What's the harm in waiting?

Patient harms in the referral waiting gap

Vimal Patel

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Abstract

Background

Patient safety research seeks to improve the delivery of care, and ensure that patients' risk of injury from healthcare itself is minimised. Referral between primary healthcare, specialist diagnostic agencies (such as community medical laboratories and radiological centres), and hospital based healthcare is common and important in primary care, yet patients have highly variable waiting times before receiving their care. However, there is almost no research exploring what happens to patients while they wait.

Aims

This study aims to investigate patient's waiting periods between referral from their General Practitioner (GP) and receiving specialist healthcare. Specifically, this study aims to determine if patients come to any harm in this waiting gap, and if so, which patients are harmed and what types of harm happen.

Methods

I reviewed 5 years (2003-2007) of healthcare records of 201 general practice patient's notes. Each consultation record was examined to identify the types of referral that were made and to find evidence of harms while the patient was waiting for referred healthcare. A subset of 101 of these patients also had the records reviewed for investigation types and evidence of harm while waiting for investigation. A broad definition of harm was used to capture a greater number of harms. Harms were categorised as related to referral for investigation, referral to medical specialty or referral to other non-medical specialty. Harms were also graded in severity (mild, moderate and severe) and were described under the following: *'continued symptoms'*, *'delay in subsequent management'*, *'deterioration of condition'*, *'financial cost to patient'*, *'anxiety/mental harm'* or *'other'*. Comparisons were made between patients whose referrals had evidence of harm in the waiting gap with patients who did not. Comparisons included length of waiting gap, age, gender and specialty referred to and used t-tests or non-parametric tests, as appropriate.

Results

5003 Consultation records were reviewed. A referral rate of 0.21 per person per year for medical and non-medical specialties was found, and a referral rate of 1.00 per person per year for investigations was found.

45 of 183 (25.5%) of referrals to medical or non-medical specialties had evidence of harm in the waiting gap, whereas 9 of 105 (1.8%) of referrals for investigation had harm in the waiting gap.

Of the 58 total harms, 43 (74.1%) of harms were minor, 12 (20.5%) were moderate and 3 (5.2%) were severe. The largest broad classification of harm was "*continued symptoms*" with 38 harms (65.5%), followed by "*delay in subsequent management"* with 14 harms (24.1%) and "*deterioration in condition"* with 14 harms (24.1%).

There were no statistically significant relationships between the age of patient nor sex of patient nor length of waiting time and the incidence of harm in the waiting gap.

Conclusion

This is the first study of harm in the referral waiting gap. The findings indicate that harm does happen while patients wait for referred care, and more research is needed to explore these harms. While the relatively small number of patients in this study limits the ability to draw robust implications for changed clinical practice, it is a strong starting point for larger, future research.

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List of Abbreviations

ACC	–	the New Zealand Accident Compensation Corporation
ADE	–	Adverse Drug Event
ADR	–	Adverse Drug Reaction
AHRQ	–	Agency for Healthcare Research and Quality
AIDS	–	Acquired Immune Deficiency Syndrome
ANOVA	–	Analysis of variance
ASPN	–	Ambulatory Sentinel Practice Network
CPAC	–	Clinical Priority Assessment Criteria
CI	–	Confidence Interval
CT	–	Computerised Tomography
DHB	–	District Health Board
ECG	–	Electrocardiogram
FDA	–	United States Food and Drug Administration
GBP	–	Pound Sterling
GP	–	General Practitioner
HRC	–	Health Research Council of New Zealand
N/A	–	Not Available
NHS	–	United Kingdom National Health Service
NZ	–	New Zealand
NZD	–	New Zealand Dollar
OECD	–	Organisation for Economic Co-operation and Development
PHARMAC	–	Pharmaceutical Management Agency
SD	–	Standard Deviation
UK	–	United Kingdom

US	–	United States
USD	–	United States Dollar
WHO	–	World Health Organisation
e.g.	–	*exempli gratia* (for example)
etc.	–	*etcetera*
i.e.	–	*id est* (it is)

1 Introduction

The following chapter places harms related to referral waiting times in the overall context of the patient safety literature. This is in order to develop aims and objectives for this study which will contribute to the understanding of patient harms.

A search to find related published articles initially used various combinations of the keywords "referral", "waiting time", "waiting" and "harm" on the article databases Ovid™, PubMed™ and Web of Science™. However, this retuned an insufficient number of relevant results, even after broadening of search terms, and so a historical overview of the broader field of patient safety was utilised instead to define the surrounding literature.

Since patient safety is a relatively new field this literature review will first examine the field of patient safety from a broad historical approach initially, and then look more specifically at safety in primary care and referral literature.

1.1 History of harms research

The concept of iatrogenic harm is possibly as old as medicine itself, with the Hippocratic Oath containing the directive *primum non nocere*: "first, do no harm".[1] However, the academic study of patient safety and harms is a relatively new field. This section explores the relatively brief history of harms research.

Patients systemically receiving harm from the provision of investigations and treatment (or lack thereof) has been a known issue of health care systems at least since Barr's article in JAMA in 1955.[2] Eventually some small studies were carried out in the United States (US) in the 1980s, detailing the unexpectedly high levels of iatrogenic adverse events in hospitals.[3,4] But it was not until several larger US studies in the early nineties that the true extent of patient harms were known.

The first of these studies was the Harvard Medical Practice Study in New York.[5] This analysed over 30,000 hospital records sampled from New York hospitalisations in 1984 looking for adverse events present in the notes made during the 1984 admission. The researchers identified 1,133 adverse events; a rate of iatrogenic harm of 3.7% of all hospitalisations during this period. This finding is supported by other large, hospital based studies from the US, Australia, the United Kingdom (UK) and Denmark.[6-9] These show a rate (during the mid to late 90s) of harm due to adverse events between 3% and 16%.

Subsequent New Zealand studies found similar rates of adverse events in New Zealand hospitals of 12.9%, with a follow-up study determining that 37.1% of these were preventable.[10,11] These studies highlight that patient safety is also a relevant issue in New Zealand hospitals, and that preventing a large number of harms is entirely possible.

1.2 'To Err is Human'

Data from some of the earlier above studies regarding patient harm was published in the US Institute of Medicine's seminal report *To Err is Human*.[12] This report extrapolated from the studies and described medical errors that caused at least 44,000 deaths annually in the US – which, in the report, was then put in perspective as a greater cause of death in the US than motor vehicle accidents. The report went on to explore the issue of patient safety in more depth and made several recommendations and goals, including a 50 percent reduction in errors over five years.

The Institute of Medicine makes a comparison between patient safety and the safety in other industries; namely Aviation and Occupational Health.[12] *To Err is Human* notes the similarities between healthcare and these industries; namely, all three are complex systems, with a large potential for human error and all have had previously high injury and death rates.

To Err is Human notes the safety improvements in these other industries. In aviation a significant improvement in safety has been accomplished, with a recent study showing a 90% reduction in US aviation fatalities from the 70s to today.[13]

Occupational safety improvements are also similar, with rates in the US decreasing from 11 per 100 workers in 1972 to 3.6 per 100 workers in 2009.[14] The Institute of Medicine lists these industries' systems approach, reporting structures (including an independent body dedicated to safety) and research into causes of error as key reasons for the dramatic improvement in safety in these industries, and that a similar approach should be applied to healthcare.

The Institute of Medicine made several recommendations to improve patient safety within *To Err is Human*, as summarised by Donaldson: firstly, the formation of a National Centre for Patient Safety, secondly the formation of mandatory and voluntary reporting systems, thirdly involving consumer, professional and accreditation groups and organisations in improving patient safety and lastly for health care organisations to build a culture of safety- a workplace environment where safety is a top priority.[15]

1.2.1 Resulting interest in harms research

The report *To Err is Human*, especially the figure of 44,000 preventable deaths annually, was reported widely in the media, resulting in significant concern and attention to patient safety throughout the US.[16] This resulted in galvanising action and contributing to the US Healthcare Research and Quality Act of 1999.[17] This Act focused resources on implementing the Institute of Medicine's recommendations in order to make improvements in healthcare within the US.[18]

Internationally, in 2002 the World Health Organisation (WHO) published a report on patient safety, which, at the fifty-fifth World health Assembly, led to a resolution that urged all member states to improve patient safety.[19,20] In November 2003 the WHO formed the International Alliance for Patient Safety, a collaboration to improve patient safety globally.[21]

In the decade following *To Err is Human* and the increased attention on patient harms, much has been achieved in meeting some of the Institute of Medicine's recommendations. These achievements included improving awareness, formations of organisations and research.[22]

1.3 Error Theory

Both the early patient safety studies and *To Err is Human* focused on errors by healthcare professionals. While not all harms are due to errors, they contribute significantly to patient injury.[23] Therefore, understanding and preventing harms due to errors is necessary to build safer healthcare systems, as noted in *To Err is Human*.[12]

James Reason explores the theory behind error in *Human Error*.[24] While Reason describes in detail the cognitive psychology model behind errors, he also describes systems in which errors are more likely to occur. Reason, using an approach from Perrow, describes a complex system with tight coupling: 'complex' meaning that one task or component has many effects, and 'tightly coupled' meaning that one task or component is reliant upon and is strongly effected by one or more other components.[25] Reason and Perrow describe these systems as at high risk of potentially disastrous errors, as a failure in one task or component can effect multiple further components (due to complexity), and there is little tolerance or redundancy for failure of this component (due to tight coupling).

While not specifically describing patient care in *Human error*, Kohn et al applied this to healthcare in *To Err is Human*, analysing several cases in which error occurred and finding that healthcare as a system fit the description as 'complex and tightly coupled'.[12] *To Err is Human* Establishes that healthcare provision is a system prone to error, a viewpoint corroborated by other authors.[26]

1.4 Definitions of harms, errors and adverse events

Until recently, there has not been a constant definition of the terms used in patient safety research, with the definitions differing between early studies.

Table 1 (section 1.4.1) shows the range of definitions used in patient safety research.

1.4.1 Definitions between various studies

Table 1 Definition of 'harm', 'error' and 'adverse effect' in various studies.

Reference	Year	Title of study	Definition of harm	Definition of error (or similar term)	Definition of adverse event
Oxford Dictionary.[27, 28]	2015	N/A	• Physical injury, especially that which is deliberately inflicted • Material damage • Actual or potential ill effects or danger	• A mistake • [mass noun] The state or condition of being wrong in conduct or judgement • [mass noun] technical A measure of the estimated difference between the observed or calculated value of a quantity and its true value.	N/A
Steele et al.[3]	1981	Iatrogenic illness on a general medical service at a university hospital.	Iatrogenic illness: "any illness that resulted from a diagnostic procedure or from any form of therapy (excluded 'minor' problems)"	N/A	N/A
Couch et al.[4]	1981	The high cost of low-frequency events: the anatomy and economics of surgical mishaps.	N/A	"A surgical misadventure resulted from a decision that was clearly an error in the field of general surgery, as determined by the authors and the physicians responsible for the patient."	N/A
Brennan et al.[5]	1991	Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I	N/A	N/A	"Incidence during hospitalization of injuries resulting from medical intervention"
Wilson et al.[7]	1995	The quality in Australian health care study	N/A	Preventable Adverse event: "an error in management due to failure to follow accepted practice at an individual or system level"	"(1) an unintended injury or complication which (2) results in disability, death or prolongation of hospital stay, and is (3) caused by health care management rather than the patient's disease."

Reference	Year	Title of study	Definition of harm	Definition of error (or similar term)	Definition of adverse event
Thomas et al.[6]	2000	Incidence and types of adverse events and negligent care in Utah and Colorado	N/A	negligence was defined as "care that fell below the standard expected of physicians in their community"	"an injury caused by medical management (rather than the disease process) that resulted in either a prolonged hospital stay or disability at discharge"
Davis et al.[10]	2002	Adverse events in New Zealand public hospitals I: occurrence and impact	N/A	Preventability (follow-up study [11]) defined as: "Preventability of an AE was assessed as an error in healthcare management due to failure to follow accepted practice at an individual or system level."	"1) an unintended injury; 2) resulting in disability; and 3) caused by healthcare management rather than the underlying disease process. Each of these criteria had to be fulfilled"
Baker et al.[29]	2004	The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada.		Adverse Events due to health management was defined as: "the actions of individual hospital staff as well as the broader systems and care processes and includes both acts of omission (failure to diagnose or treat) and acts of commission (incorrect diagnosis or treatment, or poor performance)."	"an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay and that is caused by health care management rather than by the patient's underlying disease process"

1.4.1.1 Comparison of definitions between studies

As seen in Table 1, most studies did not define harm, and instead defined adverse event.[4-7,10,29] Adverse events were often defined as unintended injury occurring to a patient and resulting in disability. However, the injury could not be related to the disease, and usually had to be related to healthcare provision. The use of adverse events over harms was possibly due to a focus on quality improvement, as adverse effects are easier to address and to potentially prevent than harms – which can result at least in part from the natural progression of the patient's illness. Additionally, harms have a much wider and non-specific definition than adverse events.[27,28] A reasonable definition of harm may be reached by combining the Oxford dictionary definition with the various definitions of adverse events and removing some of the boundaries used in the definition of adverse event. One such definition may be:

> "Harm: Physical injury, material damage, or potential ill effects that resulted from a diagnostic procedure or from any form of therapy."

While this is not a formal definition, it is very similar to the definition proposed by modern harms researchers (see section 1.4.3).

1.4.2 Harms versus errors

Following the description of harm in the early studies, interest became focused on harms due to errors, which were often described as a "preventable adverse event".[11] Such events were defined in the Quality in Australian Health Care Study as "an error in management due to failure to follow accepted practice at an individual or system level".[7]

To further clarify, error was defined initially by James Reason in *Human Error* as "a failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance".[24] This definition has been adopted in some newer patient safety research.[30]

Consolidating the above definitions, adverse events differ from harms in that adverse events are related only to intervention or lack of intervention and not related to the disease process, whereas harms include all adverse events, but also include non-preventable, known negative consequences of treatment and all the sequelae of the initial condition.

However, the focus on errors (over harms) in the drive for quality improvement in healthcare, even in *To Err is Human*, has subsequently tangled the difference between harm and error, with

harms often becoming synonymous with errors in everyday language, although, as shown above, this is not the case.

Of interest, the New Zealand Accident Compensation Corporation (ACC), will pay patients and providers for costs related to "treatment injuries, i.e. physical injuries sustained while receiving treatment from registered health practitioners." But not "personal injuries caused by illness"– the former would fall under the definition of an adverse event, whereas the latter would not, but still be considered a harm.[31]

1.4.3 Current definition

A recent paper by Runciman suggests a simplified series of definitions to be used in future research, including the following: [32]

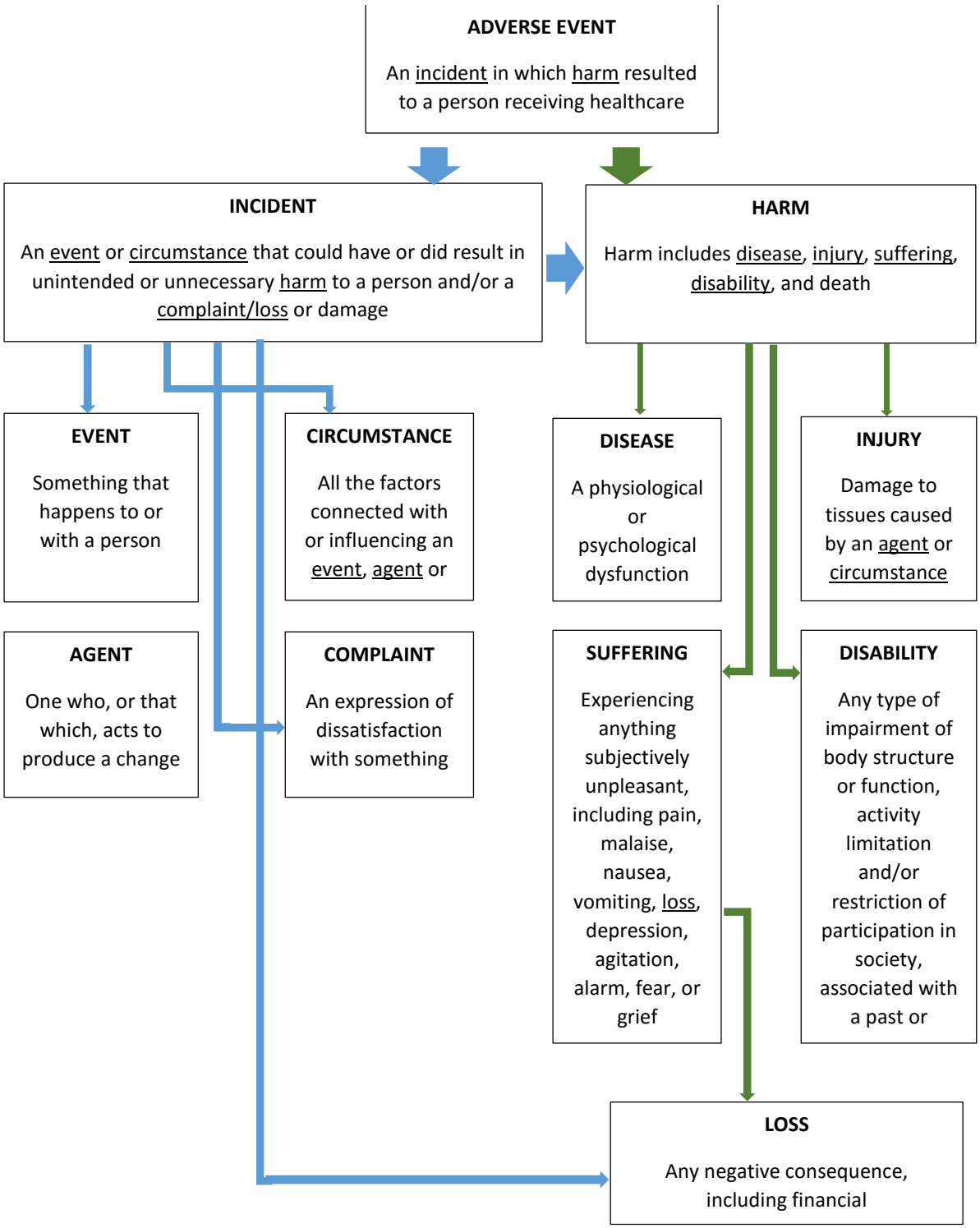
> *"Safety: Freedom from hazard.*
>
> *Hazard: A circumstance or agent that can lead to harm, damage or loss.*
>
> *Harm: Harm includes disease, injury, suffering, disability and death."*

Runciman goes on to define disease, injury suffering and disability, such that harm includes all unpleasant experiences by patients and is thus broader than previous definitions.

Because of the broad nature of these definitions and their subsequent integration into the International Classification of Patient Safety, these are the definitions that will be used in this thesis.[33] They have been adapted and illustrated in Figure 1.

Harm, by this definition, includes not only additional unintended or unexpected suffering, but also the disease process itself (defined as physiological or psychological suffering). This differs from previous studies in which the disease process was not included as a harm. However, this is justified by Runciman as closer to the colloquial use of the term 'harm'. While this may not be applicable in all safety research, when discussing waiting times this broad definition was felt to encompass the patient experience better.

Figure 1 Relationship and definitions of patient safety terms - adapted from Runciman 2006.[32]



1.5 Current areas of harms research

In the years following *To Err is Human*, there have been some significant advances in harms research and prevention, although more in some areas than others. The following are several key fields and examples of the progress made in patient safety and preventing harms.

