on PrEP, and had to actually google it while I was there. As a GP working in an urban centre with mostly young people, I think that is not acceptable, and it was a waste of my time to make the appointment with someone who had so little understanding of what she was doing.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 14. I have been a private patient of Dr x in Y for over 20 years, and never had any problems with her or her practice. I recently became a medical card holder and now I can never seem to get an appointment. I never had this problem when I was a private patient and paid for my GP visits but now every time I phone they say they have no

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

appointments available, and they suggested that I try another GP. I am very upset and embarrassed about this, and would greatly appreciate some support on this from the system.

* 15. Myself and my family have recently moved from our old GP to a new practice, as we were no longer in a position to continue our relationship with the previous GP following a number of incidents. However, we have since been trying, with our new GP, to get Dr Y to transfer our medical records to the new practice, to no avail. Dr Y is not facilitating the transfer of all of our medical records. My husband and daughter both have chronic health conditions and it is vital that all of our previous medical records are forwarded to our new GP. Please contact Dr Y on our behalf and have this investigated, and our files forwarded to Dr X.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 16. I was at my GPs office recently and was booking my next appointment but when I said I couldn't do one in the morning the receptionist got very abrupt with me. I was not happy with her attitude.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 17. I have been waiting for over 22 weeks for the result of my smear test, the GP still has not sent on my results to me. This is disgraceful as with everything going on about this test I could be dead before I even get my results sent over to me from my GP. They told me they would send them on when they got the results but they have not been in touch with me since not even to tell me that they don't have the results yet if that's what happened. I have had to call them myself which is a disgrace they should have called me with my results.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

*

* 18. I think my GP has absolutely no sense of duty of care, she failed to write me my prescriptions the last time I was in with her, leaving me short of my medication, it is vital that I don't run out of that medication and I had to go to an out of hours doctor to prescribe them to me, this could have seriously harmed me.

19. I am complaining about a doctor I saw at my GP practice in X. He was not my usual GP, who was on holidays, and he told me that I needed an ultrasound for better diagnosis of my problem. I didn't understand the explanation that he gave me, and I had to get him to write down the word he kept using so I could google it when I got home. The language in the referral letter was also very complex, and I found it hard to understand why exactly he wanted me to go for the ultrasound. A GP should be able to explain clearly to patient what is wrong with them, and it left me very upset. Please do something about this.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 20. I am writing to complain not about my GP but because the building that the surgery is in is not suitable at all, it is a very modern clean building, which is fantastic, but the design of the waiting room and lack of sound absorbing materials make the sound levels in there and in the reception area way too loud, and I find it very difficult to hear the receptionist as I have difficulty hearing at the best of times.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

* 21. I went to my GP to get a prescription for the contraceptive pill, this was my first time going on any form of contraception. The GP said he needed to examine my breasts before he could prescribe the medication, I agreed because I thought this was normal, it was only afterwards that I realised what had actually happened was not normal, and I feel like I have been assaulted. I am traumatised after this, and have not been able to go to a GP by myself ever since.

	Category	Severity	Stage(s) of care	Overall harm
HCAT-C Analysis				

If multiple stages of care are present, please write stages here:

The following complaints have more than one issue within them.

There are 6 complaints within this section. Please analyse them using the HCAT-C, identifying as many issues as you can find.

* 22. To whom it may concern, I am emailing to lodge a complaint about the treatment I have received at my GP surgery X in Y. I have been a patient there for almost 2 years, and have been having a lot of trouble there recently. Every time I go there, the receptionists are very rude to me, and I can hear them talking to each other about me in a rude way when I am sitting in the waiting room, which is very upsetting to me. The last time I was in with the doctor, I asked for a referral to a psychologist, the GP said that she would refer me, however I have since gone back to the GP and there is no referral on record for me, the last time was six months ago so the doctor has only now put me on a waiting list for a psychologist which means that I will be delayed in seeing them when I could have been on the waiting list for six months already. To top it all off the last time I was there she gave me my prescription for my antidepressants and when I took this to the pharmacist he said that the dosage was completely wrong and the GP must have made a mistake because I had always been on a higher dose and the lower dose wouldn't help me at all. I am so sick of the treatment I am getting in this GP office, they are so rude to me and I know it's because of my mental health problems, and to top it all off getting the wrong medication prescribed to me. I would appreciate if you could look into this because I'm afraid that I will not be safe here when they don't even remember to refer patients.

