Risk and Regulation in Healthcare: An interdisciplinary enquiry

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Abstract

Introduction: The practice of registered health professionals in New Zealand is regulated under the Health Practitioners Competence Assurance Act 2003. Under this Act, Responsible Authorities (RAs) aim to protect the public through ensuring practitioners are competent and fit to practise their professions. To ensure appropriate regulatory action, RAs require a clear understanding of the risks present within the professions they regulate. Although literature is available that describes disciplinary complaints against each profession, there seems to be little known about how regulators perceive the risk of harm inherent in each profession's practice. This study seeks to explore participating New Zealand health regulators' perspectives on risk and harm. Of particular interest are regulators' perceptions of specific risks, their overall understanding of risk and harm, and how these perceptions are formed. A pragmatic mixed-methods approach was utilised to explore this novel topic. The intent of this research is to facilitate efficient cross-profession regulation by identifying areas of commonality between professions and provide an understanding of the validity of RA perceptions of risk.

Methods: This study utilised a pragmatic mixed-methods approach, incorporating two parallel study arms. The first arm consisted of a two-phase sequential explanatory design. In the first, quantitative, phase of this arm, eleven of sixteen potential RAs (69%), completed a bespoke questionnaire regarding their perceptions. The resulting data were reported using descriptive statistics. Five participating RAs were purposively selected for participation in the second, qualitative, phase utilising semi-structured interviews. Data were analysed using reflexive Thematic Analysis. The second Triangulation arm consisted of a parallel qualitative review. All published cases from the Health Practitioners Disciplinary Tribunal as of 21 August 2020 (n=432) were reviewed and analysed using a directed Content Analysis approach. Integrated analysis was then performed using a process based on the Complementary Integrative Analysis Strategy.

Results: In Complementary Phase 1, 54% (n=6) of 11 participating RAs reported significant risk factors were present in normal practice or that practice errors were likely/highly likely. Eighty-one percent (n=9) of participating RAs saw practice errors as high risk, whereas 55% (n=6) saw practitioner misconduct as a moderate risk. Communication error was also identified as a high risk (73%, n=8). From Complementarity Phase 2, seven themes were identified: *'Knowing Risk' is a challenge*, *Perceptions of risk relate to societal expectations*, *Perceived risk profiles are similar but distinct*, *Perceptions of relative risks relate to the clinical role* and *Environmental pressures amplify clinical risks* were identified in participants view on the development and characteristics of risk. *Communication is a moderator of harm* and *A team approach supports risk mitigation* were apparent in exploring risk management. In the Triangulation arm, seven major themes were identified, being *Disruptive behaviour*, *Boundary violations*, *Inappropriate care*, *Medication/Drugs*, *Health Information*, *Costs/Advertising* and *Regulatory requirements & Fraud*. Integrated analysis showed areas of significant alignment within the complementarity arm, including support from Triangulation arm findings.

Conclusions: RA perceptions of risk and harm are varied, evolving and are strongly influenced by data from complaints and notifications. While differences in risks between professions are apparent, there is a need for regulators to align their understanding of risk. Limitations of data arising from complaints creates challenges for regulators in developing an accurate perception of risk, and it is imperative that the voice of the health consumer is at the centre of this understanding.

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Abbreviations

AHPRA	Australian Health Practitioner Regulation Agency
APC	Annual Practicing Certificate
AUT	Auckland University of Technology
AUTEC	Auckland University of Technology Ethics Committee
CPD	Continuing Professional Development
CME	Continuing Medical Education
DHSc	Doctor of Health Science
HDC	Health and Disability Commissioner
HPCA Act	Health Practitioners Competence Assurance Act 2003
HPDT	Health Practitioners Disciplinary Tribunal
PCC	Professional Conduct Committee
QUAL	Qualitative
QUAN	Quantitative
RA	Responsible Authority
WHO	World Health Organisation

Glossary of Te Reo Māori Terms

(Translations from Te Aka Māori Dictionary – www.maoridictionary.co.nz)

Hauora (noun)	Health, vigour
Whānau (noun)	Extended family, family group, a familiar term of address to a number of people - the primary economic unit of traditional Māori society. In the modern context the term is sometimes used to include friends who may not have any kinship ties to other members.

Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signature Date

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Lastly, but by no means least, I would like to acknowledge the dedication and support of my wife, Angela, throughout my DHSc journey. Thank you for all that you do.

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Chapter One – Introduction

1.1 Opening statement

The Health Practitioners Competence Assurance Act 2003 (HPCA Act) was brought into effect in 2003, aiming to “protect the health and safety of members of the public” (s. 3) through ensuring regulatory oversight for each of the health professions identified under the Act. The HPCA Act seeks to achieve this aim by “providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions” (Health Practitioners Competence Assurance Act 2003, s. 3).

While significant work has been undertaken to investigate the risks in healthcare that may impact the health and safety of the public, there seems to be a paucity of literature investigating the perceptions of regulators themselves. This research investigated the understanding and perceptions of risk and harm of Responsible Authorities (RAs) under the HPCA Act.

This first chapter presents an introduction to the topic, including New Zealand regulation and considerations of harm and practitioner competence. This situates this research in the New Zealand context, and in the work of an RA. To provide an overall orientation to the study itself, the study rationale is then presented, including an outline of the significance of this study. The aims and objectives of the study are also presented, followed by an exploration of the place of the researcher within the study context. The final section of the chapter then serves to provide an outline of the thesis structure and subsequent chapters.

1.1.1 Describing healthcare users

While the HPCA Act refers to protection of the public, there is varied terminology used to refer to those who may use healthcare services. This may include, for example, the terms patient, client, consumer, or service user (Fischer et al., 2020).

While it is outside of the scope of this study to explore these terms in depth, some consideration was given to the appropriate terminology to use in this thesis. In New Zealand, Te Tāhū Hauora | the Health Quality & Safety Commission uses the term ‘consumer’ to refer to “anyone who has used, is currently using or is likely to use a health service” (Te Tāhū Hauora Health Quality & Safety Commission, 2023a). This definition includes whānau, family and carers, as well as the individual receiving care.

This use of ‘consumer’ mirrors the terminology used by the Health and Disability Commissioner. The Health and Disability Commissioner Act 1994 refers to ‘health consumer’ as including “any person on or in respect of whom any health care procedure is carried out” (Health and Disability Commissioner Act 1994, s. 2).

While acknowledging that alternative terms may be preferred by particular groups, this thesis will use the term ‘health consumer’ to reflect the broad definition of ‘consumer’ provided by Te Tāhū Hauora | the Health Quality & Safety Commission.

1.2 Aims and Objectives

This study sought to explore the profession-specific risk factors to public safety from a New Zealand health regulatory perspective. This was achieved through answering the following research question:

‘What are New Zealand health regulators’ perspectives on risk and harm?’

This primary research questions includes two sub-questions:

1. How do New Zealand health regulators form their perceptions on risk and harm?
2. What are the profession-specific risk factors to public safety from a New Zealand health regulatory perspective?

1.3 Background

1.3.1 Origins of the Health Practitioners Competence Assurance Act 2003

The regulatory reform that led to the passing of the HPCA Act arose in an environment of concern around the effectiveness of the incumbent health consumer complaints process (Scragg, 2003). These concerns led to the New Zealand Government commissioning a review in 2000 to investigate the current situation and potential areas for improvement (Scragg, 2003). The Terms of Reference of this review, the *Review of*

Processes Concerning Adverse Medical Events, focused on four areas that could lead to improving the health consumer complaints process. These included identifying any barriers to the identification and investigation of complaints, data sharing and cooperation between agencies, and identification of any areas that may improve health consumer access to these complaint mechanisms (Cull, 2001). The principal findings of the review demonstrate a range of systemic issues within the complaints process at the time, including:

- Multiple complaint processes by multiple agencies,
- Delays in undertaking complaint investigations,
- No disclosure of information between agencies or reporting of practitioners who are practicing below the required standard, and;
- Difficulties for health consumers in accessing the complaint mechanism due to a lack of health consumer knowledge and poor referral to the appropriate service.

(Cull, 2001)

While the New Zealand Health and Disability Commissioner was envisaged as the primary portal for health consumers to engage with a redesigned complaints process, the recommendations of the review helped to inform the development of the eventual HPCA Act. In this manner, the HPCA Act was strongly influenced by the aim of seeking to reduce the risk of harm by adverse events through ensuring a robust and responsive complaints system.

There are three main areas from where the HPCA Act is concerned that risk of harm to the public may arise; these being related to competence (under Section 34), health (under Section 45) or conduct (under Section 68). Section 34 of the HPCA Act describes how an RA may be informed if a practitioner "may pose a risk of harm to the public by practising below the required standard of competence", whereas Section 45 requires that an RA be notified if there is a belief that "a health practitioner is unable to perform the functions required for the practice of his or her profession because of some mental or physical condition". Under Section 68, an RA may also refer a case to a Professional Conduct Committee for further investigation if there are concerns regarding the "appropriateness of the conduct or the safety of the practice of a health practitioner". Under Section 69A, an RA may even suspend a practitioner's practicing certificate where, in the opinion of the authority, the practitioner "poses a risk of serious harm to the public" (Health Practitioners Competence Assurance Act 2003). Much of the success in achieving the aims of the HPCA Act seems to depend on identifying areas where a practitioner may pose a risk of harm to the public and, to a degree, on determining the level of this risk.

1.3.2 Public Safety and the Risk of Harm within the Act

The New Zealand government expects that, among other considerations, regulators should ensure that their regulatory objectives are clear, while seeking to achieve these objectives in the most efficient (least-cost) way (Government of New Zealand, 2017). The Ministry of Health, as administrators of the HPCA Act, have also set an expectation of efficient regulation, aligning with the principles of right-touch regulation (Ministry of Health, 2020); specifically, that regulation should be *proportionate* to the risk posed, and *targeted*, to minimise unwarranted side-effects from the regulatory process (Professional Standards Authority, 2015). The risk the HPCA Act seeks to mitigate is to public safety; however, although the HPCA Act refers to the terms 'harm' and 'serious harm' with respect to public safety, these terms are not defined in the HPCA Act.

The initial development of the Health Practitioners Competence Assurance Bill (Ministry of Health, 2000) considered the Policy Framework for Occupational Regulation (Cabinet Office, 1999) as a source of guidance. This framework was developed to provide guidance on when regulatory intervention is necessary and discusses how to balance the risk of 'significant harm' to the public against the idea that "the amount of intervention should be the minimum required to solve the problem". The framework suggests that 'significant harm' has a more substantial case for regulatory intervention if it is irreversible, involuntary (e.g., the level of risk is unknown) and/or the harm has a high probability of occurring. Again, the framework does not provide a clear definition of what 'significant risk' means but notes that the definition may change in different circumstances.

In the 2012 review of the HPCA Act (Ministry of Health, 2012), this lack of definition was noted, and it was recognised that RAs each need to determine their own working definitions of what 'harm' and 'serious harm' mean. Although some submissions favoured individual RAs determining their own definitions, there were a greater number of submissions that considered a common definition more appropriate (Ministry of Health, 2013).

Definitions of these terms used by the New Zealand Medical Council were also provided as an example and, although these were considered to be a useful starting point, submissions indicated they were not broad enough to encompass the range of potential harms in healthcare. Ultimately, the final Regulatory Impact Statement that resulted from the Review did not consider the issue of defining these terms (Ministry of Health, 2015), and each RA is still required to work under their own definitions.

The lack of clarity and agreement about the definitions of harm may therefore affect the development of competence assurance processes. If the aim of competence assurance is to minimise the risk of harm to the public, but the risk of harm is not defined, it is difficult to ensure that the competence assurance process is both *targeted* and *proportionate*, and RAs lack assurance that their processes strike an appropriate balance between minimising risk of harm and over-regulating health practitioners. It is therefore important that the understanding of risk and harm developed by each RA is accurate and clearly articulated. Inconsistent or inaccurate concepts of harm may impair both the efficient work of the RA and the ultimate goal of protecting the public.

1.3.3 Competence in Healthcare

The World Health Organisation (WHO) described ‘competence’ in 1988, recognising it as requiring “knowledge, appropriate attitudes and observable mechanical or intellectual skills, which together account for the ability to deliver a specified professional standard” (WHO Study Group on Multiprofessional Education of Health Personnel, 1988). Despite further inquiry into this topic over the intervening years, there is still a significant lack of consensus around the definition of competence (Garside & Nhemachena, 2013; Yanhua & Watson, 2011). There does, however, seem to be reasonably wide adoption of the definitions provided by Eraut (1998). Eraut considers that ‘competence’ refers to a holistic view, including consideration of a practitioner’s knowledge and understanding, whereas ‘competencies’ relate to specific capabilities that a practitioner possesses (for example, the ability to perform certain skills) (Moghabghab et al., 2018). The attainment of key competencies alone is not sufficient to demonstrate competence, as this can be seen as a ‘reductionist’ view of competence that does not necessarily represent a practitioners development of understanding in a clinical context (P. Gallagher et al., 2012). Nevertheless, they help to delineate some of the factors that contribute to overall competence.

The principal purpose of the HPCA Act suggests that practitioner competence can be used as an indicator of the degree of risk of harm. This implies that by ensuring health practitioners are competent in their practice, the risk of harm to the public is potentially mitigated. To consider competence as an indicator of risk, however, the expected threshold of competence also needs to be determined. Competence can be variously considered as a binary system (competent or not competent), a staged system (of which 'competent' may be a single stage), or a continuous scale (where only the degree of competence varies) (Clinton et al., 2005).

Many RAs under the HPCA Act have developed a list of competencies or capabilities that delineate the required knowledge, skills and attributes of competent practitioners. Practitioners are typically reviewed against the listed competencies in a binary fashion, being judged to either meet the expected standard (i.e. demonstrate competence) in each competency, or not (see, for example, the Nursing Council of New Zealand *Competencies for registered nurses* (Nursing Council of New Zealand, 2007) or the Osteopathic Council of New Zealand *Capabilities for osteopathic practice* (Stone et al., 2009)). In practice, a practitioner should be able to demonstrate adequate performance in each competency, but these must also be considered in the light of a practitioner's overall practice in order to infer their overall level of competence (Garside & Nhemachena, 2013). These competencies can also seek to cover a broad range of topic areas, which may be more or less amenable to conceptualisation as a list of requisite knowledge, skills and attributes.

Clinical competencies consist of the specific abilities of a health professional, underpinned by recognised 'best-practice' (McKeithen et al., 2011). A practitioner that is observed to meet these competencies can be considered clinically competent (Frank et al., 2010). Conversely, cultural competence may be more difficult to fully describe through a set of individual competencies. Cultural competence can be considered as a framework for “promoting respect for cultural diversity and difference” (Danso, 2018, p. 411), and is a specified area of health practitioner competence under the HPCA Act (s 118(1)(i)). Meeting a specified list of particular skills and knowledge, however, may be insufficient to provide assurance of cultural competence and, alone, may not indicate that a practitioner is competent to work with health consumers from a range of different cultures (Ide & Beddoe, 2022).

Attaining competence has been linked to the ability to function safely in practice, but not necessarily able to handle challenges that a more skilled practitioner could manage (Garside & Nhemachena, 2013). This, however, links back to the attempt to define public safety and risk of harm – if the risk of harm can never be eliminated, and the practice of a highly skilled practitioner engenders less risk of harm than that of a competent practitioner (i.e. a practitioner that just meets the threshold of competence), there needs to be some acceptance that an at-threshold but competent practitioner may still pose a higher risk than one performing at a higher level.

In this manner, the threshold for competence may be defined as *that resulting in the maximum acceptable risk to public safety from standard practice* – in other words, a competent practitioner is one who's practice (including their demonstration of the skills and knowledge associated with their clinical practice) results in an acceptable level of risk of harm. A practitioner operating below this level would be recognised as providing an unacceptable risk of harm, therefore the threshold of competence may demonstrate the level of performance where the risk of harm becomes (just) acceptable. As suggested by Watson (2002), this may mean that the most understandable definition of being competent may just be 'a lack of demonstrated incompetence', as even competence reviews may just provide more opportunity for areas of incompetence to be recognised. If this is the case, then the ability to only recognise a lack of competence through directly observing incompetence seems to be, in itself, a high-risk process.

Ultimately, each RA is responsible for setting the standards of clinical and cultural competence for the profession, and although identifying incompetence is one of the mechanisms for assuring competence used under the HPCA Act (i.e. a notification under section 34 that practice is below the required standard of competence), the HPCA Act also has other mechanisms for competence assurance to help ameliorate this issue.

1.3.4 Risk Mitigation through Competence Assurance

There are two main areas of focus on competence assurance provided for under the HPCA Act; the consideration of competence on initial registration and the monitoring of continued competence through recertification activities and notifications of competence concerns.

Attaining Competency

When a practitioner first applies for registration in a scope of practice, the RA must, in part, ensure that the applicant has the necessary qualifications for that scope of practice, and be satisfied that the applicant is generally competent to practice within that scope of practice. This two-fold approach helps to ensure confidence in the applicant's competence on entry into their profession.

Under section 12 of the HPCA Act, an RA must prescribe necessary qualifications for each scope of practice described. These qualifications are, in part, determined by what is "necessary to protect members of the public" (Health Practitioners Competence Assurance Act 2003, s. 13). RAs are then required to monitor and accredit these qualifications to ensure they maintain adherence to the accreditation standards prescribed. The focus on this pre-registration education helps demonstrate its importance "as a measure of accountability, especially to society, of the competence of individuals to enter Practice" (Curran et al., 2006, p. 87). Although the process for accrediting a qualification is not described in the HPCA Act, qualifications are generally assessed against prescribed accreditation standards developed by the RA. These accreditation standards are focused on educational quality and are also often linked to the published competency framework for the profession. There does not, however, seem to be any extensive critique of the direct impact each accreditation standard may have on competence (and therefore on public safety). There has also been criticism on the amount of power an RA has over educational practice (Tudor & Shaw, 2015).

Although attaining an accredited qualification infers that a practitioner meets the competencies of practice, an RA is not required to accept this as proof of competence at the time of registration. An RA must satisfy itself of an applicant's competence as a separate consideration, regardless of the qualification held. This helps add an extra layer of assurance on top of holding a requisite qualification, allowing RAs to consider any lapses in currency of practice or competence issues that may exist despite an applicant holding the prescribed qualification.

Monitoring Competency

Although the mechanisms for initial registration in a scope of practice help ensure a practitioner is initially competent, this does not guarantee that this competence will be maintained over their career. With the continued advancement of knowledge and best-practice in healthcare, a practitioner must work to maintain their currency of practice and keep up to date with developing standards. Furthermore, there is a professional expectation that practitioners will work to reflect on, and evaluate, their own performance to ensure their competence is maintained (Jang, 2022).

The HPCA Act allows RAs to prescribe recertification activities, which a registrant must complete on application for a practicing certificate. Recertification activities may cover a wide range of activities, such as training courses or assessment, but often serve to ensure registrants maintain some form of currency of practice (Schafheutle et al., 2013). The ability of recertification activities to assure competence has been the subject of some discussion. Traditionally, recertification has been closely linked to completing a required amount of Continuing Medical Education (CME), however there are concerns regarding how well measuring this on an hourly basis relates to improvements in competence (Ahmed et al., 2013). Other recertification activities may be based on activities around Continuing Professional Development (CPD), including incorporation of reflective practice and assessed on reported outcomes rather than hours or points (D. A. Davis & McMahon, 2018). However, while these may be successful in ensuring maintenance of currency of practice, they may not be as successful in identifying those practitioners practicing below the required standard of competency (Price et al., 2023). Other forms of competence assessments, such as practice reviews, may be considered more ‘authentic’ as the assessment seeks to mirror the same conditions as normal practice. While these forms of assessment may provide more insight, they also create a greater burden on resources (Wallis, 2014).

In addition to demonstration of competence through recertification activities, under the Section 34 of the HPCA Act, health professionals may inform an RA if another practitioner “may pose a risk of harm to the public by practising below the required standard of competence” (Health Practitioners Competence Assurance Act, 2003, s.34), and employers must inform an RA if a practitioner is dismissed because of competence issues, allowing practice below the required standard of competence to be reported. Although this allows investigation and management of practitioners who may be below the standard of competency, these mechanisms also rely on a lapse in competence being suspected. This suggests, however, that a lack of competence is typically recognised through the presence of incompetence, meaning an increased risk of harm may be present prior to issues around competence being identified.

1.3.5 Competence versus Performance

Competence is now recognised as only one of the factors that influences overall performance, as illustrated by Figure 1, below (Khan & Ramachandran, 2012). Although learned competence is a major factor in overall performance, this model suggests that other factors, such as those intrinsic to the individual or related to the environment or workplace systems, also influence performance. Ensuring the competence of a health professional is necessary, but not sufficient, to ensure a level of performance that minimises the risk of harm to the public (Vernon et al., 2019).

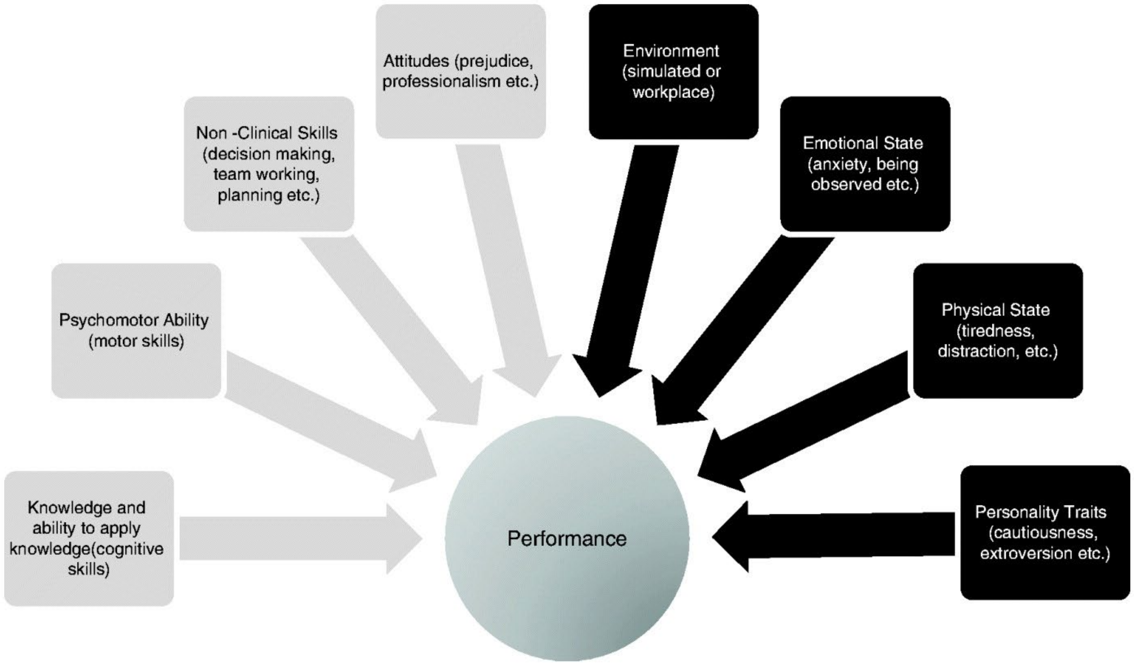


Figure 1: Factors influencing performance (grey: learned factors, black: intrinsic/environmental factors); from Khan & Ramachandran (2012)

The influence of systems-related factors has also been recognised as a significant factor behind overall risk of harm. In *To Err Is Human* (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000), the authors note that focusing on individual error and blame often does little to solve the problem. Their report considers safety from a systems perspective, noting their “primary focus is not on “getting rid of bad apples,” or individuals with patterns of poor performance” and that “the problem is not bad people; the problem is that the system needs to be made safer” (p. 49). Their view suggests that any single adverse event is due to the interaction of a complex range of factors, of which the individual is only one. They contrast the concepts of active errors, where a practitioner (or ‘operator’) makes an error and the effects are felt immediately, to latent errors, which are separate from the ‘operator’ and include such aspects as poor planning or organisational structures and systems. These latent errors tend to create higher risk, as they can be more difficult to notice and have more pervasive effects. They summarise this by noting “one of the greatest contributors to accidents in any industry including health care, is human error” but that attributing harm to human error “is not the same as assigning blame because most human errors are induced by system failures” (p. 65).

1.3.6 Expectation of Efficient Regulation

If the aim of competence assurance is to minimise the risk of harm to the public, and if the risks of harm are not defined or identified, it is difficult to ensure that the competence assurance process is both targeted and proportionate. This, in turn, means that RAs lack assurance that their processes strike an appropriate balance between minimising the risk of harm and over-regulating health practitioners.

With the recent enactment of the Health Practitioners Competence Assurance Amendment Act 2019, there is also now a mandate for RAs to “promote and facilitate interdisciplinary collaboration and co-operation in the delivery of health services” (s. 37). This suggests a trend towards team-based care and a closer working environment between RAs, however this also raises further concerns around the relationship between individual competence and the systems-related factors that influence the overall performance of the team. A team-based care environment may make it more difficult to judge the impact of a single practitioner's performance on outcomes and increase the complexity of factors influencing the risk of harm.

1.4 Study Rationale and Significance

The aims of the HPCA Act focus on mitigating the risk of harm to the public from health practitioners through a focus on assuring competence and, secondarily, by considering some of the individual-related factors that may affect overall performance.

Although the mechanisms used by RAs to achieve this aim all allow risk of harm to be reduced through assuring competence, they are not without issue. The mechanisms seem to either be reactive (i.e. only useful once a potential harm has been identified), or the relationship between regulatory requirements and a reduced risk of harm has not been clearly articulated (as may be the case with recertification programmes or certain accreditation requirements). The effectiveness of these processes relies on an accurate understanding of the factors behind the risk of harm to the public. Identifying these factors would help ensure these mechanisms are well targeted and meet the principles of right-touch regulation.

Additionally, each profession, and each place of work, introduces different factors which will influence the risk of harm to the public and, potentially, how these risks are mitigated. Comparing these factors across professions may facilitate the ability of RAs to work collaboratively or identify unique areas of risk between professions. It is also not clear how well these specific factors are understood by regulators and there appears to be a paucity of literature describing either the perspectives of RAs around risk and harm, or how they reach this understanding. Analysis of existing data in New Zealand may be impaired due to the low number of cases, the complex range of factors within each case, and the lack of data regarding each case. Together, these factors serve to limit in-depth analysis of individual cases, while also resulting in an insufficient number of cases to allow strong aggregate analysis that can be generalised across the health professions. Although high-level analysis of disciplinary cases may give some insight into areas of specific risk, this lack of data makes it difficult to draw insight into the unique makeup of risk within each profession from case data alone.

As targeted regulatory action relies on the accuracy of evidence informing these decisions, it is vital to understand the validity of these perceptions and how they may relate to the health consumer experience.

This study arose out of recognising the importance of a clear understanding of current regulatory perceptions of risk and risk mitigation mechanisms (including identifying the factors beyond competence that may need addressing). This understanding will help ensure the drivers behind regulatory decision making are overt and allow further insight into the intent and justification for regulatory action. This also provides an opportunity to identify areas of commonality or difference between the 16 professions currently regulated by the HPCA Act. This cross-regulator view will serve to help promote better interdisciplinary regulatory collaboration where practicable and help ensure a robust understanding of risk and harm by RAs. Ultimately, through promoting a clear understanding of harm amongst RAs, and facilitating cross-sector collaboration in mitigating harm, the aim of the HPCA Act to protect the public will be better served.

1.5 Study Design Overview

While a description and rationale of the study design is presented in Chapter Three – Methodology, this study will utilise a pragmatic mixed-methods approach, involving a multiphase design (see Figure 2) consisting of:

- A two-phase sequential explanatory design to provide *complementarity*

  This primary research arm consists of sequential quantitative (survey-based) and qualitative (interview-based) components. These two components provide *complementarity* (using different methods to investigate different facets of phenomena) through using multiple methods to explore the same topic.

- A parallel qualitative review to provide *triangulation*

  This secondary (case review) arm consisting of a single qualitative content-analysis component. This arm provides *triangulation* through exploring disciplinary tribunal data as an alternative source of information on disciplinary cases.

- Integrated Analysis

  These components are then considered together through an integrated analysis process. Each component is interpreted individually, and the findings are then integrated to provide an overall interpretation.

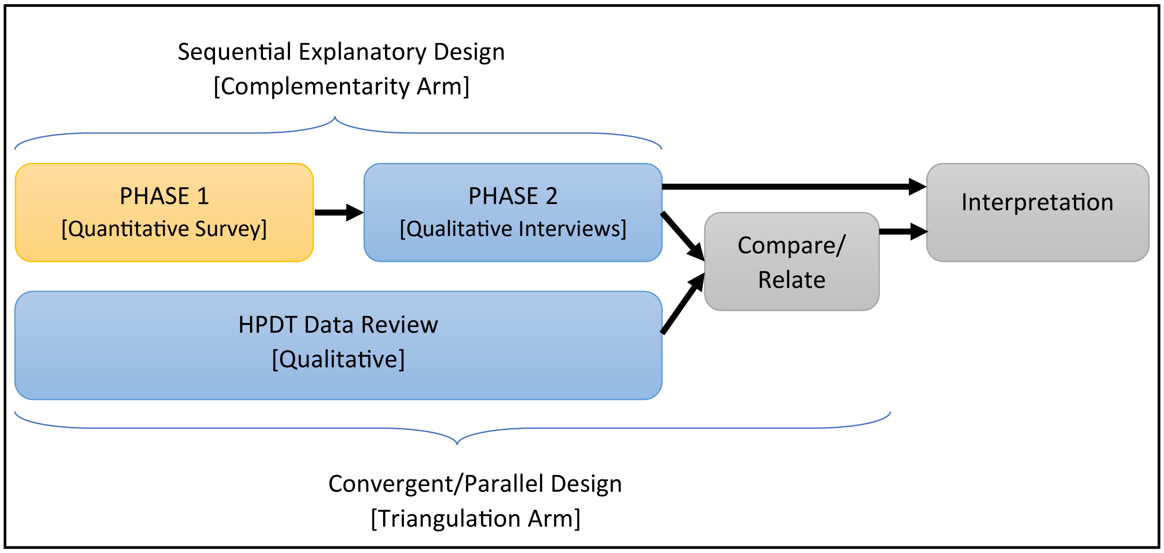


Figure 2: Summary of Study Design

1.6 The Place of the Researcher

My primary background, both in the field of healthcare and as a researcher, is through my training as an osteopath in New Zealand. My initial work included roles as both an osteopath in private practice and a lecturer in New Zealand's only osteopathic programme. As a result, I have over 10 years' experience in both clinical healthcare practice and healthcare education and research. In 2012, I was appointed as a practitioner member of the Osteopathic Council of New Zealand (an RA under the HPCA Act), where I served as a Council member for the maximum term of nine years. I have since been appointed as the Registrar for this Council.

As described in Chapter Four – Methods, and discussed in Chapter Ten – Conclusion, reflexivity is an important part of situating myself, as the researcher, within the research and the topic. This includes consideration of how my own theoretical, disciplinary, and personal views may influence the knowledge produced (Braun & Clarke, 2021b).

My experience in clinical practice, education and regulation provide insight into these areas, including how each interacts with the others. I also, however, need to be aware of how my pre-existing beliefs may influence this work. Osteopathy has a strong philosophical base, with set of fundamental concepts that can be traced back to the founding of the profession (Handoll, 2023). These principles consider a broad model of health which includes, for example, an acknowledgement of the impact of social and spiritual health on overall wellness. My clinical experience as an osteopath is also entirely in private practice. From this, my professional experience and inherent beliefs may be quite different from those health professionals working in other disciplines. As a New Zealand European male trained in a healthcare model developed in the United States of America, however, my view of healthcare has strong Western medical underpinnings.

These profession-specific factors also influence my experience as a regulator. As discussed in Chapter Eight, the osteopathic profession is comparatively small, and works almost entirely in private practice. This may again provide a different experience to larger regulators, or those who work with health professionals within the public health system. I am also not a regular user of health care services myself, and I am fortunate that neither myself nor my close family have experienced significant harm for healthcare. While I have had the opportunity to discuss health consumers' experience of healthcare within my different roles, my experience of healthcare is primarily as a practitioner or regulator. I therefore need to remain aware that my thinking may also come from the place of a healthcare practitioner rather than as a healthcare consumer.

Overall, while my professional and personal experience may help provide greater insight and understanding through this work, it is important that I remain critically conscious and reflect on any influence this may create.

1.7 Structure of Thesis

While this chapter has served to provide background contextual information on the HPCA Act, the role of an RA and practitioner factors impacting safe healthcare, Chapter Two provides a more in-depth review of literature related to this topic. Specifically, this outlines concepts of risk and harm in healthcare, including a summary of contributing factors to the risk of harm, and potential incident types that result in harm.

This is followed by Chapters Three and Four, which present the research methodology and methods used in this study.

Chapters Five through Eight present the findings of these studies. The structure of these chapters, as they relate to the study design, is outlined in Figure 3 below.

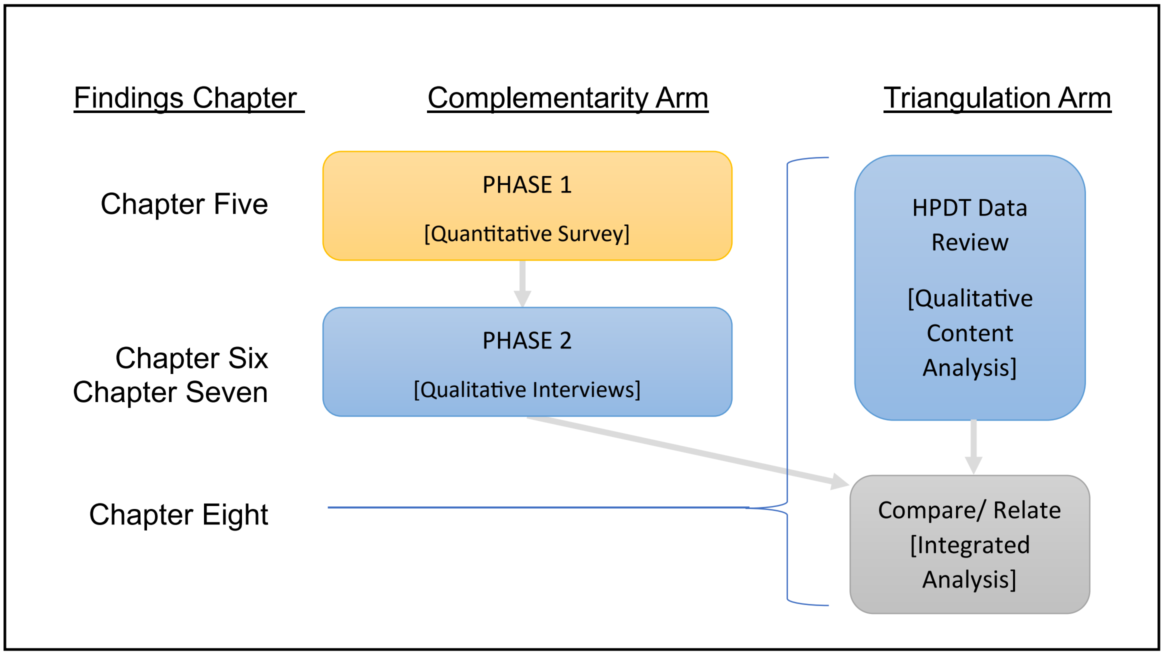


Figure 3: Thesis structure related to study design.

Chapter Five presents the findings from the first phase of the *complementarity* arm. This describes the findings from the quantitative survey performed, as well as an initial discussion of these findings as they relate to the aims of this component.

Chapters Six and Seven present the findings from the second phase of the *complementarity* arm. Chapter Six provides an overview of the themes that relate most closely to participating RA's *Perceptions of Risk* and provides an initial discussion of these themes in the context of this component.

Subsequently, Chapter Seven further expands on this by presenting themes related to participating RA's *Perceptions of Risk Management*. This separate discussion provides valuable context to how an RA's perception of risk influences their regulatory action.

Chapter Eight then provides the findings of both the single component of the *triangulation* arm as well as the findings of the integrated analysis, detailing areas of commonality and difference between the three components.

Chapter Nine provides a substantial discussion of the study findings, incorporating the findings from all aspects of the study. While previous chapters discuss the findings of each component individually, this chapter considers the importance of these findings within the context of the work of RAs and the wider New Zealand health system.

Chapter Ten then concludes this study through summarising the contribution of the research to knowledge and practice. This includes recommendations for practice and policy, as well as for future research. Strengths and Limitations of the thesis are presented, as well as a personal reflection on the research process.

Chapter Two – Literature Review

2.1 Introduction

This chapter provides an overview of the literature reviewed in order to provide context and justification for this research. It investigates the concepts of harm and risk as they pertain to health regulation, including comparison of healthcare professions in New Zealand and overseas. Following this, classifications of risk are also considered to provide a foundation for further exploration of the topic. While there is limited literature relating to the perceptions of regulators in this field, literature exploring the utility of complaints data as a source of risk information is also considered.

2.2 Literature Review Methodology

In determining the methodology for this literature review, the primary consideration was between a systematic review (such as a meta-analysis) and narrative review. Systematic reviews may be considered the 'gold standard' of literature reviews. The specific research focus and aim of reducing bias and eliminating subjectivity may, however, make these less suitable for exploring broad topics or advancing general understanding (Furley & Goldschmied, 2021). In addition, the aim of systematic reviews is often to synthesise and assess research to determine the effectiveness of a particular intervention (Greetham, 2020) or, in the case of a scoping review, to map the breadth or depth of available research (Levac et al., 2010). This may make such methodologies more appropriate for topics where a foundational body of evidence already exists.

Conversely, a narrative review can serve to provide a comprehensive background to the current topic and providing a rationale for research to be undertaken (Efron & Ravid, 2018). Narrative reviews are appropriate where a topic may have been explored from many different angles, and where there may be diverse approaches and foci within the literature (Snyder, 2019). Rather than seek to exhaustively assess all literature in a narrow field, a narrative review seeks to purposively select evidence that is most relevant to the key questions posed (Greenhalgh et al., 2018).

Due to a preliminary review indicating a lack of literature related to the perceptions of regulators, a systematic review was not considered an appropriate way of setting the foundation of this research. Instead, a narrative review was chosen to allow the context of the research question to be explored through describing other key concepts in this field.

To ensure a transparent research process, the methodology follows the four-phase approach outlined by Snyder (2019):

1. Design
2. Conduct
3. Analysis
4. Structuring and Writing

2.2.1 Phase 1 | Design

The aim of this review was to summarise the literature in the field of health consumer risk of harm with a focus on regulation. Given the breadth of the field of research, this was completed using a narrative review approach.

An initial literature search was conducted on 13th August 2019 and incorporated updates throughout the development of the thesis, with a final review being conducted in November 2023. Advise was sought from experienced library staff through the Auckland University of Technology Library to ensure all relevant databases were used and key words were developed appropriately. These searches included literature from the year 2000 onwards, using the following databases:

- Medline & Cinahl Complete (via Ebsco)
- Scopus
- Science Direct Science Direct

The initial search strategy using the following terms:

("risk of harm" OR "patient safety") AND (health OR practitioner)

This search was limited to titles, abstracts and key words, of peer-reviewed articles in English where an abstract was available.

Duplicate articles and any articles that, through a review of the title and/or abstract, seemed related to specific interventions or management protocols were also excluded from the review.

2.2.2 Phase 2 | Conduct

Use of the initial search terms returned approximately 50,000 articles. Due to the significant number of articles returned that were unrelated to the topic (primarily considering the risk of patient self-harm, and comparative safety of specific treatment protocols), iterative refinement of the search terms resulted in the follow final search terms:

("patient harm" OR "medical harm" OR "medical error" OR "patient safety") AND "risk factor*" AND NOT "self-harm"

In the initial search, this resulted in approximately 6,000 articles returned across the databases used; however, many of these focused on specific interventions.

Results were manually inspected to identify articles for inclusion. As this was a narrative review, selection was based on relevance to the review aim rather than exhaustive inclusion of literature. Article titles and abstracts were hand-searched and included based on perceived relevance.

Exclusion of duplicate articles, and manual inspection of the results from the initial search, resulted in approximately 120 articles of interest. Deep review of these articles considering perceived relevance and contribution to the narrative led to 61 articles being included in the final review. The publication year of included articles ranged from 2000 to 2023, with 2018 as the most frequent publication year (see Figure 4).

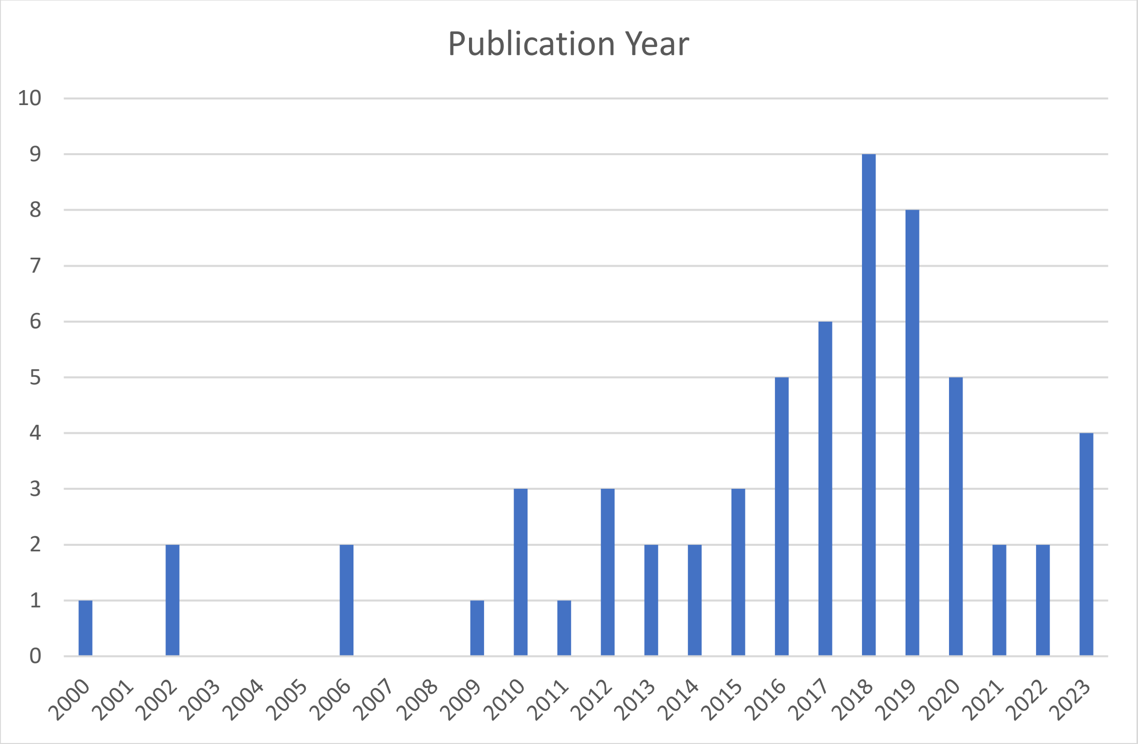


Figure 4: Publication Year of included articles.

2.2.3 Phase 3 | Analysis

To meet the aim of the review, analysis of included articles focused on identifying and exploring the significant concepts within the topic, in order to "provide an understanding of complex areas" (Snyder, 2019, p. 335). Strengths and weaknesses of each included article were considered based both on methodological strength and a subjective assessment of the contribution to the narrative. Related concepts were then organised into broad categories to provide shape to the final narrative. Concepts within each category were then compared to identify areas of agreement or contrast, also informing the narrative.

Given the subjective nature of the selection process and analysis, the researcher practiced reflexivity to identify areas that may be influenced by their own knowledge and attitudes. Expert supervisors were also consulted to provide advice and guidance throughout Phase 2 and 3. Through this process, it was identified that the included literature may be privileging western medical concepts over other models of health and harm. As shown in Figure 5, the most frequently studied categories of healthcare included hospital care and medical practitioners, representing 39% (n=24) of included articles. Further interrogation of the search results suggested that this reflected the literature returned rather than the results of article selection or analysis but is an important consideration within this review.

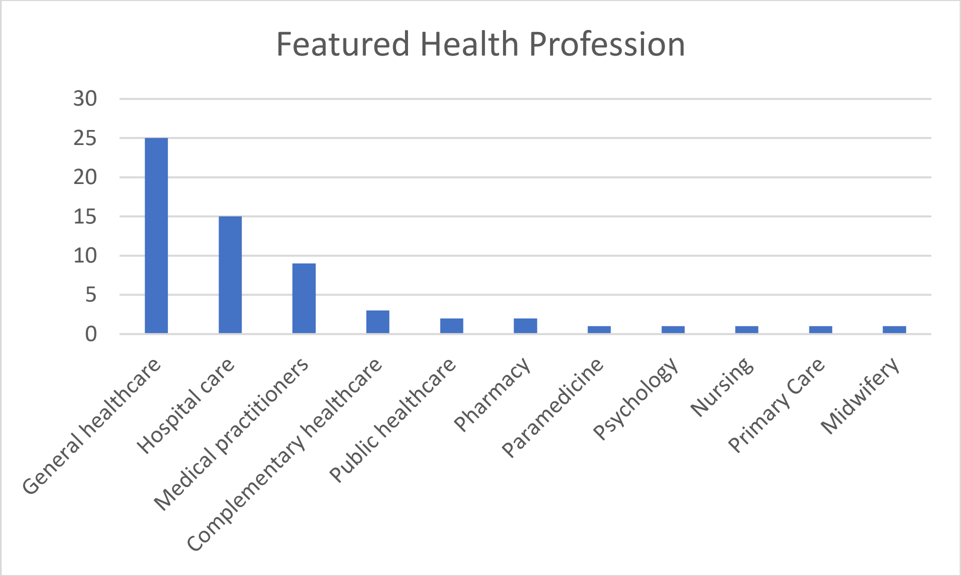


Figure 5: Health professions featured in included articles.

2.2.4 Phase 4 | Structuring and Writing

To ensure transparency of the review process, the methodological basis and methods followed have been included in this review. This includes a clear aim for the review process. The results have been drafted and reviewed for clarity by multiple parties, including the research supervisory team.