1.5.1 Anaesthetics

Throughout the health system, individual medical specialties are beginning to tackle the issue of patient safety. However, anaesthesiology is regarded as at the forefront of the field, and as a model for other specialities to follow.[34]

With studies showing high incident rates of anaesthetic mortality throughout the 1950s and '60s, significant work was done to investigate and improve the practice of anaesthesiology, resulting in lower anaesthetic mortality rates in the 1980s and beyond.[35] A US study showed a decrease from 2.16 deaths per 10,000 anaesthesia procedures in the 1950s and '60s to 0.16 per 10,000 in the late 1970s and early '80s.[36] While later data from the Australian and New Zealand College of Anaesthetists over 2009-2011 shows a rate of 1 death per 58,039 (0.17 per 10,000) anaesthesia procedures.[37]

Work done to improve patient safety in anaesthetics includes critical incident studies investigating causes of anaesthetic incidents, analysis of patient risk factors and equipment factors.[38-40] Various studies were collectively analysed by Derrington and Smith, noting specific areas of anaesthesia which posed a safety risk to patients and where improvements could be made.[41]

This work and the high costs of medical indemnity lead to the formation of the Anaesthesia Patient Safety Foundation (APSF) in 1985, to ensure "that no patient shall be harmed by anaesthesia".[35] The APSF played a significant organisational role in the formation of patient safety in anaesthesia by encouraging further research, leading safety programmes and campaigns and advocating for 'a culture of safety'.[42] The APSF is noted in *To Err is Human* as an example of organisation-level approach to improving patient safety.[12]

In describing anaesthesiology as a model for other specialties to follow, Gaba highlights several methods through which anaesthesiology has improved: the adoption of standards and guidelines, identification of human factors at a system level, developing patient simulation for research and training and, most importantly, integrating patient safety as an institution wide concern. However Gaba notes that there are still improvements in patient safety to be made in anaesthesia, since the rate of patient death due to anaesthesia is still not zero.[34]

1.5.2 Surgical checklist

A systematic review in 2007 by de Vries et al investigated the nature of events and situations where hospital adverse events occurred; showing that 80.8% occurred during hospital stays and that the largest group (41%) of these adverse events occurred in the operating room.[43]

The WHO's World Alliance of for Patient Safety developed the surgical checklist in 2008 as part of the 'Safe Surgery Saves Lives' campaign to reduce preventable harms in hospitals, targeting operating theatre adverse events.[44] Inspired by civil and military aviation safety checklists the checklist comprises of 20 checks over three stages – before anaesthesia, before incision and after wound closure – to break down complex tasks into simple steps and help avoid preventable harms.[45]

An international study in 2009 which implemented a checklist (similar to the WHO surgical checklist) across several hospitals globally, compared 3733 surgeries before implementation of a checklist to 3955 after.[46] The authors found a reduction of complication rate from 11.0% to 7.0% following introduction of the checklist. Another 2010 study which followed 3760 patients before and 3820 after implementation of a more comprehensive checklist found a similar reduction in complications; from 27.3% to 10.6%.[47] These studies convinced many hospitals globally to introduce the checklist as standard for all surgeries.

A more recent cohort study published in 2012 by van Klei et al followed 25,513 patients undergoing surgery between 2007 and 2010, with the WHO surgical checklist introduced in 2009.[48] The study found a statistically significant decrease in mortality with an odds ratio of 0.85. Additionally the authors also found that the decrease in mortality was strongly related to compliance with the checklist.

These studies emphasise the approach to identifying a problem area in patient safety and how effective implementation of a simple safety procedure can improve patient safety.

1.5.3 Medication harms

Prescription of medication is the most common clinical intervention, with the Pharmaceutical Management Agency (PHARMAC) funding 41.8 million prescription items in 2014 in New Zealand.[49] Yet, the use of medication also has a significant adverse event rate of 25%, with 11% of events being deemed preventable.[50] For this reason, medication error is one of the larger areas or harms research.

Medication error is defined as “a failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient”.[51]

Medication errors have been broadly split into two types. The first, ‘adverse drug event - ADE’ includes any injury from the use of a medication or drug, including anticipated side effects. An ‘adverse drug reaction – ADR’ however is an unanticipated ‘noxious’ response to a medication or drug.[50,51]

Systems analysis performed by Leape et al of the causes of medication errors showed that most medication errors are due to correctable errors within the system: physician drug knowledge, missing information about the patient, rule violations and others – all deemed correctable by improved information systems.[52]

Following research to identify solutions to the problem of medication errors, a systematic review found that implementation of computerized physician order entry systems (or electronic prescribing) were effective in reducing the rate of both ADEs and potential ADEs with a relative risk reduction of up to 84% and 98%.[53] However a recent study suggested that electronic prescribing facilitated new types of medication errors, and the authors suggest that electronic prescribing may need to be adopted cautiously.[54]

1.6 Harms reporting

To Err is Human recommended a national mandatory reporting system beginning with hospitals and them moving to ambulatory care for the reporting of serious harms, as well as encouraging the use of voluntary reporting for lesser or potential harms.[12] Reporting systems were developed following the success of harms reporting in other industries (Section 1.2).

Currently, the US has hospital level harm monitoring as part of the Medicare system; however a report by the Office of Inspector General found 86% of harms were not reported, and that there is no national level mandatory reporting system.[55] There is no mandatory US reporting for error reporting in primary care, and voluntary systems vary greatly from state to state.[55] However, the FDA has a robust system for voluntary reporting of adverse drug events.[56]

In the UK, The National Patient Safety Agency has established the National Reporting and Learning System to collect reports of patient safety incidents since 2003 - the system has since been incorporated into the National Health System (NHS). The National Reporting and Learning System has, according to Hutchinson et al, received over 1 million reports as of 2007.[57] Hutchinson et al also found that the rate of reporting has steadily increased as hospitals became accustomed to the system and a culture of safety developed (shown by staff surveys in

hospitals). However, problems have been noted with the non-mandatory nature of the reporting, and therefore under reporting of safety incidents especially in primary care.[58]

In New Zealand, the Health and Disability Services (Safety) Act 2001 requires all serious and near miss adverse events to be reported by the various District Health Boards (DHBs) to the national Health Quality & Safety Commission, a governmental organisation.[59] The definition of adverse event used by the Health Quality & Safety Commission is "an incident which results in harm to a consumer" [60] – only "serious" and "near miss" events are required to be reported, and each DHB uses different systems to identify these.[61]

In the latest 2013-2014 report, there were a total of 454 events reported, 149% increase since the beginning of reporting in 2006-2007 – suggested in the report as a result of an improvement in DHB incident identification systems rather than an increased rate of errors.[62] Patient falls were the greatest event reported with 248 cases. This was followed by 158 events related to clinical management; including delays in treatment, assessment/diagnosis and observation, as well as others. Events involving medications was the third largest group with 30 cases.

Adverse events from primary care have been included from the 2013 report onwards (i.e. events General Practices and other primary care facilities were reported from July 2012 onwards), however this is not currently mandatory and in the latest report only 25 incident reports were from providers other than hospitals.[62]

1.7 Cost of harms

Other than physical and emotional costs of harm, some work has been done to estimate the financial costs of harms. *To Err is Human* collected several studies estimating harm before 2000, including the following.[12] Thomas et al estimated the costs in the states of Utah and Colorado to be $348 million USD for adverse events, and $159 million USD (46%) of this to be from preventable harms. Classen et al in their study published in 1997 found an average cost of $2262 USD per adverse drug event, and an average cost of $3,634 for serious adverse events.[63] *To Err is Human* extrapolates these data to determine that, in the US, adverse events would cost approximately $37.6 billion USD, as they point out, greater than the healthcare cost of treating HIV and AIDS.[12] A 2005 UK publication from the National Audit Office estimated the UK costs to be over £3 billion GBP total to hospitals.[64]

Brown et al in a New Zealand study estimated the costs of adverse events in New Zealand hospitals – the authors calculated a cost of $10,264 NZD per a patient, per adverse event totalling $870 million NZD per year nationally.[65] An Australian study by Ehsani et al calculated a

similar cost of $6826 AUD per adverse event, comprising 18.6% of the hospital inpatient budget for the hospitals sampled.[66]

A review (for the NHS) by Øvretveit on potential savings, identified that there is very little research on the costs of harms outside of the hospital.[67] There is also little evidence of the costs of medication errors outside of the hospital, and no costing on adverse drug events outside of hospitals has been performed; the only costing study found by Øvretveit was one study costing wasted medications at $30 USD per patient.[68]

The cost of litigation is mentioned in the UK National Audit Office's report as £423 million GBP for settled claims and £2 billion GBP for unsettled claims nationally.[64] While there are no data available on litigation in New Zealand (including in primary care), a combination of ACC claims, as well as episodes of physician litigation for negligence, show that there is a level of financial cost to harms in New Zealand, although no number can currently be applied.[69,70]

1.8 Primary Care and Patient harms

The WHO conference of Alma Ata in 1978 stated that primary care is an essential approach to care to meet the majority of health needs of the world population.[71] However, the research of harms in primary care is not as extensive as the research in hospitals. The US Agency for Healthcare Research and Quality in 2001 concluded that more research was needed in ambulatory care.[72] A relatively recent review of harms in ambulatory care (which includes primary care) by the American Medical Association from 2000-2010 and found that research was still lacking in several key areas; including the actual incidence of harms, evaluation of possible interventions and the development of clear definitions.[73]

The WHO, as part of their patient safety programme, recently held a meeting to discuss improving patient safety in primary care.[74,75] They found that, again, primary care safety research was a priority and that the first step was more research into the epidemiology of harms in primary care.

1.8.1 Structure of primary care in New Zealand

Publicly funded healthcare in New Zealand operates under a gatekeeper model, similar to the NHS of the UK, and healthcare systems in Australia, Canada, Norway and Sweden.[76] The model allows access to specialist healthcare and services that is above and beyond general practice care through referral from a General Practitioner (GP).[77] The GP acts as a 'gatekeeper' who determines what services (if any) are required by patients and then refers them. Referral were usually as letters (although now electronic referral is more commonly used in New Zealand) to

a hospital service or department which then allocates an appointment with an individual consultant doctor.[78] However, in comparison to other systems (notably the NHS) patients must pay to see a GP, although this fee is reduced after 12 visits in a year.[79]

A 2009 survey of GPs from different health systems by the Commonwealth Fund found that New Zealand GPs reported good affordability, access and quality improvement incentives. However safety reporting and access to specialty care were highlighted as a concern when compared to other countries; with 52% of New Zealand GPs surveyed indicating safety reporting needs improvement and 45% indicating long waiting times to see a specialist (compared to 38% and 22% of UK GPs indicating the same for each respective question).[76,80]

The New Zealand Ministry of Health published statistics describe 12.4 million GP consultations and 2.6 million nurse consultations during the 2013 calendar year, with 4.2 million New Zealanders being enrolled in Primary Health Organisations (94.9% of the New Zealand population).[81] The same statistics show an average cost of $31.93 for an adult to attend a normal GP consultation and $15.05 to attend a low cost practice.[a]

1.8.2 Likelihood for harms in primary care

Reason's description of error prone systems (see section 1.3) can be applied to primary care. While Reason did not specifically describe medical provision as such as system, he did describe aviation as an error prone system.[24] Wilf-Miron et al point out the similarities between aviation and primary care – both are staffed by selected highly trained professionals, both require high level performance in high risk environments and both errors in aviation and errors in primary care may cost human lives.[82]

Analysis of ACC claims show that treatment injuries do occur in primary care, with Wallis and Dovey showing 3845 accepted primary care claims over a four year period (2005 – 2009): 2885 (75.0%) of these were minor claims, 701 (18.2%) were major claims, 204 (53.0%) were serious claims and 55 (14.3%) were sentinel claims (resulting in death or major permanent loss of function).[69] The ACC definitions are reproduced in Table 2.

Table 2 ACC Claim Definitions adapted from Wallis and Dovey.[69]

Level of Claim	ACC Definition
Minor	An event which results in minimal lessening of bodily function and which may require an increased level of care, review and evaluation, further investigation or referral to another clinician

[a] Very low cost access (VLCA) practice: extra funding to increase access in low income areas.

Major	An event which results in short-to-medium lessening of bodily function (sensory, motor, physiological or intellectual) unrelated to the natural course of the illness and differing from the expected outcome of patient management
Serious	An event, or related events, that has the potential to result in death or major permanent loss of function not related to the natural course of the claimant's illness or underlying condition
Sentinel	An event during care or treatment that has resulted in an unanticipated death or major permanent loss of function not related to the natural course of the claimant's illness or underlying condition, pregnancy or childbirth

Comparison between primary care and hospital care showed that the proportion of minor claims of all claims was greater in primary care, major and sentinel claims comprised a lower proportion than in hospital, and serious claims were approximately the same as in hospitals. The most common events causing primary care treatment injury claims were firstly medication (37.9%), dental care (16.3%), thirdly venepuncture, cryotherapy, ear syringing combined caused (13.5%) and fourthly vaccination (10.2%). However 179 different types of care associated with treatment injuries were classified in the ACC database. While 'delay or failure to diagnose' was responsible for only 2% of claims overall, it was highly represented in serious and sentinel events, responsible for 15% of these.

Gandhi and Lee, in an opinion piece published in the New England Journal of Medicine summarised how patient safety and harms in primary and ambulatory care are different to harms in hospitals.[83] The authors state that treatment errors, which are more common in hospitals, are less common in primary care and instead diagnostic errors predominate. Additionally, the lack of constant medical presence that features in hospitals may lead to harms in primary care occurring away from the physician or other staff - never being witnessed, and thus unrecorded.

Gandhi and Lee also highlight the difficulty faced with information transfer between different providers, especially if they have different record systems and lack face-to-face meetings.

Finally Gandhi and Lee stress the need for a culture of safety and a leading organisation to make the push for safety in ambulatory and primary care – similar to the changes seen in hospital care but still lacking in primary care.

1.8.3 Harms research in general practice

Research into harms and patient safety in primary care has advanced at a slower pace than in some specialities and has been identified by a WHO patient safety working group as an area of research priority.[75,83,84]

An analysis of the literature of medical errors in primary care found four studies directly investigating error in primary care prior to 2002.[85]

The largest of these, by Bhasale et al, collected 805 free text incident reports from a non-random sample of 324 General Practitioners in Australia.[86] Bhasale et al define an incident as "an unintended event, no matter how seemingly trivial or commonplace, that could have harmed or did harm a patient". The demographic analysis showed that female patients aged >75 years and infants of both genders were over-represented in incident reports compared to the population attending consultations.

In addition, following classification of the reports, Bhasale et al found a wide range of causes; categorised as pharmacological, non-pharmacological, diagnostic and equipment (listed in decreasing magnitude). Within these categories the most common specific errors were the prescription of an inappropriate drug (pharmacological), omission or delay of treatment (non-pharmacological), missed diagnosis (diagnostic) and equipment malfunction (equipment). The authors concluded that their analysis showed that there is a larger variety of errors (and potential for harm) that can arise within primary care in comparison to other specialities.

Dovey et al used 330 error reports to develop a taxonomy of errors occurring in primary care, splitting errors into either process (delivery) errors or knowledge (skill) errors and further classifying these.[85] The authors classified 284 (86%) as process errors and 46 (14%) as knowledge errors. When analysing the reports, the reviewers found one instance of death from error and several where death was a potential outcome.

The Linnaeus Collaboration (a primary care safety research group) examined 431 free text error reports to determine the causes of errors in primary care and possible solutions.[87] The most common types of error were broadly “treatment process error” and “office administration error” (25.4 % and 18.9% respectively). The former included late referral. With regards to solutions, the major theme in error reports from all countries was ‘more diligence’, however different care and better communication were also common themes.

Sanders and Esmail, in a literature review, found that the rate of error in primary care ranged from 5 - 80 per 100,000 consultations between two studies; Bhasale et al above, and an earlier

study based on a risk-management database by Fischer et al.[86,88,89] While this rate of error is lower than rates found in hospital based studies (see section 1.1), with over 12 million visits to New Zealand GPs in 2013 alone, there is a significant scope for harm.[81]

Makeham et al also used error reporting in Australia to determine the overall rate of errors reported in Australian primary care.[90] 84 GPs submitted 418 error reports over 12 months from 490, 864 funded appointments (85 per 100,000 consultations). This gave a estimation of the overall rate of errors in Australian primary care. However, the authors noted that with a voluntary reporting system, the number of errors were possibly under reported.

A more recent study by Singh et al examined triggers in primary care that indicated diagnostic errors.[91] Triggers are alerts generated by automated computer systems that identify patient records that may contain evidence of errors. The authors examined electronic patient records using two triggers – firstly if a primary care consultation was followed by an unplanned hospitalisation, and secondly if a primary care consultation was followed by another unplanned consultation. With positive predictive values for a diagnostic error of 20.9% and 2.1% respectively, Singh et al show that diagnostic errors do occur in practice, with at least unintended visits or hospitalisations associated with these errors of healthcare. Additionally, Singh et al show that automated electronic triggers are a potential methods of identifying errors and perhaps, harms. However, as noted by Singh et al, further work needs to be done to refine triggers in order for them to be useful clinically.

To date, the only published, large, quantitative study analysing patient records in a similar method to the large hospital studies (i.e. the Harvard Medical Practice Study) is a study conducted in the Netherlands by Gaal et al.[92] Gaal et al where the records of 1000 patients were analysed, with reviewers analysing each set of notes for 'patient safety incidents', defined as:

> "an unintended event during the care process that resulted, could have resulted, or still might result in harm to the patient"[92]

Gaal et al found 211 incidents in over 8401 patient contacts (2.2%) for 186 patients. Out of these 211 incidents, 58 caused tangible harm, and 7 resulted in hospital admission.

The number of incidents, and also the lack of severity of these incidents, were significantly lower than the rates found in hospital based studies, leading the authors to conclude that, from an individual patient's point of view, primary care is relatively safe (meaning free from harm) compared to higher hospital based healthcare. However, Gaal et al pointed out that they still did find several patient safety incidents in the notes, and so there is still potential for harm to

occur in general practice. These authors also noted some limitations of their study; the largest was underreporting in the notes by healthcare professionals, and also the small number of practices involved in the study. Also, while not a limitation, the definition used in this study specifically includes only "unintended [events]", meaning harms that result from intended events – i.e. where the healthcare provider was aware of the harm or potential harm – would not be included in their analysis. No other published study looking at rate of harms rather than errors in primary care could be found by the candidate, so it is assumed that the level of total overall harm is still unknown.

1.9 Referral

Referral is a process undertaken by GPs for a variety of reasons. Historically, reasons for referral have been indicated for diagnosis or confirmation of a diagnosis, opinion or advice of treatment, and/or or for treatment itself.[93] Additionally an analysis of US primary care visits over 1989-1994 showed that referral rates increased as conditions became less common, and also with more comorbidities; suggesting that another reason for referral is lack of familiarity with conditions and diseases.[94]

More recent research has described physicians' reasons for referral in a contemporary treatment setting. In 1998 Forrest et al studied the reasons for referral of 141 US family physicians who completed a questionnaire following each referral that took place over a three week period.[95,96] Over this period, 2165 referrals (from 5.1% of visits) had questionnaires filled out by these family physicians (93.9% response rate). Referral was defined as "a physician's decision to send the patient to see a specialist practitioner (physicians and non-physicians with specialised skills were included) for a face to face encounter". This was part of a larger study investigating referrals from the Ambulatory Sentinel Practice Network (ASPN) – a network of primary care practices collaborating in safety research.[97] The physician reported reasons for referral are reproduced in Table 3, noting that often physicians had more than one reason for referral (hence a greater total than 100%).

Table 3 Reasons for referral – from Forrest et al.[95]

Reason for referral	Percentage of referrals citing this as a reason (%)
Advice	51.5
On both treatment and diagnosis	40.3
On treatment only	7.7
On diagnosis only	3.5
Specialized skill	93.8
Direct surgical management	37.8
Direct medical management	25.9
Nonsurgical technical procedure or test	11.7
Multidisciplinary care	10.6
Mental health counselling	3.5
Endoscopy	3.3
Patient education	1.0
Patient or third-party request	19.2
Patient request	13.6
Specialist request	2.6
Administrative renewal	2.0
Insurance guidelines	1.0
Other reasons	15.4
Failed current therapy	10.9
Medico-legal concerns	2.9
Time constraints	1.6

Of note are the relatively new reasons of multidisciplinary care and patient request which were not mentioned in older research into reasons for referral.[98] Now, as shown above, these are an important reason for referral, included in 13.6% of surveyed referrals, although listed as the sole reason in only 1.1% of referrals.

Forrest et al investigated the characteristics of both patients and physicians involved in 34 069 referrals from US primary care physicians.[99] They found that 5.2% of visits resulted in referral. The only identified physician characteristics that made referral more likely was “reluctance to disclose uncertainty to patients”.

Forrest et al also surveyed 796 (98% response rate) US patients who were referred by family physicians. The authors chose to exclude investigations (laboratory and imaging) and requests

for admission (via specialist or emergency department) instead focusing on outpatient appointments. They found that 83% of patients that were intended for referral had their referral completed, with 79.2% seeing a specialist.

1.9.1 Practitioner referral rates

As discussed, Forrest et al found a rate of 5.1% of patient visits to family practitioners result in referral to a specialist in their 1998 study.[99] A US study by Franks and Clancy also found an overall rate of referral from family practitioners between 4.5% – 7% (variation depending on insurance scheme) of all visits.[100]

A systematic review of referral variation in the UK by O'Donnell [101], showed a large variation in rates of referral between different studies. Following standardisation, the rates varied from 15.4 per 1000 (1.5%) consultations and up to 191 per 1000 (19.1%) between different studies. While patient and clinician characteristics explain some of the difference in referral rate, after taking these into account, there was still a large level of variation that O'Donnell could not explain with the study data.

In a different publication Forrest et al also compare the annual rate of referral in the United States with that of the UK.[102] The authors compared the rate of referral in US health maintenance organisations that used a gatekeeping system with the rate of referral in the UK general practice database (the UK NHS utilises a gatekeeping system nationally). They found that 30.0% to 36.8% of patients were referred per a year from US organisations compared to 13.9% per year in the UK NHS. This was consistent even after stratifying by morbidity scores. The authors postulate that lower waiting times in the US play a large role in lowering the threshold for physicians to refer in comparison to the UK. Additionally the authors suggest a more 'intense' practice style in the US may also play a role in higher referral rates.