*

	Present?	Severity	Stage(s) of care	Overall harm
Safety				
Quality				
Environment				
Institutional processes				
Communication				
Listening				
Respect and patient rights				

If multiple stages of care are present, please write stages here:

* 23.

This is a complaint about how my partner X was treated at Y GP surgery. It has taken me a very long time to write this because my partner has passed away since and it was very upsetting for me to write this. I phoned the GP surgery one day because our own GP was off, and on the machine it said that Dr Y was on call in case of emergency. I explained this and the only thing they told me is that X was not their patient and they wouldn't see him. I tried to explain that X had a temperature and was a terminal cancer patient and I Was very worried about him, but they told me to bring him to a&E if I was that worried, I tried to explain that palliative care nurse had told me to bring him to the GP but they wouldnt acknowledge that. I phoned back again and they said they still wouldn't see him. Finally our pharmacist rang them and told them they had to see X and so they gave us an appointment. When I brought X in the GP Dr Z was very rude when we went to her room, she said why don't you go back to palliative care and then said she would send him to A&E but I would have to bring him myself even though I couldn't manage him he could only walk short distances, she didn't even offer to help, and another thing, she never even wrote down a list of his medications for us to take to the hospital. It was very

	Present?	Severity	Stage(s) of care	Overall harm
Safety				
Quality				
Environment				
Institutional processes				
Communication				
Listening				
Respect and patient rights				

If multiple stages of care are present, please write stages here:

* 24.

upsetting being treated like that from a GP who should want to help people. I hope this never happens to anyone else and I want you to make sure the GP pays for behaving in such a rude way.

* 25.

So this started a number of years ago, after I was discharged from hospital, my GP simply glanced at the letter that I gave her from the hospital and then threw it into desk drawer, she didn't talk through my diagnosis with me, just wrote a prescription and I left. I was shocked and lost with the lack of communication, because at that point I really needed my GPs support. I attended the GP once a month for next 10 years, on average, and Dr X never again mentioned my diagnosis even when I reminded her about it. I couldn't understand the information from my consultants and I needed Dr X to explain them but she didn't. I've also had back pain for about 2-3 years, and my GP has been prescribing me painkillers for this. I went to another GP once and she referred me to a specialist and asked was I seeing one already. Once when I needed my GP to write a medical history for me all she wrote was back pain which I was very upset by because that made it sound like nothing at all, she doesn't listen to me, she forgot about my diagnosis, and isn't interested in my wellbeing at all. I've suffered when I didn't need to because of this GP.

	Present?	Severity	Stage(s) of care	Overall harm
Safety				
Quality				
Environment				
Institutional processes				
Communication				
Listening				
Respect and patient rights				

If multiple stages of care are present, please write stages here:

* 26.

I went to my local GP practice the other day, and was really unhappy with what happened when I was there. As I was there to talk about very personal issues I asked to see a female doctor but the receptionist was very abrupt and just said I don't get a choice I just have to see who is free. I waited for over two hours to see the GP and when I went in he was very unprofessional. Instead of giving good advice he told me I should lose weight to treat my condition or else get pregnant to cure it. I found this really insensitive as I cannot get pregnant. He finally gave me a referral letter but just handed it to me to post, I even had to buy a stamp for it myself.

	Present?	Severity	Stage(s) of care	Overall harm
Safety				
Quality				
Environment				
Institutional processes				
Communication				
Listening				
Respect and patient rights				

If multiple stages of care are present, please write stages here:

* 27.

I wanted to take my 6month old son to the GP because he had very red and sore skin, it was even bleeding, and he was in a lot of pain. The receptionist told me I wouldn't be able to get an appointment, I kept phoning back all day with no luck until 4pm. This has happened before and I've had to go to the out of hours, its very hard to get an appointment. When I saw the GP the time before this he prescribed me creams for my son and told me I should have a stock of them at home I thought this was very rude and he had a bad attitude. When I came in this time I was told I'd have to see the nurse first to check that my baby really needed to see the GP I was shocked because I know my own child. The GP gave me the script and then told me to find a new doctor after that, it was very unprofessional. He never even examined my son. I had forgotten my purse and told them I would come back with the money but they refused to let me go without paying and I had to ring my partner to come down with the money I felt very low and not trusted. I think mothers should be trusted and taken seriously about their babies health, they need to look at their policies and change them to meet families needs.