2.3 Types of Harm

This section considers literature related to the types of harm that may occur in healthcare, which is outlined in Table 1. Overall, many articles explored harm from the perspectives of either the health practitioner or health consumer. For health practitioners, concepts of harm seemed primarily based on a medical model with a limited focus in physical harm and defined ‘incidents. Conversely, patient-focused research was more likely to consider broad perspectives of harm but with a focus on the perceptions of the health consumer. There appeared to be a lack of literature that sought to link these health consumer perceptions into the more limited definitions of medical harm. As discussed below, recent literature still debates whether harm to dignity should be included as a factor in patient safety (Mitchell et al., 2023).

Table 1: Literature Overview - Types of Harm

Domain - Title - *Health Practice Type*	**Publication** - Author (Date) - *Journal/Publisher*	**Scope** - Topic - Cohort - Methods	**Findings**	**Strengths**	**Weaknesses**
- To Err is Human: Building a Safer Health System* - *Hospital care*	- Institute of Medicine (US) Committee on Quality of Health Care in America (2000) - *National Academies Press (US)*	- Medical harm - n/a - Report	High burden of medical error, lack of strong safety systems	Seminal paper in medical harm	Exclusive focus on physical harm through medical error
- Quality of hospital care for Māori patients in New Zealand: Retrospective cross-sectional assessment - *Hospital care*	- Davis et al. (2006) - *The Lancet*	- Disparities for Māori - 6579 patient admissions - Retrospective review	Māori showed a higher risk of preventable adverse events	Standardised review process	Focus on adverse events doesn't incorporate other forms of harm
- He Ritenga Whakaaro: Māori experiences of health services - *General healthcare*	- Jansen et al. (2009) - *Mauri Ora Associates*	- Māori perceptions of NZ health system - 86 (hui), 651 (survey) - Face-to-face hui, quantitative survey	Reasonable satisfaction with health services, but less from younger Māori.	Large study focusing on Māori health consumers' perspectives	Some participants may not have felt empowered to express disapproval

• Abuse in health care: A concept analysis • *General healthcare*	• Brüggemann et al. (2012) • *Scandinavian Journal of Caring Sciences*	• Concept of 'abuse in healthcare' • 11 documents on core concept, 13 related articles • Literature review	Abuse in healthcare is invisible from a medical error or patient satisfaction perspective	Analyses the specific concept of 'abuse in healthcare'	Concept may not incorporate the breadth of non-physical harms
• Chiropractic leadership in the eradication of sexual abuse • *Complementary healthcare*	• Kinsinger & Sutton (2012) • *Journal of the Canadian Chiropractic Association*	• Protocol to prevent patient abuse. • n/a • Commentary	Require education in ethics, zero tolerance for abuse and mandatory CPD	Considers broad, regulatory-type actions to mitigate harm	Protocol based on commentary article; requires testing
• What contributes to abuse in health care? A grounded theory of female patients' stories* • *Hospital care*	• Brüggemann & Swahnberg (2013) • *Scandinavian Journal of Caring Sciences*	• Experience of female patients with abuse in healthcare • 12 female patients • In-depth interviews	Abuse relates to patient vulnerability and staff domination techniques	Considers reasons abuse may occur from patients' perspective	Unknown impact of potential cultural factors
• The challenges of risk control in New Zealand public hospital • *Hospital care*	• Beaver (2017) • *New Zealand Sociology*	• Understanding of patient harm • 37 nurses, doctors, and health managers • Semi-structured interviews	Specific (task) risks heightened by general (environment/systems) risks	Large sample across three professions	Findings report understanding of risks rather than understanding of harm
• The Importance of Recognizing Social Vulnerability in Patients during Clinical Practice • *Medical Practitioners*	• Loh (2017) • *Journal of Health Care for the Poor and Underserved*	• Commentary on patient vulnerability • n/a • Commentary	Social vulnerability needs addressing at clinical, institutional and policy levels.	Direct account of experienced health professional	Commentary article; requires further exploration of topic

• Adult Māori Patients' Healthcare Experiences of the Emergency Department in a District Health Facility in New Zealand • *Hospital care*	• Abraham et al. (2018) • *International Journal of Indigenous Health*	• Experience of adult Māori patients • Four female adult Māori patients • Semi-structured interviews	Lack of integration of the Māori view of health could negatively impact experience	Exploratory study in area of little research; methods incorporated appropriate tikanga	Limited sample size
• Classification of patient-safety incidents in primary care • *General healthcare*	• Cooper et al. (2018) • *Bulletin of the World Health Organization*	• Classification of harm • 21 existing classifications • Systematic review	Existing classifications informed development of new classification	Systematic approach to consolidating diverse frameworks	Heavily informed by medical model with focus on level of medical intervention required
• Adult Safeguarding: Roles and Competencies for Health Care Staff* • *General healthcare*	• Royal College of Nursing (2018) • *Royal College of Nursing*	• Competencies associated with adult safeguarding. • n/a • Report	n/a	Provides specific competencies related to preventing a wide range of harms	Competencies are outlined at a high level
• A systematic review of pharmacist-led medicines review services in New Zealand – is there equity for Māori older adults? • *Pharmacy*	• Hikaka et al. (2019) • *Research in Social and Administrative Pharmacy*	• Medicines Review effect on health equity • 7 studies with 542 total participants • Systematic review	Lack of medicines review literature related to Māori outcomes	Demonstrates literature gaps in this field	Is unable to answer aim
• Reported Māori consumer experiences of health systems and programs in qualitative research: A systematic review with meta-synthesis • *General healthcare*	• Palmer et al. (2019) • *International Journal for Equity in Health*	• Māori experiences of healthcare • 54 studies • Systematic review	Includes recommended actions, including reduced exposure to 'health damaging factors'	Systematic process behind literature review and analysis from a consumer perspective	Policy recommendations may require input from other health system stakeholders

• Vulnerability identified in clinical practice: A qualitative analysis • *Medical practitioners*	• Sossauer et al. (2019) • *BMC Medical Ethics*	• Physician classification of 'vulnerability' • 33 physicians • Semi-structured interviews	Vulnerability is the gap between a patient's needs and the means available to meet them	Provides a broad concept of vulnerability with pragmatic applications	Research based in discussions of equity; concept may not cover all instances of vulnerability
• Understanding longer-term disability outcomes for Māori and non-Māori after hospitalisation for injury: Results from a longitudinal cohort study • *Hospital care*	• Wyeth et al. (2019) • *Public Health*	• Disability outcomes for Māori vs. non-Māori • 2199 patient records • Interviews	Difficulty accessing healthcare was a significant predictor of disability for Māori compared to non-Māori	Large dataset from across New Zealand	Study does not indicate why access issues may arise
• "I haven't even taken them to the doctors, because I have that fear of what to expect": A qualitative description study exploring perceptions and experiences of early childhood healthcare among ethnically diverse caregivers in Aotearoa New Zealand • *Public healthcare*	• Charania et al. (2023) • *The Lancet Regional Health - Western Pacific*	• Experiences of parents accessing children's healthcare • 145 caregivers (Māori, Pacific, Asian, European) • Semi-structured interviews	Trusting, culturally safe healthcare relationships are required to mitigate barriers to engagement	Large cohort representing a range of ethnicities	Sample more likely to include those engaged with the health system
• Patient Safety and the Question of Dignitary Harms • *General healthcare*	• Mitchell et al. (2023) • *The Journal of Medicine and Philosophy*	• Consider 'dignitary harms' • n/a • Commentary	Patient safety should encompass dignitary harms, including the high degree of cultural specificity of these harms	Comprehensive theoretical argument supports conclusion	Article is theoretical in nature and poses questions for practical application of findings

Note: * = Article also included in other sections.

2.3.1 Harm from Medical Error

In 2000, the Committee on Quality of Health Care in America released the report *To Err Is Human* (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000). This seminal paper regarding medical harm arose from a desire to improve the quality of medical care in the U.S., and to address the concerning rate of adverse events resulting in patient harm.

The authors of the report chose to focus on patient safety through a 'medical error' lens, based on the premises that (among others), medical errors are a significant contributor to patient suffering, that it is widely accepted that errors should not occur, and that they are easily understood by the public. The authors therefore define patient safety as "freedom from accidental injury" (p. 4). In the report, preventable 'adverse events' (defined as "an injury resulting from a medical intervention" (p. 210)) are a direct result of errors. These, in turn, are defined as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" (p. 4). Here, 'harm' seems synonymous with 'injury', and preventable adverse events are determined to arise from such factors as 'technical errors', 'diagnosis', 'failure to prevent injury' and 'errors in the use of a drug' (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000). Among the report's recommendations are that identifying, reporting and learning from errors; and a greater focus on patient safety through performance standards and expected practice, are vital to reducing errors and, therefore, risk of harm.

Following on in this theme, Beaver (2017) explored the control of risk of harm from error in New Zealand hospitals through qualitative interviews focusing on the experience of nurses, doctors and managers in this field. Beaver found nine main areas of risk mentioned by staff, being: surgical complications; diagnosis and decision making; falls, physiological deterioration, immobilisation and infection; medication; education and dehumanisation of health consumers. Although many of these could fall into similar categories identified in '*To Err Is Human*', it is interesting to note the inclusion of dehumanisation as an identified risk. Beaver noted that nurses' experience of health consumer dehumanisation "did not usually compromise safety but it caused emotional distress for patients" (Beaver, 2017, pp. 74–75), suggesting that the participants identified a type of harm (heath consumer distress) not encompassed by the definition of harm as injury arising from medical error. Interestingly, however, this statement also suggests that a health consumer's emotional distress was also not considered a safety issue. This again highlights a focus on technical error as the primary concern within these participants when considering 'safety'.

2.3.2 Harm from Healthcare Interactions

As a counterpoint to the concept of harm as resulting from errors in healthcare, Brüggemann, Wijma and Swahnberg (2012) investigated harm that could arise despite the absence of any errors. The authors completed a concept analysis around the idea of 'abuse in health care', aiming to better define the term.

Based on this analysis, the authors determined that 'abuse in health care' could be defined as health consumers' "experiences of encounters with the health care system, characterized by events that lack care, where patients suffer and feel they lose their value as human beings". They also noted, however, that these events are not often considered as conscious actions by those responsible for the abuse. They may arise out of the systems and processes (structural contexts) and cultural contexts in which they take place, including incidents of unconscious bias or structural racism.

In a follow-up study investigating abuse in health care from the perspective of female health consumers, Brüggemann and Swahnberg (2013) further clarified the experience of abuse in health care tended to arise out of the loss of a power struggle between the health consumer and practitioner (or system). This loss of a power struggle arose out of the interaction between the health consumer's vulnerability, the practitioner's competence, structural limitations (e.g. procedures or regulations) and staff domination techniques. In this way, particular personal characteristics, such as age, educational level or culture, may increase a health consumer's vulnerability to abuse in health care due to these factors' effect in the interplay of power dynamics. Again, although the abuse in health care often did not arise from a conscious action, a greater awareness of the factors behind such abuse is pivotal in reducing the risk.

Although focused on a broader area of abuse than that just existing within a health care environment, the Royal College of Nursing published guidelines in 2018 to promote skills and knowledge around adult safeguarding within the United Kingdom (Royal College of Nursing, 2018). These guidelines describe a competency framework around safeguarding vulnerable adults from abuse, aimed at health professionals. The guidelines also describe a range of types of abuse that may result in harm, including many that could occur within a health care relationship, but also warn that individuals "should not be constrained in their view of what constitutes abuse, neglect or harm and should always consider the circumstances on a person-centred basis" (p. 10). This reinforces the statement from Brüggemann, Wijma and Swahnberg that abuse in health care is considered from the perspective of the health consumer and not the position of the practitioner. Eleven different types of harm are identified in the Royal College of Nursing guidelines; among these are physical, sexual, psychological, financial, discriminatory, and organisational abuse, all of which may occur in the health care context. The guidelines also recognise 'empowerment' of vulnerable health consumers as one of the key safeguarding principles, and note that practitioners' recognition of their "roles, responsibilities, and professional boundaries, including what constitutes both organisational and professional abuse" is a core competency in safeguarding against abuse.

Kinsinger and Sutton (2012) explored the concept of professional boundaries and 'boundary violation' in more depth, through their development of a protocol to protect against such violations occurring. The authors described boundary violations as occurring when a practitioner "violates the covenant to always and without exception act only in the patient's best interest, and instead consciously or unconsciously exploits the patient to meet personal needs" (Kinsinger & Sutton, 2012, p. 69). They also noted that, despite abuse being considered from a health consumer perspective, it is not always possible for a health consumer to be aware of a boundary violation. Continuing the theme of the imbalance of power in abuse, a vulnerable health consumer may be unable to legitimately consent to a proposed action due to the inherent power differential. Following the proposed model from Brüggemann and Swahnberg (2013), a health consumer may not even be aware a power struggle has been lost. Kinsinger and Sutton, then, proposed that the key concepts to protect against boundary violations are those of professionalism and ethics, and that education in these topics should be a foundational component of professional education (Kinsinger & Sutton, 2012).

This concept of health consumer vulnerability has been further considered in the literature, where Loh (2017) identified that vulnerability serves to increase the susceptibility of health consumers to harm. While this may reflect the potential lack of legitimate consent described above, Loh suggested this increased susceptibility arises from the competing life demands a vulnerable health consumer may experience.

Vulnerability may also be seen as something that arises from the interaction between a health consumer and the environment, rather than an aspect of the health consumer themselves. Sossauer, Schindler and Hurst (2019) considered that vulnerability is an expression of a gap between the health consumer's needs and what is provided by the health system. Here, vulnerability can be created through a health system that provides too little, or too much, care for a health consumer.

Mitchell, Cribb and Entwistle (2023) expanded on this concept by considering the harms that may arise. Exploring the topics of 'dignitary harms', the authors considered whether such harms should, or could, be included within the scope of patient safety practitioners. The broad and pervasive nature of such harms may mean that currently regulatory systems will need to adapt to complex and pervasive harms arising from disrespectful and inappropriate behaviour of all types (Mitchell et al., 2023).

2.3.3 Cultural Harm

The HPCA Act specifically requires RAs to set standards of "cultural competence (including competencies that will enable effective and respectful interaction with Māori)" in addition to standards of clinical competence and ethical conduct (Health Practitioners Competence Assurance Act 2003, s. 118). This inclusion recognises the harm that is associated with poor cultural safety practices and serves as an example of the potential harm from healthcare interactions.

The recognition of a potential relationship between health disparities in minority populations and poor healthcare interactions led to research jointly funded by the New Zealand Ministry of Health and Accident Compensation Corporation. This report, *He Ritenga Whakaaro* (Jansen et al., 2009), reported on Māori experiences of health services and potential barriers to care. In addition to the cost of care, the behaviour of health providers was identified as a significant contributor to accessing care. Poor communication and potentially uninformed, disrespectful, or racist attitudes could impair health consumer satisfaction and the effectiveness of healthcare. This, in turn, could lead to an expectation of substandard care and a reluctance to access healthcare in the future for Māori.

These findings were supported by later research from Wyeth et al. (2019), who considered the disability outcomes after injury for Māori and non-Māori. Here, the authors demonstrated poorer outcomes for Māori who experienced difficulty accessing care. Again, these barriers to access included a lack of culturally appropriate care and less ability for health providers to appropriately engage with populations such as Māori. The deleterious impact of barriers towards accessing care and experiencing poorer quality healthcare can be seen in many areas, including the likelihood of adverse events in: hospital care (P. Davis et al., 2006), emergency department management (Abraham et al., 2018), medicine review services (Hikaka et al., 2019), and the experience of caregivers in seeking child healthcare (Charania et al., 2023).

While health outcomes may be impacted by social and environmental factors, a systemic review of Māori health consumer experiences Palmer et al. (2019) found that the most frequently identified factors were those involving direct interaction with the health system. The authors also found that actions designed to reduce the risk of health consumers to ‘health damaging factors’ during the healthcare interaction (such as those related to experiencing racism) were the most highly recommended, rather than those focused on reducing the unequal consequences of illness. This highlights the degree of harm (both clinically and culturally) that can arise from a lack of culturally safe services.

2.3.4 Degrees of Harm

It seems, then, that there are several types (and sources) of harm to be considered when determining where a risk of harm may exist. Harm from a medical error perspective considers injury caused through improper medical care – whether that arises from a lack of technical skill, flawed diagnostic methods or other error. These can be identified from a practitioner perspective, and may be mitigated by learning from increased reporting, and clearer standards and practices designed to mitigate identified risks. Conversely, harm from health care interactions (whether unintentional or not), may only be recognised from the perspective of a health consumer, and is conditional on their experience irrespective of whether a medical error has been made (or whether a physical injury has occurred). Here, it is the power dynamic that exists between a health consumer and practitioner that is important, and it is vital that a practitioner has the knowledge of both the potential factors behind this power imbalance and how it may influence the health consumer’s experience. In addition, the practitioner must understand the professional and ethical standards to not abuse the position of power they have.

Identifying the need for a ‘universal’ classification of the severity of harm, Cooper et. al. (2018) undertook a framework analysis of existing classifications of harm severity to develop a unified classification system. The authors’ analysis of classification systems showed a strong bias towards physical health outcomes as a measure of severity, with less than a third of rating systems including reference to emotional, mental or psychological harm. They acknowledged the difficulty in determining the degree of stress or suffering experienced after an incident and consider the term ‘emotional harm’ for mild, generally transient harm, compared with ‘psychological harm’ for moderate or severe and/or more enduring harm. As a result, the authors presented a classification system for the degree of harm, which describes the effect on the health consumer’s physical health, but also incorporates distress, impacts on mental or social function, and psychological harm. While this classification system aimed to provide a ‘universal’ system, it again highlights the disconnect between experiential, patient-focused studies and those developed from a health professional perspective. Being based on a review of existent classification systems, the authors do not seem to have sought any health consumer input into their review. As such, although this classification system provides a valuable amalgamation of existing systems, it risks failing to match health consumer’s understanding of safety and harm.

2.4 Risk of Harm

The first step in assessing the risk of harm is to identify where these risks may arise from. By identifying the factors behind risk of harm, specific controls can be put in place to at least mitigate these risks. As can be seen in Table 2, which outlines the literature associated with this topic, this literature is primarily in the form of reports and concept reviews. Much is again developed from a medical perspective, and underpinned by the concepts introduced in *To Err is Human* (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000).

Table 2: Literature Overview – Risk of Harm

Domain - Title - *Health Practice Type*	**Publication** - Author (Date) - *Journal/Publisher*	**Scope** - Topic - Cohort - Methods	**Findings**	**Strengths**	**Weaknesses**
- To Err is Human: Building a Safer Health System* - *Hospital care*	- Institute of Medicine (US) Committee on Quality of Health Care in America. (2000) - *National Academies Press (US)*	- Medical harm - n/a - Report	High burden of medical error, lack of strong safety systems	Seminal paper in medical harm	Exclusive focus on physical harm through medical error
- The relationship between competence and performance: Implications for assessing practice performance - *Medical practitioners*	- Rethans et al. (2002) - *Medical Education*	- Relationship between competence and performance - n/a - Not defined	Proposes the Cambridge Model for demonstrating the relationship between competence and performance	Articulates factors the role of systems factors versus individual competence	Primarily based on expert opinion; development methods are unclear.
- Conceptual framework for performance assessment: Competency, competence and performance in the context of assessments in healthcare – Deciphering the terminology - *General healthcare*	- Khan & Ramachandran. (2012) - *Medical Teacher*	- Competence, competency and performance related to Dreyfus and Miller - n/a - Concept analysis	Differentiates workplace vs. simulated vs. actual performance	Builds in work by Rethans et al. on influences on performance	Concepts have not been tested

• What contributes to abuse in health care? A grounded theory of female patients’ stories* • *Hospital care*	• Brüggemann & Swahnberg. (2013) • *International Journal of Nursing Studies*	• Experience of female patients with abuse in healthcare • 12 female patients • In-depth interviews	Abuse relates to patient vulnerability and staff domination techniques	Considers reasons abuse may occur from patients' perspective	Unknown impact of potential cultural factors
• From To Err Is Human to Improving Diagnosis in Health Care: The risk management perspective • *Hospital care*	• Bunting & Groszkruger. (2016) • *Journal of Healthcare Risk Management*	• Review of 'To Err is Human' and 'Crossing the Quality Chasm' • n/a • Review	After 'To Err is Human', improvement opportunities in reducing diagnostic error still exist	Summarises developments subsequent to 'To Err is Human'	Does not substantially advance the information presented in the summarised articles
• The role of the physician in transforming the culture of healthcare • *Medical practitioners*	• Smits et al. (2016) • *Leadership in Health Services*	• Explores the role of the physician in changing healthcare culture • n/a • Concept review	Physicians have a professional responsibility to promote a culture of patient care	Outlines competing values that may threaten a culture of patient care	Focuses only on physicians

Note: * = Article also included in other sections.

2.4.1 Systems-based versus Individual risk

Although the HPCA Act focuses on risk arising from the individual practitioner, studies have suggested that this is only one component of overall risk.

As outlined in Chapter One, Khan & Ramachandran (2012) described the factors that may influence performance, including both individual and environmental factors. This model was based on previous work by Rethans et al. (2002), who proposed a model by which performance is only partially related to individual competence. Under these models, both individual practitioner factors (unrelated to competence) and systemic factors have significant influence over the ultimate performance and quality of care of a practitioner.

In *To Err Is Human* (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000), the authors note that focusing on individual error and blame often does little to solve the problem. Their report considers safety from a systems perspective, noting their “primary focus is not on “getting rid of bad apples,” or individuals with patterns of poor performance” and that “the problem is not bad people; the problem is that the system needs to be made safer” (p.49). Their view suggests that any single adverse event is due to the interaction of a complex range of factors, of which the individual is only one. They contrast the concepts of *active errors*, where a practitioner (or ‘operator’) makes an error and the effects are felt immediately, to *latent errors*, which are separate from the ‘operator’ and include such aspects as poor planning or organisational structures and systems. These *latent errors* tend to create higher risk, as they can be more difficult to notice, and have more pervasive effects. They summarise this by noting “one of the greatest contributors to accidents in any industry including health care, is human error” but that this “is not the same as assigning blame because most human errors are induced by system failures” (p.65).

Bunting and Groszkruger (2016) built on this in their review of the Institute of Medicine’s reports (including *To Err is Human*). They noted that, as suggested above, the first step of improvement of health care safety is the recognition and acknowledgement that errors occur, followed by identifying how often these occur, and quantifying the effect. In specifically considering diagnostic error, they note that diagnostic error can arise either from cognitive error (i.e. practitioner error) or systems errors but, most commonly, arise from a combination of both.

This interplay of organisational and individual factors was also recognised by Brüggemann and Swahnberg (2013) when considering the factors behind abuse in health care. They suggested that while both *staff's domination techniques* and *structural limitations* (e.g. procedure and routine) were significant factors in creating the power struggles behind abuse in healthcare, *staff's domination techniques* were in turn influenced by procedure and regulation; that is, the behaviour of staff that increased the risk of abuse in healthcare (even if unintentional) was influenced by the constraints on staff by organisational procedure.

Smits, Bowden and Wells (2016) considered some of the factors behind the changing culture within medicine that may aggravate these issues. They argued that, from a western medical viewpoint, the traditional 'people-oriented' culture of medicine is defined by caring and person-centred behaviour, leading to a strong relationship between the practitioner and health consumer. Their concern was that this culture is being threatened by depersonalisation, through science and technology; bureaucracy, through increasing regulation and oversight; and commoditisation, through the increasing nature of healthcare-as-a-business. They concluded that these threats can undermine the 'caring' relationship inherent in the patient-practitioner relationship and argued for professionalism as a buffer against these threats.

2.5 Areas of Specific Risk

Two main areas of types of harm have arisen from the literature considered above, that of medical error causing an 'adverse event', and that of abuse in healthcare, resulting from the (potentially unintentional) loss of a power struggle between the health consumer and practitioner. Although these may be based on a lack of skills and knowledge on behalf of the practitioner (and therefore fall under concerns around competence), the HPCA Act also recognises the risks involved with poor practitioner conduct, potentially resulting in intentional abuse of a health consumer, as described in the Adult Safeguarding guidelines produced by the Royal College of Nursing (2018).

The risk of harm in all categories is related to the operational environment in which a health practitioner works, and a professions' culture may have a significant impact on their professionalism and ethical beliefs (Taylor, 2018). Due to this, there may be significant variability in the individual risk factors for each profession under the HPCA

Act. Although there is a paucity of research directly involving a comparison of risk of harm in health professions under the HPCA Act, this section considers several studies that have considered data from complaints and notifications in health regulation in New Zealand and overseas. An overview of this literature is provided in Table 3, which also outlines some of the associated limitations. Many of the case reviews are limited to considering a relatively small number of cases, and these can tend to focus on superficial categorisation rather than in-depth analysis of cases. These highlight the difficulty in developing insight into profession-specific risk from discipline case reviews as discussed in Chapter One.

2.5.1 Competence versus Conduct Concerns

In a retrospective cohort study, Ryan, Too and Bismark (2018) investigated complaints about chiropractors, osteopaths and physiotherapists in Australia, between 2011 and 2016. Although the small number of osteopathic complaints received (due in part to the smaller size of the profession) made comparison difficult, the authors found a number of interesting results in exploring the three professions. For both osteopaths and chiropractors, over two-thirds of complaints were regarding professional conduct issues (with a smaller number of competence concerns, and very few health-related complaints), whereas approximately half of physiotherapist complaints were of this nature. For all groups, approximately a fifth of complaints were regarding the actual treatment provided. The authors noted that chiropractors received a higher proportion of complaints regarding fees and/or honesty, which they suggest may be related to business processes and pressures, while osteopaths were over-represented in complaints regarding sexual boundaries and/or interpersonal behaviour.

Table 3: Literature Overview – Areas of Specific Risk

Domain - Title - *Health Practice Type*	**Publication** - Author (Date) - *Journal/Publisher*	**Scope** - Topic - Cohort - Methods	**Findings**	**Strengths**	**Weaknesses**
- Outcomes of notifications to health practitioner boards: A retrospective cohort study* - *General healthcare*	- Spittal et al. (2016) - *BMC Medicine*	- Notifications regarding the health, performance, and conduct of practitioners - 8307 notifications - Retrospective cohort study	Restrictive actions taken against health practitioners vary depending on source of notification, profession, and type of issue	Analysis includes a substantial number of complaints; Australia likely to be comparable regulatory environment	Variation in restrictive action may not be well explained by data available from notification characteristics
- New Zealand's Health Practitioners Disciplinary Tribunal: An Analysis of Decisions 2004-2014* - *General healthcare*	- Surgenor et al. (2016) - *Journal of Law & Medicine*	- Procedural and outcome factors of HPDT decisions - 288 decisions - Exploratory descriptive analysis	The majority of cases result in a determination of guilt. Nurses are more likely than medical practitioners to have their registration cancelled.	Includes all HPDT cases over more than 10 years; directly relevant to topic	Focus is on process and outcomes, which provides less information about the nature of each complaint
- Complementary health practitioners disciplined for misconduct in Australia 2010-2016* - *Complementary healthcare*	- Millbank et al. (2017) - *Journal of Law and Medicine*	- Trends in practitioner misconduct - 32 cases - Case review	Sexual misconduct was most common type. Removal from practice was more common than for medical practitioners.	Built on earlier work using a standardised taxonomy.	Only 32 cases identified over 6-year period.

• Practitioner Health Issues Featuring Before New Zealand's Health Practitioners Disciplinary Tribunal: An Analysis of Cases 2003-2014 • *General healthcare*	• Surgenor et al. (2017) • *Journal Of Law and Medicine*	• Health practitioner health conditions relevant to HPDT cases • 288 decisions • Case review	Health issues were primarily mental health or substance misuse conditions.	Includes all HPDT cases over more than 10 years; directly relevant to topic	The findings do not include an assessment of the relationship between the complaint and the health condition
• Fitness-to-practise concerns and preventative strategies • *Paramedicine*	• Gallagher et al. (2018) • *Journal of Paramedic Practice*	• Methods of reducing fitness-to-practice concerns • 25 international experts • Delphi process	Preventative strategies require the involvement of employers, regulators, educators, registrants, and the public.	Diverse international panel showed strong consensus in major areas	Recommendations are high-level and poor consensus shown on low-level factors
• Complaints about chiropractors, osteopaths, and physiotherapists: A retrospective cohort study of health, performance, and conduct concerns • *Complementary healthcare*	• Ryan et al. (2018) • *Chiropractic & Manual Therapies*	• Differences in complaints between professions • 1139 cases • Retrospective cohort study	Male practitioners older than 65 in metropolitan areas were at higher risk of complaint. Chiropractors demonstrated a higher rate of complaints than others studied	Analysis includes a substantial number of complaints; Australia likely to be comparable regulatory environment	Data relies on accurate coding from regulatory staff and is only based on complaints
• Outcomes of Notifications against Psychologists in the New Zealand Health Regulation Context 2004-2015 • *Psychology*	• Surgenor & Diesfeld. (2018) • *Journal of Law and Medicine*	• Characteristics of psychologists subject to notifications • 396 notifications • Case review	Less than 2% of practitioners were subject to a notification and the majority of notifications resulted in no further action being taken.	All NZ psychologist notifications to the RA were included in this review	Complaints made to other bodies would not be represented in the data

• Workplace Culture • *Nursing*	• Taylor. (2018) • *Australian Nursing & Midwifery Journal*	• Nurses and organisational culture • n/a • Commentary	Empowering staff through workplace culture can lead to improved patient outcomes	Links workplace culture, and cultural safety, to positive outcomes	Brief commentary article lacks rigour
• Adult Safeguarding: Roles and Competencies for Health Care Staff* • *General healthcare*	• Royal College of Nursing. (2018) • *Royal College of Nursing*	• Competencies associated with adult safeguarding • n/a • Report	Describes the associated competencies	Provides specific competencies related to preventing a wide range of harms	Competencies are outlined at a high level
• Doctors, drugs of dependence and discipline: A retrospective review of disciplinary decisions in New Zealand, 1997-2016 • *Medical practitioners*	• Wallis & Middleton. (2019) • *New Zealand Medical Journal*	• Disciplinary cases related to drugs of dependence • 25 decisions • Retrospective case analysis	Cases often included other forms of misconduct, and all were found guilty. There was often no patient harm documented.	Reviewed all cases over 20 years	Only 25 decisions identified; misuse of drugs may be considered a health issue and not appear before the HPDT

Note: * = Article also included in other sections.

Recognising that the nature of practice may have an impact on the nature of complaints received, the authors recommended that further investigation could focus on “the impact of profession-specific techniques, patient volume, group practice, interdisciplinary integration, and evidence-based approaches to practice” and concluded that “programs designed to address hotspots of complaint risk for these professions may help to avert patient dissatisfaction and harm” (Ryan et al., 2018, p. 8). They also warned, however, that notifications or formal complaints may only represent a small aspect of concerns about quality of care, and that most instances of concern do not result in a formal complaint. As such, it is difficult to determine how much the reported cases represent the frequency and nature of potential conduct issues in practice and highlight a significant flaw in the use of this case data in making conclusions about professional conduct.

Surgenor and Diesfield (2018) investigated complaints made against psychologists in New Zealand from 2004-2015. In comparison to the professions considered by Ryan, Too and Bismark above, complaints regarding psychologists were significantly weighted towards conduct concerns, with less than five percent relating to formal competence concerns, and three percent relating to fitness notifications. It is interesting to note, however, that of the approximately 90% of notifications that were classified as ‘complaints’, over three-quarters resulted in ‘no further action’ at triage, and less than five percent progressed to the Health Practitioners Disciplinary Tribunal (HPDT) As some of the remainder resulted in the practitioner being referred for a competency review, it may be that some of the initially classified ‘complaints’ were based in concerns around competency rather than conduct. This suggests that the initial classification of a notification may not accurately represent the underlying issues of a complaint. In their discussion, the authors also raised questions regarding profession-specific patterns in health or criminal conviction-related concerns, especially around the misuse or misappropriation of drugs by those with ready access to medication. Again, the underlying issue here may be related to a health condition rather than a simple conduct matter, making a disciplinary process less appropriate.

2.5.2 Profession-Specific Concerns

As an example of concerns that may relate to specific professions, Surgenor, Diesfield, Kersey and Ip (2017) considered the potential causes of health concerns, reviewing the health notification cases for all registered health professionals before the New Zealand HPDT from 2003-2014. Their review found that the majority of health-related cases involved mental health concerns, with these representing two-thirds of cases, followed by substance use conditions, representing almost a quarter of cases. Like previous discussions, the authors suggested that profession- or organisation-specific factors may influence the risk of these conditions occurring. They proposed that “some types of professional misconduct may be health related and predictable, and some professions offer temptations that lead to ill health and misconduct” (Surgenor et al., 2017, p. 595). For example, practitioners who are socially isolated may be at more risk of developing mental health issues, and concerns around substance use conditions may be greater amongst those whose occupations provide them with greater access to medication.

With specific reference to substance misuse, Wallis and Middleton (2019) performed a retrospective review of disciplinary decisions regarding New Zealand doctors from 1997-2016. They found that 11% of disciplinary cases involved inappropriate prescribing of drugs of dependence (whether to themselves or others), and these cases often involved other misconduct in addition to inappropriate prescribing. Interestingly, although all cases resulted in a finding of professional misconduct and tended to have severe consequences for the practitioner involved, some decisions noted that there was no harm to health consumers or safety concerns. The authors also noted that, for doctors, drug dependency is recognised as a health issue, not a crime, and that disciplinary action appears to be used as a last resort. This would likely mean that the number of discipline cases would not accurately represent the extent of this issue with the profession.

2.5.3 Organisational and Professional Influences on Risk

As the factors behind the risk of harm can vary between professions, so can the severity of the harm and, consequently, the likelihood that a complaint or notification will result in some restrictive action by a regulatory authority.

A disproportionally high number of fitness to practice concerns against paramedics and social workers in the UK led to a study by Gallagher et al. (2018) to explore the reasons behind these concerns. Through an international Delphi panel, the authors found that public attitudes and expectations, the pressure on services, and media, regulatory and workforce factors were all reasons behind the increasing number of competence and conduct concerns in the profession; in summary the concerns are related to the professions “working in pressurised environments with limited resources and high, sometimes unreasonable, public expectations” (A. Gallagher et al., 2018, p. 167). Interestingly, the authors noted that there was little data received on ‘micro-level’ (i.e. individual) factors, and that most of the discussion related to societal or organisational factors. These results suggest that many fitness to practice concerns may arise from factors at a level above the individual practitioner.

In reviewing the notifications received by the Australian Health Practitioner Regulation Agency (AHPRA) over 24 months, Spittal, Studdert, Paterson and Bismark (2016) explored the factors that might influence the outcome of notifications. Here, the authors found that although doctors had one of the highest rates of notifications, these were less likely to result in restrictive action being taken. Conversely, notifications regarding dentists or psychologists, or those involving health concerns, were more likely to result in a limitation on practice and/or a requirement for the practitioner to complete further action. They also found that although concerns about performance represented approximately half of all notifications across all the regulated health professions, it was unlikely that these concerns would lead to restrictive actions. The authors suggested several explanations for the different likelihood of restrictive actions occurring, such as the likelihood of substandard care directly causing harm and how strictly each different regulatory board may respond but note that the data available to them cannot provide sufficient insight into the details of each case.

The lower rate of restrictive action being taken against doctors was also recognised in a further study by Surgenor, Diesfield, Ip and Kersey (2016), analysing New Zealand HPDT decisions between 2004-2014. Here, the authors found that “nurses were significantly more likely to be deregistered when compared with medical practitioners” (Surgenor et al., 2016, p. 250) as the outcome of the hearing. They suggested that although this could be related to more serious transgressions by nurses, it is also possible that “nurses may have engaged in serial misconduct which may be more likely to transpire during repeated, prolonged and sometimes intimate contact with patients/consumers” (Surgenor et al., 2016, p. 250). They also noted, however, that the more severe penalties for the nurses could be influenced by the culture of the profession, and a desire of the profession to uphold their professional reputation. Similarly, doctors were more likely to have legal representation, and it was more likely for nurses to not attend their hearing.

Similar results were found by Millbank et al. (2017), when considering disciplinary proceedings brought against complementary medicine practitioners in Australia. The authors found that 72% of disciplinary cases against complementary medicine practitioners resulted in deregistration or suspension, compared to 43% of doctors. Although the small number of cases studied make drawing conclusions difficult, the authors suggested that, although this may be due to a stricter response from professional boards, it may also be influenced by doctors having better legal representation, or that there may be less public interest in the ‘rehabilitation’ of complementary medicine practitioners. They suggested that there may be a debate as to whether ‘high-status’ health professionals may be treated differently to ‘low-status’ health professionals. This suggests that the outcomes of disciplinary findings may be influenced by factors such as public perception, rather than just the potential ‘risk of harm’.

These studies suggest that, although notifications may be a useful source of data for investigating areas where practitioners may pose a risk of harm, there are other factors involved that make it difficult to draw strong conclusions from this data alone.

Table 4: Literature Overview – Identified Risk Factors

Domain - Title - *Health Practice Type*	**Publication** - Author (Date) - *Journal/Publisher*	**Scope** - Topic - Cohort - Methods	**Findings**	**Strengths**	**Weaknesses**
- A preliminary taxonomy of medical errors in family practice - *Medical practitioners*	- Dovey et al. (2002) - *BMJ Quality & Safety*	- Developing a taxonomy of errors - 42 physicians/ 344 reports - Immersion/ crystallization analysis	Developed a preliminary taxonomy, including 'process errors' and 'knowledge and skill errors'	Systematic process towards developing a taxonomy of errors; used a broad definition of 'error'	Limited to medical practitioners from USA; moderate sample size relying on self-disclosed error
- Patient Safety: The Role of Human Factors and Systems Engineering - *Hospital care*	- Carayon & Wood. (2010) - *Studies in Health Technology and Informatics*	- Approaches for analysing, mitigating and preventing medical error - n/a - Book chapter (peer reviewed)	Outlines concepts in patient safety, including human factors vs. systems factors	Provides broad overview of patient safety from a 'systems' perspective	Summarises existing information but does not advance current understanding
- Patient safety: Latent risk factors - *General healthcare*	- van Beuzekom et al. (2010) - *British Journal of Anaesthesia*	- Patient safety from a systems approach - n/a - Commentary	Focusing on latent systems factors may improve safety culture and effectively improve patient safety	Provides comprehensive overview of latent risk factors	Little insight into development of article/selection of evidence
- The Conceptual Framework for the International Classification for Patient Safety (ICPS) - *General healthcare*	- World Health Organization. (2010) - *World Health Organization*	- Categorisation of patient safety incidents - n/a - Delphi method	Provides 10 classes of concepts within patient safety, including Incident Types, Contributing Factors and Patient Outcomes	Comprehensive concept framework that aids standardisation of terms	Complex document which may not result in widespread uptake

• Doctors disciplined for professional misconduct in Australia and New Zealand, 2000–2009 • *Medical practitioners*	• Elkin et al. (2011) • *Medical Journal of Australia*	• Typology of professional misconduct • 485 discipline cases • Retrospective analysis	Most common offenses were sexual misconduct, prescribing-related charges and substandard treatment. Developed new taxonomy due to issues perceived with previous attempts.	Large number of cases across Australia and New Zealand	Reliance on Tribunal decisions may not capture all misconduct cases or details. Limited to medical physicians.
• Analysis of contributing factors associated to related patients safety incidents in Intensive Care Medicine • *Hospital care*	• Martín Delgado et al. (2015) • *Medicina Intensiva (English Edition)*	• Contributing factors to patient safety incidents • 1017 patients • Retrospective analysis	Patient related factors (such as the complexity or severity of illness) were most common, followed by working conditions, and practitioner factors	Incorporates a large number of cases from a range of hospitals	Data limited to intensive care patients, who may have a different risk profile to other patients. Narrow incident classifications based primarily on medical error.
• Outcomes of notifications to health practitioner boards: A retrospective cohort study* • *General healthcare*	• Spittal et al. (2016) • *BMC Medicine*	• Outcomes of notifications against practitioners • 8307 notifications • Retrospective cohort study	Restrictive actions taken against health practitioners vary depending on source of notification, profession, and type of issue	Analysis includes a substantial number of complaints; Australia likely to be comparable regulatory environment	Variation in restrictive action may not be well explained by data available from notification characteristics

• New Zealand's Health Practitioners Disciplinary Tribunal: An Analysis of Decisions 2004-2014* • *General healthcare*	• Surgenor et al. (2016) • *Journal of Law & Medicine*	• Assess procedural and outcome factors of HPDT decisions • 288 decisions • Exploratory descriptive analysis	The majority of cases result in a determination of guilt. Nurses are more likely than medical practitioners to have their registration cancelled.	Includes all HPDT cases over more than 10 years; directly relevant to topic	Focus is on process and outcomes, which provides less information about the nature of each complaint
• Sources of unsafe primary care for older adults: A mixed-methods analysis of patient safety incident reports • *Primary Care*	• Cooper et al. (2017) • *Age And Ageing*	• Factors behind harm for patients aged 65 years or older • 1951 incident reports • Cross-sectional review	Incidents were most likely due to inappropriate medication, communication failure and errors in clinical decision-making.	Large number of included incidents. Methods included developing a classification system for incident reports.	Limited definition of harm (serious harm = hospital admission, permanent injury or death)
• Complementary health practitioners disciplined for misconduct in Australia 2010-2016* • *Complementary healthcare*	• Millbank et al. (2017) • *Journal of Law and Medicine*	• Practitioner misconduct • 32 cases • Case review	Sexual misconduct was most common type. Removal from practice was more common than for medical practitioners.	Built on earlier work using a standardised taxonomy.	Only 32 cases identified over 6-year period.

• Spoken communication and patient safety: A new direction for healthcare communication policy, research, education and practice? • *Public healthcare*	• Iedema et al. (2019) • *BMJ Open Quality*	• Conceptual map of challenges with spoken healthcare communication • Not described • Retrospective analysis and focus groups	Critical domains for success include the environment, information exchange, attitude and listening, aligning and responding, team communication and care communicating with unique groups	Provides outline of what 'good communication' may look like, and how this may be achieved	Article acknowledges that implementing recommendations will be difficult and complex
• Prevalence, severity, and nature of preventable patient harm across medical care settings: Systematic review and meta-analysis • *Medical practitioners*	• Panagioti et al. (2019) • *BMJ*	• Quantify the nature of patient harm • 70 studies • Systematic review and meta-analysis	Prevalence of preventable patient harm was 6%; 12% of preventable patient harm was severe or led to death. 'Medication and other treatment' was the most likely cause of harm.	Large study. Meta-analysis shows CI for findings, demonstrating reliability	High variability in prevalence of patient harm found. Narrow definitions of harm used, considering adverse events/accidents.
• Language and Communication: A Vital Component of Health for People with Refugee Backgrounds • *General healthcare*	• Field et al. (2020) • *Kai Tiaki Nursing Research*	• Health and wellbeing implications of learning English for refugees to NZ • 60 adults • Supplementary analysis/Thematic analysis	Refugees have challenges accessing healthcare and health literacy. Culturally safe practice is important to mitigate these issues.	Provides insight into challenges faced by a less-researched group	Article provides insight into experience, but does not suggest how changes may be accomplished

- The Engaged Patient: The Relevance of Patient–Physician Communication for Twenty-First-Century Health - *General healthcare*	- Timmermans (2020) - *Journal of Health and Social Behavior*	- Concept of the 'engaged patient' - n/a - Commentary	Highlights that patients are more active in advocating for their own health, limiting the expectation that the health professional is the ultimate authority.	Considers various roles the patient may take in the patient-practitioner relationship and considers the impact on patient-centred care	Proposes conclusions on a theoretical basis
- Medical Care Safety—Problems and Perspectives - *Hospital care*	- Voskanyan et al. (2020) - *Integrated Science in Digital Age*	- Define 'medical care safety' and assess epidemiology of adverse events - 14 articles (incidence) & 20 articles (cause) - Systematic review and meta-analysis	Medical care is a high-risk service. Addressing this requires action at all levels of health systems, including society.	Meta-analysis includes a diverse range of countries, incorporating a large number of hospitals and observations	Methods are unclear, especially for analysis of the cause of adverse events
- Dissecting Communication Barriers in Healthcare: A Path to Enhancing Communication Resiliency, Reliability, and Patient Safety - *General healthcare*	- Guttman et al. (2021) - *Journal of Patient Safety*	- Describe facets of communication in healthcare - n/a - Commentary	Communication barriers can include behavioural, cognitive, linguistic, environmental, and technological categories. Each has different strategies for improvement.	Explores specific issues within communication to promote more targeted consideration of the topic.	Provides high-level commentary but less focus on pragmatic application

• Seeing chronic inequities: A health communication call to action • *General healthcare*	• Simpson et al. (2021) • *Communication Research and Practice*	• The role of communication in inequality in health care practices and systems • n/a • Editorial	COVID-19 response highlights the potential stigmatisation in healthcare decisions, however culturally safe practice can help counteract inequalities	Highlights key topics in healthcare inequality and culturally safe practice	Expert opinion/Editorial
• Impact of Teamwork and Communication Training Interventions on Safety Culture and Patient Safety in Emergency Departments: A Systematic Review • *Hospital care*	• Alsabri et al. (2022) • *Journal of Patient Safety*	• Effect of teamwork and communication training on patient safety • 16 studies • Systematic review	Training interventions improve patient safety culture and patient outcomes	Systematic process behind literature review and analysis, including critique of articles	Diverse training programmes and outcome measures make comparison difficult
• Exploring informed consent in midwifery care • *Midwifery*	• Madeley. (2023) • *British Journal of Midwifery*	• Provide historical and legal context to informed consent • n/a • Commentary	Good informed consent procedure safeguards patients but may challenge inflexible processes	Concise summary of foundations of informed consent	Commentary article doesn't provide strong addition to evidence base.

Note: * = Article also included in other sections.

2.6 Identified Risk Factors and Events

There appear to be two main levels to consider when attempting to identify the factors behind the risk of harm to the public from health care practitioners. To understand the potential for harm to occur to a health consumer, it seems useful to consider both the underlying contributing factors as well as the nature of the events themselves.

Table 4 outlines the literature discussed within this topic. Many of the studies agree that each case represents a complex scenario with multiple contributing factors. There seems to be a lack of consensus on what these factors may be, however, with competing lists developed by different authors. The determination of factors is also underpinned by the authors understanding of harm, and this results in many discussing risk factors with a focus on medical error.