A recent 2015 Irish study also found large variation amongst Irish GPs (who are also gatekeepers to specialist healthcare), overall there was a mean referral rate per consultation of 11.7%, ranging by GP from 1% to 26%, similar to the range found in the above, earlier, systematic review by O'Donnell.[101,103]

In New Zealand, a study published in 1991 linked general practice data with hospital data finding a rate of referral of 0.27 per patient per year and consultation rate of 4.3 per person per year.[104] When calculated, this showed a rate of referral per consultation of 6.7%, again fitting within the range of rate of referral found in overseas studies.

An older 1990 study reviewed a 1% of New Zealand general practice appointments in a single city (Hamilton) during 1979.[105] They found a referral rate that varied similarly between practitioners in recent international studies, with an average referral rate of 7.7% of consultations, but ranging between 0% and 20.1%. After controlling for patient attributes, the statistically significant attributes that altered referral rate were 'low consultation fees' and 'non-urban practices' (odds ratio of 0.80 and 0.79 respectively). Older GPs (aged 50+) had 1.18 odds ratio for referral, and although not statistically significant, this suggested that, in New Zealand, practitioners who charge lower fees or work rurally are less likely to refer a patient and older practitioners are more likely to refer. In terms of patient characteristics, no results were statistically significant, however again odds ratios of 0.81 for patients in the 65+ age group and 0.78 for those of Māori ethnicity suggest that these groups may be referred less – perhaps suggesting a disparity between these groups.

Also in New Zealand, Nixon et al investigated the use of computerised tomography (CT) in the Otago Southland region, noting that when a new scanner was made available, referral for CT in that region increased by 119%, suggesting that availability of services may also be a factor behind variation in referral rates between regions and/or practices.[106]

1.9.2 Referral process in New Zealand

Access to specialist care in New Zealand is through a 'gatekeeper' system similar to the UK's NHS (rather than a generally open access system in the US), where a GP first assess patients and then determines if they require referral, and which specialty to refer to.[107] Gatekeeping is implemented to save costs, as primary care is considered a cheaper setting to provide care in than in hospital (partly because of the patient co-payment system in New Zealand general practice which does not apply to hospital care) and also to improve matching of patients to the correct speciality.[108-110]

However, the cost-benefit of a gatekeeper system is currently not scientifically established as in the long run gatekeeping may cause hospitals to become over specialised, according to Brekke et al.[109] These authors hypothesise that gatekeeping drives specialists away from generalist training and general skills, and instead focuses on specialization to increase differentiation between clinicians and between hospitals. This increases competition and profits, but may reduce the overall quality of healthcare provision in each hospital due to becoming less generalised and more inefficient in the long run.

Between 1996 and 2000, the New Zealand health system replaced the traditional waiting lists for referred care with a booking system that prioritises patients according to clinical priority

assessment criteria (or CPAC) scores to indicate greatest patient need and patients who can benefit most from referred care. CPAC criteria were determined by clinicians and health economists. The intention was to enable more efficient use of limited health resources and to enable those patients who were worse off to be treated first.[111,112]

1.9.3 New Zealand referral patterns

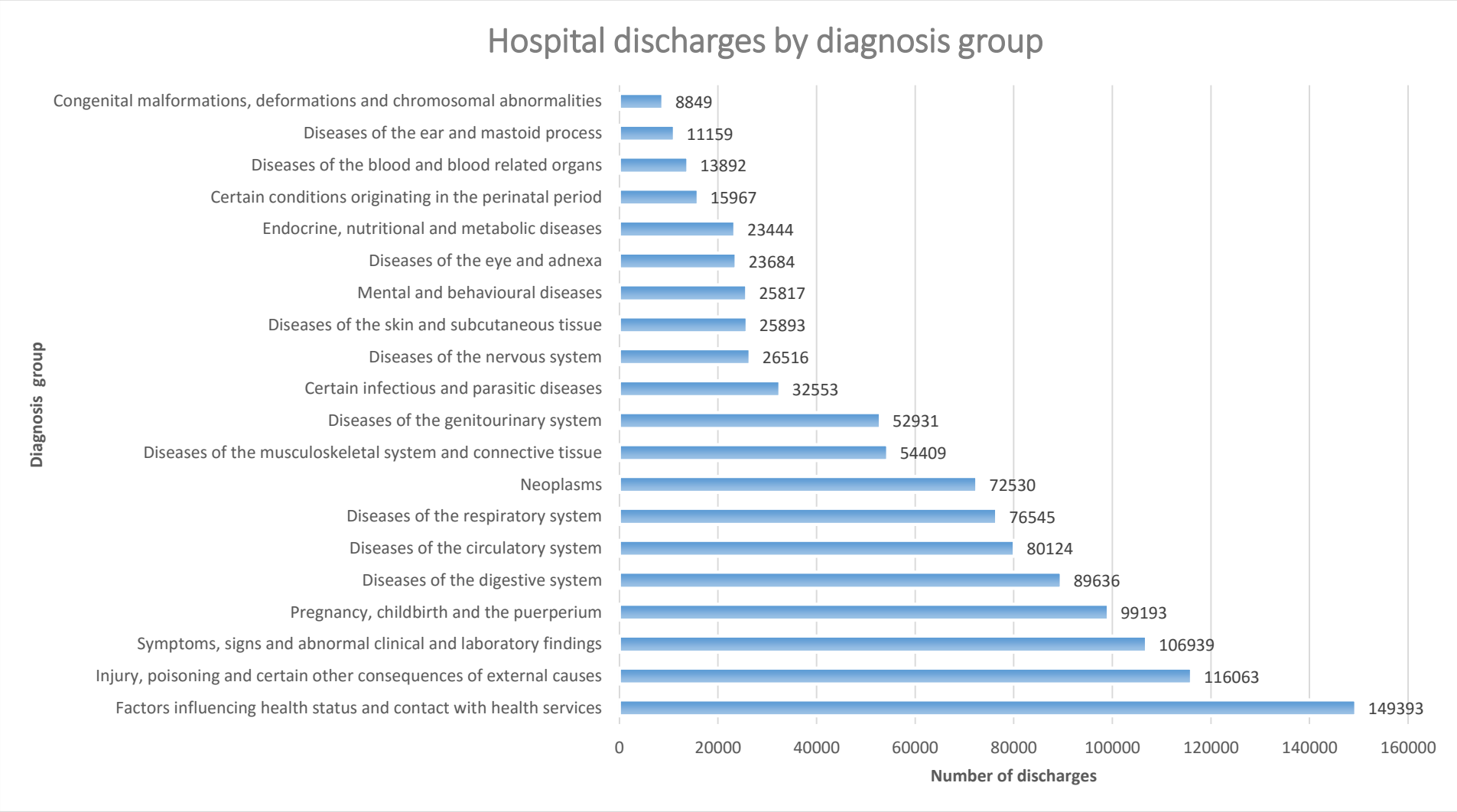
No recent data are available for number of referrals in New Zealand, however with 12.4 million GP visits annually, and an assumed rate of referral between 1% and 20%, it can be estimated that there would be between 124,000 to 248,000 referrals every year in New Zealand.[81] With regards to waiting times, the Ministry of Health as of January 2015 specifies a target waiting time of less than 4 months and although this is not always met, over the Jan 2015 to May 2015 period, between 95.2% and 100% of patients were seen within this target (the data is reported per month, stratified by DHB).[113]

Dovey et al surveyed 200 random New Zealand GPs about 33 conditions and how likely they would be to refer.[114] The authors found a high degree of consensus between practitioners amongst all 33 cases. Several conditions were reported as seldom or never needing referral including hypertension, hypothyroidism, rheumatoid arthritis not requiring second line therapy and obesity, highlighting that there were many conditions that GPs felt comfortable managing in primary care without referral. However there were several conditions where almost all (>82.9%) of GPs would always refer – post menopausal bleeding, rheumatoid arthritis requiring second line therapy, multiple sclerosis, insulin dependent diabetes and patients with altered bowl habit with rectal bleeding. The high degree of consensus amongst these conditions on either end of the referral spectrum show that for certain conditions, referral (or non-referral) in New Zealand is likely to be the same regardless of GP. However, the survey results indicated many 'sometimes refer' conditions; including mental confusion in the elderly, indigestion and dyspepsia, feeding problem in infancy, and problems in relationships: while the majority of GPs indicated 'sometimes' (i.e. still a high degree of consensus), this shows that many conditions depend on the presentation and interpretation by the GP – signalling possible reasons for very different rates of referral between GPs. This would fit with the international data which shows a wide variation in referral rates.

Additionally, as mentioned above, while Dovey et al looked at referral patterns for a series of conditions in 1993, and Davis reviewed data from 1979, no more recent data on overall referral patterns are available in New Zealand. However, public hospitalisation data is available for diagnosis upon discharge.[115] While this does not detail the numbers cared for by each specialty,

it does describe broadly the conditions New Zealanders are hospitalised for, and give an indication which services are in demand. Figure 2 displays the proportion a group of diagnoses of the total discharges over the 1st July 2012 to 30th June 2013. The largest category, “factors influencing health status and contact with health services” describes patients admitted for observation, or procedures. This includes new-born infants following delivery.

Figure 2 NZ public hospital discharges by diagnosis group. Adapted from Jun 2012 - Jul 2013 Ministry of Health discharge data.[111]

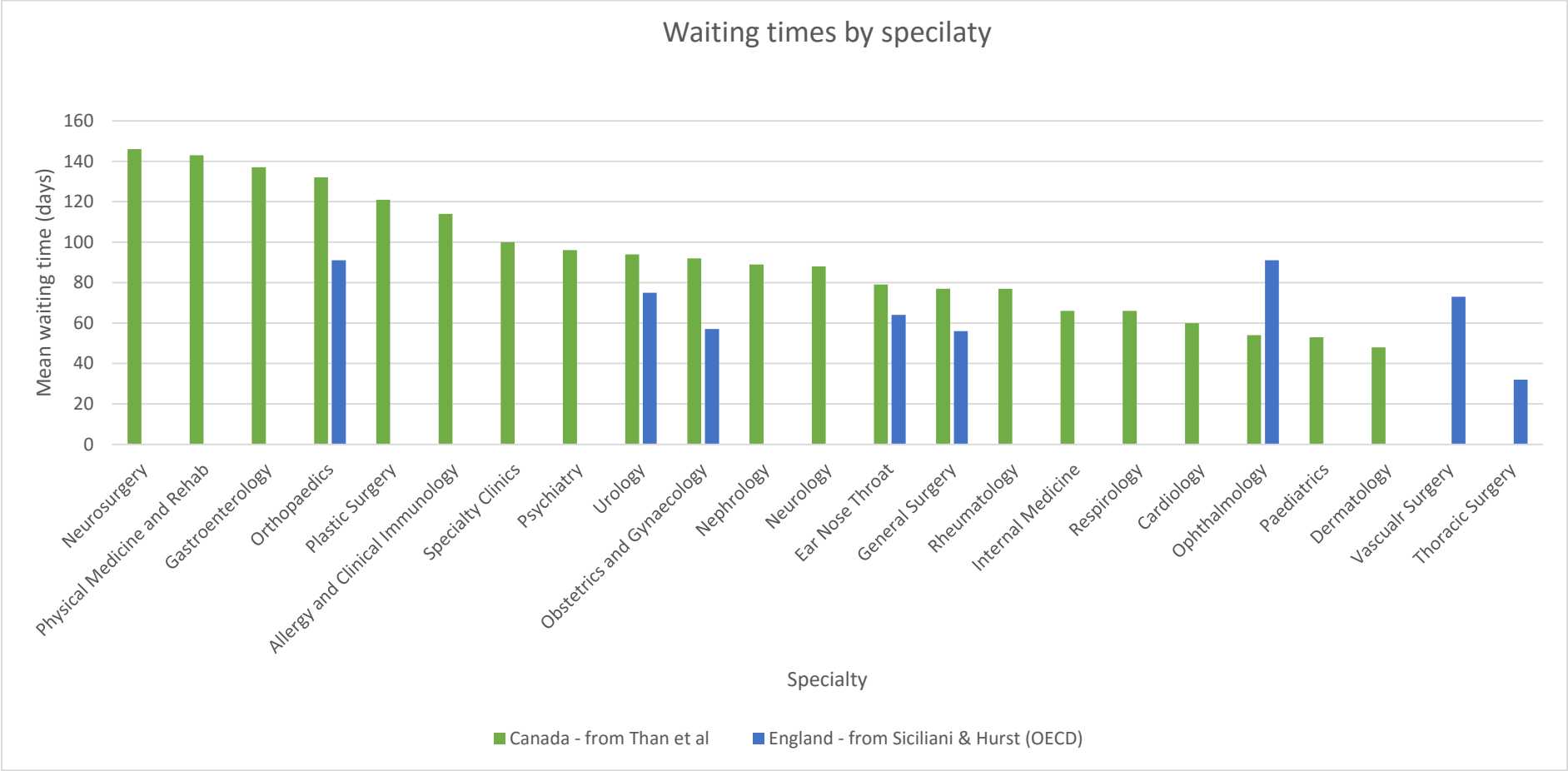


1.9.4 International and New Zealand waiting times

Several studies measuring waiting times have been conducted internationally. A 2013 Canadian study by Thanh et al examined waiting times (the time from referral by a family physician to an appointment date) by specialty over 2009, 2010 and 2011.[116] The authors examined 33,281 referrals from family physicians and found an average waiting time of 86 days, although the average waiting time decreased over each subsequent year of the study. The overall rate varied greatly by specialty. For example, ophthalmology had an average waiting time of 54 days and neurosurgery an average of 146 days. The most common demographic of referred patients was female and between 19-64 years. The mean overall waiting time by speciality is adapted in Figure 3, shown in green shaded bars.

Part of an OECD report in 2003 described outpatient waiting times (time between referral from a GP to a specialist appointment) for only elective surgery, excluding non-surgical referrals.[117] Data were available from England (2001), Denmark (2000) and Norway (2001) (the latter two were estimated). Only the data from England were analysed by speciality, and is adapted in Figure 2 shown in blue shaded bars.

Figure 3 Waiting times by Specialty - adapted from Than et al and Siciliani & Hurst.[116,117]



Kelly et al investigated patient satisfaction in outpatient facilities in the US. Although they were investigating wait times in waiting rooms (an average of 22 minutes for treatment appointments) rather than days between referral and receipt of care, the authors found that average patient satisfaction scores was influenced strongly by waiting times – from a total score of 90.6 for 0-5 minutes to 51.1 for more than 20 minutes.[118] While this is not directly applicable to waiting times for referral, it does give some evidence that patient are dissatisfied with longer waits, and that this may negatively affect their entire healthcare experience.

New Zealand data on waiting times, while recently collected by DHBs for the Ministry of Health, had not yet been collated and published at the time of writing this thesis. There are plans in the future for these data to be published as part of a new data collection the National Patient Flow, but it is not currently available for analysis.[119]

However, the New Zealand Ministry of Health does publish data on the regional DHBs' achievement of first specialist assessment targets. The Ministry defines an acceptable waiting time as less than 4 months. In their May 2015 publication all DHBs had <1% of patients waiting longer than four months.[113] No further details were available from the Ministry.

1.9.5 Media attention on referrals

While there is little published epidemiological data about harms during referral waiting periods, local and national media have published individual anecdotal accounts of patients suffering while waiting. New Zealand local newspapers have published articles about patients on 'waiting lists' and discussing their waiting time lengths – both in terms of number of patients and time spent waiting.[120-122]

Much attention has been made of surgical waiting lists. Numerous articles detail individual cases of patients who have been waiting a long time and personal stories of emotional and physical difficulties while waiting for surgery.[123-125] One recent article described the experience of a patient as he waited for a specialist appointment regarding bariatric surgery, including his difficulty with daily living (showering and mobilising) and anxiety about if he was to receive surgery in the future.[126]

From a healthcare provider perspective, a 2003 article in the NZ Doctor (a monthly publication for medical professionals in general practice) highlighted issues with GPs having to manage the care of patients who would not be seen by specialty services, as they did not meet criteria for appointments in the public hospital system.[127] Following referral from GPs, due to limited resources, hospitals re-referred these patients back to GPs to manage patients' symptoms, with

the advice to refer them to the hospital again if their condition was to worsen. The article highlights GPs' frustration and difficulty in having to manage symptoms for which there is a known treatment, but has been denied to patients by administrative funding decisions.

Media accounts of individuals suffering harm waiting, while not definitive, do suggest that there may be a wider problem in the healthcare system that requires further scientific study.

1.9.6 Potential of harms to arise from the referral process

The Institute of Medicine's follow up to *To Err is Human* was *Crossing the Quality Chasm*, which discusses methods to improve healthcare quality.[128] One of the six aims is related to timeliness of care. The authors suggest that long waiting times signal poor organisation and a lack of patient catered care.

New Zealand research by Derrett with patients waiting for prostectomy and hip joint replacement showed no relationship between CPAC scores and patient experience of need and symptoms.[129] Derrett interviewed 149 patients, finding that all had some symptoms – at least mild pain in the hip replacement group, and 'bother' (at least one urinary symptom) in the prostectomy group.

While Derrett focused on surgical waiting periods for two specific surgeries, and so the findings are not applicable to all patients waiting for referral or treatment, this study shows that while waiting, patients experience negative symptoms, (or harms) which may have been prevented by patients being treated earlier (i.e. a shorter waiting period).

1.9.7 Referrals and patient anxiety

A qualitative study by Preston et al in Leicester, UK interviewed 33 patients about their experience of the interface between primary and secondary care.[130] Participants were selected randomly from hospital discharges, outpatient appointment lists and from GP referrals – meaning not all participants had experience of referral waiting periods. When speaking of referral waiting, participants felt that referrals for chronic health problems or stigmatising conditions were often delayed, causing them to feel their problems were less legitimate or real. On the other hand, participants reportedly had more confidence with their referral if they had a good doctor-patient relationship with their GP. Participants often expressed intense relief at 'getting in' when their referral was accepted, and receiving an appointment, implying, that during the waiting period patients were under some level of emotional stress, although this was not specifically expanded upon by the authors.

The participants also described a common experience of 'limbo', which the authors described as a state in which patients feel as if they are not making any progress – including periods of indefinite waiting, uncertainty, and feelings of unimportance and insignificance. This occurred mostly as participants moved through the interface between primary care and hospital level care, or vice versa. Additionally, participants' experiences were worse when the waiting times were unknown or when the waiting time seemed disproportionate to the urgency of their problem.

While the sample by Preston et al was limited to 33 United Kingdom patients, their experiences show that there is some emotional harm related to referral that may be almost unavoidable. The similarity of the UK 'gatekeeper' system to New Zealand's system strongly suggests that the same might occur here.

1.10 Laboratory tests

Modern medicine is relying more and more on the use of laboratory investigations to aid, confirm and rule out diagnosis and monitor existing conditions. Laboratory tests include blood tests and microbiology services.[131]

Using the definition of referral as "a physician's decision to send the patient to see a specialist practitioner (physicians and non-physicians with specialised skills were included) for a face to face encounter", as used by Forrest et al above, laboratory tests may not always count as a traditional referral. On the other hand, GPs are requesting an investigatory service with possibly additional opinion or interpretation of the results, and there is a waiting time where harm could foreseeably occur (a 'referral waiting gap'). In this study the candidate considered laboratory requests as a potentially different type of referral, and within the scope of 'harms in the waiting gap'. This section gives a brief overview of laboratory services and related harm.

1.10.1 Rate of Laboratory tests

A collaborative European study selected 340 GPs from several European countries (Belgium, Ireland, Italy, the Netherlands, Portugal, Spain, Switzerland and the United Kingdom).[132] Over the study period, there were 156,021 patient contacts resulting in 37,772 blood tests, (i.e. 24.2% of consultations involved a blood test). Overall 7.7% of patients had one or more blood tests over the observation period, although this varied greatly by country, from 5.1% in the UK to 13.1% in Switzerland. Females aged 25-64 years had the most blood tests (except in Switzerland where Females 65-74 had more), and the least blood tests were for males aged 0-4 years. The analysis of several factors explained 49% of the variation between practitioners, of those, the

largest contributor was the country of practice, although 15% of variation was due to practice characteristics including distance to hospitals. These results suggest that to a degree laboratory testing is culturally determined and also that that GPs are less likely to order a blood test if it is less convenient for the patient (further away from the practice). The large variation between GPs even after standardisation also suggests that some GPs are overusing blood tests (assuming that those using less tests are still practising safely).

Labtest New Zealand, which supplies Auckland with laboratory services states on their website that they perform over 200,000 tests per a week for the Auckland population of approximately 1.4 million people.[133,134] Unfortunately, this statistic includes hospital tests, and no information on tests in New Zealand general practices was found by the candidate.