* 28.

	Present?	Severity	Stage(s) of care	Overall harm
Safety				
Quality				
Environment				
Institutional processes				
Communication				
Listening				
Respect and patient rights				

If multiple stages of care are present, please write stages here:

This a complaint about the lack of care my late mother received at her GP. Even though she had a lot of chronic illnesses there are only 10 visits ever to the GP recorded, which I was so surprised by, I phoned the GP who said that was true and that my mother preferred my dad to go collect her prescriptions and didn't like to go to the GP. This is not the full story, because my mother was a wheelchair user and couldn't access the surgery, once the GP even examined her in the garden of the practice. She was on daily medications for over 15 years, none of which were on her medical notes, it seems crazy that the GP could have kept prescribing all these medications with no record of them, there are also no record of the referrals to hospital that the GP made, which the hospitals had but not the GP. If better records had been kept, and she was able to go to the surgery properly, she would have been diagnosed with her cancer earlier and it could have been treated and I think it's absolutely disgraceful, the GP should have been monitoring her more closely because

* 29.

he knew she had a problem with her lungs and he just never followed up with this or watched out for it. No other family should have to live through what we experienced.

	Present?	Severity	Stage(s) of care	Overall harm
Safety				
Quality				
Environment				
Institutional processes				
Communication				
Listening				
Respect and patient rights				

If multiple stages of care are present, please write stages here:

HCAT-GP evaluation

Thank you for participating in this survey. Please answer the questions below regarding your experience of using the HCAT-GP

* 28. The HCAT-GP was easy to use

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
○	○	○	○	○

Comments:

29. The HCAT-GP was useful

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
○	○	○	○	○

Comments:

30. The HCAT-GP does everything I would expect it to

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
○	○	○	○	○

Comments:

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
○	○	○	○	○

Comments:

31. The HCAT-GP is user friendly
32. I learned to use the HCAT-GP quickly

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
○	○	○	○	○

Comments:

33. I would recommend the HCAT-GP to a colleague

Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
○	○	○	○	○

Comments:

34. If you have further feedback on the HCAT-GP, please comment here.

* 35. Thank you for participating in the HCAT-GP validation study. Please leave your email address below to collect your €25 one for all voucher

Appendix 5: Interview Schedule

The questions I'm going to ask in this interview relate to your experiences managing or processing complaints made by patients about general practice. When discussing complaints, I'm not going to ask about specific instances or events, but rather your general experience of complaints. I will be asking questions concerning the process of complaints management, and the impact of complaints, along with the learning that can come from complaints.

I want to remind you that your responses will be confidential. Only my supervisors and I will have access to the transcript of this interview, and if any identifying details are mentioned during the interview, I will remove them from the transcript. When we write up this research study, your responses will be presented in a way that ensures you cannot be identified.

Demographic questions:

Position/Job title?

Years of experience?

Interview questions:

Role

1. What is your experience of complaints relating to care in general practice?

Patient motivations

2. What do you think are patients' motivations to complain?
3. Why might patients not complain when they've experience poor quality care in general practice?

Process

4. Can you talk me through the process of managing a complaint? **(ASK GP ONLY)**
5. How do you think the complaints system is functioning at the moment? (prompt- for the patient, for the system, for the doctor)
6. What could be done to encourage the resolution of complaints at the lowest level/informally?

7. How could the complaints process be improved? (prompt- what are the barriers to this?)

Impact of & learning from complaints

8. What impacts can patient complaints about general practice have? (Prompts – on doctors, patients, practices, system, positive or negative)
9. What is your perception of the learning that comes from complaints about general practice?
    - (prompts- does learning happen?
    - Examples- changes in processes within practice [i.e., relating to audits etc.],
    - changes in care delivery,
    - changes in complaints management)
    - What factor(s) might determine if learning happens?

Other issues

10. Do you have any other thoughts or opinions about complaints in relation to general practice that have not been covered?