In 2010, the WHO published a Conceptual Framework for the International Classification of Patient Safety, outlining a model of patient safety incidents (Figure 6) (World Health Organization, 2010). This model describes the relationship between a number of 'classes' that make up the overall picture of an incident. The central line of this model suggests that both 'contributing factors' and 'incident type' influences the overall outcomes for health consumers, which may be ameliorated by effective detection mechanisms and any mitigating factors present.

While exploring the factors that were associated with safety incidents in Intensive Care Medicine, Martín Delgado et al. (2015) followed a similar structure, looking at 'Contributing Factors' as their primary measure, and 'classes of incidents' as a secondary measure. These were then considered in light of the severity of the incident, based on the degree of harm to the health consumer.

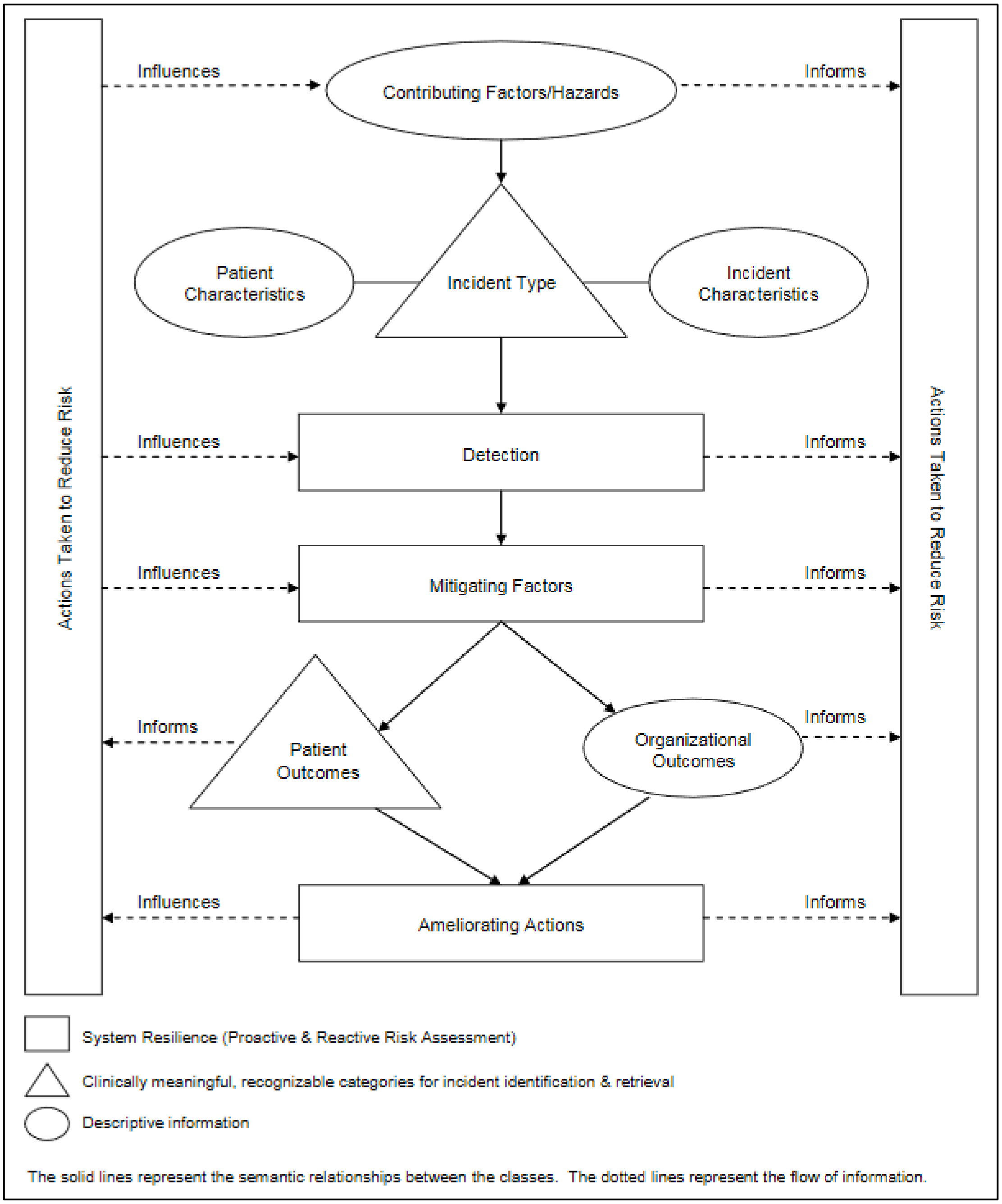


Figure 6: The Conceptual Framework for the International Classification for Patient Safety, World Health Organisation (2010)

2.6.1 Contributing Factors

Several organisations have developed lists of potential contributing factors, to help facilitate investigation and research into the causes of health consumer safety incidents.

The World Health Organisation International Classification for Patient Safety (World Health Organization, 2010) identifies five broad categories of contributing factors, covering a range of sub-factors. In comparison, van Beuzekom, Boer, Akerboom, and Hudson (2010) adapted a taxonomy developed for oil and gas operations to develop a set of ten ‘latent risk factors’ that may influence the risk of a harmful event in a medical setting and, in particular, in the Operating Theatre. Similarly, Martín Delgado et al. (2015) adapted a model developed by the National Patient Safety Agency of the United Kingdom to describe eight potential causative factors in critical safety incidents.

Despite their differences, there are areas of overlap in these models, and a summary is presented in Table 5.

Table 5: Summary of Contributing Factors

Author	**Contributing Factors (Major Categories)**				
World Health Organisation (2010)	Staff Factors	Patient Factors	Work/ Environment Factors	Organisational/ Service Factors	External Factors
van Beuzekom et al. (2010)	Training		Housekeeping	Staffing	Equipment, Design and Maintenance
	Communication			Teamwork and Team Training	
	Situational Awareness			Procedures: protocols	
				Incompatible Goals	
				Planning and Organisation	
Martín Delgado et al. (2015)	Training and Education	Patient Related Factors		Team and Social Factors	Equipment and Resources
	Communication Factors			Task Related Factors	
	Individual Factors of the Professional			Working Conditions	

2.6.2 Incident Types (Error)

Incidents that may result in harm to health consumers have also been categorised in a number of studies. The World Health Organisation International Classification for Patient Safety (World Health Organization, 2010) describes thirteen classifications of incident type, however these range from very specific types (e.g. “Oxygen/Gas/Vapour”) to broad (“Infrastructure/Building/Fixtures”) (p. 16), and may not be immediately useful for the current study.

Several studies have developed lists of ‘incident types’ that are attributed to medical error, through either investigation of healthcare data, or meta-analysis of research on harm to health consumers. These classification systems tend to be developed according to the specifics of the environment investigated, whether hospital-based (Martín Delgado et al., 2015; Voskanyan et al., 2020), primary care (Cooper et al., 2017; Dovey et al., 2002) or across all medical care environments (Carayon & Wood, 2010; Panagioti et al., 2019). As with Contributing Factors, above, there seems to be a degree of overlap in these classification systems (Table 6), however some classifications may be less useful in other professions (e.g., surgery errors in non-surgical professions).

Table 6: Summary of Incident Types

<table>
<tr><th rowspan="2">Author</th><th colspan="6">Incident Type</th></tr>
<tr><th>Medication</th><th>Communication</th><th>Clinical Decision-Making</th><th>Procedural</th><th>Infection</th><th>External</th></tr>
<tr><td rowspan="4">Dovey et al. (2002)</td><td>Medication</td><td>Communication</td><td colspan="2">Investigations</td><td rowspan="4"></td><td>Office Admin.</td></tr>
<tr><td rowspan="3"></td><td rowspan="3"></td><td colspan="2">Other Treatments</td><td>Payment</td></tr>
<tr><td>Mis-diagnosis</td><td>Execution of Clinical Task</td><td rowspan="2"></td></tr>
<tr><td>Wrong treatment decision</td><td></td></tr>
<tr><td>Carayon & Wood (2010)</td><td>Medication Errors</td><td>Transition of Care</td><td>Diagnostic Errors</td><td></td><td>Nosocomial Infection</td><td></td></tr>
<tr><td rowspan="5">Martín Delgado et al. (2015)</td><td>Medication</td><td rowspan="5"></td><td>Diagnostic Error</td><td>Surgery</td><td>Nosocomial Infection</td><td>Equipment</td></tr>
<tr><td rowspan="4"></td><td rowspan="4"></td><td>Procedures</td><td rowspan="4"></td><td rowspan="4"></td></tr>
<tr><td>Care</td></tr>
<tr><td>Diagnostic Tests</td></tr>
<tr><td>Vascular Access, Catheters</td></tr>
</table>

				Airway and Mechanical Ventilation		
				Transfusion		
Cooper et al. (2017)	Medication Provision	Communication Process	Clinical Decision-Making	Investigative Processes		Equipment Provision
						Access to Healthcare Provider
Panagioti et al. (2019)	Drugs		Diagnosis	Other Therapeutic	Healthcare Infections	
				Procedure		
				Surgical Procedure		
Voskanyan et al. (2020)	Drug Therapy		Late or Incorrect Diagnosis	Surgery		
			Incorrect Treatment Plan	Manipulation		
				Other Interventions		

The summary tables provide above serve to amalgamate the various incident types and contributing factor categorisations provided by different authors, but also serve to illustrate the continuing lack of agreement around the taxonomy of these complex factors.

2.6.3 Incident Types (Misconduct)

While the classifications above tend to consider medical error as a source of harm, the HPCA Act also considers the risk of harm created through conduct issues of practitioners. The HPDT makes determinations regarding proceedings brought against health practitioners, under the auspices of the HPCA Act (Health Practitioners Competence Assurance Act 2003).

The types of misconduct leading to medical practitioner disciplinary cases from 2000 to 2009 across both Australia and New Zealand were described by Elkin, Spittal, Elkin and Studdert (2011). The major categories of types of misconduct described were: Sexual misconduct towards patients; Illegal or unethical prescribing; Inappropriate medical care; Misconduct not in relation to patient; and Other misconduct.

Although this study only considered disciplinary complaints against doctors, Millbank et al. (2017) adapted the typology proposed by Elkin et al. (2011) to investigate disciplinary cases against complementary health practitioners in Australia (Chinese Medicine, Chiropractic and Osteopathy), with the recognition that ‘illegal or unethical prescribing’ was unlikely to be central to the practice of the professions investigated (and, indeed, was only present as minor breaches in relation to Chinese herbal medicine).

Spittal, Studdert, Paterson and Bismark (2016) investigated all notifications (including those related to Performance, Conduct and Health) lodged with the Australian Health Practitioner Regulation Agency (AHPRA), which regulates a range of health professions similar to those under the HPCA Act. In addition to performance and health concerns, the categories of issues behind conduct notifications were described as: Disruptive behaviour; Improper use or management of health information; Non-compliance (admin/regulatory requirements/fraud); Unlawful use or supply of medications; Unfair costs or misleading advertising; and Breaches of boundaries.

Although these studies tended to consider notifications arising in Australia, or in both Australia and New Zealand combined, there seems to be a lack of literature regarding the type of incidents arising in notifications to RAs across all professions under the HPCA Act in New Zealand alone. A review of all HPDT hearings (across all professions) from 2004 to 2014 investigated the procedural factors and outcome factors (including practitioner characteristics) (Surgenor et al., 2016), but did not describe the incident types that led to notification.

2.6.4 Communication – a complex factor

As an area of risk, communication arises here as both a contributing factor and as an incident type. Given the breadth of issues that can be attributed to communication error, and the vital place of communication in healthcare, there has been criticism that collating all such issues together prevents learning from such errors (Guttman et al., 2021).

Communication can be considered from the perspective of simple information transference but is more recognised to be a powerful influence of social dynamics both within a healthcare team and with the health consumer (Iedema et al., 2019).

Within a healthcare team, communication has been found to impact the safety culture and ability of a team to work together, with communications training resulting in a direct improvement to health consumer safety (Alsabri et al., 2022).

More broadly, however, good communication has been recognised as a powerful factor in mitigating the risks associated with vulnerable populations. Recent studies have identified that communication is key for improving culturally safe practice and addressing health inequalities for vulnerable populations within New Zealand (Field et al., 2020; Simpson et al., 2021).

Clear communication is also vital for effective informed consent processes and empowering health consumers in their own healthcare journey (Madeley, 2023; Timmermans, 2020).

Therefore, while communication is specifically categorised here as both a contributing factor and incident type, aspects of communication pervade all areas of the health consumer experience.

2.7 Understanding Risk through Complaints

Although the data described in section 2.5 *Areas of Specific Risk* is often derived from complaints and notifications received by regulators, there are some challenges in using such complaints as a primary source of data.

The literature in this section, outlined in Table 7, seems to show broad acceptance that complaint data may be useful, but that there are several key issues. These include the requirement for substantial amounts of data and a more consistent approach to analysing the details in each complaint. With poor predictive results being seen even in studies with a substantial amount of data (for example, Spittal et al. (2019) with over 39,000 complaints) the challenge of drawing valid conclusions from the few cases seen in New Zealand is clear.

2.7.1 Challenges with complaint data

In reviewing health consumer-reported safety concerns in hospital, O'Hara et al. (2018) determined that health consumers in the United Kingdom were readily able to provide valuable information regarding their own safety. The content of these concerns, however, differed in nature from those collected from hospital incident reports, and tended to focus more on 'suboptimal' issues rather than overt safety concerns. The authors suggested such concerns were potentially most useful as an additional source of information to traditional safety reviews.

van Dael et al. (2022) further supported this conclusion after reviewing five years of health consumer complaints and incident reports within a London hospital environment. Here, the authors found a small overlap between complaints and incident reports, but concluded that health consumer complaints were useful, in that they may "supplement, test, and challenge" incident report data (van Dael et al., 2022, p. 48). A similar review of Turkish hospital complaints by Zengin et al. (2014) also found that health consumer complaints served to provide a useful tool for quality assurance, with a greater focus on systems factors and poor practitioner attitudes

Table 7: Literature Overview – Understanding Risk

Domain - Title - *Health Practice Type*	**Publication** - Author (Date) - *Journal/Publisher*	**Scope** - Topic - Cohort - Methods	**Findings**	**Strengths**	**Weaknesses**
- Relationship between complaints and quality of care in New Zealand: A descriptive analysis of complainants and non-complainants following adverse events - *General healthcare*	- Bismark et al. (2006) - *BMJ Quality & Safety*	- Characteristics of injured patients who make complaints - 398 complaints/ 847 non-complaint adverse events - Retrospective review	0.4% of adverse events resulted in a complaint to the HDC. Severity of injury was the main predictor of likelihood to complain.	Provides insight into rates of complaints through triangulating data	Only considers complaints made to HDC; complaints may have been made and resolved through other means.
- Identification of doctors at risk of recurrent complaints: A national study of healthcare complaints in Australia - *Medical practitioners*	- Bismark et al. (2013) - *BMJ Quality & Safety*	- Risk factors for the likelihood of complaints against doctors - 18907 complaints - Recurrent-event survival analysis	Risk factors include number of previous complaints, specialty and gender. Suggests likelihood of complaint can be predicted for individual doctors.	Conclusions based on large sample size; both case numbers and individual doctors	Does not consider nature of cases or context of practitioner (i.e. non-individual factors)
- Patient complaints in healthcare systems: A systematic review and coding taxonomy - *General healthcare*	- Reader et al. (2014) - *BMJ Quality & Safety*	- Develop a coding taxonomy for complaints - 59 articles inc. 88069 complaints - Systematic review/bespoke coding system	Complaints are most likely to refer to communication or treatment issues. Inconsistent analysis requires improvement in methodology.	Systematic review includes a substantial number of cases. Clear methodology.	Lack of comparability and limitations of data prevent robust conclusions.

• Analysis of complaints lodged by patients attending a university hospital: A 4-year analysis • *Hospital care*	• Zengin et al. (2014) • *Journal of Forensic and Legal Medicine*	• Evaluate nature of complaints by patients and relatives • 453 complaints from 2,031,361 patients • Retrospective analysis	Low frequency of complaints (0.22 per 1000 patients). Complaints were most likely regarding attitude of staff.	Considers a large patient population over 4 years	Comparably low complaint numbers may suggest complaints may not fully represent concerns.
• Resilient health care: Turning patient safety on its head • *General healthcare*	• Braithwaite et al. (2015) • *International Journal for Quality in Health Care*	• Discuss limitations of a common patient safety model and propose an alternative • n/a • Commentary	A greater focus on successes, rather than failures, may ameliorate challenges with ensuring safe healthcare.	Applies developments in general safety thinking to healthcare	Suggests a significant paradigm shift without addressing likely barriers to implementation
• From Safety-I to Safety-II: A White Paper • *General healthcare*	• Hollnagel et al. (2015) • *The authors (self-published)*	• White paper proposing the concept of Safety II • n/a • Report	A focus on 'what goes right' rather than identifying/fixing errors may be a more useful method of improving healthcare safety.	Outlines proposed new model of approach to safety	Discussion of model is at a theoretical level.
• What patients' complaints and praise tell the health practitioner: Implications for health care quality. A qualitative research study • *Hospital care*	• Mattarozzi et al. (2016) • *International Journal for Quality in Health Care*	• How patient complaints and praise to inform quality of care • 1235 complaints/ 1536 incidents of praise • Content Analysis	Both complaints and praise were likely to relate to 'relationship' aspects of care. System management was the most frequent cause of complaint.	Combines both negative (complaint) and positive (praise) feedback in a novel manner.	Authors recognise difficulties on standardising analysis of data.

• New Zealand’s Health Practitioners Disciplinary Tribunal: An Analysis of Decisions 2004-2014* • *General healthcare*	• Surgenor et al. (2016) • *Journal of Law & Medicine*	• Assess procedural and outcome factors of HPDT decisions • 288 decisions • Exploratory descriptive analysis	The majority of cases result in a determination of guilt. Nurses more likely than medical practitioners to have registration cancelled and not receive permanent name suppression.	Includes all HPDT cases over more than 10 years; directly relevant to topic	Focus is on process and outcomes, which provides less information about the nature of each complaint
• Learning from incidents in health care: Critique from a Safety-II perspective • *General healthcare*	• Sujan et al. (2017) • *Safety Science*	• Offers a Safety-II perspective of learning from incidents in healthcare • n/a • Commentary	Suggests a dual process of responding to individual complaints and broader analysis for learning.	Considers practical implications of a combined Safety-I/Safety-II approach	Does not provide robust evidence of efficacy of changing paradigms
• The problem with using patient complaints for improvement • *General healthcare*	• de Vos et al. (2018) • *BMJ Quality & Safety*	• Authors' concerns with the use of complaint data for healthcare improvement • n/a • Commentary	Complaints processes and case complexities provide barriers to the validity of complaints data	Considers a counterpoint to the use of a common source of data	Is primarily based on expert opinion
• What can patients tell us about the quality and safety of hospital care? Findings from a UK multicentre survey study • *Hospital care*	• O’Hara et al. (2018) • *BMJ Quality & Safety*	• The nature of patient-reported safety concerns • 2471 inpatients • Patient interviews	23% of patients reported concerns. More than half of concerns reported would not typically be seen as Patient Safety Incidents.	Incorporates direct interviews with patients about their care eliciting a broad range of concerns.	No triangulation performed to determine accuracy or context of concerns

• Identification of practitioners at high risk of complaints to health profession regulators • *General healthcare*	• Spittal et al. (2019) • *BMC Health Services Research*	• Algorithm to predict likelihood of complaint • 715,415 health practitioners/ 39,575 complaints • Retrospective cohort study	Algorithm showed variable success across professions but showed promise for doctors and dentists	Incorporates a very large data set and a number of diverse variables to determine score	Despite large dataset, shows poor accuracy for many professions. Authors note reliance on large complaint rates to be effective
• Resilience and regulation, an odd couple? Consequences of Safety-II on governmental regulation of healthcare quality • *General healthcare*	• Leistikow & Bal. (2020) • *BMJ Quality & Safety*	• Application of 'Safety-II' to healthcare • n/a • Commentary	Safety-II approach may provide advantages, but may require significant changes in regulatory approaches	Provides examples of how regulation may utilise a Safety-II approach	Provides expert opinion on topic, including pertinent examples, but variance in regional regulatory schemes add complexity to implementation.
• Learning from complaints in healthcare: A realist review of academic literature, policy evidence and front-line insights • *General healthcare*	• van Dael et al. (2020) • *BMJ Quality & Safety*	• Integrating patient complaints into quality systems • 74 studies and 10 policy documents • Literature review/patient co-design/expert review	Complaint analysis studies rarely situated in practice. Complaints may be used for triangulation but need to be reliable/valid.	Incorporates several different sources of evidence to explore varied facets of topic.	Indicate high-level potential improvements but needs to be situated in the context of local systems
• Getting the whole story: Integrating patient complaints and staff reports of unsafe care • *Hospital care*	• van Dael et al. (2022) • *Journal of Health Services Research & Policy*	• Integrate patient and staff reporting to understand risk and harm • 5,265 patient complaints, 81,077 staff reports • Retrospective review	7.6% of complaints and reports overlapped, with patients reporting higher harm in most cases. Patients and staff tend to present different perspectives on the same incident.	Combines views from both patients and staff to determine areas of similarity and difference.	Retrospective review prevents analysis of incidents to provide independent view

- Grading pharmacists' risk of complaints to a regulator: A retrospective cohort study - *Pharmacy*	- Morris & Spittal. (2023) - *Journal of Pharmacy & Pharmaceutical Sciences*	- Grading tool to categorise the magnitude of risk represented by complaints - 3675 complaints - Survival analysis	Risk factors include male gender, increased age (to 59 years), international training and presence of previous complaints	Design allowed tracking of practitioners over 11 years; based on previously developed taxonomy	Primary outcomes seem based on likelihood of receiving complaint, not on severity or nature of complaint

Conversely, de Vos et al. (2018) raised a number of concerns with the use of health consumer complaint data to inform perceptions of risk. For these authors, complaints result from a complex situation leading to an incident of harm but the information they contain may not fully represent the facts of the matter. They warned that complaints are often considered as isolated incidents, and are a “complex and elusive information source with data of low and unreliable volume” (de Vos et al., 2018, p. 761). Again, the authors recommend that complaint data is not used as a single source of information but is considered in combination with other data representing health consumer safety.

A review of complaints to the New Zealand Health and Disability Commission by Bismark et al. (2006) also led the authors to warn of the significantly low proportion of incidents of harm that result in complaints, especially amongst some vulnerable groups. These two studies suggest that complaints may provide limited insight into the risks leading to an incident of harm, and that many incidents of harm go unreported – more so amongst the more vulnerable health consumer groups.

In recognition of the complexity of data that can be found in health consumer complaints, however, attempts have been made to standardise reporting and analysis of this information.

Through synthesising the findings of a systematic review on the safety of health consumers, Reader, Gillespie and Roberts (2014) developed a coding taxonomy for complaints. A further study by Mattarozzi et al. (2016) found that application of this taxonomy provided valuable insights into healthcare practices, including the analysis of both complaints and praise from health consumers.

Through co-design with health consumers, van Dael et al. (2020) developed a series of mechanisms to achieve a more health consumer-centric method of handling complaints and providing quality improvement. Again, the authors here concluded that health consumer complaint data could be valuable is collected, analysed, and used in a systematic and standardised manner.

Overall, then, these studies suggest that health consumer complaint data can be a valuable addition to assuring safety, but it requires a purposeful and standardised approach, in collaboration with other sources of data.

2.7.2 Prediction of complaint data

Using large volumes of complaint data, however, attempts are being made to proactively identify areas (and practitioners) of higher risk.

Bismark et al. (2013) found that the number of previous complaints received about individual Australian doctors was a strong predictor of further complaints. This process was further developed in a subsequent study, which used complaints data (both number of complaints and complaint issue) as factors with a wider 'risk score' model named PRONE-HP (Spittal et al., 2019). A later study focusing on pharmacists rather than other health professionals found the model useful in ruling out 'low risk' practitioners (Morris & Spittal, 2023).

While such use of complaints data shows some promise within these studies, it requires very large numbers of complaints, with the two earlier studies including 18,907 and 39,575 complaints respectively (Bismark et al., 2013; Spittal et al., 2019). This may be less practicable for health professions in New Zealand, with the HPDT seeing less than 300 cases across all professions between 2004 and 2014 (Surgenor et al., 2016).

2.7.3 Alternative approaches to complaint data

While understanding risk through the use of complaints data is common, other methods have been explored in the literature. The most common of these is an approach known as 'Safety-II'.

Initially presented by Hollnagel, Wears and Braithwaite (2015), this approach focuses on exploring where a health system may show resilience (e.g., resistance to poor outcomes despite risks) rather than on historical incidents. The potential application of this to the safety of health consumers was published by Braithwaite, Wears and Hollnagel (2015), recognising that clinicians are constantly responding to adverse conditions without necessarily impacting the delivery of care.

Further discourse by Sujan, Huan and Braithwaite (2017) provided both a rationale and potential pathway for introducing Safety-II as a process for enhancing learning from past incidents, through a focus on normal practice (rather than incidents of poor care).

While these articles provided promising theories of how this approach could improve safety, a further study by Leistikow and Bal (2020) sought to explore the utility of such an approach in health regulation. While the authors again recognised the value of this approach, they warned that enacting such a change in paradigm would present challenges for regulatory practice and that “regulation can probably never be premised exclusively on Safety-II” (Leistikow & Bal, 2020, p. 872).

As such, while a Safety-II approach may provide value to health regulators, it may not be a simple process to enact due to the broad changes in both process and fundamental approach to considering safety.

2.8 Conclusion

This narrative review has provided an outline of literature related to risk and harm in health consumer safety.

As a concept, ‘harm’ contains a broad range of potential impacts on a health consumer, and discussion around the breadth of what may be considered ‘harm’ and where this sits within the remit of public safety is still ongoing. Much of the literature investigating this topic seems to be based on a traditional medical view of healthcare, and incorporation of the health consumer voice into these discussions seems to be at an early stage. The risk factors that may lead to harm are complex and include factors both related to the individual practitioner and the surrounding environment. To provide a platform for further discussion, this review has presented current classifications of both risk factors and incident types, and proposed an amalgamated classification based on these reviews.

There is limited literature regarding how regulators may form their perceptions of risk, however. Literature discussing the utilisation of patient complaint data indicates that, while this data has some value, there are challenges associated with its collection and representation of clinical incidents. While this data may show some promise for ‘big data’ predictive modelling, this requires significant amounts of data and may not be viable in the New Zealand context. Similarly, while there may be alternative approaches to understanding risk and improving safety (such as a Safety-II approach) moving to such a system would provide challenges for current regulatory processes.

This highlights the importance of research into the perceptions of New Zealand regulators around risks in healthcare. A clear understanding of RAs' perceptions of risk may help provide insight into the accuracy of these perceptions or suggest areas of improvement in how these are understood. Exploring the relationship of these perceptions to the views of health consumers can also help ensure that regulatory action is acting to meet the expectations of the public. Without clear and accurate knowledge of the risks they are aiming to mitigate, and the harms they are trying to prevent, RAs will be poorly placed to meet their obligations under the HPCA Act and protect consumers from harm.

Chapter Three – Methodology

3.1 Introduction

This chapter describes the identification of an appropriate research paradigm, then presents the methodology and methods for the overall study, as well as each of the three major components. Firstly, the research context is outlined, leading to a discussion on the identification of pragmatism as the guiding paradigm behind the methodology of this mixed methods study. Secondly, the methodology is described, including an explanation of the design decisions behind the use of a two arm, multi-phase study design and consideration of the overall analytical process.

3.2 Research Paradigm

This study sought to explore New Zealand health regulators' perspectives on risk and harm. Specifically, the focus of this study was not to identify the risks to public safety that may actually exist in practice, but to explore the perceptions of regulators (here, RAs under the HPCA Act), with the aim of informing and enabling practical change. While many studies investigating health practitioner complaints focus on notification and regulatory decision data (such as from notifications or disciplinary outcomes), there seems to be limited information regarding the perceptions and decision-making processes of New Zealand RAs themselves.

This limitation in the literature may be linked to specific challenges researching this field. Collectively, the approximately 110,000 health practitioners with practicing certificates (as of 2019) are represented by sixteen RAs. While each of these RAs must follow certain processes prescribed by the Act, there is a large degree of flexibility in how these can be interpreted and implemented. Each RA may have different factors that influence the decision-making process leading to, for example, a notification being referred through a formal disciplinary process. There may also be a significant difference in the number cases each authority reviews, with some authorities having never referred a case to the HPDT. Taken together, this can mean a lack of standardised data available for review. Furthermore, while key members or staff or RAs may provide deep, insightful information about their perceptions and factors around decision-making, the limited number of RAs and difficulties generally encountered in accessing such people for research can limit the opportunities for gathering data. To overcome these challenges, two key considerations were identified that would allow the research question to be answered in a way that allowed for meaningful, practical change.

3.2.1 Exploring Belief and its Application to Practice

The first of these considerations is through exploring belief and how these beliefs may influence practice. Aligning both with the aim of the Doctor of Health Science programme; to "inform and impact on practice" (Auckland University of Technology, 2022) and with the intent of the primary researcher to create a 'useful outcome' (i.e. either informing or directly changing regulatory practice to enhance public safety), an appropriate research paradigm would be one that prioritises a direct impact on real-world practice.

A Participatory research paradigm, such as Action Research, can be a popular research methodology for practising professionals, as it can focus at a very 'applied' level through the construction and testing of local knowledge and solutions (Edwards & Willis, 2014). This type of research has a focus on collaborative, community engagement (Higginbottom & Liamputtong, 2015), however, this approach was considered less suitable for an inter-professional research project involving a collection of ostensibly independent RAs, where the potential for coordinated change is not known. Additionally, the ongoing process of co-design, reflection and action inherent in a Participatory model may be hampered by the requirement of careful and well-justified change within the regulatory field, making this an impractical approach for this research.

A Pragmatic paradigm is intimately linked with action and practice - valuable research is considered that which results in a positive impact on action (Cornish & Gillespie, 2009). In addition, Bishop (2015) states that the aim of a Pragmatic approach is to reveal knowledge that has "valuable external consequences in the context of the researcher's own time and place" (p. 7). This paradigm also supports the research focus on the beliefs and perceptions of RAs as a source of insight into regulatory practice; that is, why exploring these beliefs may provide an understanding of the decisions regulators make, and the function of the regulatory process in achieving its aims.

For Pierce, the aim of inquiry is to settle opinion or ‘fix belief’, and the primary way to test belief is to consider it against the practical consequences this belief may have (Peirce, 2012). While regulators may hold beliefs about the risks associated with healthcare, there is limited information on what these beliefs are, and how cohesive or disparate they may be within regulation and the wider healthcare system. John Dewey, who further developed the work completed by Pierce, also argued that it is the interaction of people and their environment that leads to the development of knowledge, and that considering actions and their consequences are of particular importance in this development (Allemang et al., 2022). In considering this interplay between belief and action, Dewey highlighted the difference between semi-automated, habitual actions and more self-conscious decisions that may arise through the process of inquiry (Morgan, 2014b). Valuable information can best be gained through investigating the experiences of those closest to the ‘problem’ an investigation seeks to address (Cornish & Gillespie, 2009) and considering how their experiences and beliefs may lead to decision making and the resultant actions.

While the primary arm of this study focuses on the identification of these beliefs, this will allow further review of the potential impact on regulatory decision making, thereby completing the link to action and regulatory practice. Through the secondary arm, the practical results of these beliefs will be considered through triangulation with the outcomes of professional conduct cases arising within each profession. The overall results of this study will set a foundation for further inquiry in this area. As Pierce wrote, “To know what we think, to be masters of our own meaning, will make solid foundation for great and weighty thought” (Peirce, 2012, pp. 97–98).

3.2.2 Sources and Availability of Data

The second of these considerations involves acknowledging the challenges with research in this field. Given the research context outlined above, an appropriate research paradigm must also show some tolerance towards the lack of availability of standardised data and the limited population being studied. Risk analysis typically exists in a context of limited data and a large amount of unknown factors, and this can lead to significant issues when aiming for epistemic justification of knowledge (Lindaas, 2016).

Taking a postpositivist approach for this study could result in significant methodological challenges as, for many health professions in New Zealand, there seems to be very little, if any, standardised data on the risk factors behind incidents of health consumer harm. Similarly, there are a limited number of RAs under the HPCA Act, meaning that it is unlikely any meaningful inference would be possible from the data of individual professions, or from individual regulators. Data would likely need to be aggregated across all professions, and this would suffer from significant disparity in the size of the various professions.

Pragmatism ascribes to the notion of ‘fallibilism’ in that it accepts that the validity of knowledge gained through inquiry cannot be known with absolute certainty (Hammersley, 2004). The value of knowledge is instead ultimately judged by the predicted or actual consequences of this knowledge in solving an identified problem or shaping perceptions (Long et al., 2018). As described in the research question, the focus of this study was not to identify the risks to public safety that may exist in practice, but to explore the perceptions of regulators (here, RAs under the HPCA Act), with the aim of enabling and informing practical change. Identifying the perspectives of decision makers (those creating practical change) helps inform further discussion and identifies areas where improvements (such as increased efficiencies) can be made, while accepting potential limitations on the accuracy of these perceptions.

In part, this acceptance of fallibilism and evaluation of knowledge based on its utilitarian consequence in a particular context, is also reflected in the pragmatic concept of pluralism. William James suggested that particular ideas or theories may not hold more inherent value than others, but that this value could again be determined by their utility in a particular situation (Dolan et al., 2022). For James, this held true for questions of epistemology as well as other views, allowing a pragmatist to consider the utility of research approaches and methodologies over their epistemological foundations (Allemang et al., 2022). In developing a pragmatic research methodology, a researcher can consider how quantitative, qualitative and/or mixed research approaches may each best serve to address the real-world problem encapsulated by the research question (Morgan, 2014a). Utilising these multiple approaches may also serve to mitigate any issues resulting from reliance on one source of information, such as the availability of data. These themes of plurality and fallibilism are reflected in Peirce's approach to reasoning, where he states the process "should not form a chain which is no stronger than its weakest link, but a cable whose fibres may be ever so slender, provided they are sufficiently numerous and intimately connected." (Peirce, 2012, p. 157) In this way, multiple approaches to the same issue may be more useful that a single approach.

In designing this study, then, the flexibility of a pragmatic approach allowed the best utilisation of a limited population through the use of both qualitative and quantitative approaches. The utilisation of multiple methods of enquiry (each representing the 'slender threads' of Pierce) to provide *complementarity* in the primary arm of this study will serve to avoid error, while still allowing both a breadth and depth of practically useful knowledge to be found within the limited sources of data available.

3.3 Methodology

3.3.1 Design of the Study

The study utilised a pragmatic mixed-methods approach, involving a multiphase design (see Figure 7) consisting of:

- A two-phase sequential explanatory design to provide *complementarity*
- A parallel qualitative review to provide a degree of *triangulation*

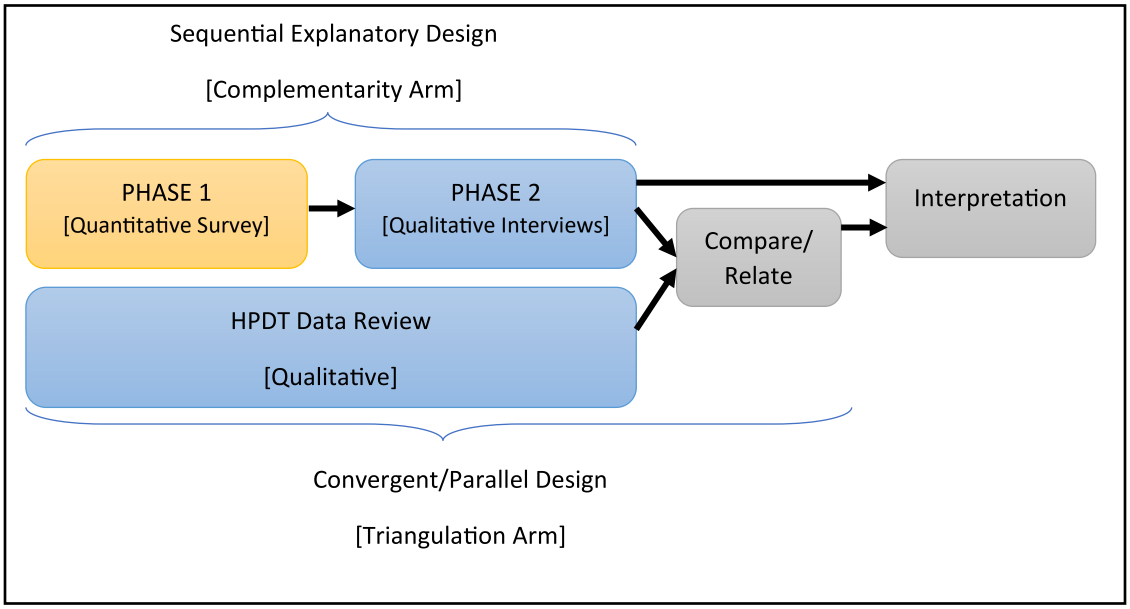


Figure 7: Summary of study design

A composite definition of mixed methods research developed by Johnson et al. (2007) described this research paradigm as allowing a researcher to combine “elements of qualitative and quantitative research approaches … for the broad purposes of breadth and depth of understanding and corroboration” (p.123). This study has sought to both develop knowledge across the breadth of RAs under the HPCA Act (using quantitative methods), as well as investigate selected RAs in more depth (using a qualitative approach).

Greene (2008) describes five main aims of mixed methods research; triangulation (using different methods to seek corroboration), *complementarity* (using different methods to investigate different facets of phenomena), *development* (using the results of one method to inform the other), initiation (using different methods to offer new perspectives) and *expansion* (using different methods to expand the range of enquiry). By using a two-armed design, this study utilised mixed methods to allow both *complementarity* and *triangulation* of results.

The *complementarity* arm of this study sought to ascertain knowledge of regulators' perceptions through the initial development and use of a quantitative questionnaire. The data resulting from this survey was then analysed and used to further explore the phenomenon using a smaller set of qualitative interviews. While both phases of this arm sought to explore the same topic (i.e., regulators' perceptions), the different approaches inherent in the QUAL and QUANT phases allowed different aspects to be considered; namely, tightly defined, commensurable data collected using the quantitative questionnaire providing a comparison across RAs, versus the rich data collected through the qualitative interviews providing detailed information on individual regulator's perceptions. As this arm was designed to allow *complementarity* of this data, the final analysis was able to use the qualitative data collected in the second phase to provide elaboration and clarification of the phase one, quantitative results.

The taxonomy of mixed methods research proposed by Leech and Onwuegbuzie (2009) considers three main criteria as most important in mixed methods designs – the level of mixing, the time orientation and the emphasis on each method., This arm of the study incorporated a two-phase design, with each phase being analysed separately before being combined at the final interpretation phase. As the quantitative and qualitative phases were considered with equal weighting, this would be considered a *Partially Mixed Sequential Equal Status Design*, notated as:

QUANT → QUAL

Three basic types of design are further explored by Klassen et al. (2012), who describe three main types of design: *convergent*, where data is collected concurrently and merged before analysis; *sequential*, where one data collection activity builds on the results of a previous activity, and *embedded*, where the use of one approach is embedded in the other. A sequential design (as described in this arm of the study) may be further described as exploratory sequential (where exploratory qualitative data may be used to help design a qualitative instrument) or explanatory sequential (where qualitative data is used to help explain quantitative results). This study utilised the second-phase qualitative approach to further explore the results gained in the first phase and could therefore be considered *explanatory sequential*.

Where the *complementarity* arm aimed to investigate different facets of the same topic, the *triangulation* arm sought to compare the views of regulators with data from a different source (in this case, HPDT decisions) to provide some corroboration of their views with practice. In developing a conceptual framework for mixed method research, Greene et al. (1989) note that unique to *triangulation* is the recommendation that the different methods are implemented independently, and that the qualitative and qualitative aspects are weighted equally and completed simultaneously. Unlike the *complementarity* arm above, this arm of the study was designed to be conducted independently until the final analysis, with data being collected concurrently to, and initial analysis performed separately, from the *complementarity* arm. To maintain this independence while also assessing the same phenomenon (here, the overall perception of risk of harm by health regulators), the results of cases before the HPDT were identified as a source of data regarding incidents of harm, or potential harm, related to conduct. While this data only related to one aspect of harm considered (i.e., *contributing factors*, *practice errors* and *practitioner misconduct*), it was seen to provide an external data set with which to compare regulators' perceptions.

3.3.2 Quantitative Questionnaire Design

The initial aim of the complementarity arm was to explore the views of RAs, and to provide a method of comparing the views of the RAs responsible for each profession. As an explanatory sequential study design, a quantitative questionnaire was used to provide a broad base of data for further exploration in the second, qualitative, phase.

In this study, the quantitative questionnaire aimed to provide an initial commensurable dataset from each RA that allowed efficient comparison and initial determination of any profession-specific trends. Designing the questionnaire to be a tightly structured instrument helped ensure that responses from individual RAs were also structured in the same manner, enhancing the ability to directly compare one dataset with another (Yilmaz, 2013). Any areas of interest (such as factors that show high variability in the responses received) or specific similarities or differences between RAs then informed the interview process in Phase 2.

Saris and Gallhofer (2014) recommend that the design of a survey considers the following areas:

1. Choice of a topic (descriptive or exploratory)
2. Choice of the most important variables
3. Choice of a data collection method
4. Choice of operationalisation
5. Test of the quality of the questionnaire

Although these areas will be discussed in more depth in *Methods*, the response categories provided to questions form part of the 'choice of operationalisation'. For this survey design, Likert-type scales were the primary response scale used.

Likert-type scales are one of the most used techniques to measure the strengths of attitudes (i.e. perceptions), thereby providing ordinal data (van Peer et al., 2012). Although these scales provide a useful estimate of the strength of an attribute, there are potential difficulties in the use of this method. A researcher must ensure that each question explores only one dimension, that the ranking system used gives a clear explanation of order, and that adjectives used can be clearly understood and whether such adjectives cover the whole scale or only delineate the extreme ends of the scale (Fowler, 1995). Also, scales must be designed to provide a sufficient number of ranks and allow for a lack of opinion. When assessing attitudes, it is also important to note that although such scales measure the strength of an attitude, they do not directly measure the respondent's belief of the importance of the subject or how sure they are of their opinion (Foddy, 1993). To alleviate these problems, Lietz (2010) suggests that scales should contain five to eight categories, that a 'don't know' option should be offered, and that labels are provided for the end and middle categories. As described in *Methods*, below, the initial 7-category design in this questionnaire was reduced to a 5-category design after consultation.

3.3.3 Quantitative Sampling

This study sought to understand the perception of the RAs, rather than the individual perceptions of members or employees within the RA. While focused on the interview process, Ma et al. (2021) note that research involving high-level members of an organisation may be *individual-based* (focusing on individual activities and narratives) or *firm-based* research designs (focusing on patterns of firm-based activities or narratives). While a focus on the individual may be useful for identifying personal narratives, designing research to focus on 'firm-level' phenomena include a greater focus on organisational contexts and how the participant contributes to, and may be impacted by, firm-level Activities. High level members of organisations (such as registrars/chief executives) may provide useful information on an organisation's decision making processes (Solarino & Aguinis, 2021), and may be more likely to represent the position of a business rather than their own personal views (Harvey, 2010).

As RAs make decisions as an organisation through consensus of the council or board members (and delegated authorities to the registrar/chief executive), this study sought to focus on the views of each participant in their role within the RA. Question design was designed to accentuate the organisation over the individual, and two participants from each RA were asked to work collaboratively and reach a consensus in answering the questionnaire.

There are a limited number of RAs under the HPCA Act, as the population in question, with only 16 appointed as of 2019. Although this low number precludes any inferential statistics or generalisation of results, the use of a quantitative questionnaire was still seen to be useful as a way to ensure comparability between participating RAs. Although this study sought participation from the entire population (i.e., all 16 RAs), and the results were not intended to be generalised to any RAs who did not participate, sampling methods were not identified as necessary for this phase.

3.3.4 Quantitative Data Analysis

Whereas inferential quantitative methods seek to generalise data from a sample to a broader population, descriptive methods seek only to describe the sample themselves. As this study aimed to survey the entire population, and not to generalising any findings into a wider context, generalisability (and, by extension, the use of inferential statistics) was not required in this study (Turner & Houle, 2019).

As such, analysis was limited to standard descriptive statistics, such as the distribution, central tendency and dispersion of responses, as these are useful for synthesising and describing data (Polit et al., 2001).

3.3.5 Qualitative Interview Design

Building on the broad data gathered in Phase 1 of the complementarity arm, the interviews in Phase 2 sought to further develop this knowledge through more in-depth investigation of selected RAs. Semi-structured interviews allow for specific topics to be addressed in a qualitative interview, while still allowing room for participants to introduce new ideas or concepts in their responses (Galletta & Cross, 2013), and may be especially useful in developing an understanding of how participants perceive an issue (Silverman & Patterson, 2015).

Galleta and Cross (2013) suggest three phases during a semi-structured interview – the initial phase should consist of open-ended questions, in order to “create space” (p. 47) for participants to share their views. The middle phase should then become more focused on asking specific questions, before the final phase revisits and explores any important connections from the initial discussion and allows the participant to voice any final thoughts.

Silverman and Patterson (2015) describe their concept of ‘grand-tour’ questions and probes, where questions seek an overview of general themes, whereas probes aim to elicit further information as a result of initial questioning. In this study, the development of questions and probes will have the advantage of being based both on existent literature, and the results of Phase 1 of this arm.

3.3.6 Qualitative Sampling

Rather than looking for a generalisable theory, the aim of Phase 2 of the *complementarity* arm was to develop knowledge around how individual RAs perceive risks. When looking to make the best use of limited resources, as with the limited population in this study, Palinkas et al. (2015) recommend the use of purposeful sampling. Such sampling can help ensure that the cases selected will provide rich information and meet research goals (Patton, 2002).