1.10.2 Harms related to blood tests

It is a recently recognised aspect of patient safety that the overuse of investigatory and diagnostic laboratory procedures can be harmful to patients. Several studies have shown harm related to investigations. Specifically in primary care, the lack of follow up for investigations, as well as the lack of informing patients of blood test results, both result in harm.[135-138] Additionally there is the potential for physical harm from the procedure itself, including nerve injury, infection, haematoma and needle-stick injuries to healthcare workers.[139-141]

A review by Callen et al of studies on failure to follow up test results showed a large variation, from 6.8% of tests, where computerised pop-ups were used, to 62% in a different practice without computerised records.[142] Additionally the impact to patients reported in some studies in the review included missed cancer diagnoses, hospital visits for raised blood potassium, and under-supplementation of thyroid hormone resulting in adverse drug events. Additionally, in one study, diabetics whose results were checked were more likely to receive follow-up appointments than those whose tests were not.[143]

Hickner et al collected reports from primary care professionals of errors related to testing process (including lab tests, diagnostic imaging and other tests).[144] Over 32 weeks 661 events were reported by 243 participants. This varied by practice from 25.87 to 1.5 reports per participant per practice. Of the patients involved, 64% were female, and 70% were aged 18-64 years, similar to the demographics of patients having blood tests, as above.[132] The major types of errors were 'reporting to clinicians' (24.6%), implementing tests (17.9%), availability of results (17.6%) and test ordering (12.9%). Errors related to responding to tests made up 7% of reports. Patient harm was reported in 18% of all reports, and of these, temporary physical harm occurred in 69 cases (11% of total reports), and emotional harm in 33 (6%). Permanent harm

was reported in 3 cases (0.5%) and there was 1 case of temporary harm that required hospitalisation. The research showed the types of harm that result from investigation and the management thereof, and that some of these are 'serious'.

The increased amount of information offered to GPs without systems to manage and distribute this information is leading to what has been described by Beasley et al as 'information chaos' due to both too much information (overload) and missing important information (under-load).[145] The authors describe how this leads to difficulty in making decisions, and increased risk for decision errors, which (as described in section 1.3) could result in patient harm.

Elder, in a recent editorial, highlighted the fact that laboratory tests are still a problematic area in primary care safety and a risk to patients.[146] However Elder states that advances in information technology which involve patients with their laboratory results hold promise in making the process safer and more beneficial for patients.

1.11 Summary of the literature review

Harms related to referral, both to specialties and to laboratories is an under-researched field. What research there is shows the importance of referral (section 1.9) but also varied rate of referral between practitioners (sections 1.9.1 and 1.10.1). Waiting times for referral are also highly variable, and likely to vary between the health systems of different countries (section 1.9.4). Additionally, the referral process also generates a level of patient anxiety, (section 1.9.7) and during the referral process there is an opportunity for harm (section 1.9.6). How much harm however, especially in New Zealand, is currently unknown.

1.12 Aims generated from the literature review

Following a review of the literature, a gap in current harms research emerged regarding harms to patients while waiting for hospital specialist cares and investigations. While waiting time variability as well as potential for harm was identified in the literature, no study found by the candidate during the literature review identifies nor details harms during the referral waiting period.

The aim of this study is to address this gap in the literature by investigating patient's waiting periods between referral from their General Practitioner (GP) and receiving specialist healthcare or investigation responses. This study's objectives are to determine if patients in the study sample come to any harm in this waiting gap, and if so, the rate of this harm, which patients are harmed, what types of harm happen and if these harms are preventable. As this is

the first known study of harms during referral waiting gaps, this study aims to be a preliminary investigation of this topic for future research.

2 Methods

2.1 Data collection

2.1.1 Extraction for the HRC Safety in general practices feasibility study

In 2006, 36 practices from an existing research network were recruited into a feasibility study designed to establish the design of a full study of the epidemiology of harm in general practice (see Appendix B). These practices provided all their patient notes to analyse. The notes covered a period from 2003 to 2007. Notes from a random selection of 2400 patients were extracted into a database file. The patient names and other identifiers such as NHI codes were not extracted into the database file in order to anonymise the data. For study purposes each patient file was assigned a number beginning from 1, up to the last patient (2400). Additionally, each practice and each provider (GPs and nurses) were assigned a unique identifying number also used in the database.

The data extracted included: the sex of the patient, the date of each entry, the date each component of the health record was made, the type of entry (see below), and the data from this entry. A description of the data extracted is provided in Table 4.

While these data were subsequently used in the feasibility study, the data used for the current project were in the unaltered and preserved file produced by the extraction process. However the original database of patient records was unavailable for confidentiality reasons, so repeat extraction or confirmation of data (e.g. clinic letters) was not possible.

Additional information such as clinic letters from outpatient appointments and non-text investigation results (imaging, ECG etc.) were not included in the extracted data, due to an inability to anonymise this information. However, this information was often included in a consultation note by the practitioner.

In the event of uncertainty over the referral dates, this was marked in the data table (See Section 2.3 and Appendix B).

2.2 Sample selection

As the patient numbers assigned to the notes were already randomly assigned, the sample was selected in ascending numerical order; from 1 to 100. This was not strictly random in this study, however as the patients were randomly ordered in the original database, this was deemed appropriate. Additionally, a randomly selected set of notes (patient number 2016) was randomly selected to test the coding system initially, and remained in the study.

A sample size was not established in advance, as the expected level of harm was unknown as well as the expected level of referral was also unknown. It was decided that the as many records as possible would be analysed within the limitations of the project timeframe. A number of 101 notes was selected, and following preliminary analysis of the results, the study group size was expanded to 201. This was due to the high number of investigation data in the first selection of notes, and the time consuming nature of recording the data. In order to collect more non-investigation referral data in the study timeframe, the second study group did not have investigation data collected by the candidate, although it was present in extracted record.

This is shown in Figure 4.

Table 4 Description of Data fields

Type of data	Data included in this field
Consultation	The electronic notes written by the practitioner.[a]
Read code	Any diagnoses 'coded' to this patient – Read codes for current diagnoses.
Measurement/Screening	Electronic entry for patient characteristic to be tracked by the provider – including weight, blood pressure etc. Can also include measurements/ investigations taken at the practice (including urine dipstick).
Vaccination	Record of vaccination by practitioner.
Hospital admission	The automatic discharge summary of the patient. Dates of admission and dates of discharge, diagnoses and procedures carried out during admission are included in these entries.
Lab test	Includes all investigations, blood tests, microbiology, radiology and other. Dates on these entries were usually from when the lab received the test request. However some notes contained additional entries when results were reported.
Prescription	Electronic prescriptions made by the practitioner.

[a] Due to the data extraction process, these entries were unintentionally truncated at 256 characters.

2.3 Analysing the notes

Each set of patient notes was read in order of patient ID – this was randomly assigned during the extraction process. The notes themselves were read in a chronological order, with reading the consultation note first to give context to other entries occurring on the same and following date.

Each consultation note was examined for evidence of referral following a presentation; often written as “refer to”, or “plan: ref to” or “to see” or “letter to” as well as others. When a referral was found in the notes, the date (or approximate date if this was uncertain) was recorded. The service referred to was also recorded. In addition other details unique to the referral were entered into a freeform ‘notes’ field, in order to give context to the referral for review of the data at a later period.

Referrals services were classified by the following categories of speciality services, modified from a recent Canadian referral study by Thanh et al.[116] Radiology was added as a category, as in New Zealand, a radiology referral is required for some imaging studies. “Specialty clinics” was removed from Thanh’s list as a category, due to it being inapplicable as a category for this study in New Zealand. The final modified specialty list is presented in Table 5.

Following a consultation which resulted in a referral, all entries present in the notes following the referral date and up to the conclusion of the referral (i.e. the patient being seen by the referred service) were read, and checked to see if they contained any indication of harm. This involved closely reading each consultation entry and identifying any evidence of harm. Harm was defined as “including disease, injury, suffering, disability and death” as described in section 1.4.3 and Figure 1. The result (harm present or not) was then recorded in a new data table constructed for the current research. An excerpt of this data table is available in Appendix B.

Reading the consultation records was often difficult, with notes often using idiosyncratic shorthand to the particular practitioner. In addition truncation of the notes at 256 characters may have excluded important information at the end (including referral plans). In the event of truncations, and a following entry about a referral result, the context of the consultation would often allow the researcher to determine that the referral would have occurred during the truncated entry in hindsight.

Figure 4 Flowchart showing study group and data selection

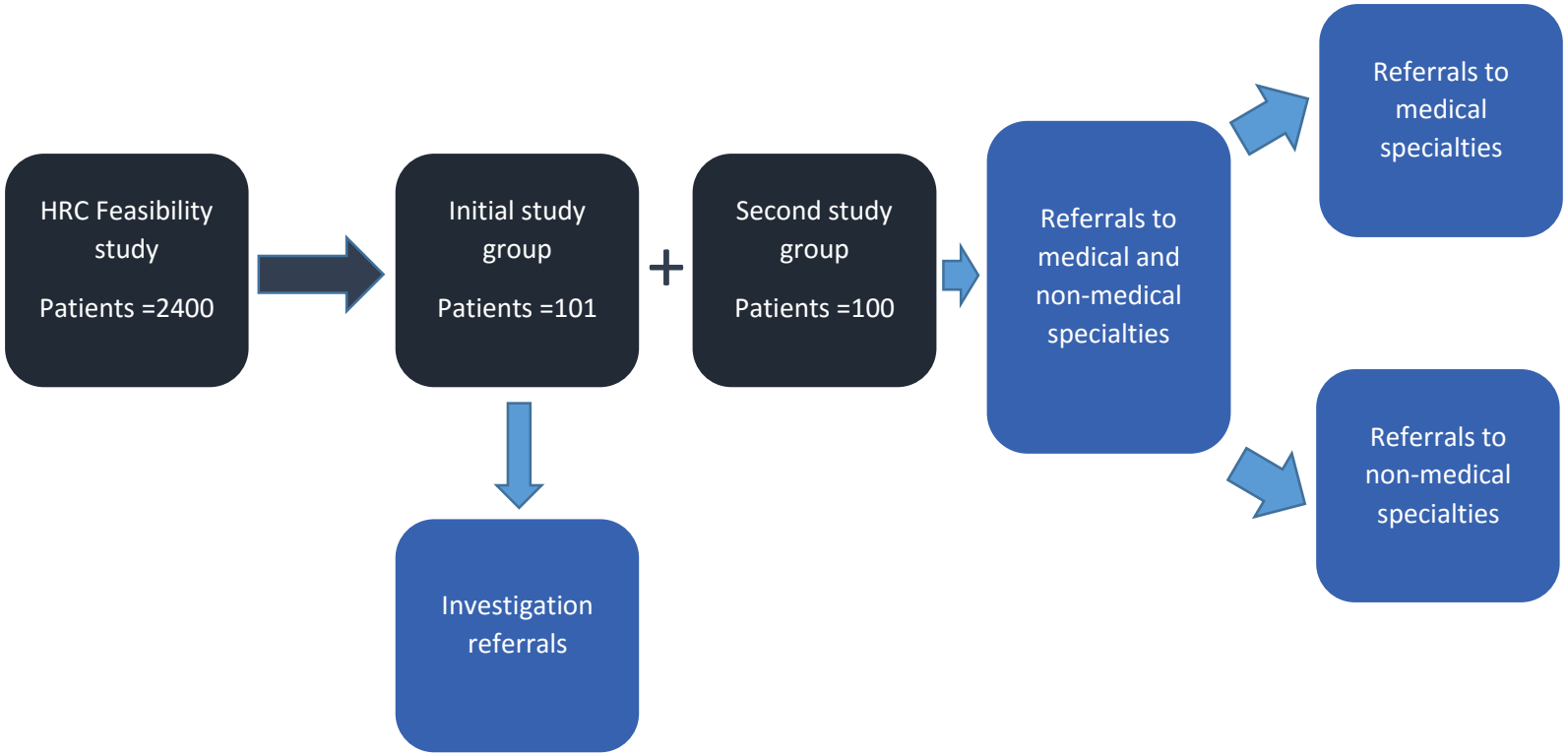


Table 5 List of Specialty services

Specialty
Allergy and Clinical Immunology
Cardiology
Dermatology
Gastroenterology
General Surgery
Internal Medicine
Neurosurgery
Neurology
Nephrology
Obstetrics and Gynaecology
Ophthalmology
Orthopaedics
Ear Nose Throat / ENT
Paediatrics
Physical Medicine and Rehab
Plastics
Psychiatry / Psychological services
Radiology
Respiratory
Rheumatology
Urology
Vascular
Other Specialties

2.3.1 Classifying Harms

When a harm was found, the following data were recorded in the data table. The severity of the harm (mild, moderate, or severe) and the type of harm. Notes about each episode of harm were also written in the freeform field.

Severity was defined as in Table 6.

Table 6 Definition of severity classification

Severity	Definition
Mild	Causing temporary loss, disability or suffering that resulted in little to no impairment.
Moderate	Causing temporary or permanent loss, disability and/or suffering that resulted in some loss of function and/or impairing daily activities to some degree.
Severe	Causing temporary or permanent loss, disability or suffering that resulted in significant loss of function, and/or preventing daily activities completely, or death.

These definitions were developed for this study, modelled on the definitions of harm, loss, suffering and disability proposed by Runciman as well as severity definitions used by the ACC.[32,69] These definitions do have a level of overlap between mild to moderate and moderate to severe, and so a case may fall into either category due to the lack of specifics in the definition. Where overlap occurred the candidate chose the higher of the two overlapping severity codes as a rule, so not to underestimate and minimise harms.

Harms were described and coded using a modified newly developed coding system developed by Dovey and Leitch for the currently in progress 'Patient harms in New Zealand general practices: Records review study'. As all harms were related to referral, only the cause of harm coding axis and the subjective patient experience sections was applicable to this study. The coding system is reproduced in Appendix B.

Following final coding of all harms it was found that there was a large range of codes used. Therefore, harms were additionally coded into several broad categories for ease of analysis. These broad codes were developed uniquely for this study following initial data collection. This was done by grouping initial codes (as above) and their sub codes and grouping other harms by analysing the free form note fields written during data collection (see excerpt of data table in Appendix 2). Note that an individual harm related to referral could be classified with multiple codes, and placed in more than one broad category. These broad categories are defined in Table 7 below.

Table 7 Definitions of broad harm categories

Broad Category of harm	Definition
Continued symptoms	The symptoms with which the patient presented with continued throughout or at some point during the referral waiting period, requiring a visit to the GP and/or continued treatment.
Delay in subsequent management	Management or treatment was delayed due to waiting for referral (i.e. due to waiting, the patient did not have the appropriate next step in management).
Deterioration of condition	Additional development of worse or subsequent symptoms or increased impairment or increased suffering.
Financial cost to patient	Any event documented in the notes related to waiting that cost the patient in time or money or both.
Anxiety/Mental harm	Any mental stress or harm that arose from waiting or as a result of the patient's condition during the waiting gap.
Other	Any other harms that did not fit into the above categories (these were recorded as freeform fields, and are presented in the results section).

While these above definitions are broad, the harm must have been recorded in the consultation notes in order to be classified as such.

Additionally, for unclear episodes of harm this was recorded as 'query harm' (a '?' in the table). These uncertain harms were reviewed with the project supervisor (Professor Susan Dovey) to determine if they were a harm and if so, what severity. Following this these entries were entered into the data table as normal 'certain' entries with a severity assessment as shown in table 3

2.4 Data collection for blood tests and other laboratory investigations

Data about blood tests and other laboratory investigations were collected for the first 101 patients. These were classified as shown in Table 8, using a simplified grouping of tests for ease of analysis.

Table 8 Definition of Investigation types

Investigation classification	Description
Blood test	All tests ordered involving the collection of patient's blood by either a separate laboratory service or blood collected at the general practice e.g. 'Full blood count', drug levels, 'renal function' etc. and more specialised tests e.g. Protein electrophoresis genetic test panels etc.
Microbiology	All tests sent for organism culture and/or antibiotic sensitivity testing. Includes blood, swab, sputum, skin, faeces etc. Excludes urine microbiology
Urine microbiology	All urine specimens sent for organism culture, and or antibiotic sensitivity
Urine biochemistry	All urine specimens sent for electrolyte analysis
X-ray	All types of x-ray imaging ordered, either through hospital or private service. (excludes CT, MRI or other radiology)
Ultrasound	All types of ultrasound imaging ordered, either through hospital or private service.

The simplification of the above classification was also due to the low numbers of more specific groupings; for example there were only two examples of genetic testing found, and so genetic testing was included in 'blood tests'.

Blood tests were not classified further by what parameters were being tested (e.g. full blood count, creatinine, electrolytes, CRP etc.) as it was difficult to know which were 'routine' tests

from the practitioner, and what was a test for a specific complaint/symptom. However as the majority of blood tests take approximately the same amount of time to process (in days), this grouping was deemed acceptable. Also, analysing wait time and harm by type of blood request was beyond the scope and resources of this study.

Urine microbiology was recorded separately from other microbiology, as it was much more common. Separating out other microbiology would allow waiting times and harms from theses less common microbiology test to be analysed without them being lost amongst the large number of urine microbiology tests.

As x-ray and ultrasound could be requested without radiology referral, these were categorised separately from radiology requests. They were also categorised as investigations and not as referrals. As they are different tests, often from different providers and different wait times, they were grouped separately from each other as well.

2.4.1 Waiting times for investigations

The data extracted only included the period in-between the practitioner requesting the test and the patient presenting for the test. The results were then backdated in the electronic system to the date when the patient presented for the test to the laboratory, and thus the time taken to do the laboratory testing itself was not included in the data collection. However, notes following each blood test were and these periods following the blood test were analysed to see if any harms occurred during this period, and recorded in the data table, using the same criteria as harm during waiting periods, described above in section 2.3.

Lab results were automatically entered in the original electronic notes, with the date corresponding to the date that the lab received the request - i.e. when the lab received the sample from the patient. Data for processing times for most lab results were not available. However for some (e.g. cervical smears) waiting periods for reports were available and were recorded. In addition, periods between the lab sending the results and the practitioner reviewing the results were not available.

Blood test data were only recorded if the referring practitioner was the GP or another clinician in the practice (i.e. blood tests ordered from outside the practice were not recorded). This was due to lack of notes about blood tests ordered by other specialists from outside of the practice, as reasons for request with resulting interpretation and treatment were not available, thus making waiting periods and presence of harm indeterminable.

2.5 Preventability

An aim of this project was to investigate if the harms found were preventable by being seen earlier. If a harm was present in a referral waiting period, the notes following the patient receiving specialist care were examined to determine the outcome of referral (what care was recommended and/or preformed). The outcome was considered alongside the harm, and a judgement on preventability was made by the candidate. This was recorded as either preventable (yes), non-preventable (no) or undeterminable (marked as "?"). However a large portion of harms were marked as undeterminable due to lack of detail in the notes of what treatment was initiated by specialists. This may have been due to the lack of information in the notes or the lack of clinical expertise of the candidate. Therefore, a judgement on preventability was found not to be reliable. This aspect of the study was not further analysed and is not presented in the results section. For illustration of this, the percentages (marked as "yes", "no" or "?") are presented in Table 9 below.

Table 9 Frequency and percentage of preventability of harms

Preventability	Frequency	Percentage of total harms (%)
Undeterminable "?"	23	39.7
Yes	21	36.2
No	14	24.1
Total	58	100.0

2.6 Statistical analysis

IBM SPSS 22 was the electronic statistics package used for all data analysis.

The data were analysed in two stages. The initial stage was analysis per patient; gender and age distribution were obtained along with mean and median age. Additionally the patients who experienced harm were compared to patients who did not. Pearson Chi-square tests were performed to see if gender differed significantly between the two groups. ANOVA (one way analysis of variance) tests were performed for continuous variables -age and number of referrals per patient- to compare the groups. All comparisons were made separately for investigations and all referrals. Referrals to medical specialties and referrals to other specialties were combined for this analysis.

The second stage was the analysis of individual referrals. The mean patient age at referral, the median waiting time[a] at referral were calculated, in total and also by the three types of referral (investigation, referrals to medical specialties and referrals to other specialties). Referrals that resulted in harms were compared to those that did not, with ANOVA tests for age and waiting time. This was done separately for all three types of referral. The specialty that each referral was made to was analysed as was the mean waiting times for each specialty.

The referrals resulting in harm were further analysed to provide proportion of the broad categories of which the harms were classified as, as well as the proportion of the severity of harms.

[a] Median was chosen instead of mean due to the skewed distribution of waiting times.

3 Results

3.1 Patient characteristics

Five years of complete general practice records for 201 patient notes containing a total of 5006 entries marked as 'consultation notes' were completely analysed. There was a mean number of 113.7 'consultation notes' per patient record (standard deviation of 135.4).

The demographics of these patients are explored below, and compared to national demographic data adapted from the 2006 NZ census, in order to gauge the generalisability of this study. The 2006 census data was used in preference to the 2013 census, as the notes from this study came from 2004 to 2007 - therefore the 2006 census is more applicable.

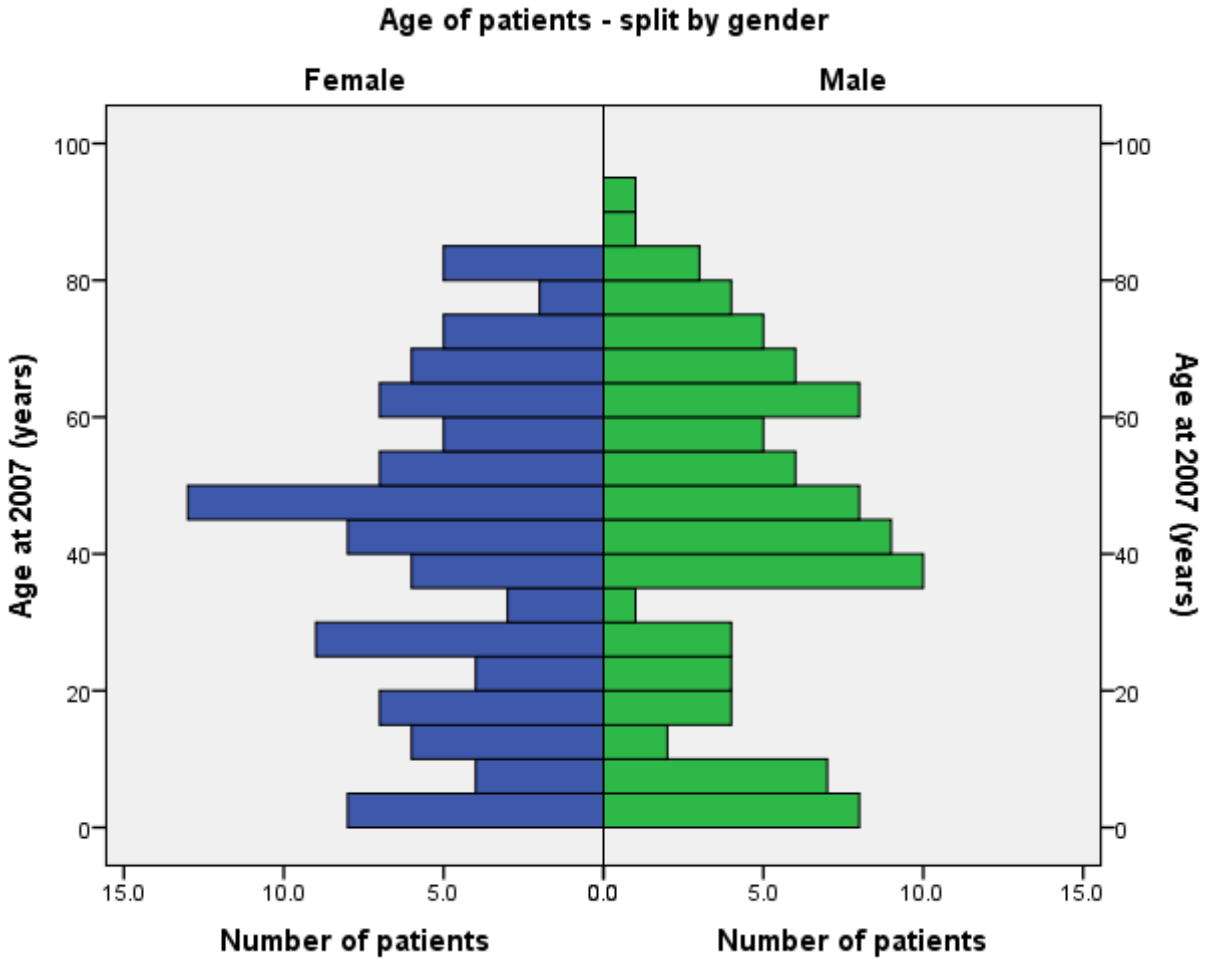
Of the 201 patients, 105 were female (52.2%) and 96 male (47.7%). Figure 5 shows the age and sex profile of the study patients. The median age of all patients was 44 years and the median for males was 44 years and for females was 42. Table 10 shows how the age and sex of the study group compares with 2006 census data. The similarity between percentages of females and males in the study group and the New Zealand census indicates that neither males nor females are over represented in the study group.[147]

Table 10 Demographics of study sample compared to New Zealand 2006 census data.[147]

	2006 Census data[147] (n=4027947)	Study sample (n = 201)
Total median age (years)	35.9	44.0
Female median age (years)	36.7	42.0
Male median age (years)	35.1	44.0
Proportion of females (%)	51.2	52.2
Proportion of males (%)	48.8	47.7

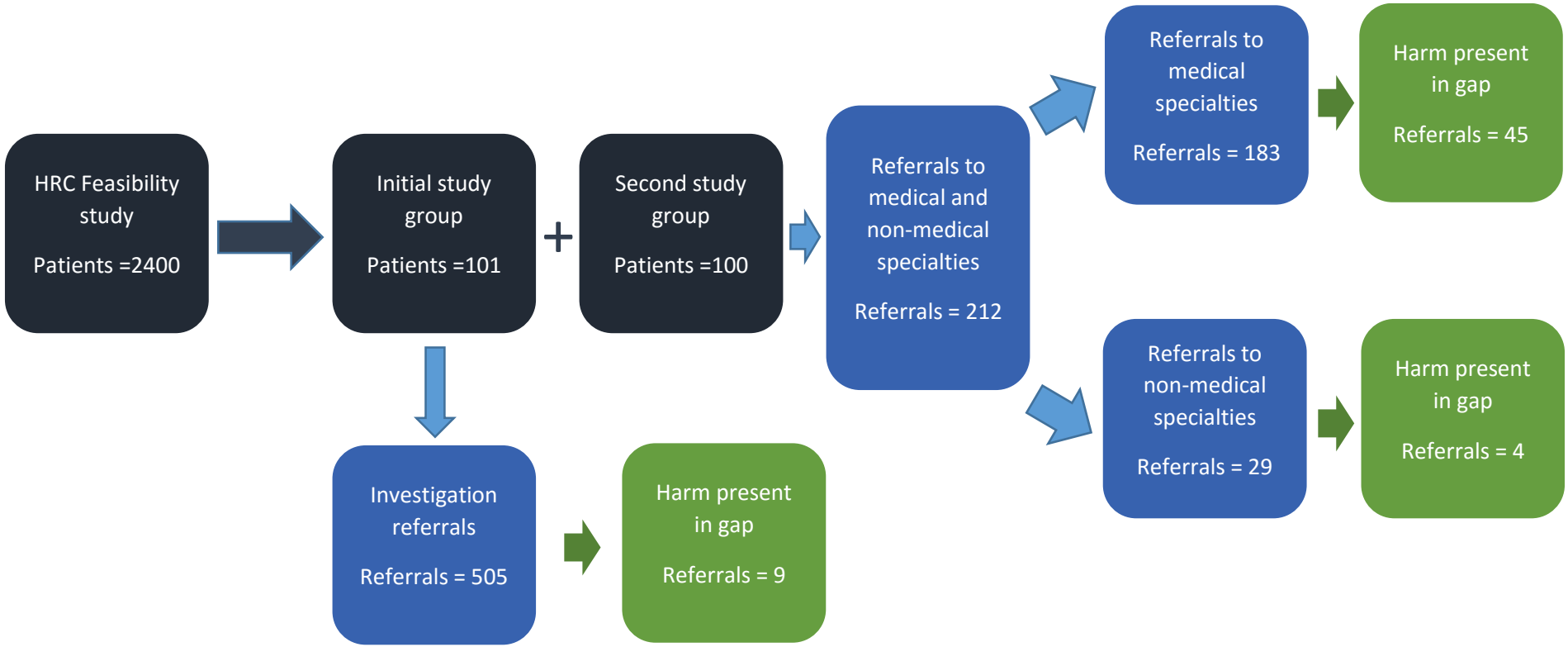
The census found an overall median age of 33.0 years and that females made up 51.2% of the total New Zealand population. The census also found a median age of 36.7 years for females and 35.1 years for males. The mean age for the study group was 41.3 years, (95% confidence interval (CI) of 38.02 to 44.6 years) and the mean age of the New Zealand census population in 2006 was 36.3 years, which lies outside the 95% CI of the study group's ages. This suggests that the study group is older than the New Zealand population. The distribution of ages in the study group is shown in Figure 5 below, separated by sex.

Figure 5 Age and sex distribution of study sample



The outline of the data collection is shown in the flowchart Figure 6 below (from Chapter 2, with additional results added)

Figure 6 Flowchart showing study group and data selection – with results added



3.2 Patients who experienced harm

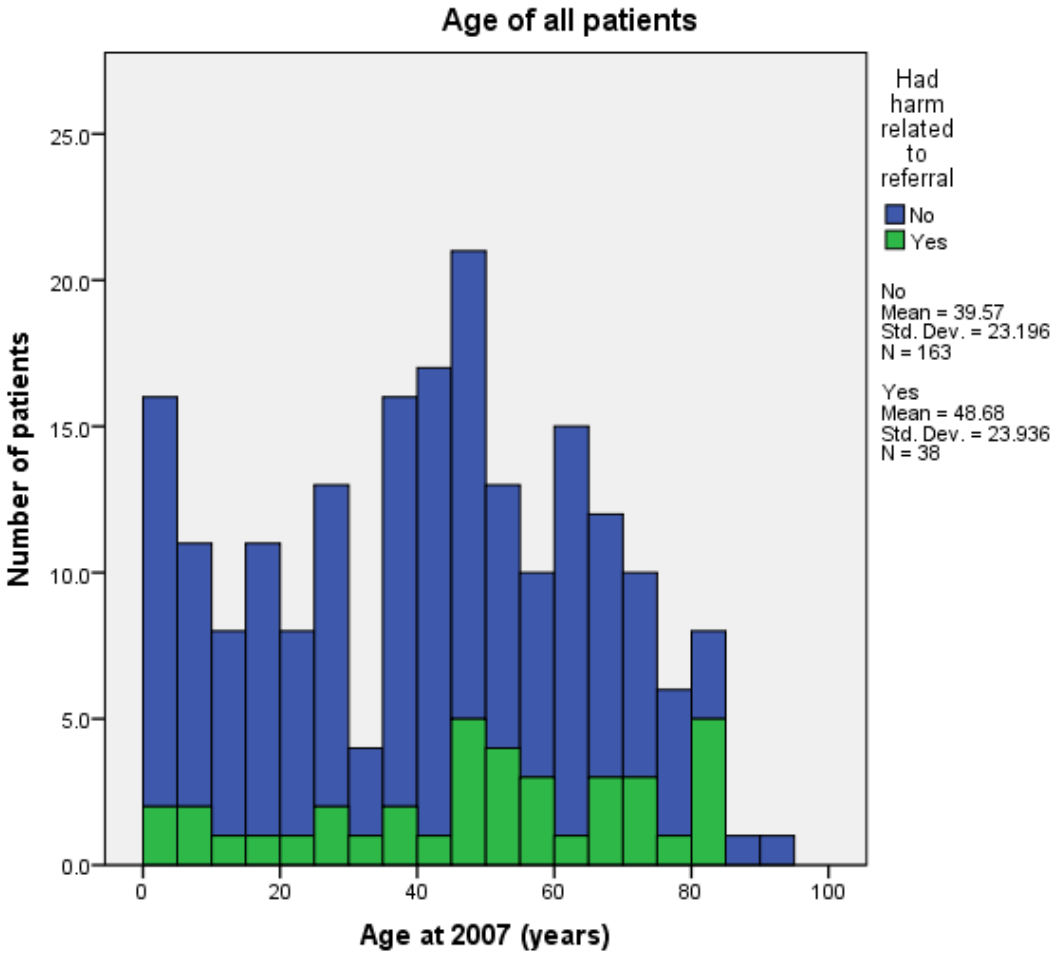
Of all 201 patients, 38 (18.9%) experienced one or more harm related to referral while 163 (81.1%) did not. The characteristics of these two groups are shown in Table 11 below and the age distributions are shown in Figure 7. The Pearson Chi-Square test for difference between the two patient groups[a] in the proportion of each group who were male and female was 0.601, (p-value = 0.438). This result suggests that sex has no significant relationship with likelihood of harm in the gap between referral and receiving referred services. The details for the Chi-Square test are provided in Appendix C.

Table 11 Demographics of patients who did and did not experience harm related to referral (to medical or other speciality)

	Experienced harm (n=38)	Did not experience harm (n=163)	Total (n=201)
Mean age (years)	48.7	39.6	41.3
Median age (years)	51.5	42.0	44.0
Range (years)	78 (4-82)	92 (0-92)	92 (0-92)
Proportion female (%)	57.9	50.9	52.2
Mean number of referrals per patient	3.0	0.6	1.1

[a] Patients who experienced harm verses those who did not

Figure 7 Patient ages at 2007 (bars are proportionally shaded to show those who incurred harm)

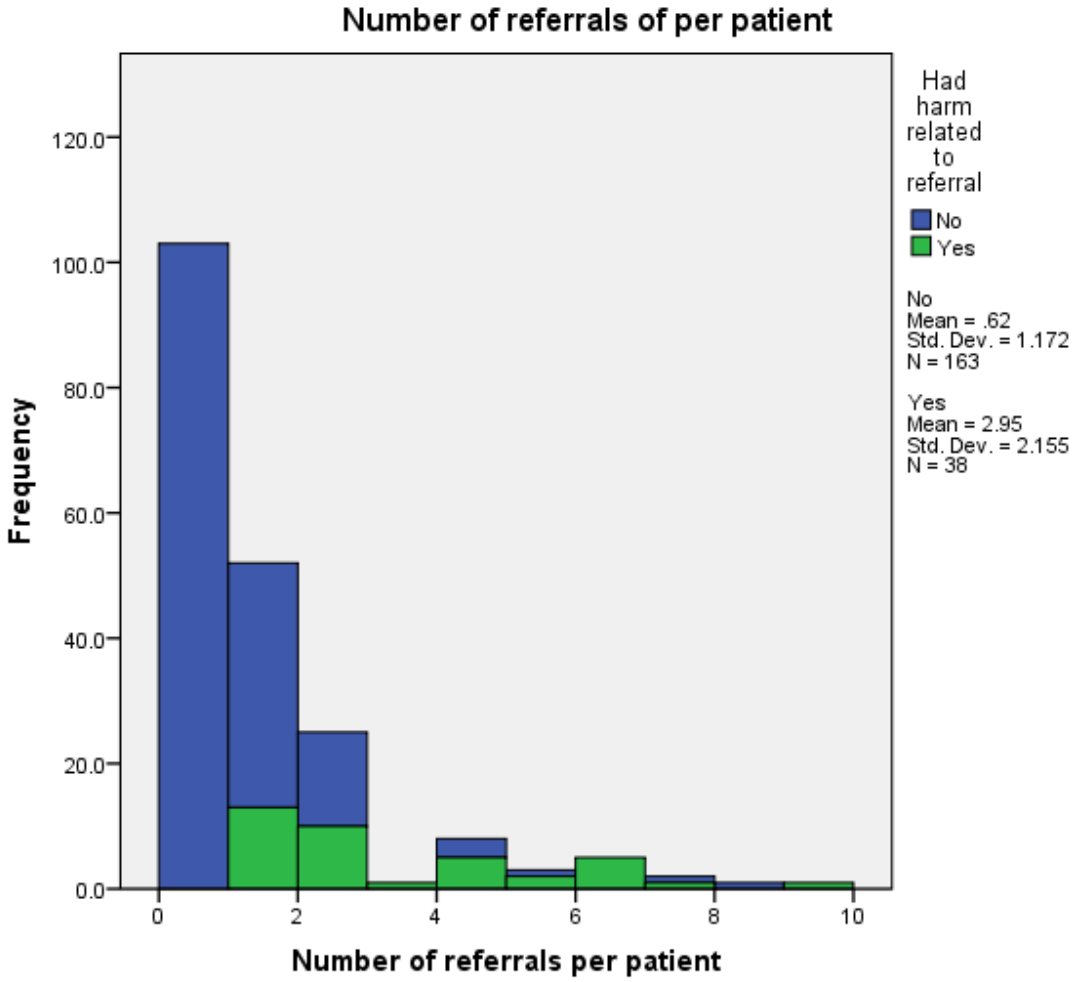


An ANOVA test of the difference between the two study groups in age shows significance between age and harm related to referral (p = 0.031). This result indicates that age has a significant relationship with likelihood of harm in the gap between referral and receiving referred services. However the Eta Squared value of 0.023 indicated that the effect size was small. The ANOVA table is available in Appendix C.

The mean number of referrals per patient was 1.1 over the five year period that the notes cover (a rate of 0.2 referrals per patient per year or 1 referral per year for every 5 patients). The mean number of referrals (excluding investigations) for those who did not experience harm was 0.6 per patient, compared to 3.0 referrals per patient for those who did experience harm. When removing those who did not have any referrals (for whom it would not be possible to have harm related to referral) the mean is 1.7 for those with no harm.

The distribution of number of referrals is shown in Figure 8.

Figure 8 Referrals per patient – excluding investigations (bars are proportionally shaded to show those who incurred harm)



An ANOVA test of the difference between the two study groups[a] in number of referrals shows a significant difference (p-value = 0.01). The Eta squared value of 0.115 indicated that the effect size was small to medium. The ANOVA table is available in Appendix C.

3.2.1 Patients who experienced harm related to investigations

Similar results were obtained for patients who experienced harm related to referral for investigation; however, this is only for the first 101 patients for whom investigation data were recorded (this information was not collected for the next set of patients [101-201] and were not analysed). Overall 8 patients had harm related to investigation (7.9%) and 93 did not (92.1%). The characteristics of these groups are shown in Table 12. Figure 9 shows the age distribution

[a] Patients who experienced harm verses those who did not, while excluding patients who have had no referrals

of the investigation group (n = 101), and demonstrates that all patents experiencing harm while waiting for referral for investigations were aged >40 years.

Table 12 Demographics of patients who did and did not experience harm related to referral for investigations

	Experienced harm (n=8)	Did not experience harm (n=93)	Total (n=101)
Mean age (years)	62.8	39.57	41.29
Median age (years)	65.0	42.0	44.0
Proportion female (%)	62.5	50.5	51.5
Mean number of investigations per patient	17.6	3.9	5.0

The mean number of investigations for those who experienced harm was 17.6 compared to 3.9 for patients who did not experience harm. Figure 10 shows the distribution of number of investigation referrals ordered.