While the first, quantitative, phase of this study aimed to provide a broad view of RA perceptions, qualitative methods may be better placed to provide a deeper understanding of individual cases (Patton, 2002). Palinkas et al. (2015) identifies the concept of 'maximum variation' in purposeful sampling. Here, cases are selected to represent maximum variation to both explore these variations as well as identify common patterns that exist despite these variations. This contrasts with other strategies, which may seek to focus on similarities between cases, which is more reflective of a goal to identify homogenous experience. Given the explanatory nature of this phase of the study, exploring the range of potential variation in perceptions may be more fruitful than focusing on more common beliefs. The use of purposeful sampling allowed the selection of RAs that were more likely to be 'information-rich' for inclusion in the qualitative phase (Merriam & Tisdell, 2016), and purposeful sampling for maximum variation (i.e. aiming to sample the RAs that show the greatest variation in their responses to the first phase) helped explore any unique characteristics they may have (Silverman & Patterson, 2015).

Although the rationale for a particular sample size in qualitative research is often tied to saturation, Braun and Clarke (2021c) suggest that, while this concept may useful for studies utilising coding reliability, or codebook types of Thematic Analysis, it may be difficult to predict when initially developing a study, and that estimations may not always be accurate. Furthermore, they note saturation is less useful when considering a reflexive Thematic Analysis approach. In further work, Braun and Clarke (2021b) suggest that the underlying concepts of sample size may be inconsistent with the values associated with reflexive Thematic Analysis, being more aligned with positivist views around the potential representativeness of results. Instead, they recommend a more pragmatic approach, based on the richness of the dataset and the aims of the study. Similarly, Sim et al. (2018) argues that determining a sample size prior to conducting the research is problematic and this should be decided during the analytical process, with the focus remaining on what is necessary to achieve the study aims. Given that this interview series formed part of a greater study within a limited population and, more pragmatically, to ensure this study fitted within the confines of the DHSc, six interviews were considered appropriate.

3.3.7 Qualitative Data Analysis

A Qualitative Descriptive approach is considered to involve a more semantic level of interpretation than inferential qualitative methodologies, although this still allows the use of other qualitative methodologies as a 'lens' to help interpret data (Colorafi & Evans, 2016). There are few limitations on sampling methods, and data may be collected from a range of sources such as focus groups, individual interviews, observation and documents. Although both qualitative aspects of this study (*Complementarity* Phase 2 and *Triangulation*) were considered under a Qualitative Descriptive methodology, Vaismoradi, Turunen and Bondas (2013) note that Thematic Analysis and Content Analysis could be seen as representing a more 'qualitative' or 'quantitative' analytical approach (respectively) within a Qualitative Descriptive study.

Braun and Clarke (2021a) recommend Thematic Analysis as a useful analytic method for exploring understandings and perceptions, and note that several varieties of Thematic Analysis exist, dependent on the aims and design of the study. Thematic Analysis variations include coding reliability approaches, which emphasise a structured approach to coding; reflexive approaches, which emphasise a subjective, unstructured code development process, and codebook approaches, which may use a more reflexive approach, but with a structured coding approach similar to coding reliability approaches. As a counterpoint, Braun and Clarke (2021a) also describe Content Analysis as being a more quantitative approach to analysing qualitative data, although *Qualitative* Content Analysis bears many similarities to Thematic Analysis, and that there may be significant overlap between Qualitative Content Analysis and codebook or coding-reliability Thematic Analysis. Cho & Lee (2014) suggest that Qualitative Content Analysis focuses primarily on extracting categories from data, however, and involves minimal interpretation. Similarly, Vaismoradi et al. (2013) argue that Qualitative Content Analysis is distinct from Thematic Analysis, and takes a more descriptive approach and may focus on a quantitative 'count' of codes. Hsieh and Shannon (2005) note that qualitative content analysis can be described through three main approaches: Conventional, where the aim is to describe a phenomenon, and in which coding is generated from data. Directed, where the aim is to test a theory, and in which coding is generated from key concepts from pre-existing literature. Summative, where the aim is to explore the usage of specific key words, where these keywords are identified by the researcher's interest and/or existing literature.

Triangulation Arm

While the data source for the Triangulation arm of this study was qualitative in nature, the aims of this arm suggested a more quantitative approach in order to identify the proportional representation of incident types in the data. For this study, then, the more quantitative aspects of Content Analysis seemed suited to the exploration of the data gathered from HPDT decisions. The focus of this analysis was on identifying the presence of key words (i.e., conduct incident types) at an entirely semantic level. Directed Content Analysis (Hsieh & Shannon, 2005) was chosen as the most appropriate methodology, as the previous literature review had provided an existing set of codes on which to base this analysis. Given the purely semantic analysis of structured data, the likelihood of failing to identify relevant text was considered to be negligible. As such, the second strategy provided by Hsieh & Shannon (2005) was followed, incorporating the following stages:

1. Initial coding using pre-determined codes, noting any data that cannot be coded.
2. Consider data that could not be coded in Stage 1 for inclusion under a new code, or a new subcategory of an existing code.
3. Consider breadth and depth of initial and developed codes for potential identification of sub-categories.

Utilising pre-existing codes in this manner allows comparability and consideration of results against previous research (here, an analysis of Australian disciplinary cases by Spittal et al. (2016)).

Complementarity Arm Phase 2

As the aim of the interview process focused on developing more insight into the perceptions of RAs through consideration of richer data, however, analysis required consideration of latent themes. This deeper insight was developed through the use of Thematic Analysis. Specifically, reflexive Thematic Analysis was used as the flexibility inherent in this methodology allowed a deductive approach (utilising existing research on risk) to be combined with a more experiential framework, in line with a Pragmatic approach, focusing on the perceptions and experiences of the RAs involved.

3.3.8 Integrated Analysis

While the sections above indicate the analysis for each individual component, a mixed methods study design calls for a combined analysis of the results from all aspects of the study.

Onwuegbuzie & Johnson (2021) describe mixed method analysis as including both non-crossover analysis (where the data and analysis types are the same; for example, quantitative data is analysed using quantitative analysis) and crossover analysis (where the data and analysis types may differ; for example quantitative data being analysed using qualitative methods). As data from each component of this study are analysed using their respective methods, this study uses non-crossover analysis.

As shown in Figure 8 below, non-crossover mixed analysis can further include both ‘vertical’ analysis, where qualitative or quantitative findings may inform the other branch of the research process, and ‘horizontal’ analysis, where qualitative and quantitative results are analysed together at the final data interpretation stage (Onwuegbuzie & Johnson, 2021).

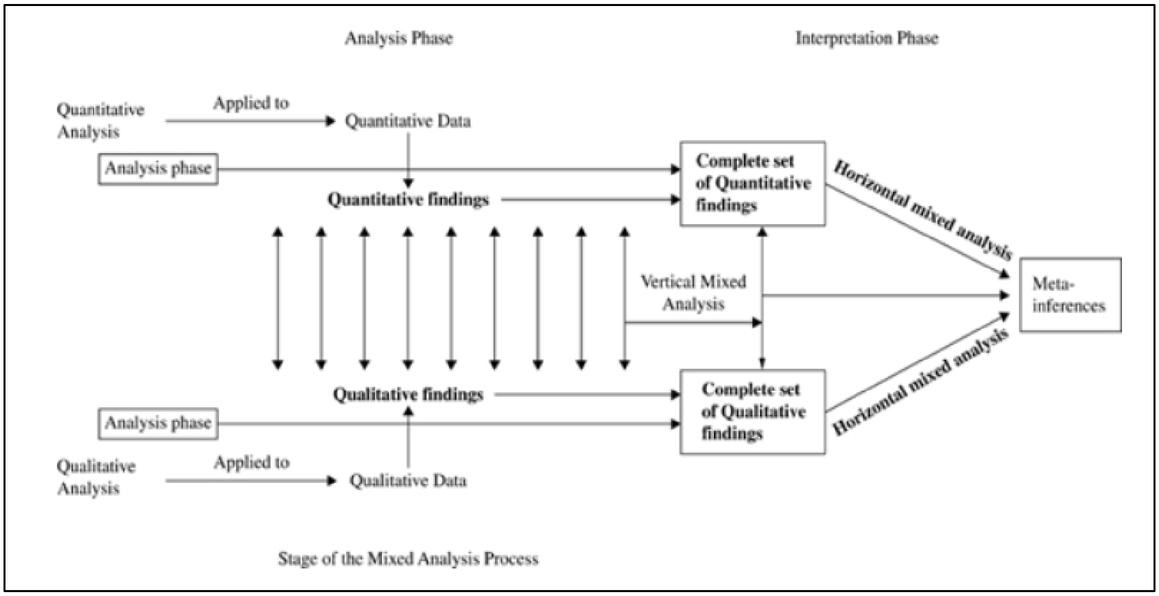


Figure 8: The non-crossover mixed analysis process decomposed into the vertical mixed analysis (i.e., minimal interaction) and the horizontal mixed analysis (i.e., full[er] interaction) process. (Onwuegbuzie & Johnson, 2021)

As the design of this study only allowed for limited, one-directional vertical mixed analysis, in that the findings of the quantitative Phase 1 informed the qualitative methods in Phase 2, the primary method used was horizontal mixed analysis. This was determined to be the most appropriate method due to the predominantly independent nature of each phase (despite the small amount of interaction), and the inclusion of both independent arms of the study in the final analysis. The mixed analysis was conducted after analysis of each individual phase of the *complementarity* arm, as well as the single-phase *triangulation* arm, had been completed.

To enable the ‘horizontal mixed analysis’, a Complementary Integrative Analysis Strategy was used to consider data from multiple sources and types. In general, this strategy begins by taking descriptive results of initial analyses, and uses elements from the variety of data sources to iteratively build a more complete, coherent picture using the strengths of each method (Figure 9) (Bazeley, 2018). The Complementary Integrative Analysis Strategy provides parallel processes for integrative (left-hand column) and comparative (right-hand column) analysis, and this was utilised to enhance the intended role of each arm.

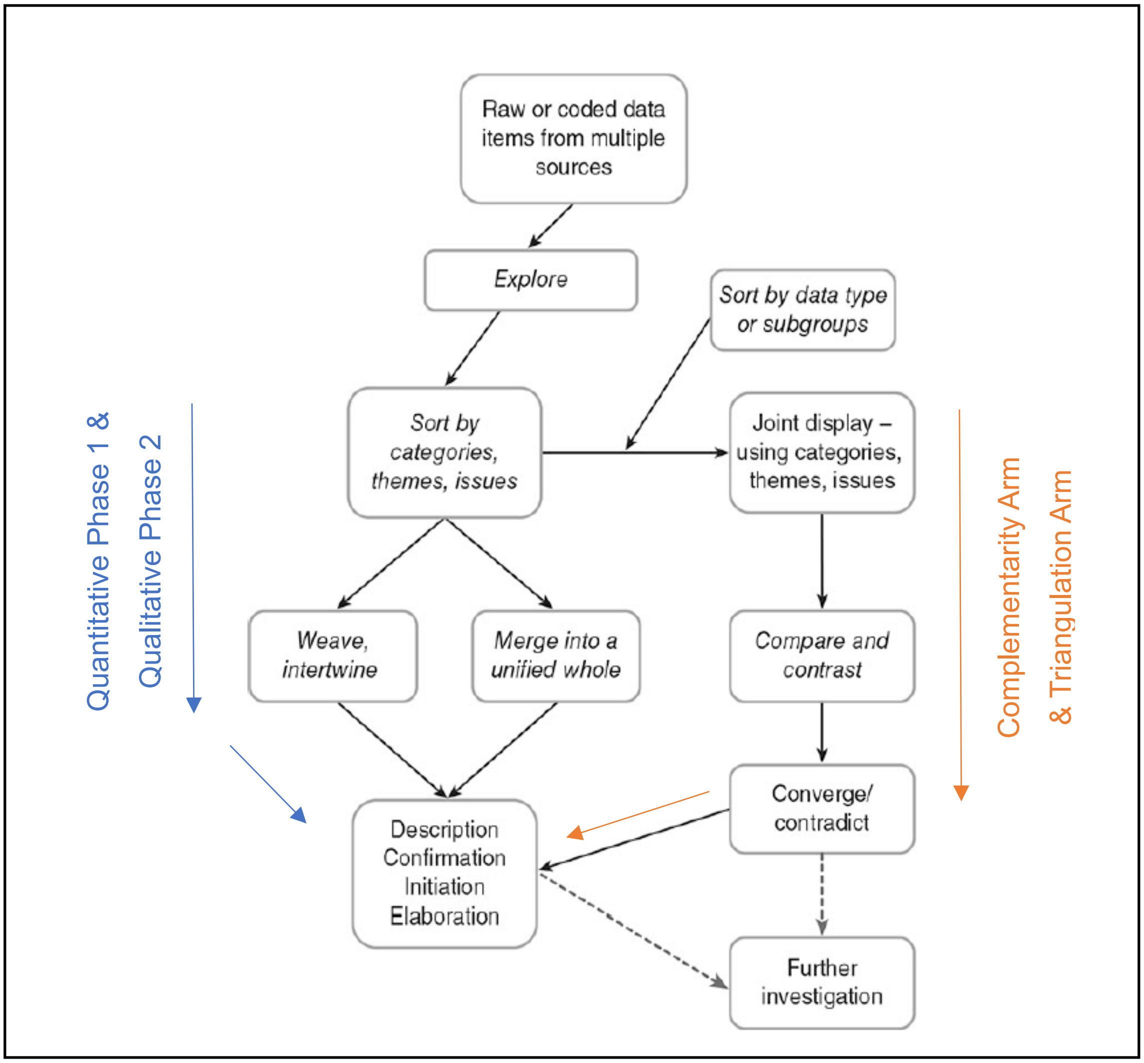


Figure 9: Mapping complementary analysis (adapted from Bazeley, 2018)

As the two phases in the complementarity arm were designed to focus on investigating different facets of the same phenomena, analysing combined results from these phases aligned with the integrative analysis pathway. This utilised the findings of each phase (qualitative and quantitative) to provide a unified analysis for this arm of the study.

With the two-armed study design providing a triangulation arm to compare RA's perceptions with data from a different source, the more comparative analysis pathway was used to analyse where findings from the two arms may have converged or contradicted one another. The overall findings from both these processes were then reported on to provide an overall description and discussion, as well as recommendations for further investigation.

Chapter Four – Methods

4.1 Introduction

This chapter describes the research methods of this research project in detail, including the aim, design, recruitment, and data collection and analysis for each component of the study, concluding with a description of the overall analysis.

This study consisted of three distinct, but inter-related aspects. The main arm sought *complementarity* through a two-phase sequential explanatory design, while the secondary arm sought *triangulation* through a qualitative analysis of disciplinary tribunal decisions.

4.2 Complementarity Arm – Phase 1

4.2.1 Aim

The aim of this Phase was to provide a broad overview of regulators perceptions regarding the risk of harm to the public, to both allow comparison between RAs and to inform Phase 2 of this arm.

A cross-sectional, descriptive study design was used, utilising a bespoke quantitative questionnaire to assess RAs' perceptions of risk in the practice of their respective health professions.

4.2.3 Participants and Recruitment

All sixteen RAs under the HPCA Act, as of 31 December 2019 were invited to participate via email using publicly available contact details. Each RA was asked to nominate two participants from the RA (members and/or secretariat staff) to complete the quantitative survey.

RAs who did not respond to the initial recruitment email were sent a reminder email six weeks after the date of the initial email.

Overall, the recruitment period (including attaining the required consent and permission forms) extended over approximately five months (March – August 2021). This extended period was due, in part, to the unavailability of participants due to the impact of COVID-19 on workloads. Continuing the recruitment process was considered important, due to the small population and the value of each additional participant.

Positive responses were received from eleven RAs (69%) and these formed the sample of the study. As of 2019, these RAs represented a total of 80,588 (74%) of the approximately 110,000 health practitioners holding Annual Practising Certificates under the HPCA Act (as per RA Annual Reports 2019).

Additionally, three RAs declined participation due to a lack of participant availability, and one RA approved participation but did not complete the questionnaire. One RA did not respond.

To allow participants to represent the RA, the following was requested:

- The RA were asked to nominate participants based on their expectations of who can best represent the views of the RA as a whole.
- The two participants from each RA were asked to come to a consensus as to their views, and complete one response between them.

Once approval for participation was received from the RA and participants had confirmed consent, the participants were sent a single link to an online questionnaire for completion with an electronic copy of the questionnaire available on request (Appendix F).

Ethical approval was received for this study, and the confidentiality of participants was maintained throughout (AUTEC 20/252) (Appendix A).

4.2.4 Questionnaire Design and Data Collection

The development of the questionnaire considered the five areas suggested by Saris and Gallhofer (2014), as follows:

1. Choice of Topic:

As the first phase of a mixed-methods design, the focus of this survey was to describe the beliefs or perceptions of RAs (rather than draw any causal links), with exploration of any results occurring in the second phase. As such, the topic of the survey is *descriptive* in nature.

2. Choice of the Most Important Variables:

As this research focuses on identifying areas of risk, the main variables considered were those that are used to formulate a standard risk matrix (Kaya et al., 2019) – those being the perceived *Likelihood* and *Severity* of potential risks. Descriptors indicating various levels of *Likelihood* and *Severity* formed the categories used in the scales.

Based on the Conceptual Framework for the International Classification of Patient Safety developed by the WHO (2010), three main areas of focus were developed for the questions. Firstly, potential *Contributing Factors* (factors that may increase the risk of an incident occurring) were considered, followed by *Incident Types* that specifically lead to a risk of harm. To mirror how reported incidents might be classified by an RA, these *Incident Types* were sub-categorised into *Error* and *Misconduct* issues. Here, *Error* refers to incidents involving unintentional issues, such as technical errors, miscommunication/misunderstanding or equipment failure, whereas *Misconduct* refers to improper or unacceptable behaviour, malpractice, or negligence.

To determine items under each category and subcategory, a review of the literature was conducted to identify which classifications may already exist. Both *Contributing Factors* and Incident Types were summarised (as described in the Literature Review) and adapted to provide the items used in the questionnaire.

3. Choice of a Data Collection Method:

To facilitate ease of distribution and response, the primary method of data collection was through an online survey using a self-completed questionnaire. The questionnaire was created in Qualtrics Online Survey Software (n.d.) with unique links generated for each RA.

Participants were also offered an electronic document version of the questionnaire to aid their collaborative response. The option of completing the questionnaire via hardcopy was also provided, however no participants utilised this method.

4. Choice of Operationalisation:

To help attain an initial commensurable dataset from each RA the survey instrument was designed to be tightly structured. This helped to ensure that responses from individual RAs were all structured in the same manner, allowing for easier comparison of data. As such, all questions in the questionnaire consisted of closed questions, using rating (Likert-type) scales as shown in the examples below (see Table 8).

Table 8: Sample questions.

How likely are the following issues to be present in the profession regulated by the RA? [Issue 1]	Highly Unlikely	Unlikely	Neither Likely nor Unlikely	Likely	Highly Likely	Unsure
How severe is the harm that could occur to patients in the following situations? [Situation 1]	No harm*	Mild harm*	Moderate harm*	Severe harm* or Death*	Unsure	

*Note: *Definitions of harm adapted from Cooper et al. (2018)*

Guidance and definitions of terms (such as classification of ‘harm’ and a brief description of each variable) were included to help provide consistency.

5. <u>Test of the quality of the questionnaire:</u>

During the initial development of the questionnaire, advice was sought from an experienced biostatistician. This advice included discussion and testing of the design and structure of the questionnaire, and resulted in the following adjustments being made:

- Descriptions in each question were determined to be both too lengthy and too technical. These were reworded to provide a more concise description in more accessible terms.
- The initial 7-point scale was considered to be overly specific for the categories described, and this was reduced to a 5-point scale. The criteria were also reworded to enhance clarity.
- The order of contributing factors was re-ordered to provide a more logical flow.
- Statements and question text were generally revised to be more concise and enhance clarity.

After initial development, the questionnaire was tested using people with health regulatory, health practitioner, and/or questionnaire design experience. This testing focused on both content and design aspects of the questionnaire to ensure items were consistently understood and to ensure ease of answering. Feedback led to further refinement of the question and descriptive text to ensure clarity, and highlighted minor issues related to the design and online format of the questionnaire, which were addressed in the final version. Overall, however, this testing did not lead to significant changes in question choice or structure.

4.2.5 Data Analysis

After data collection, all data needed to be collated and encoded for ease of analysis. To facilitate this process, the Microsoft Excel computer program was used as the primary database. Data collected online through Qualtrics was available to download in spreadsheet format, and responses were pre-coded into numerical values.

As such, analysis of data was primarily limited to standard descriptive statistics, such as the distribution, central tendency and dispersion of responses, as these are useful for synthesising and describing data (Polit et al., 2001). Items were considered individually and collated into scales, and the perceived *Likelihood* and *Severity* of potential risks were combined to provide a risk-matrix result for each factor or incident.

Risk matrix results were calculated from an equal weighting of likelihood and severity (consequence) for each potential risk or incident type, using a semi-quantitative design, with a maximum score of 25. Although the design of a risk matrix and associated thresholds should be designed to reflect the preferences of the individual decision maker (Li et al., 2018), for ease of reference, risk thresholds have been set at the following levels:

Low: $0 < \text{score} \leq 3$ | Moderate: $3 < \text{score} \leq 9$ | Serious: $9 < \text{score} \leq 17$ | Critical: $17 < \text{score} \leq 25$

4.3 Complementarity Arm – Phase 2

4.3.1 Aim

The aim of this Phase was to develop more in-depth knowledge of selected regulators perceptions regarding the risk of harm to the public and to build on and illustrate the results of Phase 1. This also allowed the topic to be considered from a different perspective, providing the *complementarity* sought in this arm of the study.

4.3.2 Participants and Recruitment

Participants were selected based on the results of Phase 1 of this arm of the study.

Determination of ‘maximum variation’ in cases arose from consideration of the initial quantitative analysis of Phase 1 data and sought to maximise the variety of RA responses considered for this phase. The researchers identified six responses that provided the most unique results from Phase 1, including responses that indicated:

- A low consideration of risk across all factors
- A high consideration of practice errors (versus misconduct)
- A high consideration of overall risk and risk of practice errors and misconduct but difficulty identifying the impact of contributing factors
- A high reported impact but with lower likelihood of occurrence
- A high consideration of practitioner misconduct
- A high identification of overall risk, but with lower risk in each individual category

Each RA related to these responses was then be considered against the following exclusion criteria:

- The respondent has declined involvement in the interview process
- The RA is that which the researcher is a member of

As none of the identified RAs met these criteria, all were included in this Phase.

The RAs represented in the responses selected through the process above were then contacted via email to consent to inclusion in this Phase. All RAs approved participation and provided a nominated participant, all of whom consented to participation. After the completion of data collection, one participant requested that they be withdrawn from the study, and that their data be deleted, as they were no longer associated with the RA. This was completed and the RA contacted for an alternative participant, however no reply was received. This resulted in five interviews being included in the final analysis.

4.3.3 Interview Design and Data Collection

An interview guide was developed using topics identified from both existing literature and the initial quantitative analysis of Phase 1 of this arm of the study. As suggested by Silverman and Patterson (2015), this included the following elements:

- Confirming informed consent
- Both broad ‘questions’ and specific ‘probes’ covering the identified topics
- ‘Transition’ phrases to introduce new topics

Interviews were conducted primarily in the place of work of the participant; however, one interview was conducted via electronic communication (videoconferencing). All interviews were recorded (either via recording device for face-to-face interviews or using computer software for videoconferencing) for later transcription.

4.3.4 Data Analysis

Data was analysed using a Reflexive Thematic Analysis approach, following the ‘six phase’ process outlined by Braun and Clarke (2021b); namely:

1. Dataset Familiarisation
   Initially, familiarisation started through immersion in the data. Transcripts were re-read multiple times. First readings were completed of each transcript as individual sets of data, with subsequent readings incorporating more cross-checking between transcripts as potential common ideas or points of difference were recognised. Raw audio recordings were also incorporated into the reading process, especially where meaning was unclear, or more than one interpretation of a phrase was possible (such as joking or sarcastic statements).
   Throughout this process, and as familiarisation with the data increased, care was taken to reflect on the understanding gained from reviewing the data and to ensure reflexivity. As the researcher had experience within this field, it was important to interrogate opinions formed during familiarisation to ensure these weren’t unduly influenced by pre-existing beliefs and knowledge. The researcher consciously worked to understand the viewpoint of the participants and consider what assumptions might be being made – both by the participant and researcher.

2. Coding

   Coding was started by tagging specific phrases and blocks of text that contained a potential point of meaning.

   Codes were initially overly verbose, incorporating phrases describing the meaning of the block of text. Over time, these were revised to include more concise descriptors.

   When tagging new text, existing codes were considered to determine whether an appropriate code had already been identified or whether a new code should be created. Occasionally, this led to an existing code becoming overly broad, and this was recoded to two codes, each representing a subset of the original.

   Once a first pass of coding had been completed for all transcripts, very low frequency codes were reviewed to see whether they should be included under larger codes. While this occurred when appropriate, other low-frequency codes were determined to be sufficiently different in meaning and were kept.

   While there was potential for early themes to become apparent during later stages of coding, especially where there was strong repetition of codes, engagement with these potential themes was suppressed to avoid ‘analytic foreclosure’ (Braun & Clarke, 2021b).

3. Generating Initial Themes

   Initial theme development started through grouping similar codes together, where these showed some shared meaning. While these provided a summarised version of codes, they also tended towards providing a ‘topic summary’ rather than a developed theme.

   To avoid this, consideration was given to the ‘meaning’ each code represented, rather than the more superficial topic. New initial themes were then devised around where these areas of ‘meaning’ coincided with other codes.

4. Developing and Reviewing Themes

   Themes were further developed and reviewed by returning to the original data represented by each code and initial theme, then checking how this fit with the overall pattern of meaning.

   Here, it was again important to practice reflexivity to ensure the themes fit the data and were not unduly influenced by any preconceptions of the researcher.

The internal consistency of the data for each theme was reviewed to ensure the concepts within each matched the overall concept of the theme. Consultation with the supervisory team, who have extensive experience with RAs, occurred throughout this and later phases to provide a critical view on decisions.

5. Refining, Defining and Naming Themes
   While the underlying concepts expressed by the themed data were talking shape at this stage, the interconnected nature of the themes meant that this phase involved developing firmer boundaries between themes. This led to several iterations of defining and naming themes until they comfortably fit the emergent understanding of the data. In particular, the initial generation and development lead to a large number of themes and subthemes, which were able to be consolidated in this final phase. It was also found that the process of 'naming' a theme led to further 'crystallisation' of the associated concepts.

6. Writing Up
   In this phase, the final set of themes were set out and illustrative extracts from the data used to add definition and tie these back to participants' views.
   In relating how these themes related to the research question, it was determined that two themes provided a different focus, and these were reported separately. The expression of this stage was realised in the write up of the two findings chapters for this phase, as well as in the integrated findings and discussion chapters.

4.4 Triangulation Arm

4.4.1 Aim

The aim of this arm of the study was to provide triangulation through the comparison of external data (here, disciplinary cases that have been heard before the HPDT) with the perceptions of regulators. As the charge details provided by the HPDT do not necessarily include a detailed background to events, the focus was on *Incident Types*, not *Contributing Factors*.

4.4.2 Source Sampling and Data Collection

Registrant Data

To allow comparison of HPDT data across RAs on a standardised (per-practitioner) basis, the number of Annual Practising Certificate (APC) holders per year was sought for each RA.

This data was primarily sourced from Annual Reports published each year by each RA, available publicly through their respective websites. Where these were unavailable, data was also sought from:

- Where available (2010 and prior), Health Professional Workforce Pamphlets provided by the Ministry of Health (*Health Professional Workforce Pamphlets*, n.d.)
- Direct communication with the Registrar of the RA
- Mathematical extrapolation from prior/later figures, where data for one or two years were unavailable.

HPDT Decisions

All decisions made by the HPDT, where records are published and available on the HPDT website (New Zealand Health Practitioners Disciplinary Tribunal, n.d.) as of 21 August 2020, were considered for inclusion. An archive was taken of these records to provide a defined and stable dataset.

The following data was recorded for each case, primarily using the data available on the Charge Detail Summary provided by the HPDT:

- The health profession of the practitioner
- The year that the decision was made
  - Due to the complex timeline of some cases, the decision was made to record cases based on the decision year, rather than any initial charge date
- The charge characteristics, representing the *Incident Types* included in the case
- The outcome for each charge, and for the case as a whole
  - These were categorised as *Upheld*, *Withdrawn*, *Not established/dismissed* or *Overturned*.

Where available, charge characteristics were recorded verbatim from the Charge Detail Summary. These charge characteristics were pre-coded and available on each Charge Detail Summary to allow categorisation of cases. Where these charge characteristics were absent, the full decision was reviewed and an appropriate charge characteristic determined, using the list of charge characteristics found in other decisions. Similarly, where charge characteristics did not provide sufficient information for later categorisation (such as undifferentiated '*Breach of Act*'), further detail was identified within the details of the full decision.

Each case was then reviewed for exclusion. Based on a prior review by Surgenor et al. (2016), records were excluded where:

- No charges were upheld (e.g. charges were withdrawn)
- A non-publication order existed
- The identity of the health practitioner's profession was not disclosed, or the profession was not currently regulated under the HPCA Act

4.4.3 Data Analysis

Cases were then analysed to code charge characteristics, and to identify representation of these codes in each case, using the following process:

1. Identification of 'unique' charge characteristics
2. Coding of unique charge characteristics using Directed Content Analysis
3. Identification of codes represented in each case
4. Frequency counts of code representation within cases, reported as a proportion of all cases and on a per RA basis where appropriate

1. Identification of 'unique' charge characteristics

Charge characteristics are often recorded as standard data on HPDT Charge Detail Summaries, and are included as search filters when using the HPDT 'Search Decisions' function (New Zealand Health Practitioners Disciplinary Tribunal, 2017b).

As some standardisation exists within the charge characteristics recorded on the Charge Detail Summary, verbatim characteristics recorded from each case were compared to determine a list of ‘unique’ charge descriptors, resulting in 128 unique charge descriptors being identified.

2. Coding of unique charge descriptors

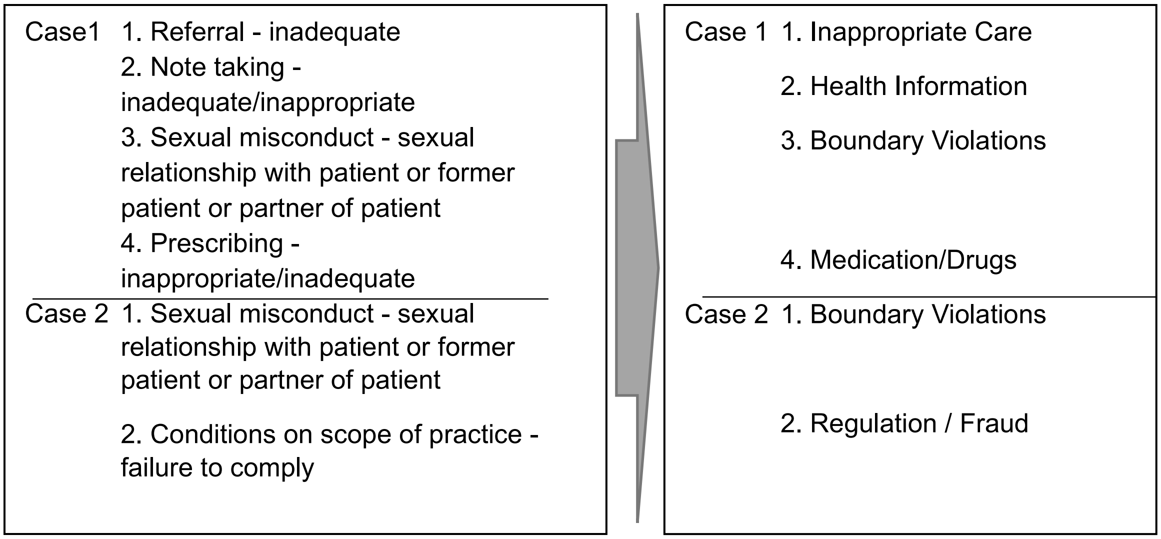
To further categorise these charge descriptors, the list of unique charge descriptors was analysed using directed Content Analysis. Coding was developed from the same key concepts and literature that was used in developing the questionnaire and interview questions in the Complementarity Arm of this study. Initial codes were adapted from categorisation of conduct issues reported by Spittal et al. (2016) in their previous review of health practitioner notifications. This allowed analysis of this data within the framework of the overall study, improving comparability with the data gained from the Complementarity Arm during later overall analysis of the overall results.

Assignment of charge descriptors to codes was reviewed to ensure consistency, including seeking advice from the supervisory team. This initial analysis resulted in seven codes being identified within the list of unique charge descriptors:

- *Disruptive Behaviour*
- *Boundary Violations*
- *Inappropriate Care*
- *Medication/Drugs*
- *Health Information*
- *Costs/Advertising*
- *Regulation/Fraud*.

3. Identification of codes represented in each case

Charge characteristics for each case were then reviewed to determine which codes were represented within the included charges. Using the initial data set containing every included case and relevant charges, each charge characteristic was replaced with the associated code (see Figure 10).



Case	Charges	Codes
Case1	1. Referral - inadequate	1. Inappropriate Care
	2. Note taking - inadequate/inappropriate	2. Health Information
	3. Sexual misconduct - sexual relationship with patient or former patient or partner of patient	3. Boundary Violations
	4. Prescribing - inappropriate/inadequate	4. Medication/Drugs
Case 2	1. Sexual misconduct - sexual relationship with patient or former patient or partner of patient	1. Boundary Violations
	2. Conditions on scope of practice - failure to comply	2. Regulation / Fraud

Figure 10: Example of application of codes to case charges

Where a case included more than one charge represented by a single code (for example, two separate breaches of the Misuse of Drugs Act 1975 representing the code of '*Medication/Drugs*'), the duplicate code was removed to record a single representative instance of that code. This then showed, for each case, which *Incident Types* were represented within the case.

4. Frequency counts of code representation

The frequency of each code within the data set was counted and compared to both the total number of cases, both across the full data set, and for cases related to each RA. As several RAs had a small number of total cases included across the time period, those with six or fewer cases were not considered for individual analysis (representing 12 of the 19 individual professions).

4.5 Integrated Analysis

Once initial analysis of both study arms has been completed, the results were compared to explore the degree of corroboration between the HPDT decision data and regulators perceptions regarding misconduct incidents.

4.5.1 Aim

The aim of the integrated analysis was to synthesise the findings gained from all aspects of the study, in order to develop an overall appreciation of the topic and identify areas of alignment and contradiction.

4.5.2 Vertical Mixed Analysis

Mixed analysis was inherent in the design of this study, with Phase One of the *complementarity* arm informing the development of Phase Two.

This mixed analysis consisted of two parts – *participant selection* and *instrument design*.

Participant Selection

As described in 3.3.6 *Qualitative Sampling*, Phase Two of the complementarity arm took a purposive sampling approach, with the aim of maximizing variability. Preliminary analysis of data from Phase one of this arm was used to inform this sampling.

This preliminary analysis provided initial insight into participating RAs' perceptions on areas of risk for their professions. Aggregate risk ratings for overall risk, contributing factors, errors and misconduct were compared across individual RAs. Potential participants for Phase Two were then selected to maximise the difference in these scores.

Instrument Design

Preliminary analysis data from Phase One was also used to inform development of the semi-structured interview plan for Phase Two. Matching individual RA responses in Phase One to participants in Phase Two allowed individual variations in response to be further explored during the interview process. More generally, this also allowed specific findings from Phase One to also be considered as specific questions during the interview process.

While providing a small degree of vertical mixed analysis, the use of Phase One data to inform Phase Two also helped realise the explanatory nature of the research design.

4.5.3 Horizontal Mixed Analysis

Following the process outlined in 3.3.8 *Integrated Analysis*, a two-stage approach was taken to analysing the complete set of findings (see Figure 11), based on the Complementary Integrative Analysis Strategy (Bazeley, 2018).

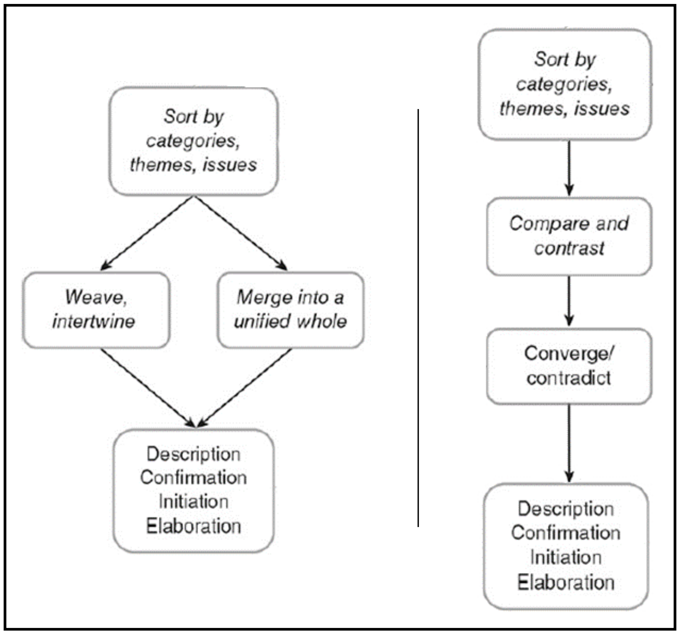


Figure 11: Integrative Analysis (L) vs. Comparative Analysis (R)

Integrative Analysis

The first stage in this analysis was to recognise the complementary nature of Phase One and Two of the *complementarity* arm. While these were undertaken using different methodologies (quantitative and qualitative), they both explored the same phenomenon using different approaches.

Here, findings from Phase One was considered against those from Phase Two to provide a combined description of results. As these two phases were designed with this analysis in mind, the categories presented in Phase One overlapped closely with the topics explored in Phase Two. Themes from Phase Two were used to provide potential explanation of correlated Phase One data, and areas that lacked such corroboration were also identified.

The aim of this process was to provide a more complete picture of the research topic than either could individually.

Comparative Analysis

The second stage of this analysis was to compare and contrast the findings of the complementarity arm with those of the triangulation arm.

Findings from the triangulation arm were considered against the results of the integrative analysis above. Each theme or area of understanding found in the complementarity arm was compared against the findings of the triangulation arm. This served to identify areas where the two arms agreed, disagreed, or where there was no overlap.

In contrast to the Integrative Analysis above, which sought to develop a more fulsome picture of the topic, the aim of this analysis was to provide some contrast or support of those findings from an alternative (but related) data source.

4.5.4 Reporting

The findings from this mixed analysis are reported in Chapter Eight of this thesis and included in the consideration of findings within the discussion chapter.

4.6 Summary

This chapter has described the methods for the three distinct but related components of this study, each of which contribute to answering a different facet of the research question. The discrete methods used in each component outline the individual aims, sampling, data collection and analysis approaches used for each aspect of this study.

As a mixed-methods approach is used for the overall study, the manner in which findings from each component contribute to the overall findings requires careful consideration. This chapter has also presented a systematic approach to integrating the analysis of the individual component findings to provide a combined answer to the overall research question.

Chapter Five – Complementarity Arm Phase 1 | Findings

5.1 Introduction

This chapter will present the results of Phase 1 of the complementarity arm of the research project. The aim of this arm of the study was to provide broad overview of regulators perceptions regarding the risk of harm to the public, to both allow comparison between RAs and to inform Phase 2 of this arm.

As this study used a quantitative approach, utilising a quantitative questionnaire to assess RAs' perceptions of risk in the practice of their respective health professions, this chapter will include separate sections considering the results and an initial discussion of how these results answer the aim of this arm of the study.

5.2 Results

Responses were received from 11 of 16 RAs, representing a 69% response rate.

When considering the overall likelihood of risk, six responses reported that it was either likely or highly likely that significant risk factors were present in normal practice or that practice errors might occur (see Figure 12). Conversely, only two responses reported that it was likely that practitioner misconduct might occur. When considering the degree of potential harm, however, respondents noted that all three areas could result in severe harm or death for the health consumer, with *practice errors* being the most common (n=6), followed by both *practitioner misconduct* (n=4) and *risk factors present in normal practice* (n=4). For most respondents (n=6), however, the *risk factors present in normal practice* were only seen to result in potentially mild harm to the health consumer.

When considered from a risk-matrix perspective, *practice errors* were rated by the majority of respondents as being a serious or critical risk (n=9), with both *practice errors* and *risk factors present in normal practice* each being categorised as a critical risk in four responses. Comparatively, six responses rated *practitioner misconduct* as only a moderate risk. No responses rated any of these three factors as a low risk overall.

Figure 12: Overall Risk. Number of responses categorising misconduct, errors and presence of risk factors according to likelihood, severity and overall risk rating.

5.2.1 Contributing Factors

An overview of participating RA's perceptions about potential Contributing Factors is presented in Figure 13. Respondents rated the eleven potential contributing factors on the likelihood of risk and severity of harm, resulting in an overall risk rating.

Likelihood of risk

Of these eleven factors, *communication issues* were seen to be the most likely contributing factor to exist within normal practice, with nine reporting this was either likely or highly likely to exist. *Individual patient characteristics* (such as behaviour leading to an increased risk of harm) and *poor working conditions* (such as the lack of clear policies and procedures, or workload issues) were also seen to be highly likely to exist, each with eight respondents reporting these were either likely or highly likely to exist. *Training and education* factors were seen to be the least likely to be present, however, with eight respondents considering these were either unlikely or highly unlikely to be present in the practice of the regulated profession.

Severity of harm

Despite this low likelihood, *training and education factors* were often seen to have the potential to be highly harmful, with seven respondents reporting that incidents related to this factor could result in moderate or severe harm. Only the *performance of high-risk procedures* was seen by more respondents to potentially result in a higher level of harm, with nine respondents reporting this might result in moderate or severe harm.

Inter-professional factors were seen as less likely to result in a high level of harm, with a high proportion of respondents noting that *team dynamics* (n=8) and *social issues in the workplace* (n=7) may only result in either mild, or no harm.

Overall risk rating

When considering both the likelihood and potential impact of these contributing factors as an overall risk rating, both *individual patient characteristics* and *communication issues* were most often seen to be high risk, with eight responses rating each of these to be a serious or critical risk. *Practitioner characteristics* (such as personality or behaviour leading to an increased risk of harm) and *poor working conditions* were also more often seen as higher risk factors, with seven responses rating these as be a serious or critical risk. Although a relatively high proportion of responses rated *performance of high-risk procedures* as a serious or critical risk (n=6), the high impact of harm reported above seems to be offset by the lower perceived likelihood.

Of all the contributing factors, *social issues in the workplace* (such as workplace culture and professional or personal respect) were most often seen as a lower risk, with seven responses showing this to be a low or moderate risk. *Training and education* (n=6) and *team dynamics* (n=6) were also more often considered to be a low or moderate risk, with *team dynamics* being considered a low risk in three responses.

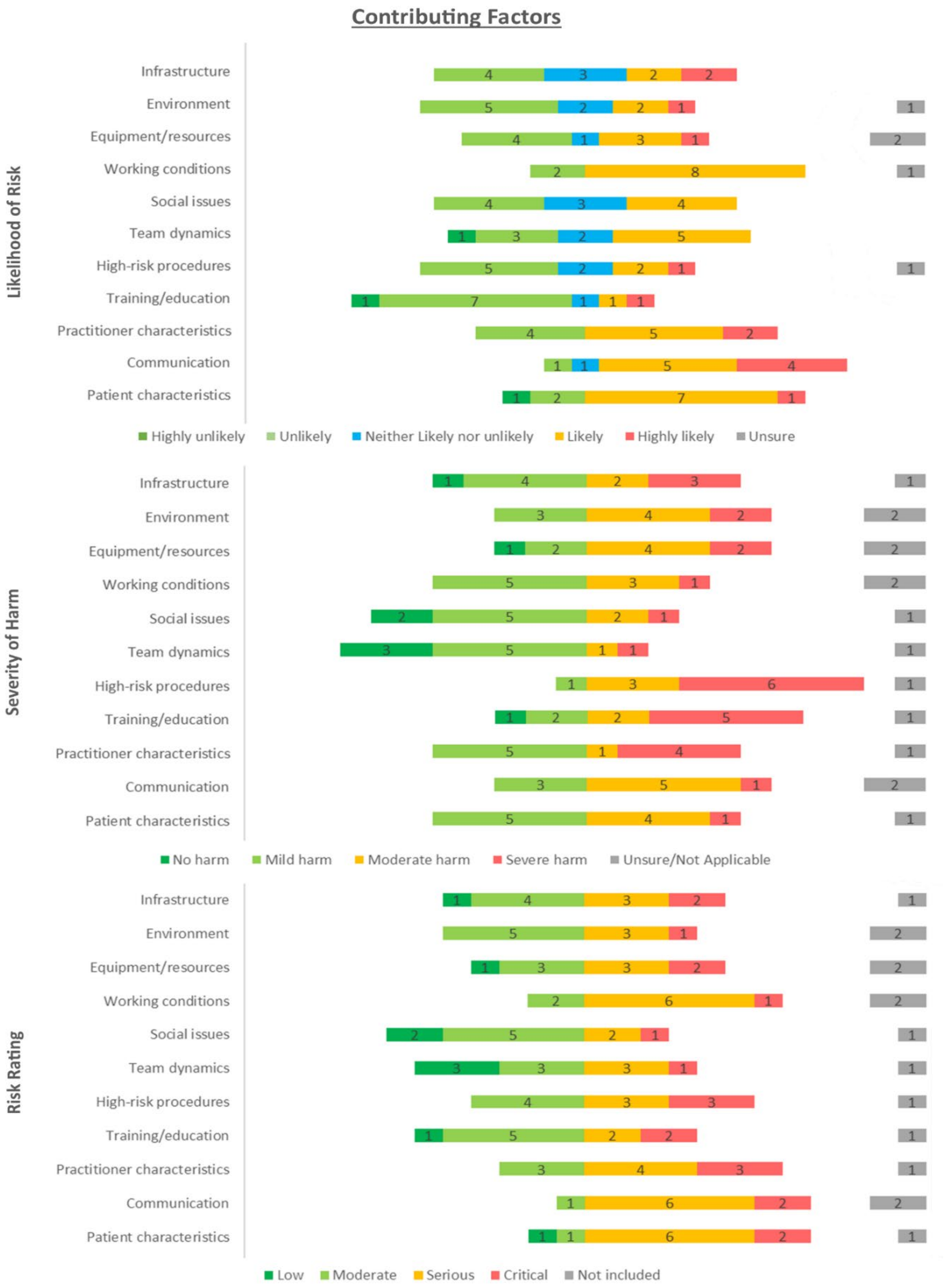


Figure 13: Contributing Factors. Number of responses categorising each contributing factor according to likelihood, severity and overall risk rating.

5.2.2 Practice Errors

Figure 14 outlines participants perceptions of risk and harm related to various types of practice error. This section sought to determine how likely the RA would consider particular errors are to occur in the profession, and the potential harm they may create.

Likelihood of risk

Despite being regarded as a serious or critical risk overall by a large proportion of responses, most practice errors were considered to have a lower likelihood of occurring. Only *communication errors* were considered by over half of respondents to be likely or highly likely to occur (n=7), and the only practice error to be considered highly likely to occur (by two respondents). Both *diagnostic errors* and *treatment errors* showed a fairly even spread of likelihood, with four respondents considering *treatment errors* to be likely or highly likely, versus four respondents considering these to be unlikely or highly unlikely and three considering these to be neither likely nor unlikely. Similarly, *diagnostic errors* were considered likely or highly likely by four respondents, versus unlikely or highly unlikely by five, and neither likely nor unlikely by three respondents.

Equipment failure, or lack of access to equipment, was considered the least likely practice error, with eight respondents considering this unlikely or highly unlikely to occur. *Infection* (n=5) and *medication errors* (n=4) both showed the highest proportion of respondents considering these as highly unlikely to occur, although both saw two respondents still considering these likely.   *Administrative errors* were also considered less likely, with six respondents considering these either unlikely or highly unlikely.

Severity of harm

The impact of harm from errors showed three error types as being considered more harmful by a majority of respondents, with a higher portion of responses classifying the likely severity of harm from *treatment errors* (n=8), *communication errors* (n=7) and *diagnostic errors* (n=6) as likely to be either moderately or severely harmful.

One respondent did not answer the items considering the potential severity of harm from *medication error* or *infection*, and a substantial number of respondents were unsure (n=4) of the likely severity of harm from these two practice errors, potentially due to these factors being less relevant to the profession in question (for example, professions where the use of medication is outside their scope of practice). Of the six remaining responses that rated the likely severity of harm, however, three considered *medication errors* and three considered *infection* to be likely to result in severe harm or death.

Administrative errors were seen as the least potentially harmful by most respondents, with eight considering these errors would most likely result in either mild or no harm, and five considering these would likely result in no harm at all.

Overall risk rating

When combined into a risk matrix rating, *communication errors* were again seen as the highest risk, being rated as a serious or critical risk in eight responses. *Treatment errors* and *clinical or procedural errors* were also seen as a high risk, with seven responses rating these as either serious or critical risks.

Administrative errors and *equipment failure* were seen to be lower risk in most responses, with each resulting in seven responses classifying them as low or moderate risk.

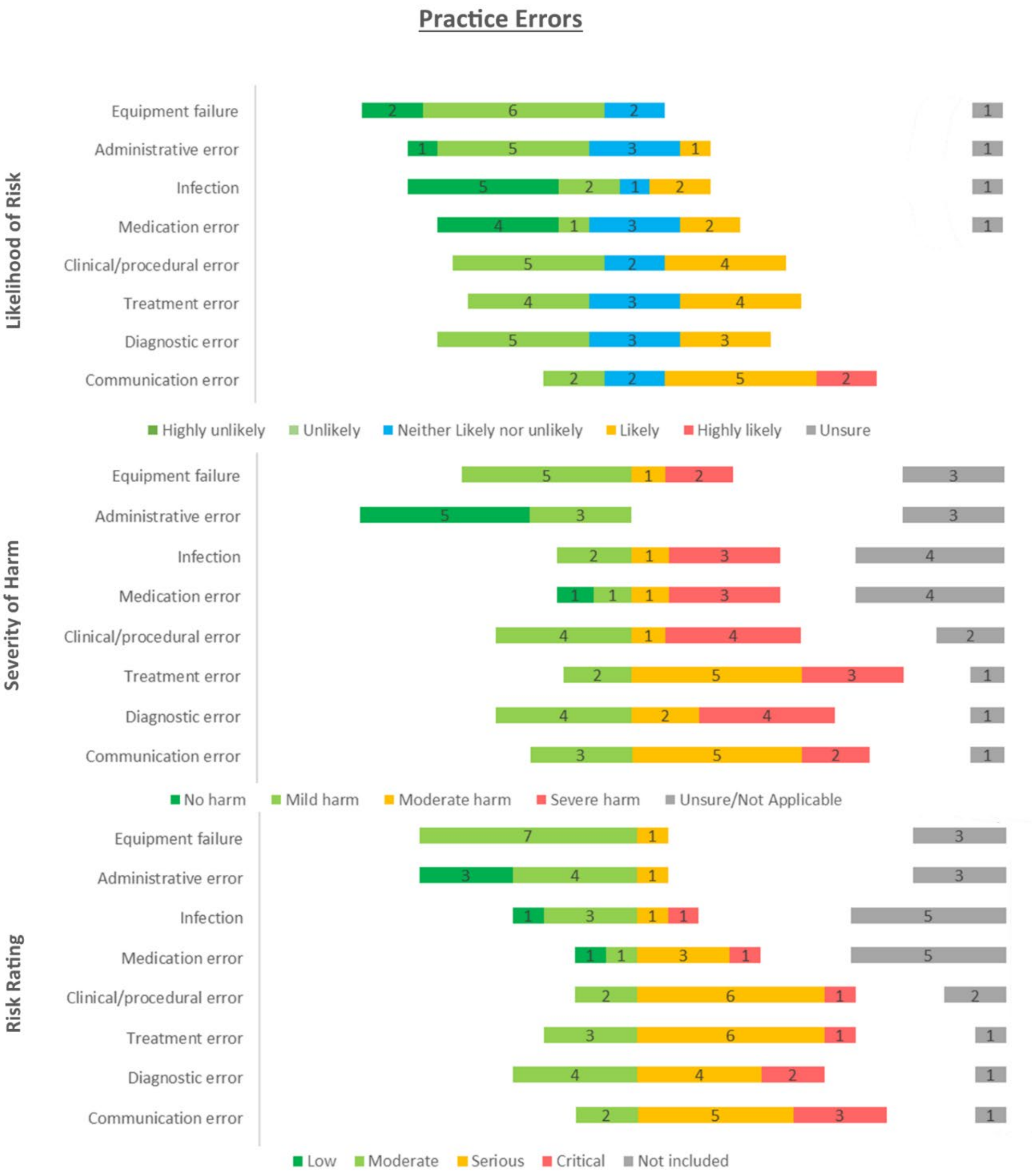


Figure 14: Practice Errors. Number of responses categorising each error type according to likelihood, severity and overall risk rating.

5.2.3 Practitioner Misconduct

Whereas errors are seen as unintentional incidents that may result in harm, misconduct refers to improper or unacceptable behaviour, malpractice, or negligence. Figure 15 shows participating RA's perceptions on the likelihood, severity and overall risk of seven categories of potential misconduct.

Likelihood of risk

In general, all categories of practitioner misconduct were not considered to be likely or highly likely to occur by a majority of respondents, with *non-compliance with administrative, contractual or regulatory requirements, or fraud* showing the highest proportion of responses (n=5) considering this to be either likely or highly likely.

Disruptive practitioner behaviour was seen to be unlikely or highly unlikely to occur by a strong majority or respondents (n=9), as were *boundary violations* (n=8) and *unlawful use of medication* (n=8). Conversely, *boundary violations* was also the only item to have more than one respondent report this as being highly likely to occur (n=3).

Severity of harm

Boundary violations were also seen to be highly harmful by the largest proportion of respondents, with eight considering these incidents to be likely to result in moderate or severe harm, including four considering the likely harm to be severe. As with *medication errors* described above, *unlawful use of medication* showed a higher number of respondents (n=4) answering that they were unsure about the likely level of harm. Of the seven remaining responses, six considered that the likely level of harm from *unlawful use of medication* would be either moderate or severe, including four considering such use to result in severe harm.

Some categories of practitioner misconduct showed a split in the level of harm respondents considered likely, with *disruptive behaviour* (n=4, no or mild harm vs. n=4, moderate or severe harm), *management of health information* (n=5, no or mild harm vs. n=5, moderate or severe harm) and *non-compliance with administrative, contractual or regulatory requirements, or fraud* (n=5, no or mild harm vs. n=5, moderate or severe harm) showing varied perceptions on the likely level of harm.

Only misconduct related to *unfair costs or misleading advertising* was not considered to have a higher level of harm by most respondents, with eight considering this to likely result in no, or mild, harm.

Overall risk rating

As seen for the likelihood of practitioner misconduct, the overall perceived risk from most categories of practitioner misconduct resulted in a lower risk rating from most respondents. Over half of the responses resulted in a categorisation of *boundary violations* (n=6), *management of health information* (n=6), *unfair costs or misleading advertising* (n=6) and *non-compliance with administrative, contractual, or regulatory requirements, or fraud* (n=6) as a low or moderate risk. Again, however, a smaller number of responses resulted in *boundary violations* being of higher concern, with three of these being categorised as a critical risk.

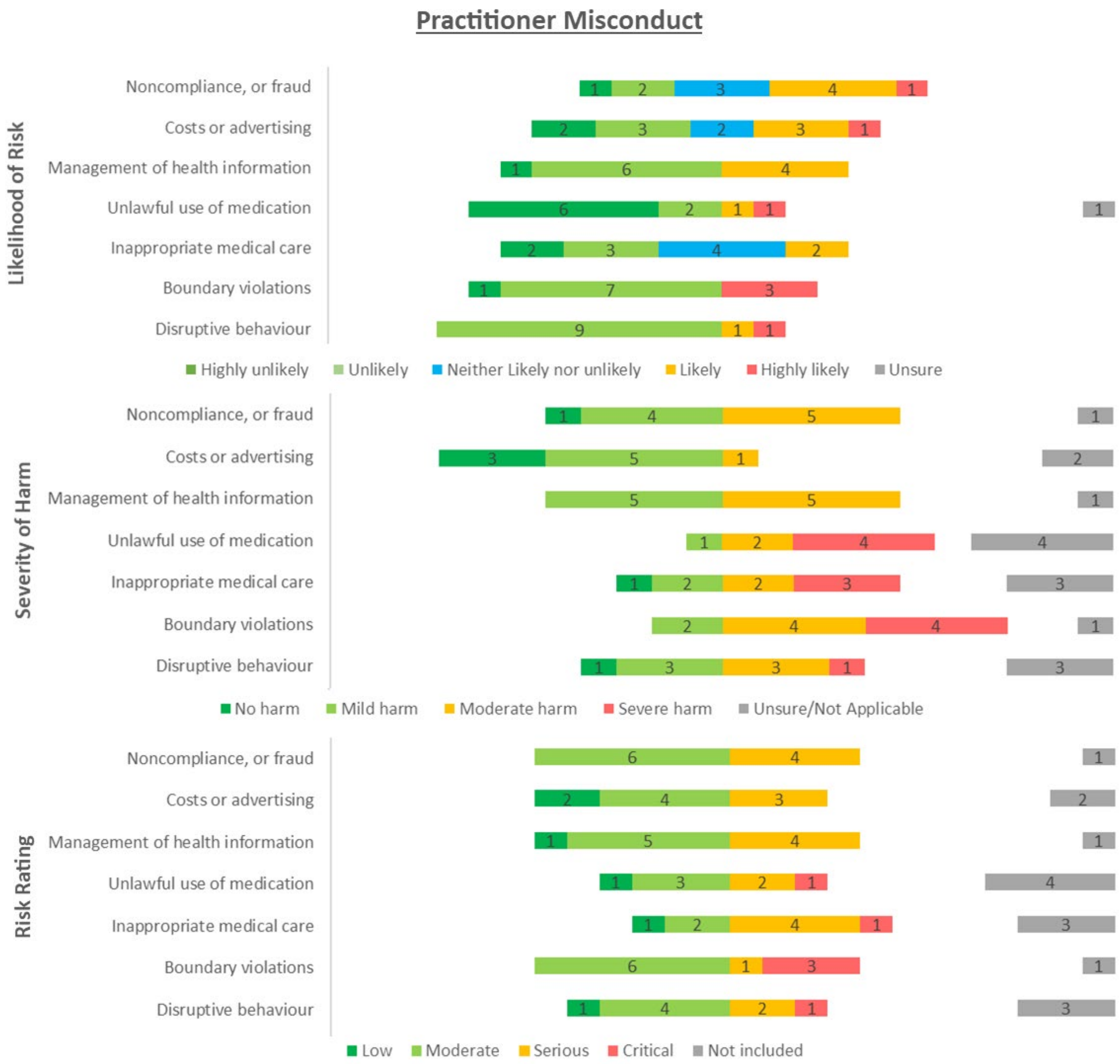


Figure 15: Practitioner Misconduct. Number of responses categorising each misconduct type according to likelihood, severity and overall risk rating.

5.3 Discussion of Phase 1 Results

This section serves to provide an initial discussion of the results as they relate to this arm of the study. Further discussion of these results in the context of the overall research project, including their relationship to the other components of the project, are discussed further in Chapter Eight, Integrated Findings.

5.3.1 Practice Errors versus Practitioner Misconduct

A majority of RAs involved in this study saw the risks present in normal practice, practice errors and practitioner misconduct as potentially causing either moderate or serious harm. A substantial number, however, also reported that practitioner misconduct, overall, was unlikely to occur. Previous research investigating complaints made against health professionals in New Zealand has indicated that conduct concerns make up a relatively high proportion of complaints (Ryan et al., 2018; Surgenor & Diesfeld, 2018). However, previous research by Bismark et al. (2006) suggests that complaint rates are often low, especially when considering less-serious adverse events and that health consumers may either be unaware that they have sustained an injury, or ascribe an adverse event to ‘bad luck’. These perceptions may be less likely in the case of practitioner misconduct and where health consumer concerns may not be related to a physical injury.

Under the HPCA Act, RAs may treat practice errors, and matters of competence, differently from misconduct concerns (Health Practitioners Competence Assurance Act 2003). Complaints involving conduct concerns may result in disciplinary proceedings through the HPDT (New Zealand Health Practitioners Disciplinary Tribunal, 2017a), and information from these cases may become publicly available. Conversely, competence matters may be more readily addressed within the workplace or involve more direct activity between the health practitioner and regulatory authority, and information regarding these cases may not enter the public domain. Conduct issues, therefore, may be more visible despite being seemingly less likely.

Despite this, a small number of RAs consider that practitioner conduct issues are likely to occur in the profession they regulate, and further research may help identify why these professions are seen by regulators to have a greater likelihood of misconduct.

5.3.2 Competence versus Performance

Competence is now recognised as only one of the factors that influences overall performance, as illustrated in the model of *Factors influencing performance* denoted in Figure 1 (Khan & Ramachandran, 2012). This model suggests that, although competence is a major factor in overall performance, other factors such as individual- or systems-related factors also influence performance.

Most RAs recognised that workplace factors (such as the lack of clear policies and procedures, or workload issues) were likely to exist in practice and, although many did not consider this factor would lead directly to moderate or severe harm, workplace issues may have a more indirect impact on safety (Taylor, 2018). RAs were more diverse in their consideration of the risk related to infrastructure, environment and equipment and resourcing, however, suggesting larger differences between professions.

Health consumer characteristics, such as disruptive behaviour, were also seen as a likely contributing factor and a source of high risk for almost three-quarters of RAs involved in this study – more so than any other contributing factor except for communication. Practitioner characteristics were also seen to be a likely factor by many RAs, but there were differing views on how severe the resulting harm might be – whereas five RAs reported that practitioner characteristics may only result in mild harm, four considered that this contributing factor may result in serious harm or death. Conversely, while both poor training and education, and the performance of high-risk tasks in normal practice were both seen by many RAs to potentially result in moderate or severe harm, the likelihood of these factors existing was generally seen to be low.

This suggests that factors outside of those related to the individual practitioner may be a significant component of the overall risk, however these are also factors that RAs, through the mechanisms provided by the HPCA Act, may have less ability to constrain.

5.3.3 Communication

Communication is seen by a large number of RAs as both a likely and highly impactful contributing factor, and communication errors are seen as a source of high risk across many professions.

Health communication is a topic of significant interest and has been identified as a highly prevalent factor in adverse events (Ellahham, 2021; Guttman et al., 2021). The World Health Organisation Global Patient Safety Action plan 2021–2030 similarly recognises that communication issues, both miscommunication within a healthcare system and failure to communicate well with health consumers, are significant risk factors in the safety of clinical processes (World Health Organization, 2021). Furthermore, inappropriate communication has been identified as a factor behind inequitable access to healthcare and can impact culturally safe practice (Field et al., 2020; Simpson et al., 2021). This broad impact may suggest some incongruity between the perception of communication factors as source of high risk and the lower risk rating ascribed to team dynamics and social issues, and further exploration may be useful in identifying the areas of communication that most influence the risk of harm. Appropriate training in communication skills, however, can have a positive effect on both safety culture and health outcomes (Alsabri et al., 2022), and developing approaches to communication improvement may be a critical contributor to safety (Iedema et al., 2019).

Communication can be seen to be an important, albeit complex, topic that crosses all aspects of healthcare. Given the large numbers of RAs recognising this as a significant area of risk, this may represent a key area of collaborative work across many of the professions regulated under the HPCA Act.

5.3.4 Considerations for Phase 2

As the aim of this study was also to inform Phase 2 of the research project, some initial considerations added to the development and protocol for this second phase.

As discussed earlier in Chapter Three, Methodology, Phase 2 sought to build on, and explore the results of this first phase. This chapter also describes the selection of participating RAs based on their answers to this study. While the semi-structured interview process used to gather data in Phase 2 allowed for participants to discuss the topics they felt were important, the initial interview guide was developed using the findings discussed above. This included specific questions related to the answers participating RAs gave in Phase 1, allowing for these to be explored in more depth. As the interviews were conducted by the primary researcher, familiarity with the findings of this phase allowed these to be interwoven into the interview discussion where appropriate.

5.3.5 Limitations of this Study Arm

This study sought to report the perspectives of the participating RAs and does not seek to generalise these results further. Further research would be necessary to determine whether similar results would be found from other health regulators. The RAs involved, however, do represent a majority of regulated health professionals in New Zealand. The correlation between health regulator perceptions and actual risks is also unknown, and this study does not seek to describe the risks that may exist in practice. As regulatory action will be based on the perspectives of health regulators, however, understanding their perceptions on risk provides its own value.

5.3.5 Summary of Findings

This study explored the perceptions of RAs to areas of risk in the professions they regulate. While the accuracy of these perceptions to actual risk is unknown, exploring these perceptions allows insight into where each regulator sees the main areas of risk, and how these compare across the diverse healthcare professions regulated under the HPCA Act. Practice errors tended to be more often seen as an area of high risk than practitioner misconduct, with the harm from many types of misconduct being often recognised as severe but with misconduct unlikely to occur. Boundary violations, however, stood out as highly likely, and therefore being of particular concern, for a small number of professions.

While the results show some variance between professions, poor communication is broadly recognised as both a significant contributing factor and source of risk of potential harm to health consumers. Given the international focus on this topic, health communication may therefore be a fruitful area of collaborative work between New Zealand RAs. Given the lack of public information regarding competence issues seen by RAs, and the low number of disciplinary cases associated with a number of professions under the HPCA Act, this information provides valuable insight into both where the most significant risks to public safety are seen to lie, and where there may be areas of commonality between professions. In turn, this may allow targeted exploration and intervention in these areas and ensure regulatory action is well-targeted and proportionate to the given risk.

Chapter Six – Perceptions of Risk | Findings

6.1 Introduction

This chapter will present the findings of Phase 2 of the complementarity arm of the research project. The aim of this phase was to develop more in-depth knowledge of selected regulators perceptions regarding the risk of harm to the public and to build on and illustrate the results of Phase 1.

Seven main themes were developed from the data, each relating to one of three broad areas of focus – the development of perceptions of risk, characteristics of perceptions of risk, and management of perceived risks. Table 9, below, provides an overview of these themes, and outlines the characteristics of each. This chapter will consider the themes under the first two areas of focus, illustrated by representative quotations from participating representatives of the RAs involved. These are then summarised in the discussion of a potential model of perception development.

While the themes discussed in this chapter relate directly to regulators perceptions regarding the risk of harm to the public, the management of risk considers a different facet of this topic. The themes concerning the management of perceived risks will then be presented in Chapter Seven.

Table 9: Overview of Themes

Focus	Themes/Subthemes	Characteristics
Development of Perceptions of Risk	'Knowing Risk' is a challenge.	There is a reliance on externally reported complaint and notification data to inform understanding of risk. Challenges with these data result in a reliance on institutional knowledge.
	Perceptions of risk relate to societal expectations.	Perceptions of risk and harm change over time, in response to changing expectations from society around acceptable or tolerable behaviour.
Characteristics of Perceptions of Risk	Perceived risk profiles are similar but distinct.	Perceived risk profiles are benchmarked against other health professions, showing both areas of common risk and profession-specific differences. These differences include the relative focus on physical versus non-physical harms.
	Perceptions of relative risks relate to the clinical role.	Risk is seen as an inherent part of healthcare, but the specific nature of that risk relates to the vulnerabilities required of the health consumer.
	Environmental pressures amplify clinical risks.	Systems factors, such as resourcing issues, rigid institutional requirements, and conflicting priorities, impair a person-centred focus
Perceptions of Risk Management	Communication is a moderator of harm.	While communication can be a risk itself, it can also serve to moderate the perception of harm. It may have the potential to either aggravate an existing harm or reframe a potential harm as a tolerated outcome.
	A team approach supports risk mitigation.	For risk management to be most effective, participation and buy-in needs to occur across the health sector. Regulators recognise the limitations of the levers available to them to enact systemic change.

6.2 The Development of Perceptions of Risk

To be able to set relevant standards and take appropriately targeted regulatory action, it is important that RAs understand the risks that exist within their respective professions.

As the development of understanding requires accurate knowledge, it is vital that there is a flow of high-quality information to RAs on which they can base this understanding. In turn, the development of perceptions of risk formed by RAs will be substantially influenced by both this information and their experience and understanding of the profession they regulate.

6.2.1 ‘Knowing Risk’ is a Challenge

Participants were aware of the need for accurate data, and there was an intent to seek trustworthy information. There was a sense, however, that significant barriers exist that make collecting accurate and timely data difficult for many RAs.

Many participants described their understanding of risk and harm developing through the consideration of the externally reported complaint and notification data they received, with a comment from RA1 being indicative of this approach:

> *“I think that it's really been a coal face, primarily a coal face understanding, so it's looking at the sort of conduct issues we've got coming in, the sort of complaints that we've got coming in”.* [RA1]

While complaints from health consumers are recognised as providing useful insight into the quality of healthcare (Mattarozzi et al., 2016), a reliance on this externally reported data may be insufficient to build an accurate and complete picture of clinical risk.

Participants demonstrated an interesting juxtaposition between recognising a reliance on data from complaints and notifications to provide information, with an understanding that this is an imperfect process. While this was commonly recognised by participants, RA3 shared a specific example where this was made clear to them:

> *“A few years ago, we tried to do some research on, were there any particular red flags within [our profession]? But we have quite small numbers of notifications, and so it meant that it was really sort of meaningless in a way …*

> *you certainly can't do any kind of meaningful tests on it or anything like that when you've got such small numbers because it's so variable".* [RA3]

For RA3, the key difficulty arose from the very limited amount of data to base any conclusions on. As recognised by RA2, a substantial amount of information may never reach the attention of an RA as complaint or notification data:

> *"I think you're never gonna have full understanding because you just don't know as much what's happening in practice. So, you see the sharp end of the issues, but you don't know the full extent of other things that may not ever, like near misses for instance, and the risks that have to land as an adverse outcome to really make it to us".* [RA2]

As well as the recognition that incoming data may not provide a full picture of clinical risk, this example also talks to the natural bias that may exist in the information that does reach an RA. Complaints and notifications may be skewed towards more serious or overt concerns or represent 'critical incidents' of harm. Other incidents of harm that may not reach the threshold of what the service provider or health consumer determines to be harmful may not result in a complaint or notification being made. This poor awareness may extend to the readiness of the profession to meet standards, such as reported by RA1:

> *"So, we thought that the profession was at a certain level, but we were shocked to realize that it actually quite a level behind that. And as a Board we're very aware of the risk that unconscious bias can have around a patient's cultural safety".* [RA1]

This exemplifies a situation where the data received by an RA was insufficient to identify an existing risk until they directly engaged with the profession to clarify expected standards of care. While there may not have been sufficient complaints or notifications to bring this to the RA's awareness, it still represented a potential risk of harm within much of the profession.

As described by RA2, larger health providers may provide a lower number of reports to regulators, however it is not known whether this is due to better management of potential risks, or that cases are being resolved internally.

> *"Our competence numbers are not massive, but I think a lot of that is because … it can be adequately dealt with at the employee level … that's not to say there might not be competence issues out there. It's just they are being managed without Council's involvement".* [RA2]

Here, even though individual cases may be resolved internally, there is no visibility of these to the regulator, precluding any awareness of poor outcomes or underlying risks related to these practitioners that may indicate broader issues within the profession. RA1 also considers this from the view of an individual practitioner successfully managing an incident of harm:

> "*What I'm fairly confident about is that they [adverse events] are very professionally and well handled by practitioners. So they don't reach a threshold for complaint*". [RA1]

While there seems to be an assumption from RA1 and RA2 that any concerns arising from these cases have been addressed, it is difficult to know how these were resolved without adequate reporting. This lack of visibility could also preclude any lessons learned from these incidents. While incident reporting may provide some information (for example, Serious Adverse Event Reports provided by Te Whatu Ora Waitaha Canterbury (2020)) these may not provide the specific information RAs require to inform future regulatory action and risk awareness or mitigation.

This threshold of reporting also relies on those in the clinical environment (whether this is the health consumer, practitioner or health institution) to actively consider the incident and take action to inform the regulator. Medical errors are often poorly reported, with less than half of health consumers suffering harm reporting this to an oversight agency (Lyu et al., 2017). There may also be significant barriers to reporting concerns to regulatory authorities, even from other health professionals (Ekpenyong et al., 2021), and this corresponds to the experience of RA4 in gathering data to support decisions:

> *"If you're not getting the information about sub-optimal practice from individuals who are seeing that, you also don't have the data to support your actions. So that's the broader concerns around the readiness that practitioners have to, essentially, to fulfil their professional obligations to highlight concerns when there's a risk of harm to the public".* [RA4]

While RAs may work to develop their relationships with health consumers and the profession to allow easier communication, there is still concern that reporting information is seen to be difficult:

> *"The Board has always seen it [reporting concerns] as a big scary thing … so I think people are generally quite loath to report, but we have been doing a bit of education over the last few years around making us more approachable".* [RA3]

The formal nature and prescribed processes of submitting a notification or complaint to an RA may disincentivise those with concerns from reporting these to the regulator. The depth of these concerns may be weighed against the reluctance to engage with the RA and the potential outcomes of reporting. RA1 raised this concern with respect to low numbers of complaints relating to cultural competence, noting:

> "*I would suggest personally that [the low number of complaints is] more because patients don't feel empowered to complain about it [than it not being of concern]*". [RA1]

If the process is seen as too arduous, or the outcomes not worthwhile, the RA may not receive a formal complaint or notification on which to act or understand the associated risks.

Overall, there seems to be a reliance on the willingness of those in the clinical space, be they health consumers, practitioners, or employers, to pass information to the RA. Limitations in the flow of this data, due to barriers to reporting, opaque institutional processes, and inherently low incident rates, can mean that RAs have limited information on which to form their perceptions. Potential biases in the information received, due to perceived reporting thresholds and a possible focus on incidents resulting in overt harm, can also meant the perceptions formed may not accurately represent the breadth of risks in the clinical environment.

Given these limitations in data, RAs also rely on internal expertise to inform decisions:

> *"I think that we're lucky to have staff who have been here a number of years. So, I think that institutional knowledge is really helpful".* [RA2]

RAs value those who have developed this institutional knowledge through experience, or whose professional knowledge may augment the limited information available from other sources. It can take new RA members or staff time to develop an understanding of risk, both from a general and profession-specific view. RA5 also provides evidence of this slow development of knowledge, commenting:

> *“Initially, when a new board member is on board, particularly in the first, probably two years, that they don’t understand the entirety of what risk means and they don’t understand the procedures around risk”.* [RA5]

Like RA2, RA5 highlights the time it can take for a novice regulator to form a sufficient knowledge base to make appropriate decisions, and further reinforces the value of those who hold knowledge within the organisation. This also, however, suggests a key risk for RAs – this hard-won knowledge may be vulnerable to the turnover of key personnel, either at a Board or staff level, and the loss of this knowledge may hamper the operation of an RA until it is remedied, especially for smaller regulatory organisations.

Overall, then, an RAs understanding of risk may be relatively fragile, with a holistic understanding of a profession by key people guiding decisions where there may be a lack of solid evidence. To truly understand risks to public safety, it is necessary to have free flow of information between all of those with an interest in public safety in healthcare.

6.2.2 Perceptions of risk relate to societal expectations

While the focus of this study was predominantly on exploring risk, it became apparent from the first interview that any discussion involving risk had to be contextualised by the participants’ understanding of harm.

> *“You look at the [direct cause of] harm, of course you do, and that’s a foremost of what your role is and what you’re looking at. But you do also need to focus on the actions [that led to harm occurring]”. [RA2]*

Here, RA2 references the strong focus RAs have on harm to health consumers (and the avoidance thereof), but they also recognise that the cause of harm requires attention. The identification of risks requires awareness of the potential consequences (Simsekler et al., 2018) meaning an understanding of harm may be vital to understanding the risks that may lead to this outcome.

In talking about harm, RAs demonstrated a range of views on what harm is and how it might be recognised. Rather than being a static concept, with clearly determined characteristics and measures, RAs saw ‘harm’ as a more dynamic understanding of the impact on an individual. Most RAs felt that their changing understanding of harm is being driven by changing societal expectations, and a potential change in the tolerance of certain outcomes. RA2 questioned this with specific reference to an increase in complaints related to cultural harm and racism:

> *“I wonder whether with racism, it’s just the shift in society’s expectations of calling out that it’s not okay has shifted?”. [RA2]*

With RA3 commenting more broadly on changing expectations:

> *“Society changes around what’s perceived as acceptable and risky and, so … not necessarily having that same definition of risk the whole time, and how your definition of risk evolves perhaps to reflect what society’s definition of risk is”. [RA3]*

This changing understanding of risk from RAs, and the focus on societal expectations, may be related to the reliance on externally reported concerns as discussed in *Knowing risk is a challenge*.

A lower tolerance for particular harm by health consumers (and, potentially health practitioners) may, in turn, lead to an increased number of complaints to a regulator regarding those harms. While this increased reporting may lead to a subsequent increase in RA awareness, it may not reflect an actual increase in this harm occurring in practice.

Consequently, this suggests that there may be risks present, and harms occurring, in clinical practice that are deemed ‘tolerable’, or not seen as harm, by those with the means and opportunity to report concerns to a regulator. If a minority consider a harm to be intolerable but face greater barriers to engaging with the regulatory system, these concerns or harms may not quickly come to an RA’s attention. It may only be through the development of a greater general awareness within society and by those involved in delivering and receiving healthcare that these issues are recognised and addressed by regulators.

This can be seen in the broader example of the recognition of physical vs. non-physical harm. The definition of harm provided by the WHO's Conceptual Framework for the International Classification for Patient Safety (World Health Organization, 2010) focuses primarily on physical harms. Participants in this study recognised, however, that harm may include social, cultural, psychological and financial harm, among others. This consideration is at an early stage amongst regulators, however, and there does not yet seem to be a consistent understanding of what this broader definition may be. The relatively recent nature of this discussion is illustrated by RA5 who describes a gradual shift towards considering broader concepts of harm:

> *"I think definitely in the last five years there's been a change in perception around physical, mental harm as well. I think that's been taken more seriously by everybody and I think definitely in the last three years the cultural aspect of safety has become more discussed as well ... But I think at the moment people look at the physical still – that person shouldn't have done that". [RA5]*

The perception of this regulator that there is, for some, a growing awareness of other forms of harm – such as social, cultural and psychological harm – suggests a broader consideration of the impact of harm on the health consumer will be necessary by some RAs. This change in thinking may provide challenges for some regulators in how they approach the recognition and assessment of harm. This may challenge existing beliefs; for example, RA5 highlighted the potential difficulty in developing a consensus around these changing concepts:

> *"I think a person's preconceived notion of what a harm is won't change though, even when they encounter these different situations … when we've had discussions around risk and risky behaviour, it's interesting how some people are amenable to change by some discussion, but others, their mind was made up and it doesn't change". [RA5]*

Previous definitions of physical harm have tended to focus on the severity and duration of symptoms, the loss of function, and/or the level of intervention required (J. Cooper et al., 2018) and these are unlikely to be suitable for measuring other forms of harm. This, in turn, may mean that the impact of harm may not be appropriately captured, leading to health care consumers feeling their concerns have not been adequately recognised.

For example, RA3 felt they had already experienced this difficulty when considering the harm they see compared to overt physical harm:

> *“Some would say it’s ‘did they live or die in surgery?’ … Whereas we are not measuring on those types of things, we’re tending to measure on, are they able to return to what they wanted to do? It’s not that black and white”. [RA3]*

Overall, represented through this theme is a lack of consensus on the definition of harm. While RAs are open to broader definitions of risk and harm, and some embrace such concepts of harm, those that are developing their perception are reactive, and significantly impacted by the data issues outlined in *6.2.1 Knowing risk is a challenge*.

A reliance on societal expectations may lead to bias, stereotyping and applying very narrow parameters of risk. This creates a potentially unsafe regulatory space whereby the needs of anyone who does not meet the societal expectations of the majority go unrecognised by the regulator. Proactively developing a consensual definition of harm, with a range of tools to identify and assess the impact of a broad range of harms on healthcare consumers, may go some way to ameliorating this issue. This, however, is likely to require coordinated action at all levels of the health system.

6.3 Characteristics of Perceptions of Risk

While the previous section considered how RAs may develop their understanding of risk, this section considers what those risks are perceived to be. In considering the characteristics of risk perceived by participating RAs, however, the challenges and themes discussed in section 7.2 are evident.

6.3.1 Risk Profiles are similar but distinct

Comparative risk

Participating RAs all considered the likelihood of harm from the practice of their respective profession to be medium to low. This again appeared to be based on the number of complaints received, however, especially through comparison with other professions. This can be seen in the following comments from RA1 and RA4.

> *“I believe that [the likelihood of harm is] extremely unlikely”. “In the last three years, … we've seen very little in the way of complaints … we're certainly not inundated”.* [RA1]

and

> *“I don't think I would call them high. But they’re certainly not low. From [a Health and Disability Commissioner] perspective, [practitioners] don't register in their top list of … practitioners they interact with”.* [RA4]

Given the previous concerns around bias and representativeness of data from relying on external reports, however, it is difficult to know how well the number of complaints and notifications represents the actual risk of harm in practice.

This also suggests an internal reference for judging relative risk where the perception of likelihood is based on how a profession related to a particular RA may compare against other regulated health professions. This may reflect a lack of any standard comparator for estimating appropriate risk in healthcare – what is an acceptable likelihood of risk for the practice of healthcare? This is likely to be a complex answer involving consideration of the relative benefits of any health intervention, but again speaks to the consideration of societal expectations as a guiding factor.

Most significant harm

Participants were clearer on the types of risk or harm that most concerned them for their respective professions. Two of the participants noted these as incidents involving a physical harm:

> *“Physical harm. One, physical harm. … The gravitas of the situation comes back to how much damage did they inflict on a person”. “…when you see something where there's physical damage with clear links to quality of life of the patient, that's probably the most serious thing that you see”.* [RA5]
>
> *“… the most obvious one is harm from [an error], so that can be anything from inconvenience; to minor adverse effects, … to actual harm; to more serious, you know, death”.* [RA4]

Whereas three considered boundary violations and sexual misconduct to be the most significant:

> *"We have seen sexual violation complaints in that regard … and that's a serious risk to the public obviously".* [RA1]
>
> *"I consider your conduct-type cases as to be the highest risk of harm, particularly when there's sexual misconduct because of that access, that intimate access and the risks around that".* [RA2]
>
> *"…certainly, for the person who's affected by that [a boundary violation] ... There's a lot of harm that can come out of that and for a long time for people ... for that person, it obviously is severe because they were vulnerable".* [RA3]

While these two aspects of risk may relate to the nature of the clinical environment and requisite tasks of each profession, these views may also be linked to differing concepts of risk and harm. Here, RA5 and RA4 refer to harm in terms of physiological descriptors ('damage' and 'death), whereas RA2 and RA3 refer to interpersonal power dynamics (intimate access and vulnerability).

As participants were asked about their view of the most 'significant' risk of harm, these statements contain an inherent consideration about the relative impact of harm from these different sources. It may be difficult to judge, for example, whether the harm arising from a physical injury is objectively 'better' or 'worse' than a harm arising from a breach of trust.

Financial harm

A similar difference in approach is seen in consideration of issues related to financial harm and fraud, with two RAs sharing their experience:

> *"The other one that I hope that we are through now is the potential risk to patient's financial health … in terms of trying to oversubscribe patients for care and that sort of thing".* [RA1]

and

> *"…fraud at the business level. So, the owner overclaiming or inappropriately claiming for … work that wasn't carried out".* [RA4]

Both of these participants related their concerns to artificially inflated work rates for financial reward, either through inappropriate care or fraud related to overclaiming. While RA1 considered the direct financial harm to the health consumer, however, for RA4 the resulting harm was more nebulous, with the immediate financial burden being carried by funding institutions. Here, rather than being focused on the harm, the concern was related to the breach of trust such actions suggest. This may represent a focus that prioritises either the event itself (i.e. the direct financial harm) or the implications that such activity has on the appropriate behaviour of the practitioner.

Cultural harm

There has been a significant focus on cultural competence within the New Zealand health system, represented most recently by the development of Manatū Hauora | the Ministry of Health's Anti-Racism Kaupapa *Ao Mai te Rā* (n.d.) and the Accident Compensation Corporation's *Kawa Whakaruruhau (Cultural Safety) Policy* (2023).

Participants recognised that these issues were becoming more apparent in their work as regulators:

> *"We've seen a slight increase in issues around racism, and certainly connected to online social media and racism. That's been a bit of a theme as well. Not massive numbers, but enough to draw that theme out as an increase".* [RA2]

> *"I think definitely the cultural aspect we're probably starting to bring more to the forefront because I think, and that's partly been made easier by some of these definitions that have been made around [racism]".* [RA3]

The comment from RA3, in particular, suggests that this work throughout the health system has increased the visibility of issues related to cultural safety and racism, and this has improved the ability of RAs to manage these issues.

This again ties back to the links with societal expectations considered in section 7.2.2 and exemplifies a reactive response to existing issues. While increased awareness and action within the health sector may facilitate subsequent regulatory work, it may also result in delayed regulatory action to address existing or developing issues.

Overall risk profiles

The characteristics of risks identified by RAs were generally shared across the participants, and there was a general sense that the risk of harm was moderate to low across all the professions. The level of awareness of these risks, the perception of related harm and the resulting level of concern arising from identified risks differed, however.

Given the awareness of risks seems to be reactive, and often reliant on externally reported data (as discussed in section 7.2), some of the differences in perceived risks between RAs may relate to the number and nature of complaint each receive. The clinical environment and tasks undertaken by each profession, however, also carry particular risks.

6.3.2 Perceptions of relative risks relate to the clinical role

The professions included under the HPCA Act cover a broad array of practice types, philosophies of health and clinical tasks. The degree of physical interaction and intervention or the depth of communication and relationship-forming depends on both the profession and the specific role the health professional is in (Health Practitioners Competence Assurance Act 2003).

While there may be some inherent risk in the practice of any healthcare role, the specific risks depend on what this role might be. Some may have a risk of significant physical harm (such as death), whereas others may carry a risk of other types of harm, such as boundary violations or breaches of trust.

Risk and vulnerability

Healthcare often involves working with a vulnerable population and, despite efforts to promote person-centred care, power imbalances exist between the health consumer and practitioner (Timmermans, 2020). A broad definition of vulnerability can be seen as arising from “an individual's susceptibility to harm and their exposure to risks and negative events” (Loh, 2017). Given this, it could be argued that exposure to the underlying risks that accompany any healthcare intervention could lead to an inherent, but potentially necessary, vulnerability.

This concept was reflected in participants’ views on the risks associated with each health profession, and the manner in which they work.

> *“I think particularly with the more psychosocial, perhaps, professions. Where, working with somebody, getting along, sort of being friends with them is part of the process, as opposed to perhaps a one-off intervention where, do your work and you're outta there, there's no kind of lasting relationship. So, I think that is an inherent risk around, you are building a relationship with this person”. [RA3]*

For RA3, the formation of a lasting relationship with health consumers is a key aspect of the work of their related profession, and important for successful care. They are also aware, however, that the formation of this relationship creates, for them, an increased exposure to risk that may not occur otherwise.

A similar example is raised by RA1 and RA2, who discuss the risks associated with the high degree of physical contact the practice of their related professions require:

> *“You are very much in people's personal space. It's one of the few professions that's left that you really still have to touch people and often touching people in quite private and vulnerable areas”. [RA1]*

and:

> *“I guess the hands on, in an intimate perspective, we do see unfortunately, sexual abuse type cases from that access, from that specific nature of the [profession’s] role, I think does lead to risk”. [RA2]*

These participants both speak to the concept of vulnerability, where the practice of the profession may require a practitioner to physically touch health consumers in intimate areas. As with the relationship forming described by RA3, this is seen to carry an increased risk of harm (here, related especially to sexual abuse), but is nonetheless a necessary part of care. While health professionals may have extensive standards in place, and where the competence and conduct of the practitioner may serve to mitigate the risks of this practice, this risk factor is still present in their practice.

Trust within the health consumer-practitioner relationship can be an important factor in healthcare and can ameliorate the inherent vulnerability of health consumers and improve both outcomes and health consumer satisfaction (Calnan & Rowe, 2008). Again, while trust is important for an effective clinical relationship, RA2 also sees this position of trust as increasing risk, through an increased potential for abuse:

> *"And the access that trust leads to, which is really good, can lead to, unfortunately, risk, in terms of adverse outcomes from boundary breaches or theft, that sort of thing". [RA2]*

Overall, practitioners may often be in a privileged position where they have a greater degree of permitted access to a health consumer (whether physically, psychologically and/or sociocultural) than would be granted in other circumstances. This increased access leads to an increased vulnerability, and therefore an increased risk for the health consumer, but seems to be a necessary aspect of healthcare. It is how practitioners meet these vulnerabilities through competent care and good conduct that is critical for protection of the health consumer.

Mitigating necessary risks

The regulation of healthcare, however, suggests that these necessary risks are recognised, at least at a general level. A primary tool used by RAs to mitigate risk is setting standards that practitioners must meet. By setting standards, RAs can have some assurance that practitioners are aware of the expected behaviour and level of competence required to avoid harm.

An example of this is given by RA2, in considering why particular standards have been created.

> *“A lot of the frameworks are around competencies for safe clinical care, cultural safety, and ethical safety. So, it is around ensuring safety, … and I think that recognises that harm can result”.* [RA2]

Here, RA2 ties a direct link between setting standards and ensuring safety. They suggest that the development of these standards occurs in response to the presence of risk, and that the aim of these standards is to ensure safety. A competent practitioner, conducting themselves professionally, is expected to be able to work with vulnerable health consumers without causing harm.

Given the evolution and diversity of practice, however, prescribed competencies may not reflect all aspects of practice or meet changing environments. This can be seen in the redevelopment of competencies to include a greater focus on cultural competence, or the need for business owners to be competent in that area as a complement to their clinical competence.

> *“We’re also concerned about the futureproofing of the profession and how robust is the profession to handle changes, changes in demands, because we are saying [practitioners] can do a lot more”.* [RA4]

Here, RA4 identifies that, while standards can serve to mitigate known risks and reflect the current clinical environment, they must also be responsive and broad enough to remain relevant to those practitioners at the frontier of their professional scope.

Similarly, as the healthcare role can vary within a profession, some standard competencies may not be required in all practice contexts. RA5 gives an example of where a practitioner meeting the required standards in one context, may not in another:

> *“If they got put in a new environment, maybe from a practice in [rural area] where they've been there for 20 years, and you plant them in central Auckland, what they're doing probably wouldn't be up to scratch”.* [RA5]

While RAs must ensure that standards accurately reflect the range of practice environments within the profession, a practitioner must also be able to respond to the demands of their own context. Practitioners and the profession should be self-motivated to exceed these standards and continually seek to improve their standard of practice, however RA1 was concerned that this was not always the case:

> *“I wonder if there's a feeling that, as long as we're satisfying a minimum standard, that's enough. There's not, maybe there's not an aspiration so much for a gold star standard … If you've got a competent practitioner, you're gonna have a much-reduced risk of harm, no question, but whether you actually get an elevated outcome of care for a patient, that's a different story”.* [RA1]

While regulators such as RA1 set standards for the minimum level of care, there is an expectation that health practitioners will seek to improve the quality of their practice beyond the level of competence. Even the highest level of practice, however, may not be sufficient to completely prevent a practitioner from causing harm.

> *“Even the most competent ones, even the most confident, the ones who you sort of deem at the top of the profession, they still talk about things that happened that are totally out their control”.* [RA5]

This comment by RA5 suggests that an incident of harm does not necessarily indicate a lack of competence. Errors may still occur with a highly skilled practitioner, requiring regulators to recognise when an incident may have resulted despite best practice being followed. In turn, this may mean that no fault is found with a practitioner’s actions, despite a health consumer suffering harm.

Risk and mitigation is role dependant

Each participant provided a different consideration of the specific risks related to their profession. Ultimately, however, each participant identified risks related to the particular vulnerabilities necessary in the healthcare role or tasks being carried out by the practitioner.

Key factors that were discussed by each participant, including the formation of long-term relationships with a health consumer, physical contact with sensitive or intimate areas of a person’s body, or the development of trust in the health consumer-practitioner relationship, can relate more to a heightened state of vulnerability in a health consumer than profession-specific factors. Identification of these ‘vulnerable tasks’ within the practice of each profession (or health role) may provide a useful method of identifying common risks between RAs. The development of common standards related to an area of shared risk may provide greater mobility for practitioners between healthcare roles. Similarly, these may also provide a resource for expanding professional scopes of practice which require exposure to a different risk profile.