Figure 9 Age distribution of patients with investigation data recorded (bars are shaded to show patients experiencing harm)

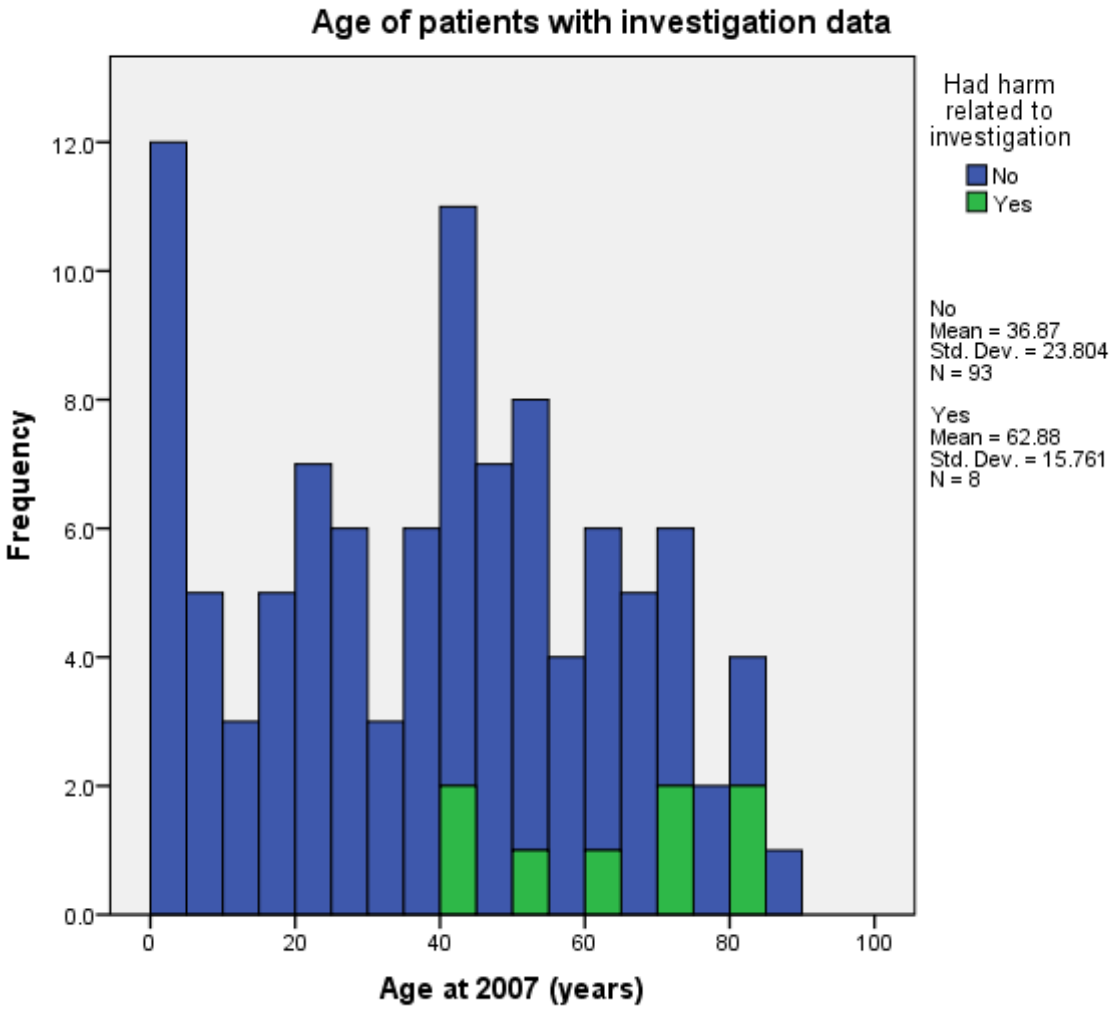
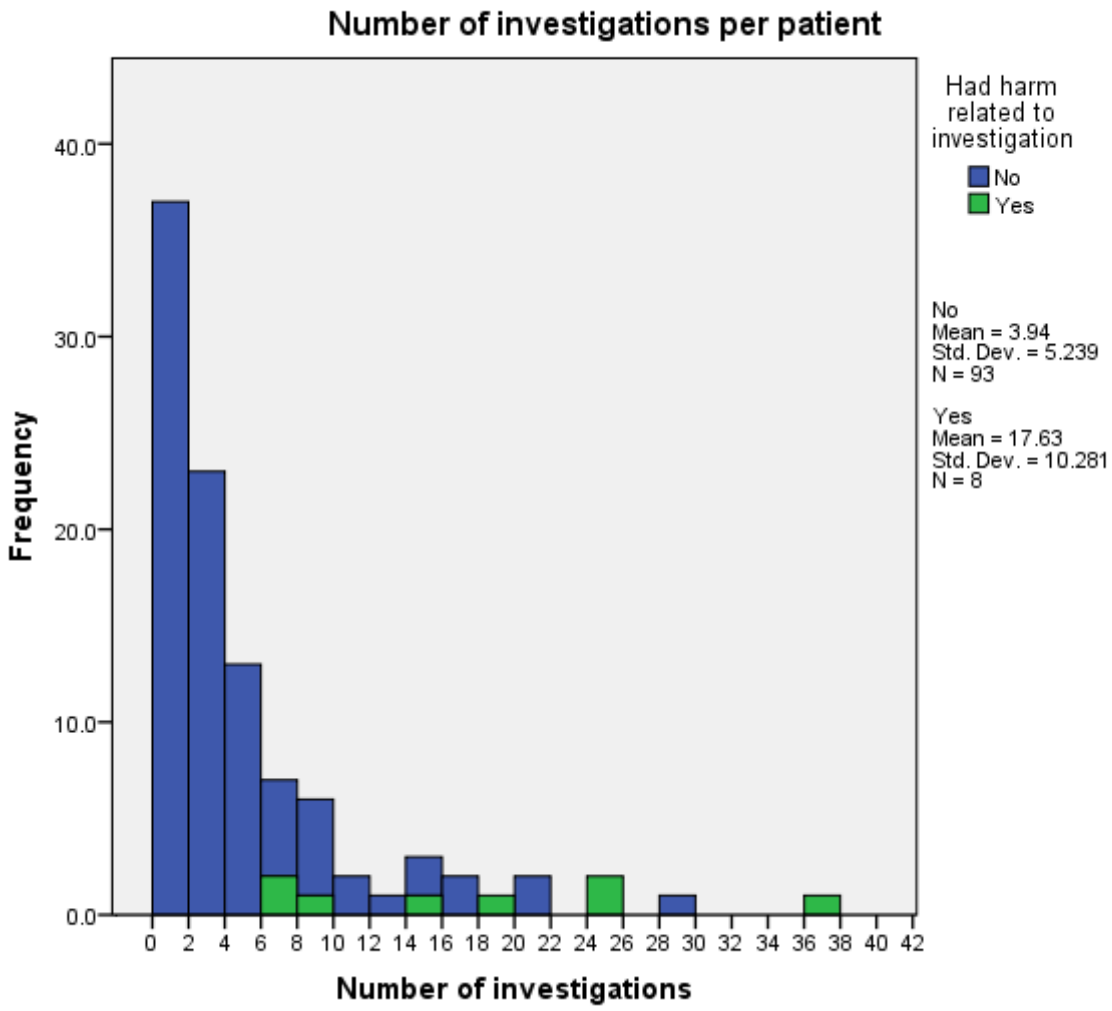


Figure 10 Investigations per patient who had investigation data recorded (bars are shaded to show patients experiencing harm)



An ANOVA test of the difference between the two study groups in number of investigations shows a significant difference (p = 0.001). This result indicates that number of referrals has a significant relationship with likelihood of harm in the gap between referral and receiving referred services. The Eta squared value of 0.297 indicated that the effect size was large. The ANOVA table is available in Appendix C

3.3 All referrals

Most patients were not referred to specialist care; with 103 (51.2%) being referred for only investigations or having no referrals at all.

The first 101 patients had information about both the specialist referrals made and also the investigations ordered (blood tests, microbiology, x-ray and ultrasound) by General

Practitioners. This enabled a comparison to be made between the referral patterns to specialists versus investigation referrals for this group.

A total of 597 individual referrals/investigations were made over these 101 patients, with only 16 patients having no referrals or investigations. Out of the 597 events, 505 were for investigations (82.4%), 78 were referrals to other medical specialties (12.7%) and 14 were referrals to other non-medical services (2.3%).

The second set of patients (n = 100) had an additional 105 referrals to medical specialties and 15 referrals to other specialties. However investigations (blood tests, microbiology, x-ray and ultrasound) were not recorded for patients. The total number of referrals for all 201 patients was 717.

Excluding investigations, 212 referrals were recorded for all 201 patients. From the first 101 patients an annual rate of referral per patient for investigation was calculated, and the same was done for referrals to medical specialties and non-medical specialties from the entire study group. This is shown in Table 13.

Table 13 Rate of referrals by type of referral

Referral type	Number of referrals	Number of patients	Rate (per person per year)
Investigation	505	101	1.00
Referrals to specialties	212	201	0.21
Medical Specialty	183	201	0.18
Other specialty	29	201	0.03

Of these referrals, 58 resulted in harm (9.72% of all referrals). 9 were from referrals for investigations (1.8% of all referrals for investigations), 45 from referrals to medical specialties (24.5% of all referrals to medical specialties) and 4 from referrals to other specialties (13.8% of all referrals to other specialties).

3.4 Per referral

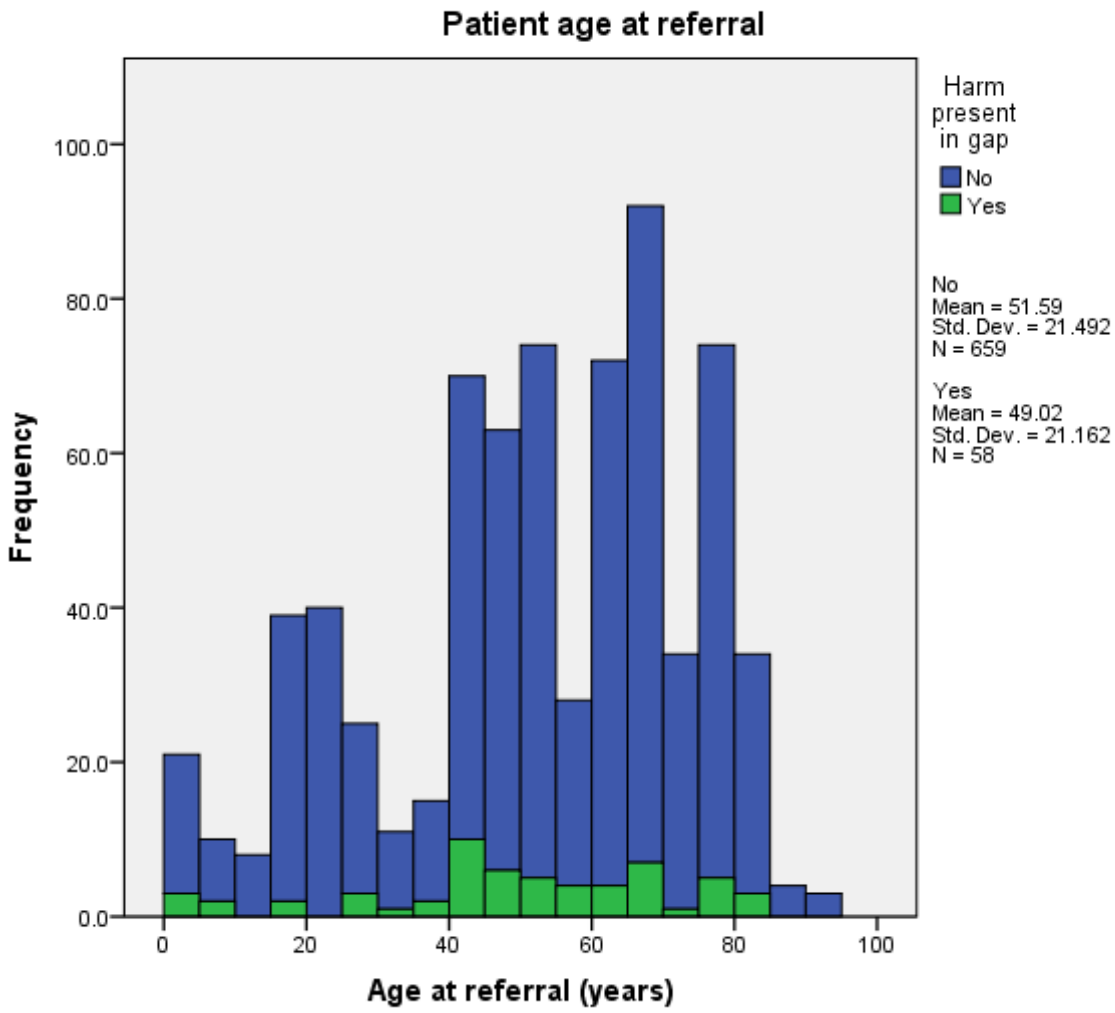
Additionally, as some patients had more than one referral, the data were also analysed per referral event. There was a total of 717 individual referrals. These referrals were categorised into 505 investigation requests, 183 referrals to medical specialties, and 29 referrals to other

studies. The mean age of patients at the time of each referral is presented in Table 14 below. Figure 11 shows the age distribution of patients for each referral.

Table 14 Mean ages for referral, by type of referral

Type of referral	Mean age (years)	Std. Deviation (years)	95% Confidence Interval for Mean (years)		Minimum (years)	Maximum (years)
			Lower Bound	Upper Bound		
Referral for Investigation (n=505)	52.0	20.5	50.2	53.8	0	86
medical specialty (n=183)	50.6	24.0	47.1	54.2	0	91
other specialty (n=29)	45.1	20.6	37.3	53.0	1	77
Total (N=717)	51.4	21.5	49.8	53.0	0	91

Figure 11 Patient age at referral (bars shaded to show patients experiencing harm)



The ANOVA test of the difference between the two study groups[a] in age at referral showed a non-significant difference (p = 0.407). This result indicates that age at referral had no significant relationship with likelihood of harm in the gap between referral and receiving referred services. The Eta Squared value of 0.001 supports this, showing no effect size. The ANOVA table is available in Appendix C

When investigations were removed from the analysis, neither the age distribution shown in Figure 6 nor the ANOVA test were significantly changed (the p-value remained non-significant). These are both available in Appendix C.

Waiting time data was available for 623 of the 717 referrals (86.9%); 488 of investigations (96.6% available), 124 of the referrals to medical specialties (69.7%) and 11 of the referrals to

[a] Patients who experienced harm verses those who did not

other specialties (37.9%). Excluded were referrals that were missing either dates when the referral was made, or dates when the patient were seen, therefore preventing a calculation of the waiting period. For the waiting periods that were available, the median wait times for each type of referral, as well as the quartiles are presented in Table 15 below (medians were used due to the skewed distribution of wait times).

Table 15 Median waiting times (in days) by type of referral

Type of referral	Median waiting time (days)	Quartiles (days)			Minimum (days)	Maximum (days)
		1st (25%)	2nd (50%)	3rd (75%)		
Referral for Investigation (n=488)	0.0	0.0	0.0	3.0	0	385
medical specialty (n=124)	43.0	6.3	43.0	122.5	0	600
other specialty (n=11)	20.0	16.0	20.0	88.0	6	106

The data regarding waiting time are also presented in the Figure 12 below; additionally, the proportion in each interval that had harm in the waiting gap is shaded according to the key.

Figure 12 Waiting times for referral (bars are proportionally shaded to show those who incurred harm)

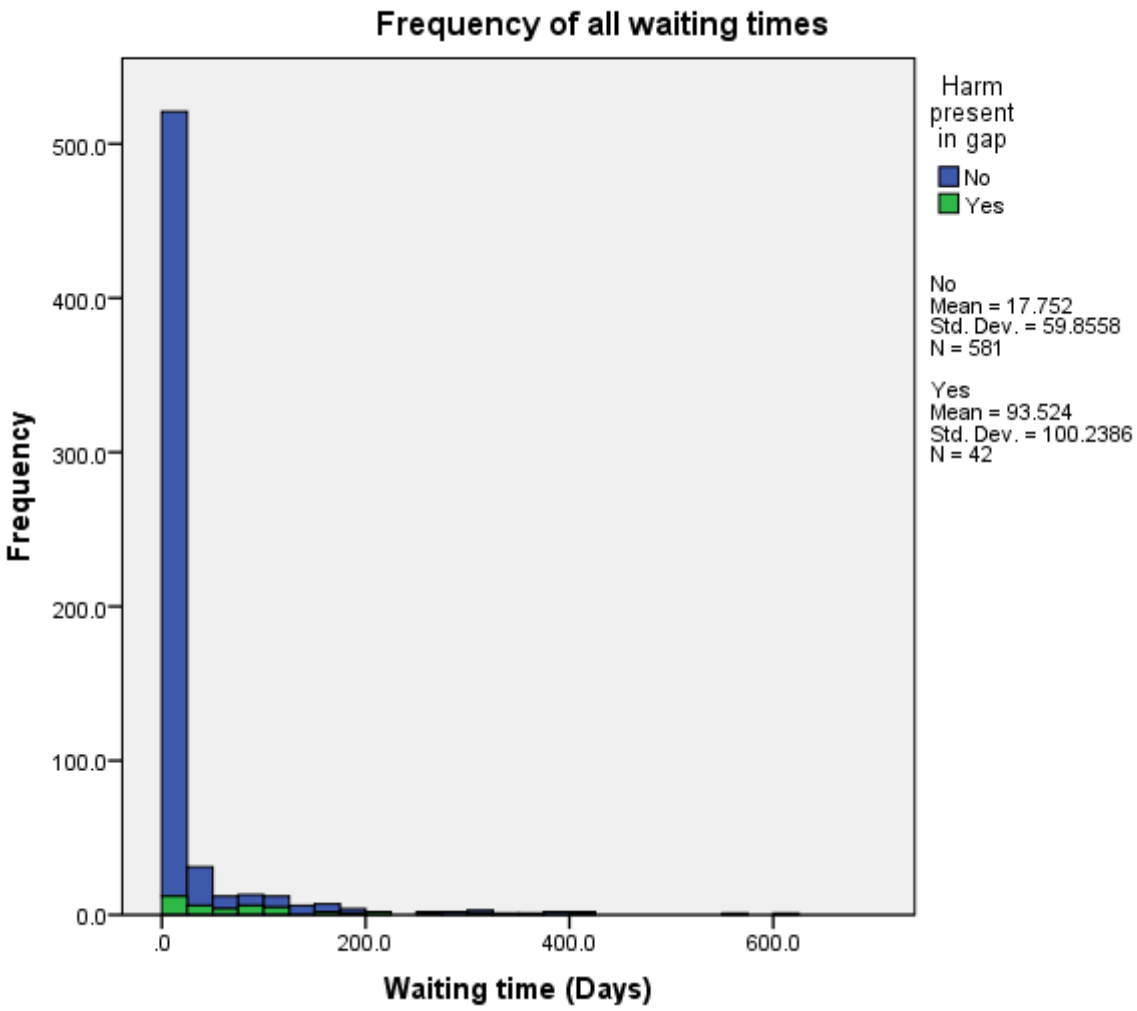
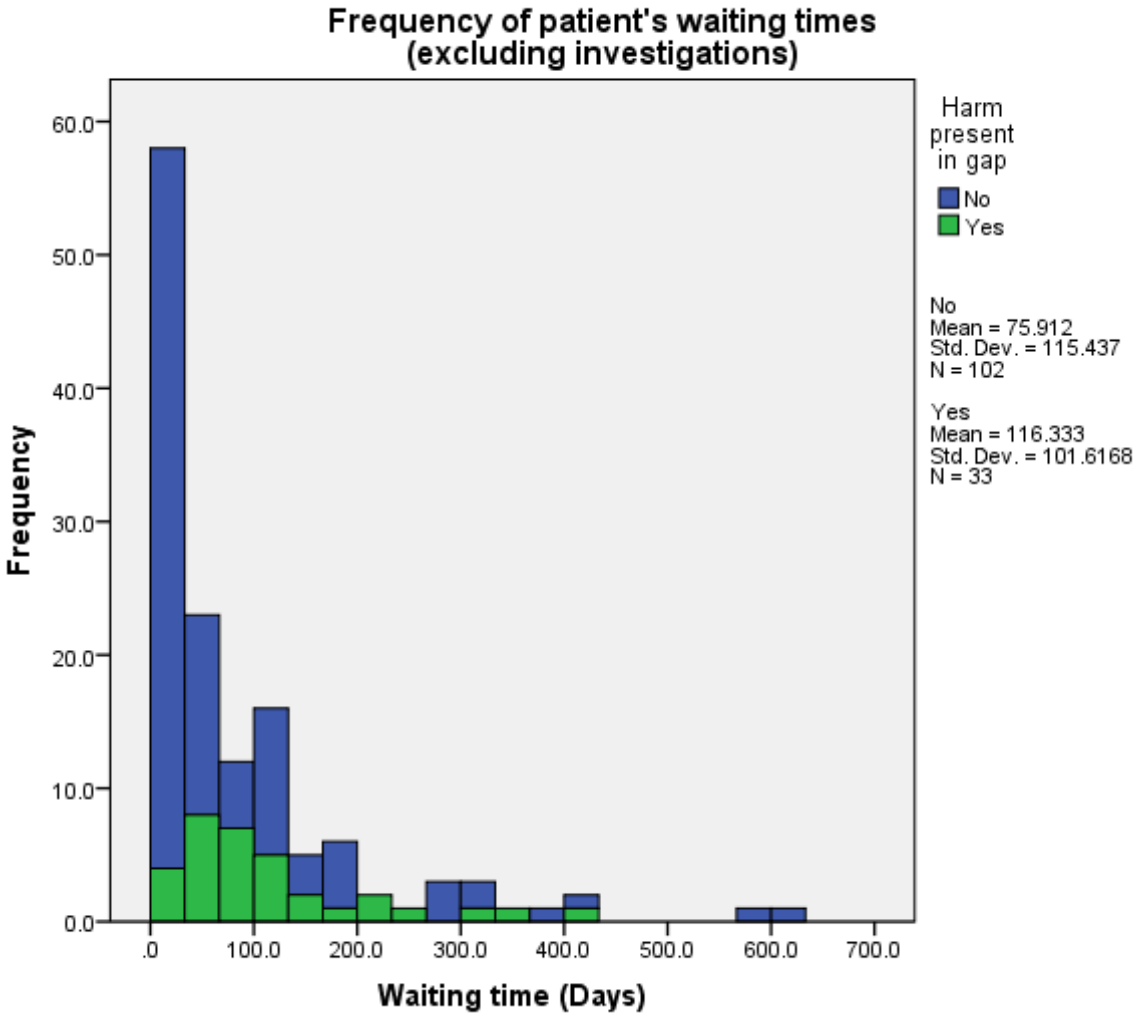


Figure 12 however, includes waiting times for investigations, which (as explained in the methods) predominantly had a recorded waiting time of 0 days. Therefore, to gain a better appreciation of the distribution of waiting times, Figure 13 excludes investigations. Again, the proportion in each interval that had harm in the waiting gap is shaded according to the key.

Figure 13 Waiting times for each referral, excluding investigations (bars are proportionally shaded to show those who incurred harm)



To test if there was an association between harm and waiting period (days), an ANOVA test was conducted for each type of referral. This gave a p value and an Eta Squared value to judge likelihood of type I error and the size of effect respectively.