6.3.3 Environmental pressures amplify clinical risks

While the risks associated with an individual’s practice have a direct bearing on health consumer safety and risk of harm, the practice of healthcare is always provided within the context of a practice or business environment. Whether this is as a team member in a large institution or a sole practitioner in private practice, this practice context also has an impact on the risks that may be present.

For those working in larger organisations, systems or resourcing issues may require a practitioner to appropriately navigate the system and provide advocacy or advice for the health consumer to ensure appropriate care.

> *“The public [heath environment is] not without its risk, because it also has resourcing constraints from … funding, but it's not at the level when you compare it with the private operators”. [RA4]*

and

> *“And same sort of things around funding. Funding says, you've got to fit ABCD criteria, but your person is actually an F. How do you put them into one of these boxes to make sure that they get what they need?”. [RA3]*

While RA4 identified a potential risk due to broad funding issues exerting pressure on health practitioners, RA3 extends this to include the need for a practitioner to advocate for the health consumer to receive appropriate care. This suggests a requirement for practitioners to learn the systems they work within to seek appropriate care for the health consumer.

Significant issues may also exist for health practitioners who both own and work in their practice. The tension between business requirements and healthcare requirements may influence decision making for the healthcare consumer or create external pressure on the practitioner’s actions. Practitioners may be competent healthcare professionals but be less experienced with the systems and processes necessary to both run a business and establish the systems processes that support quality healthcare. While resourcing was a concern for those practitioners working in larger organisations, owner-operated practices were seen as a significant risk by several participants.

> *“The real pressure now that exists, particularly in some of the larger cities, between having to have a profitable business versus actually providing a healthcare service. And often with the way that the economy and social setting is going, that's quite a hard act to juggle”.* [RA1]

For RA1, this risk is expressed as a conflict between two competing responsibilities – that of being a business owner with a drive to increase profits, and that of a health practitioner seeking to ensure the best care for the health consumer. The risk here may exist not from a lack of clinical competence or deliberate breach of ethics by the practitioner, but from the results of decisions made in seeking to balance two competing internal priorities.

> *“[The biggest concern regarding public safety] would be the interaction between the [clinic] ownership and regulatory model, and the current stresses from the broader health system in terms of resourcing, funding, demands et cetera”.* [RA4]

For RA4, in comparison, the risks that exist for practitioners working in owner-operated practices seem to come from a more external source – the demands of wider health system. Their comment suggests that the expectations of service from the healthcare system are not matched by the resourcing provided, impacting the ability to run a successful private business. This may give these practitioners less flexibility in changing how they run their business to ensure standards of clinical care are upheld.

Overall, these environmental factors serve to amplify the vulnerability of a health consumer and, potentially, reduce the ability of practitioners to mitigate these risks. Sossauer et al. (2019) discusses how a health system that is not flexible or well-resourced enough to respond adequately to a health consumer’s needs can lead to increased vulnerability, as can practitioners under financial or time-related pressures.

While RAs may not have a remit to take action where systems factors increase the risk of harm, they do take a practitioner’s unique practice contexts into account to ensure an appropriate response – as illustrated by RA2:

> *“But we look at individual practitioners through our lens and our Act and I think we've been quite strong on sometimes … holding the behaviour to account first and foremost … but not forgetting the circumstances as well”.* | *“Having said that, the more I go, the more I think context is everything and the environment is really crucial”.* [RA2]

While the HPCA Act provides a strong focus on the competence and conduct of individual practitioners, this comment suggests an important shift in approach and a greater recognition of the impact of the environment on practitioner performance. To be able to adequately manage the health consumer’s vulnerability while meeting their healthcare needs, a practitioner must be able to focus on the task at hand. Any additional pressure or complexity arising from the clinical environment can only serve to impair their ability to manage these risks.

6.4 A Potential Model of Perception Development

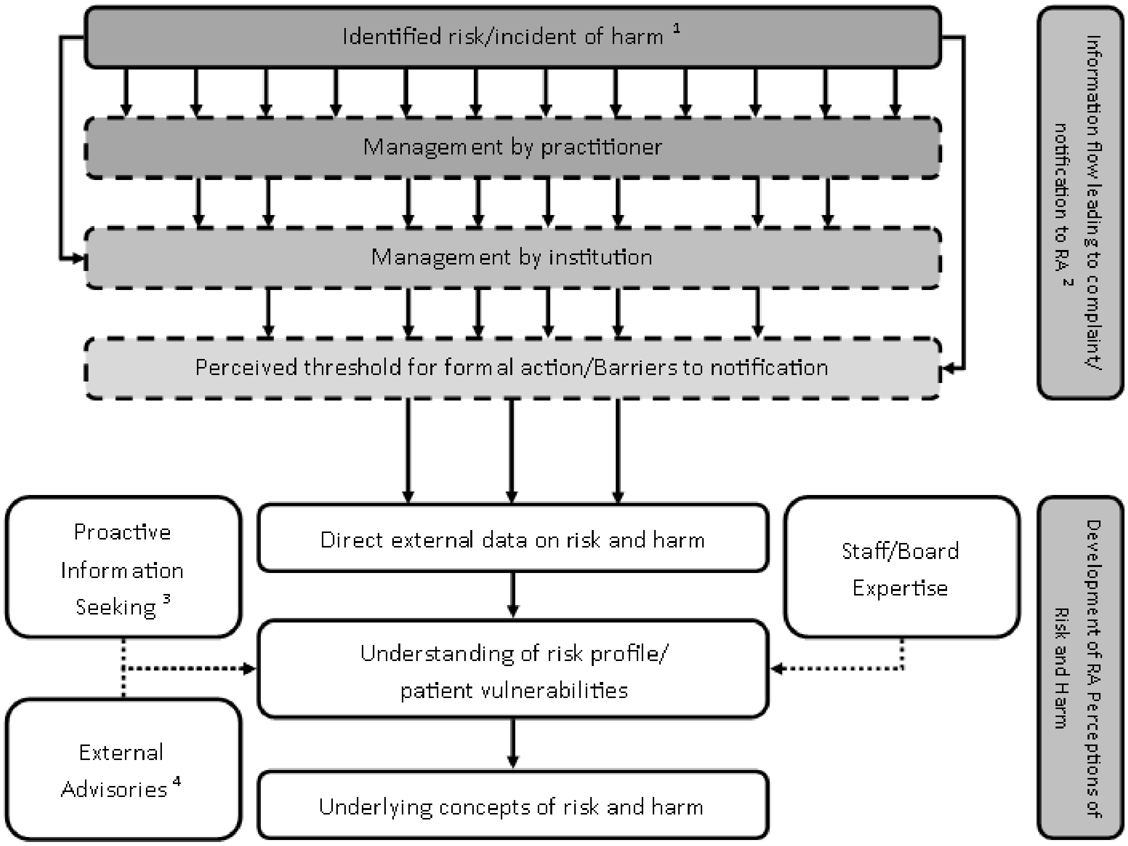
While this phase of the study set out to explore the regulators perceptions regarding the risk of harm to the public, these discussions revealed rich information about how participants developed their understanding of risk and harm as regulators.

In reaching this understanding, a risk model was developed by the author as an outcome of this component of the study (Figure 16). This model aims to illustrate these perceptions and provides a potential representation of how participants developed their understanding of risk, and the factors that provided influence.

The Information Flow that leads to RAs receiving external data on risk and harm bears similarities to the Swiss Cheese model of adverse events (Reason, 1990). In the Swiss Cheese model, each ‘slice’ denotes barriers to error propagation, with ‘holes’ representing failures in these barriers. In this proposed model, each layer represents opportunities for information to not proceed further through the chain towards awareness by an RA (for example, through a complaint being resolved or not being disclosed to a higher tier).

Areas of risk, or incidents of harm, must first be identified. As harm may only be apparent to the health consumer (especially, but not limited to, incidents of psychological, social or cultural harm), this may require them to disclose this harm for it to be identified by the practitioner, health institution or regulator.

Incidents of harm, or identified risks, may be appropriately managed by a lower-tier response (for example, by the practitioner or institution), and may not necessitate direct intervention by a regulator. If these risks or harms remain unreported in any form, however, an RA may never be aware that they were of concern. Ultimately, only a proportion of risks and harms may come to the attention of the regulator, as discussed in section 6.2.



1. Identification may require disclosure of perception of harm from patient. Does not include undisclosed or unidentified harm.
2. Harm may be directly identified or disclosed to the health institution or regulator.
3. Includes comparative analysis with other regulators (including cross-professional/international)
4. Includes other patient safety agencies; for example, Health and Disability Commissioner or Health Quality & Safety Commission

Figure 16: Potential model of risk perception development

An RA may then develop an understanding of the risk profile of their respective professions based on this information received. If this information doesn't accurately or fully represent the breadth of issues that may be present in the practice of the profession, an RA's understanding may not accurately reflect clinical practice.

As a partial remedy, RAs may also supplement information from complaints and notifications through the knowledge and expertise of staff, and information gained through proactive review or from external advisories (such as the Health and Disability Commissioner). While this may serve to both provide additional sources of information and a degree of triangulation to complaints and notifications data, these sources may also exist at a distance from clinical practice. As such, it may be important that information received directly from health consumers, practitioners and health institutions is directly incorporated into the understanding of risk developed by an RA.

The risk profiles that RAs develop also seem to be aligned with the particular vulnerabilities that a health consumer may experience while receiving healthcare from that profession, i.e. the areas of practice that may necessitate placing the health consumer in a position of higher risk. For some regulators (and/or professions), this is seen to be primarily related to the physical domain, related to complex or high-risk technical tasks, whereas others see interpersonal or trust-based aspects of the professional relationship to be of more concern.

The understanding of this risk profile may then drive the underlying concepts of risk and harm held by a regulator. Those participants who saw the most significant risks arising from physical harm tended to understand harm in the same light, focusing on harm as a representation of physical injury, whereas those who saw a higher degree of trust-based incidents tended to hold a broader view of harm.

6.5 Conclusion

While this phase of the study set out to identify the perceptions of regulators regarding the risk of harm to the public, exploring the process by which these perceptions are formed came to the fore through the research process.

Without robust data on which to base perceptions of risk and harm, there is a risk that these perceptions may not reflect a comprehensive understanding of risk at a clinical level.

A clear consensus on what the term ‘harm’ represents also seemed to be elusive, and influenced by the types of complaints received by each participating RA. While RAs may be in the process of exploring the meaning of harm, it would seem critical that a clear definition is reached, to enable collaborative discussions on protecting public safety.

Chapter Seven – Risk Management | Findings

7.1 Introduction

Chapter Six explored the development and characteristics of regulators' perceptions of risk, however an integral part of these discussions also pertained to regulators' perceptions on the management of risk.

While this theme may not directly answer the original research question, these discussions are important for providing a broader view on the perceptions of risk by regulators. The management of risk is a primary goal of regulatory action, and regulatory action may represent the manifestation of regulators' perceptions of risk. Exploring regulators' views on mitigating risk may provide further insight into their underlying perception and understanding of risk.

As such, this chapter considers two themes related to the management of risk - *Communication is a moderator of harm* and *A team approach supports risk mitigation*.

7.2 Communication is a Moderator of Harm

Given the preponderance of respondents indicating communication as a concern during Phase 1 of this research project, it was not surprising that communication was also raised as a potentially significant harm by several participants.

Communication was seen to be a pervasive factor in the safety of health consumers, being seen as both a risk factor and direct source of error, but also influencing perceptions of potential and actual harm.

7.2.1 Not Being Heard

While poor communication could lead to directly to harm, participants saw that a feeling of 'not being heard' was a factor in many complaints. RA1 and RA2 both talk to this concept:

> *"…in my experience, most of the complaints that come, there's an element that … the patient feels the practitioner simply hasn't listened to them".* [RA1]

and

> *“Probably, the highest one would be communication issues, and not being heard, and that probably is the highest report from health consumers of harm. It's often that, and then something else. But often, the issue for the health consumer is the interpersonal”.* [RA2]

For these participants, poor communication may result in a complaint or aggravate an existing complaint where there may have been a misunderstanding around intent or an insufficient response by a practitioner. The impact of this poor communication may also be independent of, and additional to, the harm caused by an initial incident.

This suggests that the inappropriate management of a patient safety incident may itself lead to a complaint, regardless of the level of harm that is seen to arise as the direct consequence of the initial incident. A health consumer may see harm as being more or less *tolerable* depending on their communication with the practitioner.

This is evidenced by RA5, who had previously identified physical harm as of most significant concern:

> *“I think it's communication-based in our profession and even our [physical harm] cases we've had, and the [physical] outcomes have been poor, again [the complaint’s] come down to that [poor communication]”.* [RA5]

While RA5 felt the direct harm from an incident was most likely to be physical, they also recognised that the communication that exists around an incident is a significant factor in determining whether the harm leads to a complaint from a health consumer. They further explain how an incident of harm may occur without resulting in a complaint:

> “*So I think it comes down to just, again, a mistake was acknowledged and it was communicated and the patient knows that the [practitioner] is there to keep an eye on it and make sure nothing happens to it*”. [RA5]

Here, despite an incident of harm occurring, a health consumer that feels their concerns are acknowledged and appropriately dealt with may be satisfied with the quality of care. Again, the harm may be seen as an acceptable (even if not desirable) sequelae to intervention.

While this may represent the appropriate management of an incident RA2 cautions that skilled communication from a practitioner may also serve to conceal poor practice:

> "*Well, they might be clinically not competent, but actually, fantastic communicators, so … the health consumer might actually say, "Oh, they were good." But actually, things were missing*". [RA2]

While the voice of health consumers may be vitally important in identifying incidents of harm, this example highlights that a health consumer may not always be aware of professional expectations of practice. This, in turn, reinforces the need for practitioners to be considered against external standards of practice, independently of health consumer complaints or concerns. A health consumer may hold concerns, or feel they have been harmed, without standards being breached, but poor practice or harm may also occur without being identified through complaints.

7.2.2 Expectations of care

This potential gap between the perceptions of health consumers and professional standards was explored by participants, with RA3 sharing:

> "*People don't necessarily know what a [health practitioner] does, what they do, and what it should do. So … if you don't know what they're supposed to do, then how can you complain if you don't know what it is?*". [RA3]

Here, RA3 sees that health consumers may not complain or report their concerns because they are not sure whether their experience meets broader expectations of care. This, in turn, suggests that health consumers may make a comparative judgment of their experience against their understanding of 'normal' care before determining whether their experience was acceptable.

This aligns with the importance of the 'informed' aspect of informed consent. Informed consent should include a discussion of risk that incorporates both an exploration of a health consumer's views on risks that are important to them, but also a sufficient understanding of the intervention and expected outcome on which to make decisions (Madeley, 2023). A properly informed health consumer should have clear expectations about their care and understand potential risks. Importantly, a practitioner should also be aware of the areas of risk important to the health consumer and have taken steps to explore these concerns.

RA1 illustrates how they see setting clear expectations can serve to ‘re-frame’ the perception of a potential harm to an expected aspect of treatment:

> “*There's the two perspectives, the practitioner's perspective of a treatment intervention and the outcome and the patient's … if the practitioner's done a good job about educating the patient about why they might have experienced that, then suddenly it moves from actually being in the patient's perspective of an injury to … part of their treatment process that's actually leading to a better outcome in the long run*”. [RA1]

While RA1 acknowledges the importance of setting clear expectations for the health consumer so that they are informed about a potential treatment, they also reinforce a key concept in this theme. Communication may be seen as an important risk, not just because it can lead to harm through communication error, but because it may impact a health consumer’s perception of any incident that occurs. As discussed above, poor communication may aggravate the perception of harm, or good communication may ameliorate it. For RA1, appropriate communication may even make a difference as to whether an event or experience is perceived as harm at all.

This, in turn, raises a key question – how much does harm arise from an injury or incident, versus the experience and understanding of the health consumer suffering it? The importance of communication as both a risk factor and protective mechanism seems to suggest the latter, and highlights communication as a vital aspect of mitigating the risk of harm.

7.3 A Team Approach Supports Risk Mitigation

While communication between a health consumer and practitioner may allow for the direct mitigation of risk, communication and collaboration at all levels of the healthcare system is also seen as an important aspect of managing risk.

Regulators see working with others as important for both understanding and addressing risks, and value the opportunity to partner with both practitioners and employers to manage identified issues.

Partnership for Understanding

Working in partnership with external stakeholders is important for ensuring regulatory processes are effective and efficient, and this includes discussions with other RAs and the profession themselves. Participants talked about how similarities and differences between cases involving different regulators can be used to understand what risks may exist with each profession and how they relate to the wider healthcare group:

> *"So, I think that sort of inter-engagement and engagement also with other RAs and professions also provides an information around the risk"* | *"I think, it's really good to also learn off other regulators as well, in terms of how things are done. And one of the good things about the Health Practitioners Disciplinary Tribunal is that all the professions report their cases, so there's inconsistencies, there's differences and things like that".* [RA2]

While RA2 speaks to the benefits of interaction and learning from other RAs, they also indicate the value in being able to use the actions of other regulators as a mirror in which to consider their own performance and processes. Given the potential difficulties in finding comprehensive data about both underlying risks and the outcomes of broad interventions, benchmarking against the performance of another RA might help provide insight into the relative risk of a profession and the effectiveness of regulation.

> *"Well, from the perspective of looking at the number of [Professional Conduct Committees] and things like that … we seem to do less than some of the others that I'm aware of and that's partly looking at the Annual Reports, partly knowing what's working here, you kind of know that they've got more complaints coming through than we have".* [RA3]

In comparing the number of Professional Conduct Committees held to those of other RAs, RA3 gets a sense of how much relative misconduct their respective profession may pose compared to others. Also apparent in this comment, however, is their use of formal publications, such as Annual Reports, to make judgements about the number of complaints being received by other RAs. This suggests that RAs may currently have to proactively seek information, rather than embedded information sharing protocols naturally existing between RAs as a standard practice. The ability for RAs to partner more effectively with each other, and with other patient safety stakeholders, to better understand their shared and individual risks is an important aspect of protecting public safety in healthcare. This collaborative approach serves to ensure a solid foundation on which to base perceptions of risk and harm.

Partnership for Action

In New Zealand, RAs under the HPCA Act are just one of the statutory entities with a focus on health consumer safety, alongside others including the Health and Disability Commissioner (Health and Disability Commissioner Act 1994) and Te Tāhū Hauora, the Health Quality & Safety Commission (New Zealand Public Health and Disability Act 2000). With a clear focus on ensuring individual health practitioners are competent and fit to practise their professions, RAs may not have a remit to investigate or act upon broader issues, such as those related to institutional systems and processes, or considerations around resourcing. RA5 and RA2 approached this concept:

> *"The best thing we can do to look after the public, is liaise with the organization that's bringing these [non-regulatory concerns] to our attention to see how we can mitigate this in the future for the public".* [RA5]

and

> *"I do think there probably is some significant work within the sector in that area around [preventative work] … and I know there is a lot of work that might be more a [health] sector role rather than Council … but I also think our role is often education as well".* [RA2]

Both RA5 and RA2 see the limitations in where they can take action, but they also see that the knowledge they hold may be useful in facilitating systems-level changes to the benefit of the public. While this work may not be focused specifically on an individual practitioner, an RA may use an educative lever to create broader change within the system – in collaboration with other stakeholders.

There is a strong sense of taking a proactive approach with this work, ensuring any lessons learned from events are used to guide regulatory action and professional education going forward. RA2 and RA4 provide examples of this:

> *"An event has happened, and we need to consider and deal with that, yes, but what are our levers as regulators? It's ensuring or trying to ensure future harm doesn't happen".* [RA2]

and

> *"Putting proactive measures into ensuring those competences are in place, so that's more across the whole profession rather than addressing individual, and then the reactive competence focus".* [RA4]

These responses typify the broad approach participants discussed when discussing the response to an event. While there was a need to consider the appropriate action to be taken regarding the practitioner, this was almost a secondary focus. The main intent was to consider what an incident meant for the profession as a whole – did this incident provide any evidence of a more widespread issue?

RA1 considered the role of an RA as providing a facilitatory role in practitioners own efforts to improve practice:

> *"And that comes back to … proactive regulation, where you're actually seeking to self-motivate practitioners to improve their standard of competence".* [RA1]

Again, this use of practitioner education as a regulatory intervention aiming to help practitioners improve their own practice was a common approach amongst participants, however the outcomes to this were not so clear.

> *"It's definitely helped out a bit, but maybe that's my expectations, maybe the thing is we've done as much as we can do, and the world just moves on and things will happen irrespective of the amount of education". [RA5]*

> *"Maybe there's been more education and a shift in that [physical harm]. So, I think that's had an impact. I like to think so". [RA2]*

While RA5 and RA2 are positive about the impact of educational intervention, the language they used seems to convey the difficulty in knowing this for certain.

In part, this lack of surety on the outcome on interventions may arise from the mismatch between the information gathered by RAs, and the level at which these actions are taken. As with the overall understanding of risk, it seems that broader intervention, such as practitioner education, is driven by concerns about individual practitioners reported to the regulator. What is not known is how well these concerns serve to reflect issues present in the wider profession, and therefore whether they are amenable to change through profession-wide education. This may lead to action being poorly targeted and require work across the profession to mitigate a localised or minor risk. In turn, this may necessitate greater cooperation between regulators, health practitioners and other agencies (such as employers) to ensure any actions are effective.

Engaging with Employers

The limited role of RAs may also require them to approach systems level changes through initiating dialogue with employers or other stakeholders within the health system. The effectiveness of this process, however, requires willingness and an appropriate response from those involved as an RA has no formal power to require change.

> *"Whilst we start off with individual [practitioner], we very often are corresponding with the [practice] owner. So, we will quite often will be corresponding with them and ensuring that they've got a broad understanding of their responsibilities and they have acted on those".* [RA4]

This comment by RA4 suggests that discussion with the individual practitioner involved may not be sufficient to address an issue, and that these conversations may only be the first step in facilitating what may be a systems-level change. RA4's experience, however, suggests this may not be as effective as they might hope.

> *"You expect a sector to be more responsive to a regulator raising concerns. And so, whilst regulators have raised concerns, the sector has been a bit slow in responding". [RA4]*

Even at an individual level, the requirements of an employer or workplace environment may create difficulties in taking appropriate regulatory action, as RAs try to balance protecting public safety with ensuring conditions of practice aren't overly onerous. RA2 talked about these challenges from their experience:

> *"So often it's; How supportive is the employer? How on board are they? How resourced are they? … Sometimes the employment context and how feasible*

> *and workable some [regulatory] conditions are - that can be a bit of a dance and a bit of a work through".* [RA2]

While their comments suggest that balancing these two priorities can be challenging, they also suggest that RAs may take an individualised approach when working with others in appropriately managing risk.

Engaging with Practitioners

Participants also saw practitioners taking a role in practising safely and managing their own risk. While the RAs may set minimum standards of practice and facilitate practitioner education, the ultimate responsibility for the quality of care was seen to rest with the practitioner themselves.

> *"I think that private providers need to address the inherent risks in their system and the regulator needs to enforce that."* [RA4]

For RA4, the role of the regulator is to ensure appropriate actions are taken to address risks, but this should only be necessary where the practitioner fails to uphold their responsibilities in this area. This may require active identification of potential risks by a practitioner, rather than relying on the regulator to inform them of where they may need to focus.

To enable this, participants saw a team approach amongst practitioners as also being of important for practitioners to maintain safe practice.

> *"One of the things that I think comes from a lot of places is professional isolation. So that's one of our red flags in terms of; okay, is this person supported, are they working in a group?".* [RA3]

As a parallel to participants seeing the value in working with each other to better understand risk, RA3 provides an example of how peer contact and support are seen as a key factor in reducing risk. This peer contact may serve a similar role as the communication between RAs, by providing an opportunity for practitioners to use others' practice to inform their own reflection and assessment of their performance.

Participants also saw that a person-centred approach to care also serves to mitigate risk.

> *"People have got perceptions around what good treatment is. We have the ability to educate our practitioners but ... it's hard to educate the public about the other side of the equation".* [RA5]

Given the peripheral nature of a regulator to individual health consumers, practitioners may be best placed to set appropriate expectations around standards of treatment and expected outcomes, as this comment from RA5 suggests, but this communication with health consumers, including robust informed consent processes and clear agreement on expected outcomes, may prevent a perception of unacceptable harm.

Coordinated Efforts

It is strongly apparent that participants saw RAs as working within a complex system, and that their work was only one component of the drive for public safety in healthcare. With their legislative focus on the individual practitioner, RAs saw working in collaboration with other stakeholders as a key task in effecting successful change. Such collaboration would also likely provide significant benefits to data gathering and provide RAs with a more comprehensive picture of risk.

7.4 Conclusion

Both of these themes serve to illustrate participants views on the challenges and mechanisms by which the risk of harm may be mitigated. Both also include a central thread of relying on clear and open communication.

For those working with health consumers, there may be opportunities in a greater focus on the management and communication around adverse events. This may include greater knowledge of how to appropriately discuss these with health consumers, and ensuring these discussions are tailored to the needs and potential concerns of the individual health consumer. For those, such as regulators, working more broadly in the healthcare system, greater communication and collaboration in the identification and management of risk may help ensure a combined effort to address harm from healthcare.

What may be needed to enhance this process, however, is a clear map of responsibilities and roles, and clear coordination between the various authorities tasked with ensuring quality in healthcare and protecting public safety.

Chapter Eight – Triangulation Arm and Integrated Findings

8.1 Introduction to Triangulation Arm and Integrated Findings

This chapter will present findings related to the *triangulation* arm of the research project, consisting of a review of HPDT cases and the related charges. These findings provide a comparative view of conduct cases from a source related to, but separate from, the RAs. While this triangulation is also explored further in this chapter, the aim of this component of the study was to describe the nature of the charges upheld across the HPDT decisions, both as a whole and to provide some comparison between health practitioner groups.

In addition to considering how the findings of this study relate to the aim stated above, the potential relationship between HPDT case charges and the complaints and notifications received by RAs is also considered. Comparing the information received by RAs and that produced by the HPDT helps to provide triangulation of the RA perceptions found in the *complementarity* arm.

This is followed by a section exploring Integrated Findings, which presents a mixed analysis of all three studies, utilising the protocol described in Chapter Three - Methodology. As this section considers the findings of both arms and phases of this research, this chapter also considers how these findings relate to the overall study question, being “What are the profession-specific risk factors to public safety from a New Zealand health regulatory perspective?”.

8.2 Triangulation Arm Findings

8.2.1 Practitioner Data

HPDT data categorises the profession into a number of categories, however these differ slightly from both the list of RAs and the various health professions these RAs represent. To allow comparison between the professions, the initial focus of this study was to determine both the health professional categories represented in the HPDT data, and the population of health professionals represented by RAs. From this data, variation between RAs was apparent in both the number of health professionals and health professions they each represent.

The HPDT case data referred to nineteen different professions represented by sixteen RAs, reflecting a small number of RAs that represent more than one health profession. These include the Optometrists and Dispensing Opticians Board, representing optometrists and dispensing opticians, the Medical Sciences Council of New Zealand, representing medical laboratory technicians, medical laboratory scientists and anaesthetic technicians. It is interesting to note, however, that the HPDT does not separate data related to other RAs representing multiple professions, such as the Dental Council (representing a range of oral health professionals). For these RAs, profession-specific differences may occur within their represented practitioner base, complicating their perspectives on risk.

Table 10: APC Holders by profession (2019)

Profession (by RA)	APC Holders (2019)	Proportion	Cumulative %
Nurses	57833	52.91%	52.91%
Medical Practitioners	16925	15.48%	68.39%
Physiotherapists	5422	4.96%	73.35%
Med. Lab. Tech./Sci. & Anaesthetic Tech.	4576	4.19%	77.54%
Oral Health	4079	3.73%	81.27%
Pharmacists	3832	3.51%	84.78%
Med. Radiation Tech.	3393	3.10%	87.88%
Midwives	3309	3.03%	90.91%
Psychologists	3088	2.83%	93.73%
Occupational Therapists	2969	2.72%	96.45%
Optometrists & Disp. Opt.	942	0.86%	97.31%
Dieticians	737	0.67%	97.99%
Chiropractors	652	0.60%	98.58%
Psychotherapists	551	0.50%	99.09%
Osteopaths	550	0.50%	99.59%
Podiatrists	449	0.41%	100.00%
TOTAL	**109307**		

Substantial variation also exists in the number of practitioners each RA represents. The number of practitioners reported as holding Annual Practising Certificates (APCs) in 2019 totalled 109,307. Table 10 demonstrates the dominance in numbers of the larger professions, with over half (51.5%, n=57,833) of health professionals holding APCs at this time being registered with the Nursing Council of New Zealand and half of the RAs representing over 90% (90.91%, n=99,369) of practising health professionals. This compares with the smallest six RAs each representing less than 1% of practitioners.

8.2.2 HPDT Cases

A review of the HPDT data identified 432 cases for inclusion. After considering cases against the stated exclusion criteria, 33 cases were excluded, leaving 399 cases for review. Figure 17 outlines the overall process of identifying charge themes from the HPDT cases, and notes where case exclusions occurred.

From the 399 cases reviewed, variation between professions was also noted in the proportion of cases attributed to each profession. The mean number of HPDT cases upheld per year for each profession ranged from 0 to 9.8, with the larger professions demonstrating a higher number of cases (nurses, $\bar{x}$=9.8; medical practitioners, $\bar{x}$=7.5) and two professions showing no cases upheld (dieticians; psychotherapists) (see Figure 18).

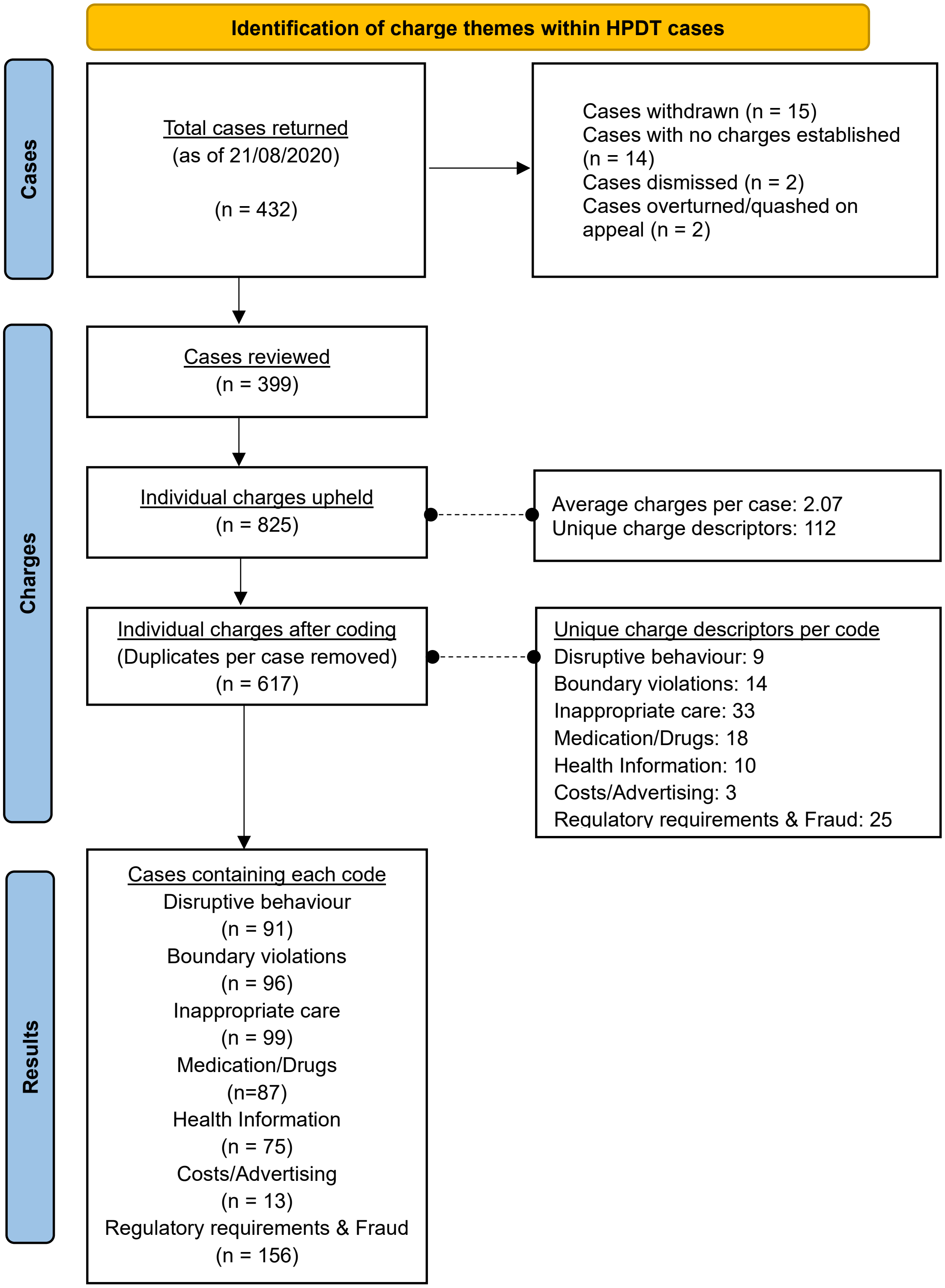


Figure 17: Identification of charge themes within HPDT cases

While the largest two professions demonstrated the largest absolute number of HPDT cases, some smaller professions showed a higher proportional number of cases, with osteopaths (x̅=0.97‰), pharmacists (x̅=0.92‰) and chiropractors (x̅=0.69‰) showing a considerably higher average number of HPDT cases upheld per year compared to the mean rate of 0.29 cases per year per thousand practising health professionals across all professions.

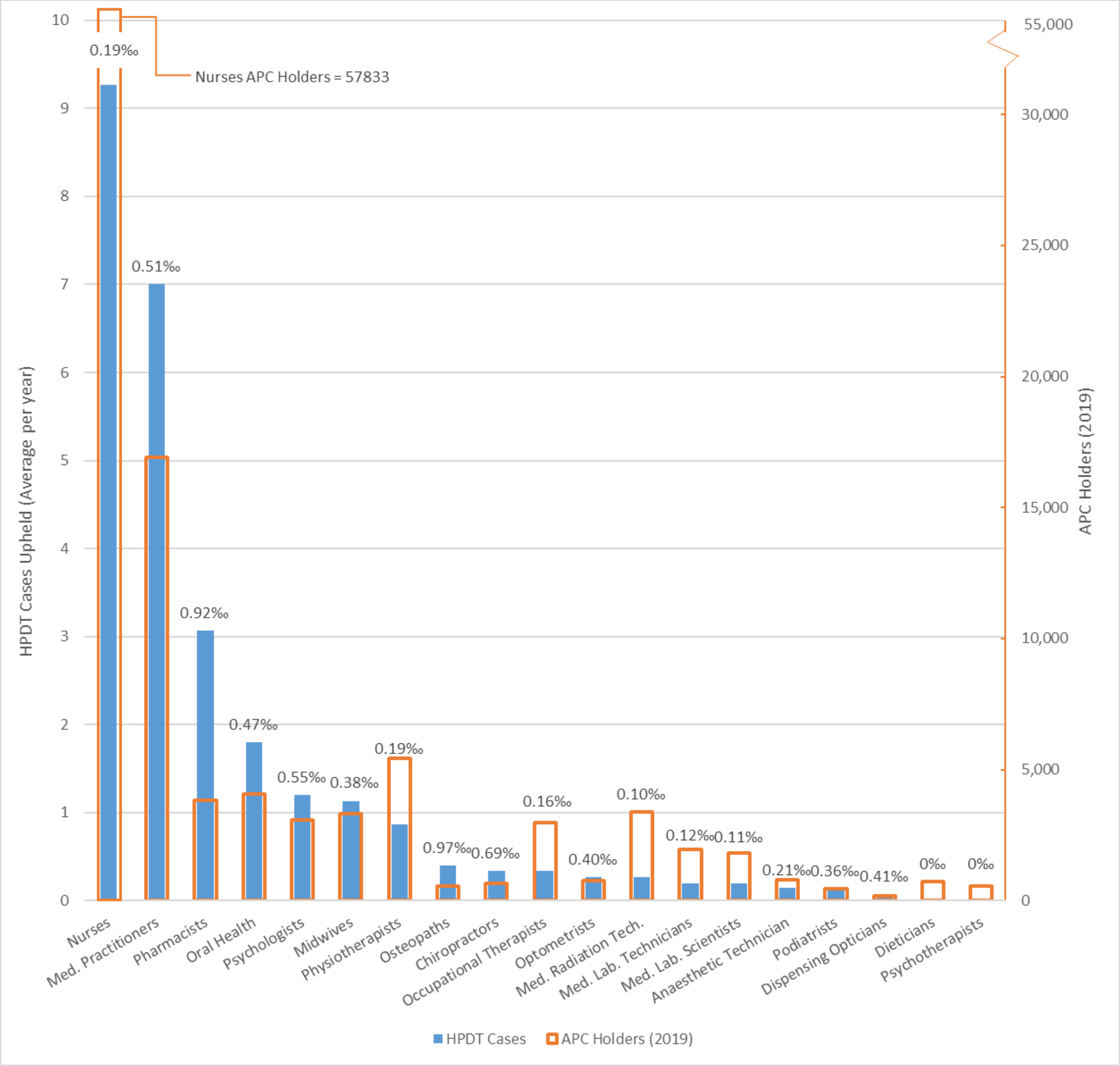


Figure 18: HPDT cases upheld per year (average). The number of practitioners holding APCs for each profession is noted to provide a proportional reference. Labels denote average cases per year per thousand APC holders.

Overall, however, the small number of absolute cases for most of the professions precludes more detailed analysis on a per-profession basis. Prior to analysis, it was determined that professions with six or less HPDT cases upheld across the included time period would not be suitable for individual reporting. While individual case identification and disclosure risk was not a concern due to the public nature of the data, reporting of results derived from small numbers of cases would risk misinterpretation of these results, such as the inappropriate generalisation of charge characteristics based on one or two cases. This resulted in twelve of the nineteen professions being excluded from individual reporting.

As seen in Figure 18, a small number of RAs and professions represent a substantial majority of both practitioner numbers and number of upheld complaints. This uneven distribution of practitioners and case numbers between the professions is an important factor to consider when reviewing the overall data set. Combined results from all the professions will be dominated by (and therefore biased towards) the results of the larger professions due to the underrepresentation of smaller professions.

While outside the scope of this study, the low number of cases for some professions across more than 15 years of data may also raise other questions around the appropriate level of regulation and efficiencies of maintaining profession-specific disciplinary tribunals.

8.2.3 HPDT Charges

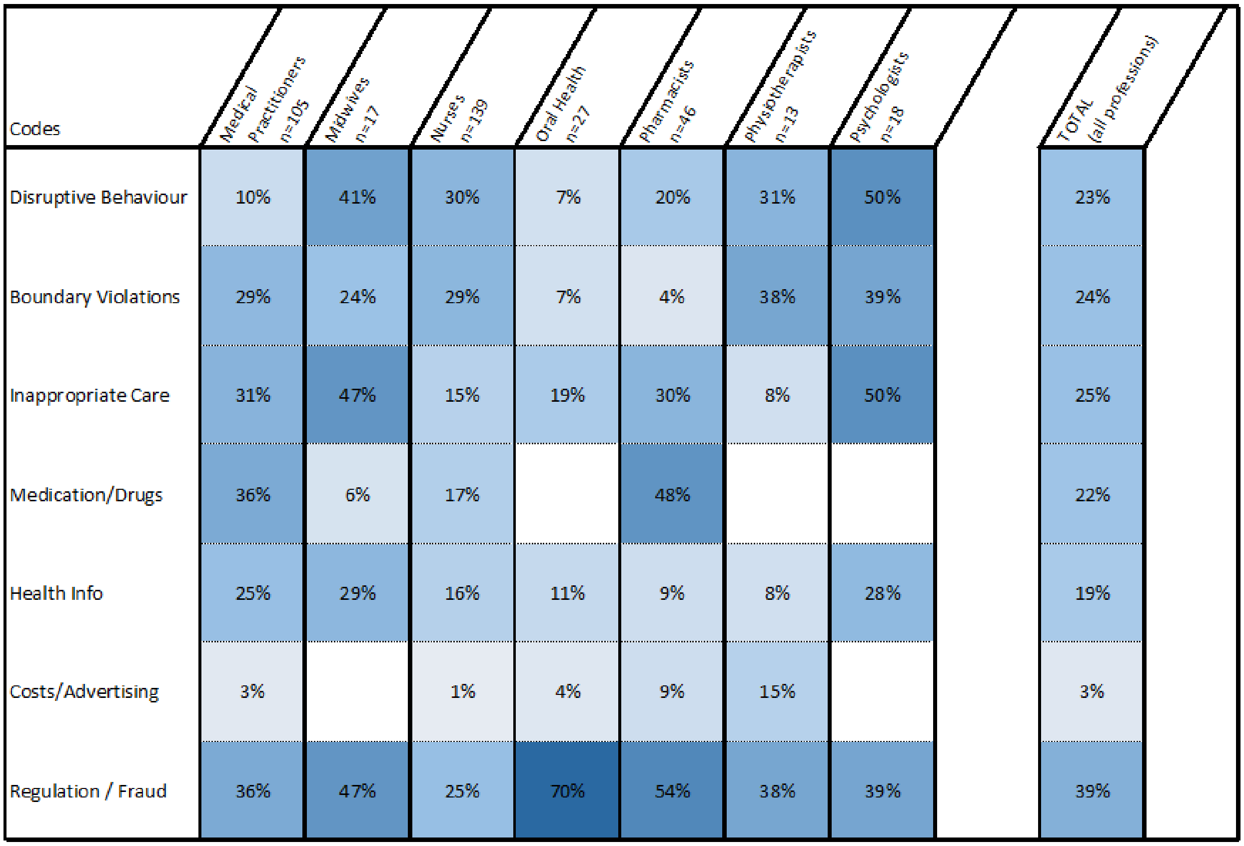
Each case before the HPDT consists of one or more individual charges, which detail the nature of the conduct concerns relevant to the case. The 399 cases reviewed represented a total of 825 charges, with an average of 2.07 charges per case. The charge types reported by the HPDT demonstrates some standardisation, with 112 unique charge descriptors being identified within the data.

During coding, seven areas were identified that represented the charge descriptors: *Disruptive Behaviour*, *Boundary Violations*, *Inappropriate Care*, *Medication/Drugs*, *Health Information*, *Costs and Advertising* and matters related to *Regulation/Fraud*.

As described in Chapter Four, Methods, these were primarily derived from categories implemented by Spittal et al. (2016) in their review of notifications to health practitioner boards. With the exception of *Costs and Advertising* (appearing in only 3% of cases), these codes are well represented in the cases upheld by the HPDT, each being seen in between 19% (*Health Information*) and 39% (*Regulation/Fraud*) of cases (see Figure 19).

Each of the seven professions explored in Figure 19, below, also show unique distributions of how each code is represented in the charges. While this aligns with the findings of Ryan, Too and Bismark (2018) in indicating that there may be profession-specific factors in conduct cases, what is not shown in this exploratory study are the reasons for this variation.

These codes are discussed further below and serve to describe the nature of conduct matters before the HPDT, as described in the study aim.



Codes	Medical Practitioners n=105	Midwives n=17	Nurses n=139	Oral Health n=27	Pharmacists n=46	Physiotherapists n=13	Psychologists n=18	TOTAL (all professions)
Disruptive Behaviour	10%	41%	30%	7%	20%	31%	50%	23%
Boundary Violations	29%	24%	29%	7%	4%	38%	39%	24%
Inappropriate Care	31%	47%	15%	19%	30%	8%	50%	25%
Medication/Drugs	36%	6%	17%		48%			22%
Health Info	25%	29%	16%	11%	9%	8%	28%	19%
Costs/Advertising	3%		1%	4%	9%	15%		3%
Regulation / Fraud	36%	47%	25%	70%	54%	38%	39%	39%

Figure 19: Representation of codes within HPDT cases. Darker shading denotes higher proportion of representation.

Disruptive Behaviour

Disruptive behaviour represents behaviour by a practitioner that is inappropriate but does not necessarily relate to interactions with health consumers. The nine charge descriptors included under this code describe behaviour ranging from inappropriate communication to assault, and breaches of legislation related to behaviour or non-clinical activities.

Overall, 23% of cases (n=91) contained charges representing disruptive behaviour from the practitioner, many of these relating to communication matters, but also a more general ‘behaviour, inappropriate’ charge. Charges related to disruptive behaviour show some variation between professions, with a higher representation in cases involving psychologists (50% of cases) and midwives (41% of cases), but not oral health practitioners or medical practitioners (7% and 10% of cases respectively).

Boundary Violations

Boundary violations represent a range of behaviours and actions that breach professional boundaries between the health consumer and practitioner. The 14 charge descriptors included under this code include direct sexual misconduct, as well as the possession of objectionable material by a health professional. Boundary violations also include inappropriate relationships with health consumers, whether related to the relationship itself, or the health professional’s use of that relationship in inappropriate ways (such as to advantage themselves in financial transactions).

Boundary violations were represented in 24% of cases (n=96) upheld by the HPDT, many related to sexual misconduct (with or without associated criminal charges) or, again, a more generic ‘Professional boundaries breached’.

A differing representation of boundary violations in certain professions (such as psychologists and physiotherapists, appearing in 39% and 38% of cases respectively) may potentially relate to profession-specific factors, such as profession-specific techniques or approaches to practice (Ryan et al., 2018) and this is an important area of further study.

Inappropriate Care

Inappropriate care relates to the clinical tasks, processes and decision making carried out by health practitioners in caring for health consumers. This code represented the largest array of charge descriptors, including actions associated with assessment, treatment, patient management, referral, and the provision of adequate staffing for the care of health consumers. In addition, charges related to informed consent and meeting professional competence standards were included in this code. Charges related to inappropriate care were included in 25% (n=99) of cases upheld by the HPDT, with a predominance of charges related to informed consent, breaching professional standards and inappropriate or inadequate treatment.

As with disruptive behaviour, an increased representation of charges related to inappropriate care can be seen in cases against midwives and psychologists (47% and 50% of cases respectively) suggesting there may be common factors for these professions between disruptive behaviour and inappropriate care.

Medication/Drugs

Charges involving Medication or Drugs incorporate 18 unique charge descriptors and relate to two main areas of inappropriate activity. This code includes mishandling of medication by a practitioner related to their normal clinical activity, such as inappropriate prescribing, dispensing and administration, as well as the misuse of drugs (including alcohol) by a health professional themselves. This code also includes drug-related breaches of a range of legislation including the Crimes Act (1961), Land Transport Act (1998), Medicines Act (1980) and Misuse of Drugs Act (1975).

Charges relating to this code are represented in 22% (n=87) of cases upheld but, within the seven explored, show a strong relationship with specific professions. Notably, Medication/Drugs charges are more highly represented for pharmacists (48%, n=22) and medical practitioners (36%, n=38), but do not appear in any cases regarding oral health practitioners, physiotherapists, or psychologists. In general, the higher rates seem to be related to those professions that have a stronger role in prescribing and handling medications, and this is consistent with an earlier review on health issues before the HPDT by Surgenor et al. (2017). It is, however, interesting to note the lack of medication or drug charges against oral health professionals, despite the use of medication and the ability for dentists to prescribe.

Health Information

Health Information incorporates ten unique charge descriptors, and these again tend to relate to one of two areas. Charges relating to health information either represent inadequate note taking and/or record management, or breaches of privacy and confidentiality. Charges related to this code are represented in 19% (n=75) of cases, and predominantly involve inadequate notetaking by the practitioner. While there seems to be less variation between professions, differences between the reported professions are still apparent. This does, however, suggest that matters related to privacy and note-taking are of concern across many professions.

Costs and Advertising

Costs and Advertising represents a relatively narrow field of charges, with only three charge descriptors included under this code, all relating to inappropriate charges, advertising, or financial gain (excluding fraud). Similarly, these charges are only represented in 3% of cases overall, suggesting this is not a common conduct matter. Despite this, physiotherapists and pharmacists show a higher proportion of cases involving these matters, at 15% and 9% respectively.

Regulation/Fraud

Regulation and fraud represent, together, matters related to deception and dishonest behaviour, incorporating 25 unique charge descriptors. Fraud charges may stem directly from criminal charges related to a range of legislation, including the Corrections Act 2004, Crimes Act 1961, Criminal Code Act 1924, Education Act 1989, Injury, Prevention and Rehabilitation and Compensation Act 2001, and Social Security Act 1964, and may also involve lying, misleading and falsification of documents. Regulatory-related charges, comparatively, may relate to failing to engage with the authority, or practising in breach of conditions or while not permitted (such as following suspension).

While this code demonstrates the highest representation across all cases, with relevant charges occurring in 39% of all cases upheld, it also demonstrates some variation between professions. Of particular note, 70% of cases against oral health practitioners include charges of this nature, including over 50% of these cases (14 of 27) including charges of *practising without a practising certificate*. While there may be profession-specific factors that lead to this significantly higher rate, this may also indicate a difference in how RAs manage such cases.

8.2.4 HPDT Referral Process Factors

While the findings above describe the nature of conduct cases before the HPDT, there is limited ability to explore the reasons for apparent differences between professions. While the discussion of charge codes above suggests potential profession-specific factors for some of these variances, the role of those referring cases to the HPDT (being the individual RAs and the Health and Disability Commissioner's Director of Proceedings) may also impact the cases that are heard.

This section discusses this process, and how this might impact the progression of a case to the HPDT. While not arising directly out of these findings, this discussion provides important context for both the interpretation of these findings, and their use as a mechanism of triangulation in the overall study.

Laying a Charge

There may be a number of decision points between an incident occurring and a charge being laid before the HPDT. RAs must first receive or hold information regarding the practice of a health practitioner that raises concern. This may be received, for example, through receiving a complaint. The RA must then determine that the case is a matter of Conduct (versus, for example, a matter of competence or health) requiring referral to a Professional Conduct Committee (PCC) (HPCA s68). A PCC may then, amongst other decisions, determine that a charge be brought before the HPDT (HPCA s80).

Similarly, for complaints received by the Health and Disability Commissioner (Health and Disability Commissioner Act 1994), the complaint must be investigated (under section 40), be seen to breach the Code and be referred to the Director of Proceedings (under section 45). Under section 49, the Director of Proceedings may then determine whether to lay a charge before the HPDT. Due to these multiple decision points, variations in this process between RAs (and the HDC) may lead to differences in the charges presented to the HPDT.

Receiving Complaints

The professions indicating a higher proportion of cases before the HPDT (osteopathy, pharmacy and chiropractic) seem to be those that may also demonstrate a high proportion of community-based or private healthcare and either self-employment or practice ownership (Glucina et al., 2021; Pharmacy Council, 2021), however, this does not hold true for all professions (Physiotherapy Board, 2022), suggesting other factors may also be in place.

Quality assurance and complaints systems that exist in larger organisations may mean that complaints are managed within an organisation and do not reach a regulatory level. For example, Te Whatu Ora Waitematā (previously Waitematā District Health Board) provides an internal complaints process (Waitematā District Health Board, 2021), where a health consumer may have a complaint investigated and be informed of any findings and/or changes that are made to improve healthcare. If the organisation receiving these complaints is satisfied that any issues raised have been resolved, they may not report these to an external authority. Health consumers wishing to raise concerns regarding a private practitioner, however, may need to raise these directly with the HDC or specific RA if they are uncomfortable complaining directly to the practitioner involved. This may lead to a higher proportion of incidents coming to the attention of the HDC or RA, and therefore resulting in eventual charges being laid with the HPDT.

Referral to Professional Conduct Committees

RAs may also vary in how specific issues are managed. Three of the RAs showing higher rates of medication/drug charges, specifically note that alcohol or drug dependence or abuse may be considered as a health condition, rather than as a conduct concern (Medical Council of New Zealand, 2019; Nursing Council of New Zealand, 2021; Pharmacy Council of New Zealand, 2021). A small number of HPDT cases related to these professions include alcohol-related charges, however, and this suggests that there may be factors that lead to such cases being considered as matters of conduct instead.

Similarly, RAs may receive and consider cases under different contexts. One profession shows over 50% of cases (14 of 27) upheld by the HPDT included charges of *practising without a practising certificate* (coded as *Regulation/Fraud*). While a more in-depth review of these cases may indicate the reasons behind this relatively high number, this may indicate a lower tolerance for such actions by this RA, and therefore lead to a higher likelihood of referral to a PCC and, subsequently, to the HPDT.

Overall considerations

The potential difference in how RAs may receive information, the variation in how this information may be managed and the different thresholds that may result in referral to a PCC means that caution should be taken in interpreting HPDT case results. These results may not indicate the actual likelihood of incident types, behaviour or overall practice safety of health practitioners in practice. Factors such as the likelihood of information being received by a regulatory body (either an RA or the HDC) and the decision making process of an individual RA may impact whether a complaint will ultimately result in charges being laid with the HPDT. The impact of these process factors would need to be determined before direct and detailed comparison of these results across RAs could be made. Despite this, considering the results for each profession on an individual basis may still reveal useful insights about that profession’s individual areas of risk.

8.2.5 Summary

The findings of this Arm show that, while case numbers may be too low to explore individual charges across many regulators, there is evidence of profession-specific patterns in both the charge types and proportion of cases that are heard by the HPDT.

What is not known, and in consideration of the discussion above, is the relationship between charges heard by the HPDT, complaints received by an RA and the actual incidence of professional misconduct in practice. While differences between professions are apparent in these findings, care must be taken not to assume these are an accurate representation of the likelihood of misconduct in a profession.

8.3 Integrated Findings

The purpose of this section is not to re-present the findings from the individual components of this study, but to discuss how these findings relate to each other, and to the overall aim of the research project, and describe any ‘meta-inferences’ arising from this process.

To briefly recap the method of this analysis, these results were analysed using a horizontal mixed analysis process to produce ‘meta-inferences’, or inferences generated from considering qualitative and quantitative results as a unified whole. To guide this analysis, a Complementary Integrative Analysis Strategy, adapted from Bazeley (2018), was used to *weave and intertwine* and *merge* the findings of Phase 1 and 2 of the *complementarity* phase and *compare and contrast* the findings of the two Arms (*complementarity* and *triangulation*).

First, findings related to the *weaving, intertwining* and *merging* of the two *complementarity* arm Phases (incorporating the quantitative survey and qualitative interviews) will be presented, followed by findings related to *comparing and contrasting* the two Arms of this research project (see Figure 20).

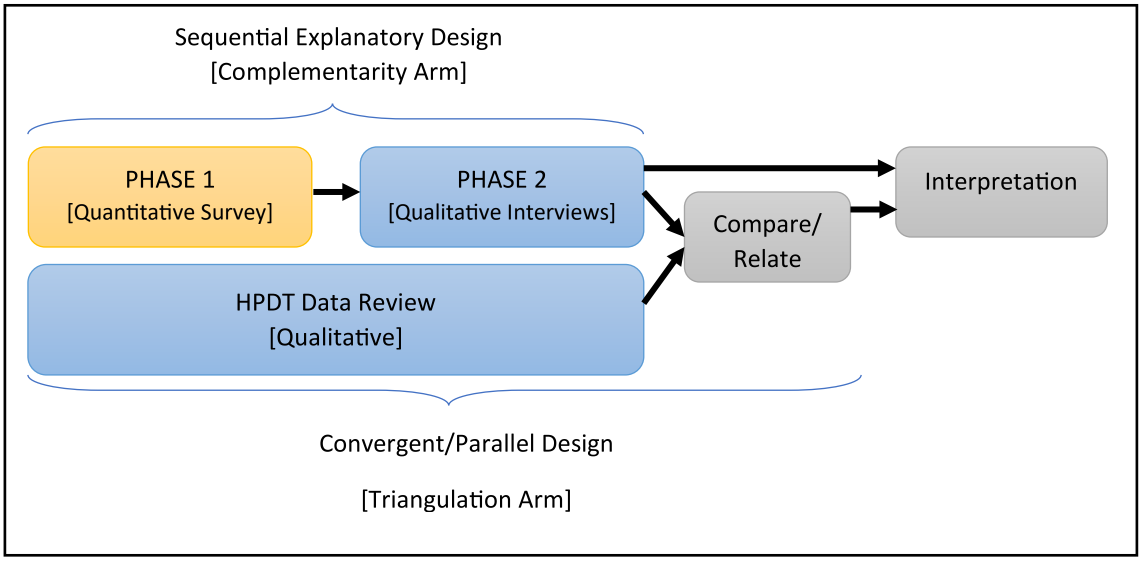


Figure 20: Summary of study design

8.3.1 Complementarity Arm

The aim of this arm was to provide *complementarity* through an *explanatory sequential* design. This was achieved through the inclusion of two sequential phases in the study design. While Phase 1 provided an initial overview of RA perceptions, Phase 2 served to explore and explain these findings in more depth.

This two-phase approach allowed both broad identification of the profession-specific risk factors to public safety from a New Zealand health regulatory perspective, as per the overall research question, while also providing some context and rationale for why those factors were identified as most significant by regulators.

Types of Risk

The findings of Phase 1 saw a majority of RAs identified that potentially serious harm could arise from both *risks present in normal practice* and *practice errors*, but also saw that these had a low likelihood of occurring.

RAs also showed noticeable differences in their assessment of the likelihood of many types of error, such as *clinical, treatment* and *diagnostic error*, *medication error* or *infection concerns*. Similarly, the assessment of potential harm related to clinical and diagnostic errors also varied in its perceived impact.

These variations in perception may be partially explained in the Phase 2 theme *Perceptions of relative risks relate to the clinical role*. The variation in RAs rating these errors as either 'likely' or 'unlikely' and either resulting in 'mild harm' or 'severe harm' reflects the concept that risk factors related to practice may vary greatly between professions and roles depending on the task at hand. Overall, however, there was a sense from both Phases that healthcare carries inherent risk, and that it may be impossible to completely eliminate the possibility of error. Instead, resources may be better focused on avoiding or mitigating risks, rather than aiming to eliminate them. This would serve to reduce the likelihood that a risk might result in harm, and limit the impact of any harm that may occur.

The discussion in Chapter Six – Perceptions of Risk | Findings noted that further research was needed to determine why a small number of RAs considered that practitioner conduct issues are likely to occur in the profession they regulate. Subsequently, some explanation for this finding was found in the Phase 2 theme *Perceived risk profiles are similar but distinct*. Here, participants in Phase 2 described how, for some, the nature of the healthcare role and relationship with the health consumer may heighten the risk of trust-based misconduct such as boundary violations. For other participants, these issues were not as much of a concern. Instead, the focus being more on the physical harm that may result from inappropriate care, and this may be more likely to arise from a technical error in practice.

The Context of Risk

Most RAs participating in Phase 1 recognised that systems factors existed in practice, however the overall impact of harm from these factors was considered to be low.

Again, these findings found an explanation in Phase 2, under the subtheme *Environmental pressures amplify clinical risks*. Systems factors, such as limited resources, business demands and responding to institutional requirements, were all identified as themes from interview participants' discussions. These were not necessarily linked directly to harm, however, and they were instead often linked to an increased risk of fraud against funding bodies. While this misconduct may impugn the professional character of the practitioner, the lack of direct harm my explain why these were not seen to result in a high impact of harm in Phase 1.

Communication

Communication was notable in Phase 1 as being both the contributing factor of most concern, and the type of error with the highest risk for most participating RAs.

Considered under the theme *Communication is a moderator of harm*, participants in Phase 2 saw communication as a common factor in many incidents that lead to complaints. This introduced the concept of communication as a ‘moderator’ to the perception of harm suffered by a health consumer due to an incident.

Communication was seen to have a broad impact, with poor communication increasing the risk of harm, and good communication providing some mitigation. Poor initial communication could lead to inaccurate expectations of care, whereas good communication after an incident could reframe a potential harm as a normal response to intervention.

Participants perception of the vital role of communication as both a contributing factor to risk, an area of error causing harm and a potential mitigation for harm was clearly seen through the findings of this research project. The suggestion by participants that the impact of physical harm could be ameliorated by clear and open communication indicates that the perception of harm by a health consumer can be moderated through practitioner communication, even in the case of objectively unfavourable outcomes.

Given the pervasiveness of this topic throughout discussions on risk and harm, improving communication may therefore present a valuable opportunity for initial action in improving public safety. This also provides an initial example of cross-profession risk that would allow a collaborative and shared approach across multiple RAs.

Areas not Addressed

As described above, a number of findings from Phase 1 found further reinforcement and explanation in the second phase. Despite this, a small number of findings were noteworthy due to their absence in the findings of Phase 2.

Health consumer characteristics were seen to be a likely or highly likely contributing factor by participants in Phase 1, however these did not appear to feature in discussion in Phase 2. While the reasons for this are not known, the findings of Phase 2 tended to relate more to the role of the RA, their understanding of practitioner risk and the environment they worked within. As factors related to health consumers are not within the control of the RAs, they may focus more on the practitioner's ability to respond to these risks, rather than the risks themselves.

Similarly, concerns related to inappropriate costs or advertising were not considered in the findings of Phase 2. Given the low risk-rating of these issues in Phase 1, this may indicate that such matters were not a high concern for participants.

Overall Considerations

Overall, significant alignment was found across the two phases of this arm of the study, and the aim of *complementarity* within this arm has been met. As intended in the study design, many of the findings that arose from the broad, commensurable exploration of RAs' perceptions in Phase 1 found further explanation in the targeted, information-rich interviews in Phase 2.

The findings in Phase 2 also served to expand on the objective of simply identifying what RAs' perceive the profession-specific risk factors to be. This deeper exploration allowed further consideration of the factors that inform these perceptions – delivering both an understanding of how they formed these perceptions, and their foundational understanding of risk and harm.

8.3.2 Triangulation Arm

As Phase 1 of this study focused on the perceptions of the RAs, the study design included a second arm to provide *triangulation*. Considering a similar topic using a different, but related, data source, allows some corroboration of their views with practice.

In considering the findings of this arm as a method of triangulation, however, the paucity of data related to many of the individual RAs precludes its use in determining how accurately a particular RA's view of their profession's risk matches this data.

Instead, the findings of this arm are used to compare with two of the major themes arising out of the *complementarity* arm.

'Knowing Risk' is a Challenge

The findings of Phase 1 suggested that RAs developed much of their understanding of risk from the complaints and notifications they received. Inherent in this process was significant difficulty related to the low numbers of cases and the variable and complex nature of the incidents and risks each represent.

This lack of data is also reflected in the findings of the triangulation arm, with twelve of the nineteen professions having less than seven cases each over the fifteen years of included data (an average of less than one case every two years).

While the number of notifications and complaints received is likely to be higher than the number of cases before the HPDT, as formal charges are only one of the potential outcomes to the complaints process, this highlights the limited data that RAs may use to form perceptions of risk.

Perceived Risk Profiles are Similar but Distinct

The findings of the triangulation arm support the finding that certain incidents are more likely for different professions.

These findings give further weight to the consideration of boundary violations being associated with certain professional roles, with physiotherapists and psychologists demonstrating a substantially higher proportion of boundary violation charges compared to pharmacists and oral health practitioners. While further investigation may be necessary to determine the reason for this disparity, the overall findings of this research suggest this may be due to the depth of relationship and/or likelihood of intimate physical contact between the health consumer and practitioner.

8.3.3 Additional Comparisons

While the topics presented above consider the two main areas of comparison between the two arms of this research project, there are also contrasting findings.

In particular, the *triangulation* arm indicated that charges related to regulation and fraud showed the highest representation across all cases before the HPDT. While findings related to fraud were identified in the *complementarity* arm, especially in relation to systems factors and financial pressures, incidents related to a practitioner's relationship with the regulator were not generally apparent.

The reasons for this absence may be twofold. Firstly, while other conduct matters may rely on complaints being received from external parties, RAs will often be directly involved with incidents related to regulation. This allows greater awareness of, and therefore action in response to, these issues, and there may also be certain regulatory charges that commonly occur alongside other conduct concerns. Secondly, as discussed earlier in this chapter, fraud may not result in direct harm to a health consumer, and this would be especially true of regulatory matters. While poor engagement with the regulator may be a more common concern in conduct matters, regulators' perceptions of risk may be weighted towards those issues that result in harm.

8.3.4 Summary

While the study design aimed to provide three different approaches to exploring the same topic, the integrated findings above show that there are areas of significant alignment within the *complementarity* arm.

Drawing strong conclusions from the *triangulation* arm was hindered by the lack of data available, limiting the degree of triangulation that could be performed. Nonetheless, comparing and contrasting this with the findings of the *complementarity* arm served to provide some corroboration with the themes identified from participant data. The challenges for RAs in 'knowing' risk, and the presence of profession-specific risk profiles were both supported across all three components of this study.

Chapter Nine – Discussion

9.1 Introduction

The paucity of research related to the perceptions of health regulators in New Zealand, alongside the challenges in accessing high-quality data in this field, have led to this exploratory study being conducted to provide some initial insight into this topic. The use of a mixed-methods approach based in a pragmatic paradigm has allowed the research question to be approached from multiple angles, and the value of these findings will ultimately be determined by their usefulness in informing and shaping the practice of regulation in New Zealand.

The research question of this project focuses on identifying the profession-specific risks from the perception of New Zealand regulators. While Chapters Four through Eight consider the findings from each phase of the research protocol, including an integrated analysis, this chapter seeks to discuss the importance of these findings within the context of the work of RAs and the wider New Zealand health system.

Throughout this process, it has been apparent that the way in which regulators form these perceptions, and their foundational understanding of both risk and harm, is of paramount importance to answering this question. This chapter will first consider the underlying concepts of harm that may be held by RAs and the implications of this on both their perceptions of risk and regulatory activity, before considering issues related to the data RAs use to form their perceptions.

The practical importance of these findings will then be explored, considering how the findings in this study may provide value to both the work of RAs and, more broadly, to enhance the quest for improving healthcare safety.

9.2 Defining Harm

As discussed in Chapter Eight *Types of Risk*, there was a clear divergence between participating RAs who considered physical harm as their primary concern, and those who saw breaches of trust as more significant. Similarly, participants reported different levels of concern and awareness of harm related to broader forms of harm, such as financial and cultural harm.

9.2.1 Variable and evolving definitions

Mirroring this disparity in definitions of harm amongst RAs, a collective and generally recognised concept of ‘harm’ seems to still be elusive within healthcare safety literature and by significant stakeholders. Despite this, a strong focus on physical harm will not fully represent the experience of health consumers experiencing negative impacts from healthcare (Mitchell et al., 2023). While participating RAs showed an appreciation of broader definitions of harm, this seemed to be an evolving concept.

Considered to be a milestone in the discussion of harm in healthcare, the seminal report To Err Is Human (Institute of Medicine (US) Committee on Quality of Health Care in America, 2000) flagged significant concerns with healthcare safety and highlighted the burden of medical error through a focus on physical harm. While this report exposed the risks associated with technical error, followed by a further report in 2015 that expanded this consideration to include diagnostic error (Committee on Diagnostic Error in Health Care et al., 2015), broader forms of harm that may occur in healthcare were not been so clearly described. Emotional harm, for example, may be under-recorded, and the severity of harm may be more difficult to determine by healthcare practitioners (Sokol-Hessner et al., 2015), meaning that the risk of emotional harm from healthcare may not be fully realised by regulators.

This range of understanding and definitions does, however, reflect the current state of how harm is understood by health consumer safety institutions. The World Health Organisation Global Patient Safety Action Plan 2021-2030 (2021) defines harm as “Impairment of structure or function of the body and/or any deleterious effect arising there from. Harm includes disease, injury, suffering, disability and death” (p.91). While this includes a reference to ‘suffering’, the primary focus remains the mechanistic concepts of structure and function. Adopting this definition of harm would create challenges for including harm related to non-physical sources, such as, for example, cultural, social or spiritual harm.

This historical focus on physical harm still also seems to pervade the regulatory system in New Zealand. While the New Zealand government has recognised the technical risks associated with various healthcare tasks, as evidenced by the restricted activities under the HPCA Act (Health Practitioners Competence Assurance Act 2003), the potential for issues such as abuse in healthcare may exist from any contact between a health consumer and the healthcare system (Brüggemann et al., 2012). Recognition of these risks is especially important given more recent research outlining the broad and impactful harms that can occur from culturally inappropriate care (Palmer et al., 2019). Decisive action to mitigate these risks through ensuring appropriate interaction with health consumers is vital to address the inequalities present in our health system (Wilson et al., 2021) and this will require a deep understanding of the harms that are caused.

While this is a field requiring further study, RAs in this study felt an association between the depth of the relationship between the practitioner and healthcare consumer and the risk of this harm. While recognising the benefits that a trusting relationship with healthcare consumers may bring (Connolly Gibbons et al., 2023), health care practitioners that may not perform high-risk technical procedures or are at low risk of causing physical harm may still represent a risk of harm arising from the relationships they form with healthcare consumers. As the level of appropriate regulatory oversight is based on the potential risk of harm of the practice of a profession (Cabinet Office, 1999), this may have implications on decisions around which professions may require a greater degree of regulation.

Aligning with this pervasive potential for non-physical harm, the Health Quality and Safety Commission's *Healing, learning and improving from harm: National adverse events policy* (2023) includes a definition of harm that specifically incorporates descriptors of psychological, cultural and spiritual harm, in addition to physical harm. Similar to the perception of RAs that their definition of harm is evolving over time, this suggests broader definitions of harm are now more commonly adopted by institutions with a responsibility for public safety.

9.2.2 Broadening definitions

This evolution of harm, and the associated risks, into a more subjective realm may result in challenges for regulators seeking to respond to these issues. RAs found that the impact of physical harm may be easier to objectively measure, and this may provide an explanation for the preponderance of definitions of harm severity based on physical outcomes (J. Cooper et al., 2018). In addition, simple review of medical errors does not generally incorporate the health consumer's perspective and may not recognise suffering related to the health consumer's personal experiences (Brüggemann et al., 2012).

These challenges are considered by Mitchell, Cribb & Entwistle (Mitchell et al., 2023) in discussing the concept of 'dignitary harms' (e.g. disrespectful or demeaning behaviour). Here, the authors argue that the field of safety for health consumers should expand to include such harms, but that the conventional manner of healthcare safety systems may not be suited for this task. Broadening the definition of harm will likely require significant thought around the impact and appropriate intervention around less overt and more longitudinal harms. For example, an incident of offensive behaviour by a practitioner may cause immediate distress, but also result in a future reluctance to seek treatment by a health consumer. If a subsequential delay in treatment resulted in a poorer health outcome, could this be considered a resultant harm of the original inappropriate behaviour?

Mitchell, Cribb & Entwistle (2023) consider that "an action's capacity to make things worse for someone is more central to understanding its harmfulness than its surpassing a given threshold [of what counts as a harm]" (p. 39) – that is, the incident itself is not as important as the potential impact on a health consumer's quality of life. A harmful incident cannot be separated from the context it occurs in. Appropriate assessment of harm would therefore require systems that would allow an accurate appreciation of factors such as a health consumer's knowledge and belief, the interaction between the health consumer and the health system or practitioner, and other sociocultural factors. This contextual nature of harm also suggests that the perception and recognition of harm lies within a deep understanding of the health consumer, rather than on the views of a detached external assessor (Mitchell et al., 2023).

As well as impacting the perception of harm experienced, these factors can also impact the acceptability of risks when making healthcare decisions. Quintard et al. (2016)

describe two perceptions, an individual ‘technical-rational’ reflection and a sociocultural reflection, as informing decisions about acceptable risk. This reinforces the idea that, while healthcare safety research and systems have traditionally focused on technical risk, decision-making by the health consumer around risk in healthcare is informed by broader considerations.

In *Perceptions of risk relate to societal expectations*, participants reflected on their own evolving perceptions of harm, and considered whether this was driven by changing expectations in society. This provides a strong example of the sociocultural factors highlighted by Quintard et al. (2016) and shows how health consumer beliefs about acceptable risk influence RA perceptions of risk. Considering the factors behind decision making by a health consumer (rather than a primary focus on expert views on risk) is an important component in providing insight as to why some risks may be prioritised, or seen as less acceptable, compared to others. As such, including robust public consultation will be a critical component of refining RAs’ definitions of harm and understanding of risk.

9.2.3 Summary

The recognition of participants that their perception of risk and harm is evolving reflects current discussion in healthcare safety literature. These evolving concepts, however, could have significant implications for the way in which RAs carry out their functions and the expectations of the public around safety in healthcare. The current fragmented understanding of harm within and between participating RAs risks regulatory action lagging behind these public expectations and a lack of alignment between regulators. Clear definitions of harm that are flexible enough to respond to changing expectations are a crucial step in ensuring public protection.

9.3 Developing a Better Understanding of Risk

Receiving complaint data is vital to the role of regulators in addressing concerns with individual practitioners. As summarised in Chapter Six, under *6.2.1 ‘Knowing Risk’ is a Challenge*, however, using complaint data as a primary source of information is unlikely to provide a fully informed understanding of clinical risk. The participants in this research were aware of this limitation and recognised the difficulty in assessing risk from a limited number of incidents.

This is not a unique problem, however. While identification of risks have been promoted as a way of improving safety in healthcare (Leonard, 2015), analysis of incident reporting has been found to be both one of the more common (Marchon et al., 2014) and less effective methods of assessing risk in healthcare (Spurgeon et al., 2017).

9.3.1 A Perceptual Delay

The strong theme in this study of using complaints received to inform perceptions of risk matches the use of such data overseas. There is heightened interest in using ‘big data’ and statistical analysis to predict the likelihood of further complaints against a practitioner (Bismark et al., 2013; Morris & Spittal, 2023; Spittal et al., 2019).

Limitations of data availability

It is apparent, however, both from the perceptions of regulators and the review of HPDT cases, that RAs in New Zealand see a comparatively low number of formal complaints on which to base such perceptions. While not inclusive of all health consumer complaints, those that were upheld by the HPDT represented a maximum proportion of 0.97 cases per thousand registrants per year. Similarly, under the theme *Knowing Risk is a Challenge*, participants reported the challenges that limited complaint numbers presented when trying to understand risk. These findings are supported by those found in the literature, where the frequency of health consumer complaints in healthcare is generally seen to be low, where rates of complaints are reported in the range of 0.1% to 0.8% of admissions (Zengin et al., 2014). In New Zealand, Bismark et al. (2006) found that only 0.4% of adverse events were reported to the Health and Disability Commissioner. RAs may also receive complaints from health practitioners and employers; however, these may be even less frequent than those received from health consumers (Spittal et al., 2016).

In this study, only three of the sixteen RAs involved had over 5,000 practitioners holding APCs as of 2019. The largest, the Nursing Council of New Zealand with 57,833 APC holders, saw the highest number of HPDT cases upheld, with an average of 9.27 per year. The remaining thirteen RAs were found to have an average of less than two HPDT cases upheld per year per RA over the period studied. Due to these low numbers, there would be significant challenges for most RAs in gathering enough data to recognise trends in a timely manner. While a recent systematic review by van Dael et al. (2020) concludes that the use of complaints data can have an important impact on the quality of care, the authors caution that the identification of trends requires a sufficiently large sample of cases. Complaints are an important way of recognising and responding to individual health consumer concerns, however a low number of cases may make it difficult for regulators to determine whether a complaint represents a wide-spread issue, or an isolated concern.

This issue is reinforced by de Vos et al. (2018), who discuss the "infrequent and imperfect data" (p. 760) that is gathered due to the infrequent nature of complaints. By the time a sufficient number of cases are received, and a potential risk is identified, opportunities for change or the circumstances of the risk may have already changed. This creates a lag between an initial concern or incident occurring and a regulator receiving sufficient data to identify an issue and take appropriate action.

A lag in risk perception

While these delays in recognising developing risks may arise from the limited amount of data, the retrospective nature of complaint reviews also adds to the potential lag between events, regulatory recognition, and action. The National State of Patient Safety 2022 report (McCrudden et al., 2022) presents data on harm gathered in England's National Health System. The authors identify this data as arising from outcomes after an incident (as also found in complaint data) and caution "these data can only tell you how safe care has been in the past, but not how safe it is in real-time or will be in the future" (McCrudden et al., 2022, p. 19).

These inherent issues with the use of complaint data to inform perspectives on risk underpins the concern of a reactive approach shared by participants and highlights the lag between the risk environment that may be occurring in practice, and that recognised by the regulator. While participants may consider that complaints data can provide a 'coal-face' understanding of risk, this lag may explain why one participant experienced ‘surprise’ at the difference between their perception and the actual level of understanding the profession held around cultural standards. While complaints arising from health consumers may be perceived to provide an accurate representation of clinical risk, this is unlikely to be the case.

As considered under the theme *Perceptions of relative risks relate to the clinical role* in Chapter Six, participants recognise the value of a forward-thinking approach, and have a focus on ‘future proofing’ their respective professions. Given the evolving nature of healthcare roles and the potential for rapid change a practitioner may face in the clinical environment, however, a retrospective understanding of risk based primarily on complaint data will not be sufficient to accurately inform regulatory action, and regulators may fall behind in the quest for safety for health consumers.

9.3.2 Potential Bias in Perception

The HPCA Act sets the focus of receiving complaints and notifications firmly around collecting information about individual practitioners (Health Practitioners Competence Assurance Act 2003). For example, a notification may be made where a health practitioner “may pose a risk of harm to the public by practising below the required standard of competence” (s. 34(1)), and an RA may refer a case to a Professional Conduct Committee where there may be concerns regarding the “appropriateness of the conduct or the safety of the practice of a health practitioner” (s. 68(1)). This creates a specific remit, and a limited scope, under which an RA might receive and consider complaints.

Limited awareness of context

Despite this, participating RAs recognised that, while the actions of an individual practitioner were important to consider, the environmental context of practice was of increasing relevance when considering a case. Similarly, *poor working conditions* were reported as being a serious or critical risk by almost two thirds (64%) of participating RAs.

While understanding these contextual risks are important to RAs, they are also less likely to come to their attention. The Policy Framework for Occupational Regulation (Cabinet Office, 1999), which informed development of the HPCA Act, highlighted the importance of considering context when considering the threshold for ‘significant risk’. The lack of a specified definition in the framework, or in the HPCA Act itself, points to the need to understand the particulars of a case to develop an accurate understanding of risk within a specific situation. Full appreciation of the causes behind an incident may only be possible through investigatory methods such as a root cause analysis, but such approaches are resource intensive and requires the collection of substantial data from the field (Cerniglia-Lowensen, 2015). Unless additional data is sought from alternative sources, RAs may not have sufficient information about contextual risks to understand their impact beyond an individual case.

The requirement for a clear link to the actions of an individual practitioner may naturally limit the cases being reported to an RA to those that have a strong connection to practitioner-associated practitioner risks. Traditional incident reporting, which seeks to identify harm being caused by a specific incident of suboptimal care, may not adequately reflect the complexities of clinical practice. Complaints are therefore likely to only be considered by a regulator where there is an identified relationship between practitioner care and a resulting harm (de Vos et al., 2018). More complex cases, where there is not a clear causative relationship between a practitioner’s actions and a poor outcome, may be missed.

With potentially 65% of concerns raised by health consumers not meeting the requirements to be classified as a specific Patient Safety Incident (O’Hara et al., 2018), a clear connection between the concerns raised and the actions of a specific practitioner may be difficult to ascertain. Additionally, while health consumer complaints may be better at identifying broader systems factors, they may also be more prone to consider a poor outcome as resulting from a lack of practitioner competence instead of the inherent risk of a procedure (van Dael et al., 2020). The use of health consumer complaints to inform perspectives on the quality of health practitioner in general may therefore lead to an overestimation of the level of incompetence (de Vos et al., 2018) and, consequently, an underappreciation of contextual factors.

This provides a challenge to the greater consideration of contextual factors RAs discuss in *Environmental pressures amplify clinical risks*. Health consumer complaints related to individual practitioners may again not provide sufficient information about environmental contexts for RAs to accurately appreciate the balance of individual and contextual risks. This supports the concerns raised by RAs in this study that they may only see the 'sharp end' of complaints, preventing a full understanding of the situation.

Harm without complaint

Under the theme *'Knowing Risk' is a Challenge*, participating RAs also considered the challenges that must be overcome for a health consumer to make a complaint. There was a sense that health consumers may be apprehensive about reporting concerns to a regulator or feel disempowered by the process. Practitioners were also seen to be reluctant to report concerns about their colleagues, also limiting the availability of data.

In support of this perception, the low rate of complaints by health consumers recognised in the literature has been linked to both how a health consumer perceives their care, and how they might interact with a complaints system. For both health consumers and practitioners to raise concerns, the level of concern held must be sufficient for them to consider laying a complaint (van Dael et al., 2020). Factors that influence whether this threshold is reached may include that the harm to the health consumer is recognised, that the perceived barriers to complaining are low, and that the complaints process is seen to provide the outcome sought (Bismark et al., 2006). While RAs considered there may also be a greater opportunity for practitioners to also report concerns, notifications submitted by practitioners or employers are also influenced by a health institutions norms and culture. As complaints laid by practitioners may predominantly incorporate incidents with a clear biomedical cause of harm (van Dael et al., 2022), they may also lead to underreporting of other forms or causes of harm.

This means that only certain cases (for example, where harm is overt, and a particular incident is recognised) may be reported. More covert harms, such as those that may occur from interpersonal racism and health practitioner prejudices, may go unrecognised. Complaints procedures themselves may reinforce this issue, with lower rates of complaints being received from people that are not readily advantaged by the health system (Bismark et al., 2006; van Dael et al., 2020). This would also serve to reinforce the perception by RAs of complaints regarding cultural harm, expressed in both *'Knowing Risk' is a Challenge* and *Perceptions of risk relate to societal expectations*. Participating RAs saw that health consumers may not feel empowered to complain in certain circumstances, and that an increase in complaints around racism may relate to changing expectations and awareness in society. If health consumers feel that a particular harm (for example, cultural harm) is recognised as a serious concern, they may feel more empowered to complain, leading to greater recognition by a regulator. Conversely, a lack of recognition may lead to fewer complaints, further limiting the awareness of a regulator.

Given this, RAs would only see a limited subset of harm within complaint data, and these complaints are unlikely to represent the full spectrum of risks present in healthcare. Reported concerns may represent incidents where there is a clearly perceived linkage between any concerns raised and the actions of a specific practitioner, and where a complainant recognises, and feels empowered to raise, their concerns with the regulator. While receiving notifications and complaints is vital for addressing matters related to individual cases, this data gap experienced by RAs hampers their ability to appropriately target actions and apply an accurately proportional response to events. Basing broad perceptions of risk on complaints data is not sufficient for RAs to remain at the forefront of understanding the risks of harm in their professions.

What is not explored by this study, however, is any limitations in other sources of data that may (or may not) be available for RAs. The awareness that participants showed of the limitations of complaint data and the lack of clear solutions to this limitation suggests the need of increased research into, and sharing of data related to, harm throughout all levels of the health system.

9.3.3 Options for Improvement

While the issues above present challenges in using individual complaint data to inform broader regulatory action, appropriate processes may help ensure that they remain a valuable component in informing an RA’s perception of risk.

Standardised complaints analysis process

While participants in this study suggested that their perceptions of risk were substantially informed by the complaints received by the RA, it was unclear whether this was through a formal process of review, or a more informal understanding based on their own experiences. To ensure complaint data is utilised appropriately, and to enhance the value of the information in individual complaints, a purposeful and systematic analysis process may provide a more robust method of exploring the data.

With the aim of providing a standardised method of assessment, Reader, Gillespie and Roberts (2014) developed a coding taxonomy for analysing complaints from health consumers. Such a system allows data from multiple complaints to be aggregated, allowing interpretation across a greater data set. Embedding a standardised system may also allow complaints to be assessed across professions and clinical contexts, allowing greater recognition of common risks and profession-specific issues.

While such aggregation may provide for a greater breadth of analysis, de Vos et al. (2018) caution that this risks taking a superficial view of the rich data contained in a complaint. Despite this, a coordinated approach to assessing and recording complaints and notifications across regulators may allow easier cross-profession analysis of developing concerns. With the addition of appropriate tools and training for assessors, and an appropriate strategy and leadership, the understanding developed from such analysis may provide substantial benefits to safety for health consumers (van Dael et al., 2020).

Such an approach may also align with the comparative analysis RAs currently undertake, as seen in Chapter Six – *6.3.1 Risk Profiles are similar but distinct*, but with a more systematic and formal process providing greater validity of the results.

A proactive approach

While spontaneous complaints are often seen to be infrequently reported, potential barriers to reporting may mask the true incidence of concerns. While data may still be limited by health consumer and practitioner numbers, there is likely to be a larger body of information than is generally available to regulators.

Health consumers may be reluctant to share their concerns through current channels and may not often volunteer information regarding their concerns. Proactively seeking input from health consumers, however, may result in a significantly higher engagement in conversations about their experience (O’Hara et al., 2018). This may provide an opportunity for regulators to seek information beyond any complaints that may be voluntarily submitted.

While working directly with health consumers did not arise in discussion of the theme *A Team Approach Supports Risk Mitigation* (Chapter Seven), this may reflect the current focus of RAs on the practitioner (and, by extension the health institution or employers) rather than health consumers. The way in which an RA may most appropriately work directly with health consumers may require further discussion and require assurance that such data is being used appropriately.

As an example, regulators may have to be careful that such proactive information gathering is not seen as a 'fishing expedition'. O'Hara et al. (2018) caution that data gained from health consumer interviews should only be used as an improvement tool and not as a tool for external regulation. These concerns, however, may be ameliorated through the appropriate use of the data gathered. Using this information as general intelligence about the clinical practice environment or emerging trends, for example, may be more appropriate than using it to justify specific, targeted regulatory intervention against an individual practitioner or institution.

This proactive approach may help address the challenges raised by RAs in this study – that there is a lack of data, and that there is a separation between the RA and what may occur in clinical practice. As well as increasing the availability of data regarding potential concerns, health consumers may be more willing to share information that would not meet the threshold for a formal complaint. Even information that does not relate to a specific harm may be useful for suggesting areas of future focus.

Incorporating minor concerns

Given that, for RAs, the focus on formal complaints is typically around the potential for regulatory intervention regarding an individual practitioner, much of the information unrelated to incidents of harm may be underutilised.

The rich narrative of complaints may provide cues to antecedents to harm – 'leading indicators' that can alert regulators (and other stakeholders) to issues before an incident of harm occurs (McCrudden et al., 2022; O'Hara et al., 2018). These may include subtle aspects of care that may not be apparent in other quality assurance methods (van Dael et al., 2022).

In Chapter Seven – *7.3 A Team Approach Supports Risk Mitigation*, RAs discussed their role in both facilitating change in response to non-regulatory concerns, as well as in education and self-improvement for practitioners. Identifying these indicators may then provide an opportunity for early intervention, either for an individual practitioner or at a broader level across an organisation or profession.

Despite this, there may be concerns regarding the level of justification an RA requires to take formal regulatory action at an individual level, and there is likely a need for further consideration of how this early intervention may best be achieved under the current regulatory framework. With participants in this study reinforcing their desire to act proactively, however, such an opportunity for latent risks to be addressed before any harm occurs deserves further exploration.

A change in thinking

While these actions may serve to enhance the value of complaints in understanding risk, they are still inherently based in the analysis of retrospective experiences and incidents of harm.

A strategy that may show some promise in bridging this gap is a concept known as Safety-II, or a resilience-based method of risk mitigation. While developed from the concept of ‘resilience engineering’ in the aviation industry, this alternative approach to interpreting safety, known as ‘Safety-II’ was proposed as a new model for healthcare safety in 2015, with the intent of shifting focus away from attempting to minimise accidents or incidents (Hollnagel et al., 2015).

The approach to understanding risk discussed above, where adverse events or potential risks are assessed and areas of poor performance identified and remediated, is considered to fall under the concept of ‘Safety-I’. For the authors, a ‘Safety-I’ approach fails to recognise the majority of incidents that go well and focuses overly much on trying to establish causality between an event and an underlying cause. They assert that this approach may not be suitable for the complex nature of modern working systems (such as the health system) (Hollnagel et al., 2015).

In healthcare, considering safety from a Safety-II approach may provide advantages through an acceptance that clinical practice exists in a range of contexts and environments, and may not be amenable to rigorously standardised processes (Braithwaite et al., 2015). While reviewing past incidents may still be part of a Safety-II approach, the focus may be more on considering how practice might dynamically change to meet demands and how clinicians may navigate tensions present in everyday practice (for example, between limited resources and health consumer needs) (Sujan et al., 2017). Here, the ability of a practitioner to recognise their context and adapt their practice to suit may be recognised as just as, if not more, important than competence in a particular technical task.

Such a change in approach may pose challenges for regulators, however, as traditional regulation has taken a compliance-based approach, where regulatory requirements seek to eliminate the 'cause' of harm (Leistikow & Bal, 2020). It could be argued that the focus of the HPCA Act 2003 on the role of an individual practitioner in an adverse incident reinforces such thinking. With a more responsive approach to regulation, however, and a focus to improving resilience in the health system, a Safety-II approach could provide significant advantages for RAs looking to understand how best to protect the safety of the public.

9.3.4 Summary

The findings of this study suggest that there are challenges for RAs in how they form their perspectives of risk. With a focus on data received from complaints, there are concerns that the infrequency and risk of bias in this data may result in an inaccurate view of risk in clinical practice. The view of risk may also be at risk of lagging behand developments in practice, limiting the ability of an RA to take a proactive approach.

While a change in approach to how this data is gathered and analysed may provide greater insight into the risks present in practice, both past and developing, a change in approach to the understanding of 'safety' may provide significant advantages – and challenges – for RAs.

9.4 Cross-Sector Collaboration

While this study considered each RA individually with the aim of identifying commonalities and differences, Chapter Seven - *7.3 A Team Approach Supports Risk Mitigation* showed how participants saw working with others as an important facet of regulatory work. While other regulators were seen to provide a useful benchmark against an RA's work, there was also a need to collaborate with others to achieve regulatory goals.

9.4.1 Balancing professional specificity and regulatory alignment

While this research sought identify profession-specific risks, these findings suggest it may be more useful to consider the task- or role-based risk, rather than those specific to individual professions. Rather than considering risk from the perspective of professional silos, a better question may be, 'What are the specific aspects of each healthcare role that relate to certain risks?'

This research has suggested that professions carrying out high-risk procedures with a greater risk of technical error may be more at risk of causing physical harm, whereas high-trust, physically or psychologically intimate patient-practitioner relationships may be more associated with practitioner misconduct, boundary violations and breaches of trust. Similarly, private practice, especially for sole practitioners, may be related to unique systems factors in the form of balancing business and healthcare demands, whereas those in larger institutions may face potential systems pressures from inflexible institutional policies and procedures. Given the diversity of healthcare, and the trend towards a more flexible, mobile health workforce, RAs (and other stakeholders) will need to consider how to best align the assessment and management of risk across professions and healthcare roles. This will also help meet the aims of the HPCA Act to provide a "consistent accountability regime for all health professions" (Health Practitioners Competence Assurance Act 2003, s. 3(2)(a)).

The Health Workforce Plan 2023/24 developed by Te Whatu Ora – Health New Zealand (2023) calls for a workforce that is flexible and adaptable, with transferrable skills that can be developed through vocational training. Scopes of practice, competence standards and codes of conduct would need to reflect this flexibility and allow responsiveness to change in practice contexts, but this flexibility and diversity in clinical roles and environments may also require individual clinicians and employers to be more aware of their ‘fit’ for any particular role. Overlaps in professional scope and an increase in team-based care may also see members of different professions sharing professional roles and responsibilities.

The ’adaptive challenge’ of practitioners responding to change has also been recognised as a barrier to implementing quality improvement changes (Pronovost, 2011), and these challenges would likely increase with a more mobile workforce. While a common approach to health safety, as suggested by the Health Workforce Plan 2023/24 (Te Whatu Ora - Health New Zealand, 2023), may reduce this adaptive challenge, it is likely that practitioners will still need to be competent in adapting to meet new demands, or to be able to recognise when they lack the level of competence required in a particular situation.

To ensure a fair and standardised approach to regulation, RAs will need to ensure that a common approach to common risks is developed in order to avoid disparity between how each profession is regulated.

9.4.2 A narrow regulatory focus

While the focus of RAs in New Zealand may be a general intent to protect the public from harm, the HPCA Act provides a much more defined scope of work.