ANOVA tests of the difference in waiting times between the two study groups[a] were done for each type of referral. The p-value and Eta Squared values are summarised in Table 16. The full ANOVA tables are available in Appendix C.

[a] Patients who experienced harm verses those who did not

Table 16 Significance and size effect for relationship between harm and waiting times. Split by type of referral

Type of referral	p-value	Eta Squared (effect size)
Investigations	0.598	0.001 (none)
To medical specialties	0.117	0.020 (small)
To other specialties	0.063	0.334 (large)

None of the ANOVA tests showed a significant difference with p-values > 0.05. These results indicated that waiting time has a no significant relationship with likelihood of harm in the gap between referral and receiving referred services. The Eta Squared values support this for two of the referral types (investigations and medical specialties) with 0.01 and 0.20 indicating no effect size and a small effect size respectively. However the Eta Squared value of 0.334 for referrals to other specialties indicated a large effect size, suggesting a possible relationship.

None of the ANOVA tests reach statistical significance ($p < 0.05$) however, the p value between waiting times for those who experience harm while waiting for referral to other specialties ($p = 0.063$) is close to statistical significance.

3.5 Types of harm

Each harm was coded as described in the methods section; however due to large variety of harms, only the broad groupings used to describe each episode are presented here – however, the coded harms are available in Appendix B. Table 17 presents the number of harms in each broad category in decreasing magnitude; note that some harms were classified under multiple broad categories.

Table 17 Proportions of broad categories of harms

Broad Category of harm	Number of referrals containing this as a harm	Percentage of total harms (%)
Continued symptoms	38	65.5
Delay in subsequent management	14	24.1
Deterioration of condition	14	24.1
Financial cost to patient	7	12.1
Anxiety/Mental harm	5	8.6
Other	3	5.2
Total	58	100.0

Other included 3 other categories; “Decreased functioning”, “Hospital admission”, and “Carer/Family not coping” with one harm in each.

The overall severity of each episode of harm is also presented in Table 18 below.

Table 18 Frequency and percentage of severity of harms

Severity of harm	Frequency	Percent (%)
Mild	43	74.1
Moderate	12	20.7
Severe	3	5.2
Total	58	100.0

3.6 Referral by specialty

The frequency of the twenty highest services (including investigations) referred to is shown in Table 19 below. Referrals to services that contributed less than one percent of all referrals (n < 7) are compounded into the “other” category for brevity. The full table showing frequency’s for all services is available in Appendix C.

Table 19 shows the twenty referral services, along with the number of referrals with harm in the waiting gap. The services are ordered by decreasing percentage incurring harm.

A Pearson Chi-square test was not possible due to n <5 in several categories.

Table 19 Proportion of referrals resulting in harm split by specialty. Mean waiting times also included

Service referred to	Total number of referrals	Number of referrals resulting in harm	Percentage of referrals resulting in harm (%)	Mean waiting times (days)
Gynaecology	9	4	44.4	70.3
Orthopaedics	29	12	41.4	154.8
Cardiology	14	5	35.7	48.4
Gastroenterology	17	5	29.4	120.0
ENT	16	4	25.0	214.3
Ophthalmology	8	2	25.0	65.0
Psychological services	12	3	25.0	35.3
General surgery	19	3	15.8	111.0
Ultrasound	10	1	10.0	105.7
Neurology	10	1	10.0	55.0
ED	21	1	4.8	0.0
X-ray	43	2	4.7	9.3
Cervical smear	43	1	2.3	5.3
Microbiology	44	1	2.3	2.5
Blood test (investigation)	288	4	1.4	2.2
Audiology	7	0	0.0	167.0
Histology	16	0	0.0	3.4
Physiotherapy	11	0	0.0	33.5
Urine (investigation)	49	0	0.0	1.4
Other	51	9	17.6	n/a
Total	717	58	8.1	22.9

4 Discussion

Following the data described in the previous chapter, this chapter examines the results and draws conclusions within the limitations of this study and with consideration to information described in the literature.

As referral and harms is an under researched field, (even within the relatively new field of primary care safety research) this study adds new information to begin exploring harms related to waiting for referral.

4.1 Summary of the main findings of this study

The major findings, as related to the aims, are described below.

Per patient, harm (as defined in this study) that was related to referral to medical and non-medical specialties occurred to 38 (18.9%) of the patients during the 5 years covered by this study.

Per patient, harm (as defined in this study) that was related to referral for investigation occurred to 8 (7.9%) of the patients during the 5 years covered by this study who had investigation data recorded (n=101).

The rate of referrals to either medical or non-medical specialties was calculated at 0.21 per person per year. The rate of referral for investigations was calculated at 1.18 per person per year. Most referrals were for investigations (82.4%) then for specialty advice (12.7%) and finally, to non-medical specialties such as physiotherapy, dentistry, audiology etc. (2.3%).

Per referral, over the 5 years covered by this study, harm occurred in 24.9% of referrals to medical specialties, 13.8% of referrals to other specialities, and 1.8% of referrals for investigations. Patients who had more referrals were more likely to experience harm in the gap between referral and receiving referred care.

Referral waiting gaps are safe for most patients. Even if harm did occur, most harms (74.1%) were classified as minor harms. However moderate and severe harms did occur such as myocardial infarct while awaiting cardiology referral (severe), and inability to work due to osteoarthritis while waiting for orthopaedics referral (moderate). Most harms were broadly grouped as “Continued Symptoms” (65.5%).

No statistically significant relationship between the length of waiting times and incidence of harm was found. There also was no difference between males and females in the likelihood of

their experiencing harm, but patients who experienced harm were older than those who did not.

No data collected in this study measures the duration of harm experienced by patients; no data of the length of each harm was collected during analysis of the notes nor was duration a consideration when grading severity or type of harm. This study is limited to incidence rather than prevalence of harm.

4.2 Discussion of findings

The findings of this study, while outlined above are presented in this section. Additionally, certain choices of methodology do affect the interpretation of the results and these are discussed.

The demographics of this study group reflect how populations enrolled in general practices differ from the wider New Zealand population. The significant difference between the age of the study group and census data suggests that the study group is older than the New Zealand population, generally. This is expected, as other studies have found that patients enrolled in General Practices in New Zealand tend to be older than the wider population.[148] When separated by sex, males in this study have a higher mean age (44 years) than females (42 years), which is not consistent with the New Zealand Census data – however when shown on a distribution (Figure 5) this is explained by the comparative lack of younger (15-35) males, who are under-enrolled in practices.[148,149]

4.2.1 Overall rate of harm

The rate of harm related to referral per patient of 18.9% is higher than the rate found in early hospital studies.[5,6] This is most likely due to use of the broader definition of harm suggested by Runciman.[32] Use of this definition included harms that may not have been classified under the definition of 'adverse events'[a] used in the hospital based studies (section 1.4.1), and therefore may have been excluded.

The broader definition used in this study may reflect patient's experiences better, as it includes all harms, but does limit comparability of the present study to the previous literature.

The broad definition of harm is moderated by an inherent clinician threshold in this study. That is, as the study data are consultation records written (mainly) by doctors, they are likely to have

[a] "an injury caused by medical management (rather than the disease process) that resulted in either a prolonged hospital stay or disability at discharge".[6]

recorded only issues that they considered important: they may not have bothered to record issues they considered minor, or expected, among complaints brought to them by patients. Overall this should limit records of harms to those reaching a certain threshold for clinicians to include an account of harm the notes. This should limit some over reporting of 'lesser' harms, yet still include 'greater' harms.

The only published general practice records review which also used a similarly broad definition to the present study was by Gaal et al.[92] There the authors found 186 out of 1000 patient records (18.6%) contained any type of harm, not just related to referral. However Gaal et al recorded only preventable harms; the present study records all harms regardless of preventability. This may account for the similar percentage of patients with harm, even though Gaal et al examined notes for all types of harms compared to the present study, which looks only for harms related to referral gaps.

The largest primary care reporting study by Bhasale et al found that patients who were female and older were overrepresented in harm reports.[86] In the present study, patients who experienced harm were older than those who did not, yet there was no relationship between sex and harm. However the calculated effect size of age was small, advising that age is not a good predictor for likelihood of harm in the waiting gap studied. This suggests that harms related to referral effects all patients of either gender and of any age (although older patients slightly more). This can be seen in Figure 7, with some patients of almost all age groups experiencing harm related to referral (green shaded portions of bars).

When examining the data by referral type rather than by patient, the proportion of referrals showed that most of referrals were for investigations (82.4%), while a smaller proportion were for referrals to medical specialties (12.7%), and fewer again for referrals to non-medical specialties (2.3%). For referrals to specialties (i.e. the latter two combined), this gives an overall rate of referral of 0.21 referrals per patient per year, which when converted to a rate per consultation[a] is 4.2% of consultations. This fits with the finding by O'Donnell that rates in the UK vary from 1.5% to 19.1% of consultations resulting in referral.[101] The only comparable research in New Zealand reported a rate of referral to hospital specialties of 0.27 referrals per patient per year.[104] However, as the present study is reliant on practitioners entering the referrals into the notes, referrals may have been missed, likely leading to underreporting of the

[a] 5003 consultations with 212 referrals (excluding investigations), approximately 4.2% of consultations resulted in referral.

true referral rate. This would still fit with the literature, which shows large variations in rate of referral.[101,103,150,151]

Out of 717 referrals, in 58 of these, the patients referred experienced harm in the waiting gap (8.1%). When split by type of referral, out of 183 referrals to medical specialties, 45 had harm present in the waiting gap (24.5%). This was a high rate of harm (alongside the rate of 13.7% of referrals to other specialities), when compared to previous patient safety studies.[5,6,92] Again, the most likely cause of this discrepancy may be the use of the broad definition used in the present study. There is no other study yet published that the candidate could find of referral harm either using a broad or narrow definition of harm, and so the degree of over estimation in this study that has been caused by a broad definition it is yet undetermined.

4.2.2 Predictors of harm

Further examining referrals, the mean age of patients at the time their referral was 51.4 years (95% CI 49.8 – 53.0), with a large range of 0 to 91 years, indicating referrals happen at all ages. However, age at referral was not statistically related to incidence of harm in the waiting gap. This conflicts with the finding that older patients were more likely to have harm in the gap (section 3.2) and is likely due to examination of a relatively small set of patient records and a Type I error (a false positive error) in the testing of statistical significance.

Additionally, length of the waiting gap (days) had no statistically significant relationship to incidence of harm in the waiting period. This means that how long a patient waited between referral and receiving services did not effect if they experienced a harm in the waiting gap. This however is not related to the length of harm experienced, as this information was not collected in this study.

The p-values for harm and waiting times in Table 16 show that, for referrals to medical specialties and other specialties (p-values 0.117 and 0.063 respectively), while not significant in this study, were approaching significance and perhaps a larger study would detect a statistically significant result. However, the effect size for referral to medical specialties was small (Eta Squared = 0.020) suggesting that even if it were statistically significant it is not a strong predictor of harm. The effect size for referral to non-medical specialties was large (Eta Squared = 0.334) suggesting that harm while waiting for referrals to non-medical specialties may be affected by waiting time, unlike referrals to medical specialties. However with a small number of referrals to non-medical specialties (29) and only a small number of these having waiting time information (11 i.e. 37.9%) this conclusion is tentative.

4.2.3 Types of harm

When examining the type of harms present, 38 of the harms (65.5%) were grouped under *continued symptoms*. Continued symptoms, (i.e. the same or similar symptoms to those presented with when the referral was made) would not have been classified as a harm in previous studies, but represents the majority of harms in the present study due to the definition of harm used which includes 'disease' within harm[a] (as discussed previously). Whether continued experience of ill health constitutes a 'harm' in a clinical use of the term is debatable, however it does indicate that for a large proportion of referrals patients re-present to general practice - with symptoms related to their referral, and that they may have been resolved or better managed with earlier receipt of referred services.

The next largest categories of harm were "*delay in subsequent management*" and "*deterioration of condition*" each with 14 episodes of harm (24.1% of harms) including these as a classification (episodes of harm may have had more than one broad classification). These delays in care may be more likely to be classified traditionally as harms in other studies.[85,88,92] "Delay in subsequent management" signals a patient receiving sub-optimal care as a direct result of waiting for referral. This circumstance is likely to have been under reported in this study, due to letters from specialists to general practitioners not being included in the data.

"*Deterioration of condition*" included harms classified as 'severe' including a myocardial infarction and an episode of self-harm while waiting for cardiology and psychological services referral respectively. Harms grouped under "*deterioration of condition*" indicate harm where patients have re-presented with worse symptoms. While similar to "*continued symptoms*", these harms represent patients with conditions which have gotten worse after being referred, and additional suffering for patients, which may have been prevented by being seen earlier. Additionally referral may have had to be expedited, or additional 'stop-gap' treatment offered. This is also likely to have been underreported in this study, again, due to unavailability of letters.

The other broad categories of harm include "*financial cost*", "*Anxiety/mental harm*" and "*other*". These categories have been included in previous studies.[69,85,92] Seven harms (12.1% of harms) were grouped under "*financial cost*". Patients experiencing *financial harm* either lost income or had to pay for appointments or treatments they may not have had to if they had been seen by the referred specialty earlier. To these patients the financial cost was significant enough to discuss it with their GP and for it to be recorded in the notes.

[a] "Disease: A physiological or psychological dysfunction".[32]

A qualitative study by Preston et al showed that patient anxiety and concern was a common theme amongst patients waiting for referral, and was included in the definition used in this study.[130] With only 5 harms being categorised under this (8.6% of all harms) this is surprisingly low, considering how common a theme this was amongst participants in the study by Preston et al. However this discrepancy may be due to the clinician threshold for recording this type of harm in the notes and possibly patient reluctance to discuss their anxiety during a consultation.

The other category included 3 harms; "*decreased functioning*" "*hospital admission*", and "*carer/family not coping*" with one episode grouped under each category. These, therefore, are less common harms and with the small numbers in this study few conclusions can be drawn. However, hospital admissions due to waiting for referral are a potentially important area for investigation for future larger studies, as these may result in important patient and healthcare costs.

The severity of harms found in this study is mainly minor (74.1% of all harms). This corresponds to previous studies, with Gaal et al finding most harms in primary care did not affect patients, and New Zealand hospital studies finding 61.6% of adverse events caused minimal disability.[10,92] This implies that for most referrals the waiting period is safe ("freedom from accidental injury") in New Zealand, as of the harms that do happen (in up to 24.1% of referrals, depending on the type of referral) the majority are minor causing no or temporary disability (the definition of 'minor' used in this study). However a small number of moderate and severe harms were found in this study (12 and 3 respectively) confirming that, while not common, referral waiting periods can contain greater harm and are not completely free of risk of injury to patients.

While data regarding preventability was collected (if being seen earlier would have prevented the harm that was present in the waiting gap), for 23 of the harms (39.7% of all harms) this could not be determined, and so was recorded as unknown. This was a larger proportion than either preventable harms (21 i.e. 36.2% of all harms) or non-preventable (14 i.e. 24.1% of all harms) and so no further analysis was performed. Any conclusion drawn from this analysis would be almost meaningless with such a large level of uncertainty regarding preventability.

4.2.4 Specialties referred to

Table 19 shows referrals by specialty, ordered by descending proportions with harm in the waiting gap. This suggests that referrals to some specialties may be more likely to be associated with patient harm in the waiting gap. The three speciality referrals with the greatest proportion of harm were Gynaecology (44.4%), Orthopaedics (41.4%) and Cardiology (35.7%). While the small numbers in this study (9, 29 and 14 referrals respectively) prevent firm indication that

these are the services that are more likely to have harm in the waiting gap, it does suggest that these services may require more attention in future studies.

Additionally data were collected about the mean waiting times for each service (available in Table 19 as well as in Appendix C), with ENT, Sleep Laboratory and Orthopaedics having the longest wait times all were over four months, the current New Zealand Ministry of Health target - although this was implemented several years after the period covered by the patient notes in this study. Waiting times in this study are similar to waiting times reported in overseas literature on waiting times, which show services having wait times over 120 days.[116] However, there is some inconsistency between wait times for individual services internationally and in this study; for example, a waiting time for general surgery of 56 days in an 2003 OECD report, compared to 110.9 days in the present study.[117] This is expected as international studies have found large variation between services and between countries. However, again with the small numbers for some services in this study, compounded with some uncertainty of the waiting periods (due to non-inclusion of letters in the data), means that this study is not definitive for waiting periods in New Zealand.

4.3 Limitations

This study is affected by several limitations, some that have already been discussed above in relation to specific findings. This section explores these and other limitations.

The small study group of 201 patients is a limitation of this study. The number of consultations (5,003) is reasonable in comparison to the literature; Gaal et al reviewed 8,401 consultation records in the only primary care records review study to date.[92] This number of consultations was achieved in the present study as each individual record covered a five year period, rather than the notes in Gaal et al covering one year. While giving a more longitudinal view for each patient, fewer individual patients were reviewed, reducing the inter-patient variety and therefore providing a narrower range of referrals and also possibly a narrower range of harms than a shorter study with more patients might have achieved.

Also, no sample size was calculated due to time constraints as outlined in section 2.2, however, this means it is unknown if the sample size was sufficient to determine significant differences between different subsets of patients. This is a significant flaw in the method, as there was no clear end point for data collection, instead utilising arbitrary targets.

The sampling of this study is a potential limitation. The notes were sequentially analysed, relying on the randomisation of the order of the HRC feasibility study records. It was unclear what

randomisation method was used in the feasibility study, and while unlikely, this may mean that the patients in the current study were a biased sample an unknown way.

Additionally, an initial subset of 101 patients had information collected regarding investigations collected, making the sample size for investigations smaller again. Also, collecting additional data for the first 101 patients but not the second 100 patients means that these two groups had slightly different methods of data collection applied. However, with non-investigation referrals a significant effort was made to keep the methods of reviewing the records the same to minimise any effect this may have had.

Another limitation in this study is the use of the records review method. Healthcare records were not written for research purposes, and so are not written with the consistent, standardised methodological approach that primary research data would normally achieve.[152,153] Further, there is variability between clinicians and so there may be little consistency between sets of records of different patients with different doctors. However, the study data does reflect real world conditions, where some clinicians may be more likely to regard an event as a clinically significant harm and record it in the notes while other clinicians may not. This means that this study determined the presence of harm related to referral in the notes rather than actual presence of harm.

The format of the extracted data is a significant limitation to this study. The extracted data did not include referral letters to specialists nor did it contain letters back from specialities to the General Practitioners. These letters were removed to successfully preserve patient anonymity but their removal also constrained precision in determining when referrals were made and when patients were seen by specialties. Some information could be gathered from manual entries in the records by practitioners. This likely led to underestimation of referral events and over estimation of some waiting periods.

In addition, in the data extraction process (which occurred before the current study began) the consultation records were truncated at 256 characters, which led to some records being incomplete. Again, as referral plans were often described at the end of records, this would result in the underreporting of referrals. However, this probably was not a major consideration because the referral rate per person per year in this study was not dissimilar to other reports of referral rates. Records of harms related to waiting for referral may also have been at the end of consultation records, and therefore harms may be underreported in this study.

The notes covered the period of 2003 – 2007, and so the data does not reflect recent change in the New Zealand Healthcare system; such as shorter Ministry of Health waiting time targets or DHB implementation of referral guidelines (or 'pathways').[113,154,155] These changes may limit the applicability of the current study to current practice – both shorter waiting times and guidelines to ensure high risk patients are seen earlier may reduce the harm in the current period compared to the period covered in the present study. Additionally, no ethnicity or socioeconomic data were available for the patients in this study – so no exploration could be preformed of the relationship between these demographic characteristics and harm in the waiting gap.

The above issues with data were not correctable within the short 12 month period of this BMedSc(hons) project. The issues with the study database were known at the start of the present study, and in order to fit within the 12 month timeframe a decision was made to continue using these records with all their limitations, rather than re-extract data. A new data collection is currently being made from randomly selected New Zealand general practices, but these data will not be available for analysis until 2017. General practice consultation data are not included in any of the Ministry of Health's publicly available data collections. If general practice data are needed for research they have to be compiled separately and with external funding and resources, so existing general practice consultation databases are rare and therefore often reused, as in the current project.

The limitation of only having one reviewer of records (the candidate) is that any bias is unchallenged. Without use of multiple reviewers, a certain type of harm may go under reported or over reported as there is potentially a subjective element in interpreting the notes and classifying harms. If present, this is unlikely to have been corrected without the use of another reviewer. On the other hand, there will be greater consistency in data interpretation with one reviewer than if more had been involved.

4.4 Strengths

There are several strengths of this study which support the findings and conclusions drawn.

Five years of records were reviewed, which is more than previous studies that usually cover a single year. For this project that identified waiting gaps over four months, a longer period of notes is an advantage as the study is more likely to cover the entire period of a waiting gap as well as examine consequences following receiving specialist services.

A strength of this study is that records were gathered from various practices and practitioners giving a wider variety of notes and clinician recording styles as well as reducing the effect of a bias held by a single practitioner.

The use of only one reviewer, although introduces bias (as discussed above) also ensures consistency of review of records, and prevents inter-reviewer discrepancies.

4.5 Implications

This study is the first records review study of harms during referral waiting gaps that I could identify in New Zealand or from the international literature.

The findings of this study do support the notion that harms to patients happen during referral waiting periods, and that additional care may be required during these gaps. This study found no strong predictors of harm during the waiting gap, and so, until further information is available, all referrals hold potential for harm.

Because of the small size of the study, the limitations outlined above, and the lack of other studies to support the findings, there should be some caution in interpreting the findings of this study to make changes in clinical practice. The most that can be applied is, for now, that clinicians should be aware that harms happen in waiting gaps and be prepared to care for the patients for whom this occurs.

The most significant implications of this study are for subsequent research. The present study is an exploratory study and hence lays the groundwork for future research in this area. This study has determined an overall rate of harm, the variety of harm and suggested that referral to some specialties may have higher rates of harm than others. These are all areas for potential future study.

Future research should address some of the design limitations of this study and further explore and corroborate or refute some of the findings – especially the finding that length of waiting times has little relationship to incidence of harm. Additionally, as this study was limited by having only clinician notes to determine harm, perhaps a future study may include more of the patient viewpoint by incorporating interviews and/or surveys. Finally, a study using a more recent period of notes or a prospective study would have more relevance to current healthcare in New Zealand and be able to develop firmer recommendations to improve current health care.

Overall this study, while limited and small in scope, is an important beginning to exploring harms in the interface between primary and secondary care. The findings confirm that harms do occur

in waiting gaps, and will enable future study design to further explore this in a larger, more detailed capacity.

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Appendix A – Documentation

Ethics approval

HD15/001

Academic Services
Manager, Academic Committees, Mr Gary Witte

27 January 2015

Professor S Dovey
Department of General Practice & Rural Health
Dunedin School of Medicine

Dear Professor Dovey,

I am writing to you concerning your proposal entitled "**What's the harm in waiting? Patient harms in the referral gap**", Ethics Committee reference number **HD15/001**.

The above research was submitted and reviewed as a 'Human Ethics Committee (Health) Departmental Conditional Approval of Projects using Health Information'. The outcome of that consideration was that the proposal was approved.

While approving the research, the Committee asks for written confirmation of the confidentiality agreement for the student.

The standard conditions of approval for all human research projects reviewed and approved by the Committee are the following:

Conduct the research project strictly in accordance with the research proposal submitted and granted ethics approval, including any amendments required to be made to the proposal by the Human Research Ethics Committee.

Inform the Human Research Ethics Committee immediately of anything which may warrant review of ethics approval of the research project, including: serious or unexpected adverse effects on participants; unforeseen events that might affect continued ethical acceptability of the project; and a written report about these matters must be submitted to the Academic Committees Office by no later than the next working day after recognition of an adverse occurrence/event. Please note that in cases of adverse events an incident report should also be made to the Health and Safety Office:

http://www.otago.ac.nz/healthandsafety/index.html

Advise the Committee in writing as soon as practicable if the research project is discontinued.

Make no change to the project as approved in its entirety by the Committee, including any wording in any document approved as part of the project, without prior written approval of the Committee for any change. If you are applying for an amendment to your approved research, please email your request to the Academic Committees Office:

gary.witte@otago.ac.nz

jo.farrondediaz@otago.ac.nz

Approval is for up to three years from the date of this letter. If this project has not been completed within three years from the date of this letter, re-approval or an extension of approval must be requested. If the nature, consent, location, procedures or personnel of your approved application change, please advise me in writing.

Yours sincerely,

Mr Gary Witte
Manager, Academic Committees
Tel: 479 8256
Email: gary.witte@otago.ac.nz

c.c. Assoc. Prof. C Jaye Head of Department Department of General Practice & Rural Health

Māori consultation

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE
TE KOMITI RAKAHAU KI KĀI TAHU

Tuesday, 27 January 2015.

Professor Susan Dovey,
Dunedin School of Medicine - General Practice and Rural Health,
DUNEDIN.

Tēnā koe Professor Susan Dovey,

What's the Harm in Waiting? Patient Harms in the Referral Gap

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 27 January 2015 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outline in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee considers the research to be of importance to Māori health.

The Committee notes the researchers have identified that ethnicity data was not collected for this study and hope that future studies will incorporate this essential information.

The Committee suggests dissemination of the research findings to Māori health organisations regarding this study.

We wish you every success in your research and the committee also requests a copy of the research findings.

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE

TE KOMITI RAKAHAU KI KĀI TAHU

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 27 January 2015 to 27 July 2016.

Nāhaku noa, nā

Mark Brunton
Kaiwhakahaere Rangahau Māori
Research Manager Māori
Research Division
Te Whare Wānanga o Otāgo
Ph: +64 3 479 8738
Email: mark.brunton@otago.ac.nz
Web: www.otago.ac.nz

The Ngāi Tahu Research Consultation Committee has membership from:

Te Rūnanga o Ōtākou Incorporated
Kāti Huirapa Rūnaka ki Puketeraki
Te Rūnanga o Moeraki

Appendix B – Additional method information

HRC Feasibility study

Coding information

Top code	Description
1	**Access/Communication** 1.1 Referral harm 1.1.1 Delay in referral from GP 1.1.2 Delay in referral processing at hospital 1.2 Delay in hospital admission 1.2.1 No bed available 1.3 Delay in receiving treatment 1.3.1 Delay in procedure 1.3.2 Delay in receiving prescription 1.4 Miscommunication 1.4.1 Miscommunication about procedure 1.4.2 Miscommunication about medication
2	**Investigation/Diagnostic harm** 2.1 Associated with diagnostic investigation 2.2 Associated with results 2.3 Associated with diagnosis 2.3.1 Delayed diagnosis
3	**Treatment harm** 3.1 Drug harm 3.1.1 Drug interaction 3.1.2 Medication Change 3.1.3 Drug not given or changed in a timely way 3.1.4 Polypharmacy 3.1.5 Drug information 3.1.6 Drug given in association with surgery 3.2 Surgical harm 3.3 Liquid nitrogen 3.4 Dressings 3.5 Other 3.5.1 Urinary catheter 3.5.1.1 Blocked catheter
4	**Economic harm** 4.1. Repeat visit 4.2. Further medication required 4.3. Time off work 4.3.1. For self 4.3.2. To care for dependant/spouse/parent 4.4. Further investigations required 4.5. Private care (patient chose to pay to go privately because of waiting times)

Top code	Description
	4.6. Hospital admission 4.6.1. ED visit 4.7 After hours care
	Death 5.1. Suicide 5.2. Other

Patient / symptoms

Top code	Description
1	**Feeling generally unwell** 1.1 Fever 1.2 Dizziness 1.2.1 Hypotension 1.2.2 Pre-syncope 1.2.3 Syncope 1.2.3.1 Banged head 1.2.4 Vertigo 1.3 Falls 1.4 Palpitations 1.4.1 Arrhythmia 1.4.1.1 Atrial fibrillation 1.5 Fatigue 1.5.1 Insomnia 1.5.2 Drowsiness 1.5.3 Vivid dreams 1.6 Nausea 1.7 Vomiting 1.8 Constipation 1.9 Diarrhoea 1.10 Cognitive impairment
2	**Pain** 2.1 Musculoskeletal 2.2 Headache 2.3 Tongue pain 2.4 Urinary retention
3	**Short of breath** 3.1 Cough 3.2 Hoarseness 3.3 Wheeze 3.4 Aggravation of respiratory condition
4	**Rash** 4.1 Photosensitivity rash 4.2 Lichen planus 4.2.1 Oral lichen planus

Top code	Description
5	**Bleeding** 5.1 Bruising 5.2 Purpura 5.3 Epistaxis
6	**Infection** 6.1 Skin infection 6.2 Persistent infection 6.3 Thrush 6.3.1 Oral thrush
7	**Wound** 7.1 Inflammation 7.2 Infection 7.3 Dehiscence 7.4 Delayed healing
8	**Oedema** 8.1 Peripheral oedema
9	**Weakness** 9.1 Atrophy 9.2 Muscle stiffness 9.3 Osteoporosis 9.4 Malabsorption 9.4.1 Iron deficiency
10	**Physiological imbalance** 10.1 Hyponatraemia 10.2 Hypokalaemia 10.3 Hyperkalaemia 10.4 Low WCC 10.5 Abnormal liver function result 10.6 Reduced renal function 10.7 Raised CK
11	**Sensory changes** 11.1 Peripheral neuropathy 11.2 Tingling 11.3 Hearing loss 11.3.1 Reversible hearing loss 11.4 Sensation of dryness 11.5 Dry Mouth
12	**Ulcer** 12.1 Mouth ulcer 12.2 Corneal ulcer
13	**Fissure** 13.1 Anal fissure
14	I**nfarction** 14.1 Myocardial infarction 14.2 Stroke 14.
15	**Cancer** 15.1 Bowel cancer

Top code	Description
16	**Fracture** 16.1 Metatarsal fracture
17	**Mental Harm** 17.1 Upset 17.1.1 Felt ignored 17.2 Anxiety 17.3 Agitation 17.4 Paranoia 17.5 Addiction 17.6 Anorgasmia
18	**Other** 18.1 Gynaecomastia 18.2 Hypogonadism 18.3 Tooth extraction

Excerpt of data table

Patient no.	Age at final consult	Gender	Referral number	Age at referral	Type of referral	Referral category	Date of referral	Date seen	Wait time (days)	Harm present?	Type of harm	Severity	Preventability	Method of prevention	Notes
47	80	M	28	79	Blood test	1	20/02/2007	28/03/2007	36	N					To wait 1 month
47	80	M	29	80	Orthopaedics	2	25/05/2007	?	#VALUE!	?					Refer to fowler - not sure if seen
48	4	F	1	4	Dentistry	3	27/06/2006	19/09/2006	84	Y	Continued symptoms	Mild	Y	seen earlier	dental abscess, referred to dental unit - unsure if original referral by Dr or directly from dental unit
49	11	F	1	6	Urine - microbiology	1	15/01/2003	17/01/2003	2	N					
49	11	F	2	6	Paediatrics	2	22/01/2003	12/02/2003	21	N					Referred to private, then bounded to public system as no private paeds service. Appt cancelled on 12/02, probably due to symptoms resolving
49	11	F	3	8	Blood test	1	22/04/2004	22/04/2004	0	N					
49	11	F	4	8	X-ray	1	22/04/2004	22/04/2004	0	N					
49	11	F	5	8	Ultrasound	1	22/04/2004	22/04/2004	0	N					
49	11	F	6	8	Blood test	1	15/10/2004	15/10/2004	0	N					
49	11	F	7	8	Urine - microbiology	1	15/10/2004	15/10/2004	0	N					
49	11	F	8	10	Blood test	1	30/05/2006	31/05/2006	1	?	Delay of treatment (gluten free diet)	Mild	?	review results earlier	Talked to patient 06/06/06 - when mother called re tests…
50	67	M	1	66	Blood test	1	18/07/2007	19/07/2007	1	N					
50	67	M	2	66	Cardiology	2	25/07/2007	n/a - 26/07	#VALUE!	Y	MI	Severe	?	Started on medication? Probably not preventable	MI following episodes of chest pain from 18/07/07
50	67	M	3	66	Domestic Assistance	3	30/07/2007	?	#VALUE!	N					

Appendix C – Additional results

The following are additional raw outputs from IBM SPSS 22 that were not included in Chapter 3, and are included here for reference. As a result all following results are unformatted and tables are untitled.

Statistic calculations

Pearson Chi-Square test for gender and harm related to referral to specialist (medical or other)

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.601[a]	1	.438		
Continuity Correction[b]	.354	1	.552		
Likelihood Ratio	.603	1	.437		
Fisher's Exact Test				.475	.277
N of Valid Cases	201				
a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 18.15.					
b. Computed only for a 2x2 table					

ANOVA calculations

ANOVA – Age vs Harm

ANOVA calculation for correlation between patient age and harm related to referral

		Sum of Squares	df	Mean Square	F	Sig.
Age 2007 * Had harm related to referral (2 or 3)	Between Groups (Combined)	2559.532	1	2559.532	4.700	.031
	Within Groups	108366.149	199	544.554		
	Total	110925.682	200			

The measure of association is shown below.

	Eta	Eta Squared
Age 2007 * Had harm related to referral (2 or 3)	.152	.023

ANOVA – Number of referrals vs Harm

ANOVA calculation for correlation between number of referrals and harm related to referral

Had harm related to referral (2 or 3)	Mean	N	Std. Deviation
No	1.68	60	1.396
Yes	2.95	38	2.155
Total	2.17	98	1.828

		Sum of Squares	df	Mean Square	F	Sig.
Number of referrals (2or3) * Had harm related to referral (2 or 3)	Between Groups (Combined)	37.173	1	37.173	12.439	.001
	Within Groups	286.878	96	2.988		
	Total	324.051	97			

The measure of association is shown below.

	Eta	Eta Squared
Number of referrals (2or3) * Had harm related to referral (2 or 3)	.339	.115

ANOVA – Investigation, number of investigations per patient vs harm

Had harm related to investigation	Mean	N	Std. Deviation
No	3.94	93	5.239
Yes	17.63	8	10.281
Total	5.02	101	6.816

		Sum of Squares	df	Mean Square	F	Sig.
Number of investigations * Had	Between Groups (Combined)	1380.472	1	1380.472	41.852	.000
	Within Groups	3265.488	99	32.985		

harm related to investigation	Total	4645.960	100			

The measure of association is shown below.

	Eta	Eta Squared
Number of investigations * Had harm related to investigation	.545	.297

ANOVA – Age at referral vs harm

ANOVA calculation for correlation between age at referral (years) and if harm was present in the waiting gap.

Harm present in gap	Mean	N	Std. Deviation
N	51.59	659	21.492
Y	49.02	58	21.162
Total	51.38	717	21.462

			Sum of Squares	df	Mean Square	F	Sig.
Age at referral * Harm present in gap	Between Groups	(Combined)	353.347	1	353.347	.767	.381
	Within Groups		329452.179	715	460.772		
	Total		329805.526	716			

	Eta	Eta Squared
Age at referral * Harm present in gap	.033	.001

Distribution of age at referral when excluding investigations

Harm present in gap	Mean	N	Std. Deviation
N	50.60	163	24.105
Y	47.49	49	21.692
Total	49.88	212	23.556

ANOVA calculation for correlation between age at referral (years) and if harm was present in the waiting gap while excluding investigations.

			Sum of Squares	df	Mean Square	F	Sig.
Age at referral * Harm present in gap	Between Groups	(Combined)	364.727	1	364.727	.656	.419
	Within Groups		116717.325	210	555.797		
	Total		117082.052	211			

The measure of association is shown below.

	Eta	Eta Squared
Age at referral * Harm present in gap	.056	.003

ANOVA – Investigation, waiting time vs harm

Harm present in gap	Mean	N	Std. Deviation	Std. Error of Mean
N	5.367	479	25.6135	1.1703
Y	9.889	9	13.2518	4.4173
Total	5.451	488	25.4398	1.1516

ANOVA calculation for correlation between waiting time length (days) for investigations and if harm was present in the waiting gap.

			Sum of Squares	df	Mean Square	F	Sig.
Waiting time (Days) * Harm present in gap	Between Groups	(Combined)	180.599	1	180.599	.279	.598
	Within Groups		314998.221	486	648.144		
	Total		315178.820	487			

The measure of association is shown below.

	Eta	Eta Squared
Waiting time (Days) * Harm present in gap	.024	.001

ANOVA – Referral to medical specialties, waiting time vs harm

Harm present in gap	Mean	N	Std. Deviation
N	79.656	93	119.8103
Y	117.742	31	104.7530
Total	89.177	124	116.9927

ANOVA calculation for correlation between waiting time length (days) for referrals to medical specialties and if harm was present in the waiting gap.

		Sum of Squares	df	Mean Square	F	Sig.
Waiting time (Days) * Harm present in gap	Between Groups (Combined)	33725.172	1	33725.172	2.494	.117
	Within Groups	1649810.925	122	13523.040		
	Total	1683536.097	123			

The measure of association is shown below.

	Eta	Eta Squared
Waiting time (Days) * Harm present in gap	.142	.020

ANOVA – Referral to other specialties, waiting time vs harm

Harm present in gap	Mean	N	Std. Deviation
N	37.222	9	36.2380
Y	94.500	2	14.8492
Total	47.636	11	40.1180

ANOVA calculation for correlation between waiting time length (days) for referrals to other specialties and if harm was present in the waiting gap.

		Sum of Squares	df	Mean Square		F	Sig.
Waiting time (Days) * Harm present in gap	Between Groups (Combined)	5368.490	1	5368.490		4.505	.063
	Within Groups	10726.056	9	1191.784			
	Total	16094.545	10				

The measure of association is shown below.

	Eta	Eta Squared
Waiting time (Days) * Harm present in gap	.578	.334

Referrals to all specialties

	Frequency	Percent	Valid Percent	Cumulative
Blood test	288	40.2	40.2	40.2
Urine	49	6.8	6.8	47.0
Microbiology	44	6.1	6.1	53.1
Cervical smear	43	6.0	6.0	59.1
X-ray	43	6.0	6.0	65.1
Orthopaedics	29	4.0	4.0	69.2
ED	21	2.9	2.9	72.1
General surgery	19	2.6	2.6	74.8
Gastroenterology	17	2.4	2.4	77.1
ENT	16	2.2	2.2	79.4
Histology	16	2.2	2.2	81.6
Cardiology	14	2.0	2.0	83.5
Psychological services	12	1.7	1.7	85.2
Physiotherapy	11	1.5	1.5	86.8
Neurology	10	1.4	1.4	88.1
Ultrasound	10	1.4	1.4	89.5
Gynaecology	9	1.3	1.3	90.8
Ophthalmology	8	1.1	1.1	91.9
Audiology	7	1.0	1.0	92.9
Radiology	7	1.0	1.0	93.9
Geriatrics	6	.8	.8	94.7
Paediatrics	5	.7	.7	95.4
Vascular	5	.7	.7	96.1
Rheumatology	4	.6	.6	96.7
Urology	4	.6	.6	97.2
Dentistry	2	.3	.3	97.5
Dietician	2	.3	.3	97.8
Domestic Assistance	2	.3	.3	98.0
Pain Clinic	2	.3	.3	98.3
Podiatry	2	.3	.3	98.6
Dermatology	1	.1	.1	98.7
GP	1	.1	.1	98.9
Midwife	1	.1	.1	99.0
Nephrology	1	.1	.1	99.2
Neurosurgery	1	.1	.1	99.3
Oncology	1	.1	.1	99.4
Plastics	1	.1	.1	99.6
Podiatrist	1	.1	.1	99.7
Rehabilitation	1	.1	.1	99.9
Sleep Lab	1	.1	.1	100.0
Total	717	100.0	100.0	

Waiting time per service (days)

Service referred to	Mean (days)	N	Std Deviation	Std. Error of mean
ENT	214.333	9	186.4511	62.1504
Sleep Lab	192.000	1		
Orthopaedics	154.778	18	125.2318	29.5174
Audiology	167.000	3	198.6530	114.6923
Gastroenterology	120.000	13	158.6942	44.0138
Neurosurgery	115.000	1		
General surgery	110.938	16	104.9759	26.2440
Pain Clinic	110.000	1		
Ultrasound	105.625	8	151.1990	53.4569
Rehabilitation	105.000	1		
Oncology	97.000	1		
Plastics	91.000	1		
Urology	86.000	2	111.7229	79.0000
Dentistry	84.000	1		
Gynaecology	70.286	7	44.5672	16.8448
Ophthalmology	65.000	5	82.5984	36.9391
Vascular	56.500	2	27.5772	19.5000
Neurology	55.000	6	57.8481	23.6164
Rheumatology	52.667	3	44.4560	25.6667
Cardiology	48.375	8	51.0348	18.0435
Radiology	39.000	5	26.4764	11.8406
Geriatrics	37.667	3	64.3765	37.1678
Psychological services	35.333	3	46.3069	26.7353
Dermatology	35.000	1		
Physiotherapy	33.500	2	23.3345	16.5000
Dietician	27.500	2	10.6066	7.5000
GP	17.000	1		
Podiatry	16.000	1		
Podiatrist	15.000	1		
X-ray	9.308	39	18.6818	2.9915
Paediatrics	7.000	3	12.1244	7.0000

Service referred to	Mean (days)	N	Std Deviation	Std. Error of mean
Cervical smear	5.275	40	5.4865	.8675
Histology	3.375	16	9.8311	2.4578
Microbiology	2.545	44	10.6257	1.6019
Blood test	2.196	285	5.6888	.3370
Urine	1.408	49	6.3177	.9025
ED	0.000	21	0.0000	0.0000
Total	22.860	623	66.0656	2.6469