Section 3(1) set out that the principle purpose of the HPCA Act is “to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions” (Health Practitioners Competence Assurance Act 2003, s.3(1)). Importantly, while the aim may be to protect the health and safety of members of the public generally, the focus of the HPCA Act is on individual practitioners. Additionally, the process for achieving these aims is specifically through providing mechanisms to ensure their competence and fitness to practice. This defined focus on competence and fitness to practice can mean that a range of risks, harms and incidents can fall outside the scope of an RA. As shown in this study, participating RAs view factors outside of those related to the individual practitioner as a significant component of overall risk.

For RAs themselves, there may be limited ability to respond to these risks, even where they may impact on the performance of an individual. An individual RA, therefore, cannot be solely responsible for preventing harm, even that arising from practitioner action. Instead, this reinforces the need for a team approach between all those who have a role in public safety.

Participants in this study demonstrated these challenges in expressing their frustration with the impact of systems factors on risk of harm, and the need to collaborate with employers and other healthcare safety stakeholders to manage these risks. Several other agencies in New Zealand have a broad role in safety for health consumers and provide an opportunity for such collaboration. The Health and Disability Commissioner (*The Health and Disability Commissioner*, n.d.) has an overlapping role with RAs, focusing more on the rights of healthcare consumers than the practitioner focused RAs. Under the HPCA Act, any complaint received by an RA has affected a health consumer, this must initially be referred to the HDC to consider further action (Health Practitioners Competence Assurance Act 2003, s. 64(1)).   Te Tāhū Hauora, New Zealand's Health Quality & Safety Commission, has a broad objective of monitoring and improving the quality and safety of health and disability support services under the New Zealand Public Health and Disability Act (New Zealand Public Health and Disability Act 2000) and provides some facilitation of collaboration on health safety systems (*System Safety Collaboration*, 2023). The membership of the collaboration groups identified by Te Tāhū Hauora do not appear to include RAs, however, and may be more focused on providers and healthcare consumers.

Concerns around the lack of appropriate information sharing and a lack of leadership in efforts towards safety for health consumers are a central issue raised in a recent discussion document from the Health Consumer Advocacy Alliance (Korte et al., 2023). In their discussion, the authors recommend the establishment of a national 'Patient Safety Commissioner' to represent the public voice and focus on preventing harm to health consumers. Such suggestions seem to mirror those of the report by Cull (2001) on adverse event reporting in New Zealand, which led, in part, to the current HPCA Act.

Alternatively, this may present an opportunity for government organisations such as Te Tāhū Hauora or Manatū Hauora, New Zealand's Ministry of Health, to provide more of a role in facilitating data sharing with, and between, regulators, health institutions, providers, and other key stakeholders.

9.4.3 Summary

To ensure a consistent and responsive system, then, clear communication across all levels of the health system is critical to understand risk and mitigate harm to health consumers.

Given the various agencies involved in this space, and the overlapping areas of responsibility and focus, an important first step is to map and define the particular roles and responsibilities held by each group. Strategic data sharing and alignment of work may provide significant efficiencies to the work of each agency, institution or group while preserving the specific proficiencies and focus each brings to the healthcare safety space.

9.5 The Continuing Potential of Person-Centred Care

Throughout the previous sections in this chapter, the importance of the voice of the health consumer in regulatory work is a recurrent theme. Participants noted that their perception of harm was influenced by their understanding of societal expectations. Harm itself is contextual, as discussed in Section 9.2 *Defining Harm*, and directly related to the experience of, and impact on, the health consumer. As such, the accurate assessment of harm cannot occur without seeking the views of the health consumer.

The influence of complaint data on participating RAs perceptions of risk was also highlighted, as was participants recognition that this was imperfect. Section 9.3 *Developing a Better Understanding of Risk* discussed how the views of participants was reflected in the literature, highlighting the gap between complaint data and what may occur in practice.

Finally, section 9.4 explored the importance of cross-sector communication, and the value of communication and data sharing between stakeholders in public safety. While this data may be primarily collected by public safety agencies, regulators and healthcare institutions, the overarching aim of public safety means that a significant amount of data on risk and harm resides with the health consumers themselves. Given this central role of the health consumer, there are also opportunities to mitigate potential harms through a better understanding of how risks interact with the health consumer experience – or, under a Safety-II approach, how successful outcomes may be realised despite the presence of potential risks.

9.5.1 Risk through Vulnerability

The relationship between risk, harm and vulnerability was explored in Chapter Six *Perceptions of relative risks relate to the clinical role*. Here, the risk of harm was seen to relate to the particular vulnerabilities experienced by a health consumer in their healthcare journey. For those undergoing high-risk, technical procedures, the vulnerability may arise from the required trust that a practitioner is competent to safely carry out that task. For others, the vulnerability may arise from permitting a practitioner to touch them in sensitive areas, to disclose information or to form relationships more openly than they may do under different circumstances. Health consumers may also experience increased vulnerability from factors outside the health system, such as from socioeconomic or environmental factors (Loh, 2017).

It may be argued that a significant amount of practitioner education and regulation seeks to ensure practitioners can operate safely within these vulnerable spaces, through ensuring they meet the professional standards and expectations of conduct deemed necessary for safe practice.

For Loh (2017), factors that lead to increased health consumer vulnerability manifest as an increased susceptibility to harm. This increased susceptibility can then result in both an increased likelihood of harm arising from latent risks, as well as a greater impact of harm, compared to a less vulnerable person in the same position. In contrast, Sossauer, Schindler and Hurst (2019) see vulnerability as arising from a mismatch between the health consumer’s needs and the actions taken to meet them. Here, vulnerability arises from the interaction between the health consumer and the healthcare system, rather than being an inherent quality of the health consumer themselves. Both of these definitions, however, require a heightened response from the health system to provide a safe experience for vulnerable people. This may be either to be more aware of, and protective against, latent risks, or to provide an increased level of care to meet specific health consumer needs.

Unfortunately, while a practitioner may recognise the vulnerabilities of the health consumer and seek to meet their needs, external factors, such as limited resources and workplace issues, may limit a practitioners ability to respond (Sossauer et al., 2019). This is reflected in participants concerns about the impact of systems issues on risk, outlined in Chapter Six - *6.3.3 Environmental pressures amplify clinical risks*. Here, the impact of systems factors was seen to restrict the ability of practitioners to manage the inherent risks in practice. Similar to the latent risks that can lead to harm, a restricted ability to meet the needs of a health consumer may arise from an individual practitioner's lack of competence or inappropriate conduct, but also from external factors beyond their control.

9.5.2 Empowerment through Communication

While all healthcare may result in the health consumer experiencing some vulnerability, identifying and meeting the unique vulnerabilities in each case and maintaining a focus on empowering the health consumer can alleviate the associated risks (Loh, 2017; Sossauer et al., 2019). Identifying such vulnerabilities may require a high degree of care in communication, however, especially when communicating with higher vulnerability groups (Iedema et al., 2019).

Health communication is seen as a significant factor in how health consumers may understand health care and wellbeing and good communication helps to foster personal agency (Simpson et al., 2021). The importance of this communication in setting expectations of care was explored in Chapter Seven - *7.2.2 Expectations of care*, where participants recognised that clear expectations helped health consumers make informed decisions about their care. Best practice in informed consent requires that a practitioner explores what may be of importance to the health consumer so that discussions around risk can be tailored to meet their individual needs (Madeley, 2023).

An ’engaged health consumer’, with a good understanding of their own care and who can ably participate in shared decision-making, is seen as an ideal for personal empowerment (Timmermans, 2020). As shown in this study, and as discussed in Chapter Seven - *7.2.2 Expectations of Care*, clear expectations may also provide a health consumer with more awareness of when care may fall short of professional expectations and make it more likely they will raise issues of concern.

From a health consumer perspective, receiving inconsistent or inaccurate information, experiencing difficulty receiving information and poor timing of communication are common concerns when making complaints (Mattarozzi et al., 2016). The lack of understanding of care caused by this poor communication leads, in turn, to greater vulnerability (Sossauer et al., 2019). While poor communication was identified by participants as a significant factor in harm to health consumers, as discussed in Chapter Seven - *7.2 Communication is a Moderator of Harm*, good communication serves to both set more accurate expectations and serve to mitigate harm, should it occur.

This focus on communication, education and empowerment of the health consumer can also hold true for RAs. The HPCA Act requires that RAs “promote public awareness of the responsibilities of the authority” (Health Practitioners Competence Assurance Act 2003, s. 118(1)(l)). This gives RAs a lever to communicate directly with health consumers about safety in healthcare, as well as reduce perceived barriers to reporting concerns. This may also allow RAs to specifically target communication with disadvantaged groups who may under-report harm, or to demonstrate recognition of broader forms of harm as discussed in Section 9.3.2 *Potential Bias in Perception*. Health consumers may benefit not just from knowing that they have a right to complain, but from greater awareness of the breadth of harms they have the right to complain about.

9.6 Summary

The findings of this study, and consideration of the literature, demonstrates the separation between an RA and the public they aim to protect.

While participating RA perceptions of risk are based on the information they receive from both health consumers and practitioners, the barriers to reporting and the notification process mean the information they receive is filtered and delayed from what is occurring in practice. While overt issues may be recognised and addressed, this leaves a risk that there are unidentified risks and harms occurring that do not meet the threshold of regulatory awareness. Without awareness, a regulator cannot act to address them.

A focus on reported incidents (where latent risks have crystallised into an incident of harm) can also leave regulators being reactive to existing harms. Alternative approaches to safety in healthcare, such as a 'Safety-II' approach, may provide opportunities for more proactive action in protecting public safety. Where risks or opportunities for improvement are identified, the focus of an RA on individual factors means they may be unable to address risks alone. Greater coordination between all levels of the health system is required for both the identification and mitigation of risks. This may require leadership from an existing or new agency in the public safety space.

Overall, however, safety for health consumers cannot be achieved without basing regulatory action in the patient context. Greater involvement of health consumers, in providing information about their experience, sharing their concerns, and providing an understanding of what they see as 'harm', is vital to accurately understanding the risks they face in healthcare.

Chapter Ten – Recommendations and Conclusion

10.1 Introduction

This final chapter sets out the value of this thesis as a body of work. Firstly, a broad discussion on what this research contributes to knowledge and practice is presented. Secondly, recommendations are presented that seek to address the points raised in Chapter Nine and suggest areas of further work. The limitations of this study are then discussed, followed by a personal statement on the authors research journey. Finally, a brief conclusion to the thesis is presented.

10.2 Contribution to Knowledge and Practice

While there is a breadth of research related to the risks of harm a health consumer might experience in their healthcare journey, there is a paucity of research related to the understanding and perceptions of risk from health regulators in New Zealand. While this may be related to challenges in accessing high-quality data in this field, RAs under the HPCA Act have a significant role, and make significant decisions, around protecting the public from healthcare-related harm.

This exploratory study is the first conducted in New Zealand to provide some initial insight into this topic. The use of a mixed-methods approach based in a pragmatic paradigm has allowed the research question to be approached from multiple angles, alleviating methodological issues around the limited availability and population of participants. The research question of this project focuses on identifying the profession-specific risks from the perception of New Zealand regulators. Throughout this process, it has been apparent that the way in which regulators form these perceptions, and their foundational understanding of both risk and harm, is of paramount importance to answering this question.

While the specific areas of risk identified by each participant provide valuable insight into safety for health consumers, this work has provided a significant contribution in identifying how perceptions of risk may be formed by regulators. It also considers the implications this creates for accurately identifying both harm to health consumers, and any underlying risks, in healthcare. This consideration of *how* RAs may develop their perceptions of risk promotes critical reflection on the validity of these perceptions – or, in the words of Pierce, helps regulators “to know what [they] think, to be masters of [their] own meaning” (Peirce, 2012, pp. 97–98).

This study also serves to provide unique insight into the challenges that regulators may face in mitigating or preventing harm and highlights the need for a coordinated approach to safety in healthcare. Furthermore, this study adds weight to the current call for greater involvement and recognition of the place of the health consumer in defining and responding to risk and harm.

As a pragmatic, exploratory study, this work sought to provide a ‘positive impact on action’ (Cornish & Gillespie, 2009). While many of the recommendations below will require further research and consideration to put into practice, they will nevertheless promote a positive change in current processes. This will allow New Zealand regulators, and other stakeholders in healthcare safety, to maintain currency with best practice as outlined in the literature.

10.3 Recommendations for Regulatory Practice

Chapter Nine outlined several recommendations for regulatory practice in New Zealand, primarily around the actions of RAs under the HPCA Act. As the primary focus group of this study, recommendations for RAs include recommendations related to understanding risk and harm, which would serve to enhance the validity and sensitivity of understanding, as well as promote a more proactive approach to identifying risk. Recommendations regarding collaboration with the public also serve to enhance a person-centred approach to understanding harm, as well as ensuring regulatory action is responsive and appropriately targeted to health consumer needs. Finally, recommendations regarding risk mitigation will provide potential immediate actions that RAs can take to improve the mitigation and prevention of harm.

10.3.1 Recommendations related to risk and harm

Ensure that regulatory decisions are based on accurate understanding of risk and that, where possible, these align across regulators. In particular:

- Develop a broad and responsive definition of harm that acknowledges its existence within the personal context of the health consumer and the potential impact on their lives. This would include recognition of the health consumers own beliefs regarding health, wellness and harm.
- Determine the unique vulnerabilities that may exist for health consumers in the role(s) of each profession, and where these may overlap with other professional roles.
- Develop a common method of analysing and reporting complaints and notifications to facilitate cross-regulator data sharing.
- Incorporate additional approaches to understanding safety, beyond the retrospective review of incidents. Models such as a Safety-II approach may serve to provide a greater focus on system resilience and proactive action.
    - This may include identification and review of low-incident or high-resilience healthcare facilities (e.g., those that maintain expected outcomes despite significant risk factors) in addition to traditional investigation of poor performance.

10.3.2 Recommendations related to collaboration with the public

Ensure that the voice of the health consumer is central to regulatory work around protecting public safety, by:

- Prioritising empowerment of health consumers to engage with the regulator through public education and revision of regulatory processes. Ensure barriers to engagement are addressed.
- Proactively engaging with health consumers to ensure that their views form the foundation of perceptions around harm and risk in healthcare.

- Providing public education on the expected standards of care and professional conduct for each profession.

10.3.3 Recommendations for mitigating risk

Ensure that strategies to mitigate risk address identified areas of risk and remain future-focused and enabling:

- Prioritise communication as an area of practitioner development:
  - To inform and empower the health consumer through a robust process of informed consent, including identifying and seeking to address vulnerabilities.
  - To appropriately respond to incidents of harm, should they occur.
- Review standards to ensure they are able to meet the needs of a dynamic and flexible health workforce, working in a range of roles and contexts.
- Align standards across professions, where these may address similar risks, while maintaining responsiveness to profession-specific factors.

10.4 Recommendations for Policy and Government

The recommendations for policy primarily relate to the need for a more aligned, strategic approach to protecting the public from harm in healthcare. These may be met either through changes in the operation existing agencies, or through the creation of new roles and responsibilities. Any significant change in the role of regulators, however, may need to be reflected in their underpinning legislation.

- Define and map the scope and role of each institution, agency or regulatory body operating in the healthcare safety space to ensure the specific responsibilities of each are well understood.
- Identify or establish a central entity to provide leadership and coordination in healthcare safety in New Zealand

    - This entity can also facilitate coordinated action to address both individual and systems-level factors in healthcare.

- Establish information sharing agreements between stakeholders in safety for health consumers to facilitate open communication about risks of harm in healthcare.
    - To alleviate privacy concerns, such information may be best shared at an aggregate level.
- Facilitate development of community engagement for regulators and other healthcare safety workers, as exemplified by Ngā Pae Hiranga, established by the Health Quality & Safety Commission (2023b).

10.5 Recommendations for Future Research

This study is a first exploratory step into the relationship between risk, harm and regulatory perceptions and decision-making in New Zealand. While the literature demonstrates ongoing investigation into safety for health consumers and concepts of risk and harm, several areas have been identified as important for furthering this research, particularly with respect to the role of the regulator:

- To conduct further studies into the perceptions of regulators on risk and harm, including higher-powered studies, to establish generalisability of results.
    - Given the small population within New Zealand, this may require judicious use of data from comparable overseas jurisdictions.
- To investigate the perceptions of risk and harm of other groups in healthcare, including health consumers, practitioners, and employers, to allow a comparative analysis of understanding.
    - This should specifically include investigations exploring the perceptions of minority groups and vulnerable demographics.
- To undertake a review of competence cases across RAs and elicit areas of commonality or difference between professional roles.

- To undertake research into the process and factors influencing how notifications are managed and responded to across RAs.
- To conduct a comparative analysis of cases initially reported to the Health and Disability Commissioner versus the RAs.
- To investigate the impact of commercial and financial factors, such as those faced in private healthcare, on the risk of harm for health consumers.
- To undertake further research into the relationship between unexpected or poor outcomes, and health consumer perceptions of tolerable or unacceptable harm.
    - In particular, this study suggests that further investigation into the relationship between practitioner communication with health consumers, health consumer expectations of healthcare, and perceived harm after a deleterious incident is warranted.
- To investigate the development of perceptions and understanding of risk in new members of a Regulatory Authority, especially new members of a governing Council or Board.

10.6 Limitations

The difficulties associated with a lack of available data is an acknowledged limitation, albeit one that the methodology of this study sought to mitigate. The low number of RAs (both in New Zealand and participating in this study) and the low number of HPDT cases for many RAs prevents any generalisability of these results. Similarly, taken on its own, the quantitative questionnaire utilised in Phase 1 of the Complementarity Arm reported insufficient numbers to undertake any detailed analysis of the results.

This difficulty in accessing data extends to reviewing objective data related to competence and fitness to practice concerns. While the Triangulation Arm was able to consider all cases published by the HPDT (including both those referred by RAs and the Health and Disability Commissioner’s Director of Proceedings), these focus on cases of professional misconduct. Detailed data on competence cases is typically not publicly available and this limits the breadth of objective case information that could be included. Similarly, while steps were taken to prime participants to answer on behalf of their Authority, their ability to respond without their personal opinion biasing their responses away from their understanding of the RA's position is unknown. This potential difficulty in an individual accurately representing the views of a regulatory body is also a potential limitation.

As the primary researcher is both a health practitioner and engaged by an RA, the subjective analysis of data may be seen as a limitation. Inherent in the reflexive approach taken, however, is a recognition of the value of a "subjective, situated, aware and questioning researcher" (Braun & Clarke, 2021b, p. 42), and this reflexivity has been the subject of conscious critical reflection throughout this work.

Finally, while not specifically considered a limitation, it is important to note that the perceptions of risk provided by this research are distinct from any actual risks that may exist in practice. As the focus of this study was on the perceptions of regulators, the findings here (excepting those specifically related to the Triangulation Arm) do not necessarily provide any indication of what risks may actually be present in practice.

10.7 Personal Reflection

Working through this doctorate research coincided with a time of great disruption in both my own journey and that of global health. The impact of the COVID-19 global pandemic on global healthcare and health workers and, more pertinently, on the work of healthcare regulators cannot be overstressed.

While access to the limited population involved in this study (RAs) had been an identified risk to the process of this study from the proposal stage, the reality of navigating participation during a time of high demand on health regulators became a significant challenge.

The attention given to the initial planning stages of the thesis, including the critical review of the methodology as part of the proposal process, resulted in an ability to rely on the underlying foundation of the study design. We were able to adjust timelines and staging of the research process to match participant availability and I benefited from the interest and support of regulatory staff in keeping the process moving. The strength of the pragmatic approach in utilising different 'threads' of enquiry allowed us to switch focus while any roadblocks in other areas were managed.

The staged approach and reflective nature of my chosen methodology and design also helped this research remain responsive to my growing development and understanding of regulatory work. Given my immersion in the concepts and issues addressed in this research, I was able to take a purposefully reflexive approach, rather than trying to distance myself from the work. This allowed – in my opinion – a much richer analysis and understanding of the data than I may have realised from a more detached view.

10.8 Conclusion to the Thesis

The aim of this study was to understand New Zealand RAs perceptions of risk of harm in healthcare. It has shown that these perceptions are varied and evolving and are strongly influenced by the data arising from complaints and notifications. As such, an RAs understanding of risk, and of the resulting harms, reflects the characteristic issues that are raised in these reported incidents.

These incidents, however, do not accurately represent the full range of risks that may occur in practice. Despite arising directly, in most cases, from the voice of health consumers, they are filtered to include only those incidents seen as significant enough to warrant further reporting and represent a biased view of what may occur in clinical practice.

Because of this, RAs will be facing significant challenges in meeting the goals of 'right-touch regulation', as the targeting and proportionality of actions will be considered against an understanding of risk that is itself inaccurate.

This thesis has set out several areas of recommendations that seek to address this issue. While these include recommendations around greater cross-sector collaboration and reframing the understanding of safety and harm, the key recommendation is to make the health consumer the centre of regulatory work. With increasing recognition of the context of the health consumer as a vital factor in recognising and protecting against harm, it is clear that the greatest risk of harm in healthcare is failing to understand the health consumer themselves.

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Appendix A – AUTEC Ethical Approval

AUT
TE WĀNANGA ARONUI O TĀMAKI MAKAU RAU

Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

5 November 2020

Judith McAra-Couper
Faculty of Health and Environmental Sciences

Dear Judith

Re Ethics Application: **20/252 Risk and Regulation in Healthcare: An interdisciplinary enquiry**

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application has been approved for three years until 5 November 2023.

Standard Conditions of Approval

1. The research is to be undertaken in accordance with the Auckland University of Technology Code of Conduct for Research and as approved by AUTEC in this application.
2. A progress report is due annually on the anniversary of the approval date, using the EA2 form.
3. A final report is due at the expiration of the approval period, or, upon completion of project, using the EA3 form.
4. Any amendments to the project must be approved by AUTEC prior to being implemented. Amendments can be requested using the EA2 form.
5. Any serious or unexpected adverse events must be reported to AUTEC Secretariat as a matter of priority.
6. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the AUTEC Secretariat as a matter of priority.
7. It is your responsibility to ensure that the spelling and grammar of documents being provided to participants or external organisations is of a high standard and that all the dates on the documents are updated.

AUTEC grants ethical approval only. You are responsible for obtaining management approval for access for your research from any institution or organisation at which your research is being conducted and you need to meet all ethical, legal, public health, and locality obligations or requirements for the jurisdictions in which the research is being undertaken.

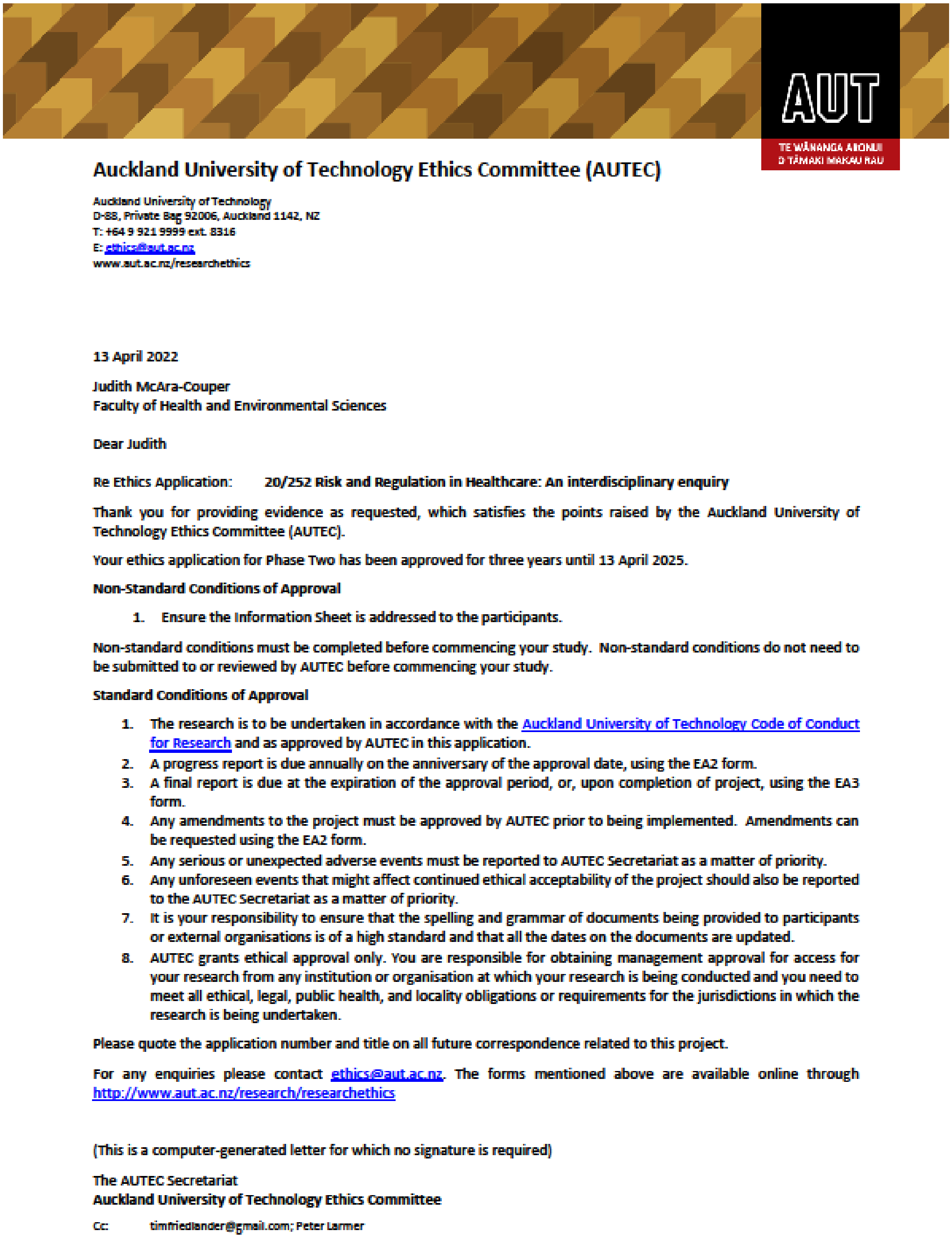
Please quote the application number and title on all future correspondence related to this project.

For any enquiries please contact ethics@aut.ac.nz. The forms mentioned above are available online through http://www.aut.ac.nz/research/researchethics

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: timfriedlander@gmail.com; Peter Larmer



Auckland University of Technology Ethics Committee (AUTEC)

Auckland University of Technology
D-88, Private Bag 92006, Auckland 1142, NZ
T: +64 9 921 9999 ext. 8316
E: ethics@aut.ac.nz
www.aut.ac.nz/researchethics

13 April 2022

Judith McAra-Couper
Faculty of Health and Environmental Sciences

Dear Judith

Re Ethics Application: **20/252 Risk and Regulation in Healthcare: An interdisciplinary enquiry**

Thank you for providing evidence as requested, which satisfies the points raised by the Auckland University of Technology Ethics Committee (AUTEC).

Your ethics application for Phase Two has been approved for three years until 13 April 2025.

Non-Standard Conditions of Approval

1. Ensure the Information Sheet is addressed to the participants.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by AUTEC before commencing your study.

Standard Conditions of Approval

1. The research is to be undertaken in accordance with the Auckland University of Technology Code of Conduct for Research and as approved by AUTEC in this application.
2. A progress report is due annually on the anniversary of the approval date, using the EA2 form.
3. A final report is due at the expiration of the approval period, or, upon completion of project, using the EA3 form.
4. Any amendments to the project must be approved by AUTEC prior to being implemented. Amendments can be requested using the EA2 form.
5. Any serious or unexpected adverse events must be reported to AUTEC Secretariat as a matter of priority.
6. Any unforeseen events that might affect continued ethical acceptability of the project should also be reported to the AUTEC Secretariat as a matter of priority.
7. It is your responsibility to ensure that the spelling and grammar of documents being provided to participants or external organisations is of a high standard and that all the dates on the documents are updated.
8. AUTEC grants ethical approval only. You are responsible for obtaining management approval for access for your research from any institution or organisation at which your research is being conducted and you need to meet all ethical, legal, public health, and locality obligations or requirements for the jurisdictions in which the research is being undertaken.

Please quote the application number and title on all future correspondence related to this project.

For any enquiries please contact ethics@aut.ac.nz. The forms mentioned above are available online through http://www.aut.ac.nz/research/researchethics

(This is a computer-generated letter for which no signature is required)

The AUTEC Secretariat
Auckland University of Technology Ethics Committee

Cc: timfriedlander@gmail.com; Peter Larmer

Appendix B – Recruitment Emails

From: Tim Friedlander
Sent: Thursday, 25 February 2021 12:01 pm
To: [redacted]
Subject: Risk and Regulation in Healthcare - Invitation to Participate
Attachments: Information-Sheet_Risk-and-Regulation.pdf; Permission-Form-RA_Risk-and-Regulation.pdf; Consent-Form-Participant1_Risk-and-Regulation.pdf; Consent-Form-Participant2_Risk-and-Regulation.pdf

Attn: [redacted]

Dear [redacted],

My name is Tim Friedlander, and I invite you to take part in a research project being undertaken as a part of my AUT Doctor of Health Science degree. This project focuses on the perception of risk to public safety from the perspective of Responsible Authorities, with the intent of helping to inform discussion and decision-making around the risks of harm in healthcare, as well as to identify areas of potential commonality between RAs (and professions), to allow more efficient interdisciplinary work.

The first phase of this research involves asking two representatives of each Responsible Authority to complete a questionnaire together, to indicate where each RA sees risks existing with the profession they regulate and how significant these risks may be.

We would appreciate your time to consider participating in this research. Further information about the project is included in the attached Information Sheet, and I have also attached Consent Forms for potential representatives, and a permission form for the RA to approve participation in the project. Please also note that, although I am currently the Deputy Chair of the Osteopathic Council of New Zealand, we have designed this study to minimise any potential bias and your choice around participation will neither advantage nor disadvantage any relationships in any way.

Should you be willing to participate, please return a signed copy of these forms to me via email (both the Permission Form signed by the appropriate person from your organisation, and a Consent Form for each participant) or, if you have any questions or concerns, please feel free to email these to me as well.

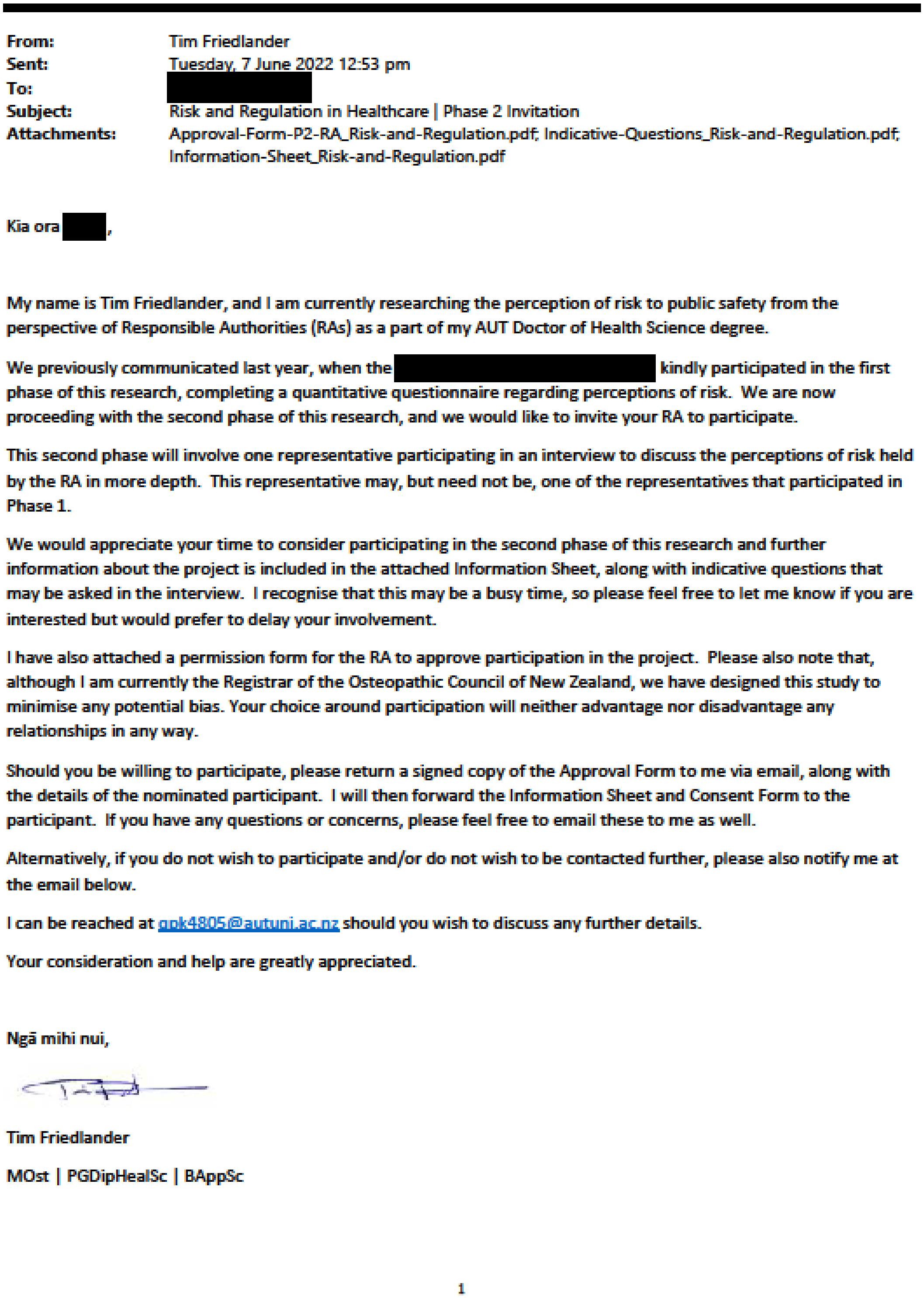
Alternatively, if you do not wish to participate and/or do not wish to be contacted further, please also notify me at the email below.

I can be reached at gpk4805@autuni.ac.nz.

Your consideration and help is greatly appreciated.

Kind regards,

Tim Friedlander



From: Tim Friedlander
Sent: Tuesday, 7 June 2022 12:53 pm
To: [redacted]
Subject: Risk and Regulation in Healthcare | Phase 2 Invitation
Attachments: Approval-Form-P2-RA_Risk-and-Regulation.pdf; Indicative-Questions_Risk-and-Regulation.pdf; Information-Sheet_Risk-and-Regulation.pdf

Kia ora [redacted],

My name is Tim Friedlander, and I am currently researching the perception of risk to public safety from the perspective of Responsible Authorities (RAs) as a part of my AUT Doctor of Health Science degree.

We previously communicated last year, when the [redacted] kindly participated in the first phase of this research, completing a quantitative questionnaire regarding perceptions of risk. We are now proceeding with the second phase of this research, and we would like to invite your RA to participate.

This second phase will involve one representative participating in an interview to discuss the perceptions of risk held by the RA in more depth. This representative may, but need not be, one of the representatives that participated in Phase 1.

We would appreciate your time to consider participating in the second phase of this research and further information about the project is included in the attached Information Sheet, along with indicative questions that may be asked in the interview. I recognise that this may be a busy time, so please feel free to let me know if you are interested but would prefer to delay your involvement.

I have also attached a permission form for the RA to approve participation in the project. Please also note that, although I am currently the Registrar of the Osteopathic Council of New Zealand, we have designed this study to minimise any potential bias. Your choice around participation will neither advantage nor disadvantage any relationships in any way.

Should you be willing to participate, please return a signed copy of the Approval Form to me via email, along with the details of the nominated participant. I will then forward the Information Sheet and Consent Form to the participant. If you have any questions or concerns, please feel free to email these to me as well.

Alternatively, if you do not wish to participate and/or do not wish to be contacted further, please also notify me at the email below.

I can be reached at gpk4805@autuni.ac.nz should you wish to discuss any further details.

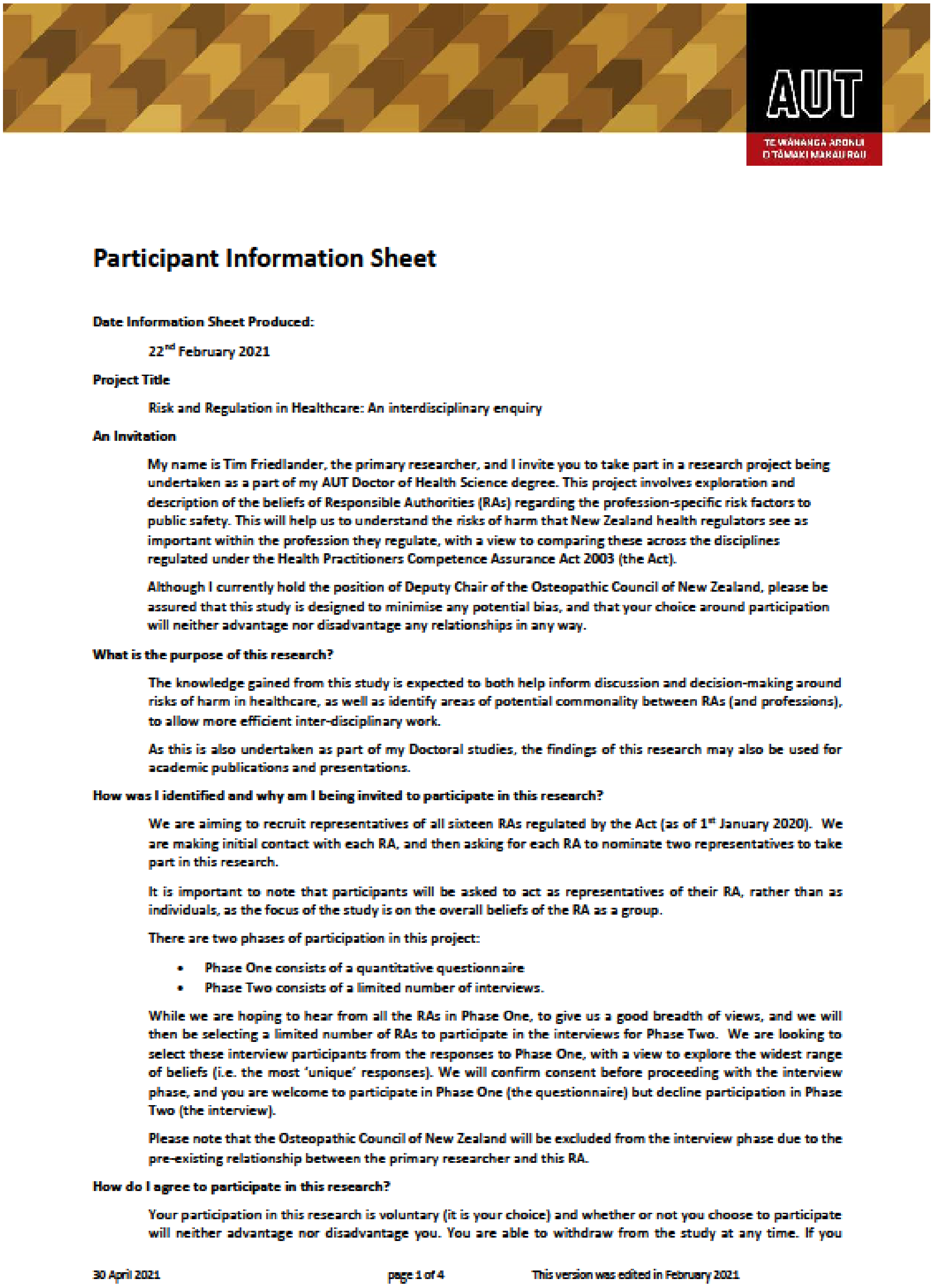
Your consideration and help are greatly appreciated.

Ngā mihi nui,

Tim Friedlander

MOst | PGDipHealSc | BAppSc

Appendix C – Participant Information Sheets



Participant Information Sheet

Date Information Sheet Produced:

22nd February 2021

Project Title

Risk and Regulation in Healthcare: An interdisciplinary enquiry

An Invitation

My name is Tim Friedlander, the primary researcher, and I invite you to take part in a research project being undertaken as a part of my AUT Doctor of Health Science degree. This project involves exploration and description of the beliefs of Responsible Authorities (RAs) regarding the profession-specific risk factors to public safety. This will help us to understand the risks of harm that New Zealand health regulators see as important within the profession they regulate, with a view to comparing these across the disciplines regulated under the Health Practitioners Competence Assurance Act 2003 (the Act).

Although I currently hold the position of Deputy Chair of the Osteopathic Council of New Zealand, please be assured that this study is designed to minimise any potential bias, and that your choice around participation will neither advantage nor disadvantage any relationships in any way.

What is the purpose of this research?

The knowledge gained from this study is expected to both help inform discussion and decision-making around risks of harm in healthcare, as well as identify areas of potential commonality between RAs (and professions), to allow more efficient inter-disciplinary work.

As this is also undertaken as part of my Doctoral studies, the findings of this research may also be used for academic publications and presentations.

How was I identified and why am I being invited to participate in this research?

We are aiming to recruit representatives of all sixteen RAs regulated by the Act (as of 1st January 2020). We are making initial contact with each RA, and then asking for each RA to nominate two representatives to take part in this research.

It is important to note that participants will be asked to act as representatives of their RA, rather than as individuals, as the focus of the study is on the overall beliefs of the RA as a group.

There are two phases of participation in this project:

- Phase One consists of a quantitative questionnaire
- Phase Two consists of a limited number of interviews.

While we are hoping to hear from all the RAs in Phase One, to give us a good breadth of views, and we will then be selecting a limited number of RAs to participate in the interviews for Phase Two. We are looking to select these interview participants from the responses to Phase One, with a view to explore the widest range of beliefs (i.e. the most 'unique' responses). We will confirm consent before proceeding with the interview phase, and you are welcome to participate in Phase One (the questionnaire) but decline participation in Phase Two (the interview).

Please note that the Osteopathic Council of New Zealand will be excluded from the interview phase due to the pre-existing relationship between the primary researcher and this RA.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

Initial written approval of participation will be required from the RA as a group, from a representative with authority to make such decisions (for example, the CE/registrar or Chair). We then ask that the RA nominate two individuals to participate in Phase One (the questionnaire).

Consent will then be sought separately from these nominated individuals at the beginning of each phase of this research. Individuals can agree to participate in Phase One (the questionnaire), whether or not they also agree to participate in Phase Two (the interviews).

Consent forms will be provided to individuals via electronic or hard-copy mediums, and questionnaires or interviews will not commence until these have been received.

What will happen in this research?

Phase One

This will involve completing a survey which explores the RAs beliefs around the risks of harm present in their profession, both in terms of types of harm and risk factors.

You may complete the questionnaire online or via post.

The two nominated representatives of the RA are asked to collaborate to complete one questionnaire together. This is to help increase the likelihood of obtaining a representative view of the RAs beliefs. You may also seek advice from other members of the RA.

The questionnaire contains only scale-type questions (such as Likert-type scales) and may take up to 45 minutes to complete. If you would like a copy of the questionnaire to inform your decision to participate, please let me know via email.

You are asked to complete the survey within a timeframe of four weeks.

Phase Two

We will choose a sample of up to six RAs to participate in Phase Two. RAs who are selected and approve participation in this phase will be asked to nominate one representative to take part in a single interview. While this representative may be one of those involved in Phase One, this is not necessary.

These interviews may occur at your place of work, or an appropriate alternative venue that you suggest. Interview over electronic communication (e.g. videoconferencing) may also be used if preferred.

The interview will be semi-structured, which means that we will use guide questions to steer the conversation, but there is room to explore the ideas you feel are important.

We will record the interview, and this will then be transcribed. Transcriptions of the interview will be sent to you (the representative) to check for accuracy. You, as a representative, may clarify or correct the transcript.

What are the discomforts and risks?

As you are providing opinions on behalf of the RA, it is not expected that there will be any discomfort or risk involved in participation.

There may be potential risk of conflict if your beliefs are different to those of the RA, however the research process has been designed to ensure involvement of multiple views prior to any data being analysed (such as through the collaborative answers to Phase One).

There may also be perceived risk in comparing the potential risks and harms of different professions, however the intent of this research is to identify areas of commonality between professions from a regulatory risk perspective and we are not looking to compare any other aspects of these healthcare professions (such as quality or scope of care).

How will these discomforts and risks be alleviated?

Any potential risks involved from differences in belief should be ameliorated through the study design. RAs are asked to nominate representatives that they believe will accurately represent their views, and you (as a participant) will be asked to answer as a representative of the RA rather than with your personal opinion (where these may be different).

The research team (the primary researcher and supervisors) are from a multi-disciplinary background, and will consult to ensure that all data is analysed and reported in an appropriate manner that minimises bias and the risk of value comparisons between professions.

What are the benefits?

Benefits to Participants

This study aims to promote the principles of 'right-touch regulation'; specifically, that regulation should be proportionate to the risk posed, and targeted, to minimise unwarranted side-effects from the regulatory process. If the aim of competence assurance is to minimise the risk of harm to the public, and if the risks of harm are not defined or identified, it is difficult to ensure that the competence assurance process is both targeted and proportionate. This, in turn, means that RAs may lack assurance that their processes strike an appropriate balance between minimising the risk of harm and over-regulating health practitioners.

The potential benefits of this study for RAs include both informing current risk mitigation mechanisms (including identifying factors beyond individual competence that may need addressing), as well as identifying areas of commonality or difference between the professions currently regulated by the HPCAA, to help promote better inter-disciplinary regulatory collaboration. Gaining a better understanding of the specific risks of harm to the public across the regulated health professions will both directly help meet the objectives of the HPCAA as well as provide a foundation for future research in this area.

Benefits to the Researcher

As the Deputy Chair of an RA, I will also benefit from this knowledge in my regulatory work. As a practitioner, this will also help me be more aware of the inherent risks in my own practice. Additionally, this research project will contribute towards gaining a Doctor of Health Science qualification.

How will my privacy be protected?

Although the data associated with individual RAs will be identified when reporting the results of this study, no individuals will be personally identified.

Your identity as a participant will likely be known to the members of your RA who are involved in this project and will be known to the primary researcher and supervisors, however your identity will be kept confidential from other people involved in the research project.

Data from all returned questionnaires and interviews will be associated only with the relevant RA, not the individuals involved. All electronic data will be protected in encrypted files, and any hard-copy data will be stored in a locked file in a secure room. Only the primary researcher and project supervisors will have access to these files. Interview recordings will be provided to a transcriber to allow transcription, however they will sign a confidentiality agreement, and keep copies of this data only long enough to complete transcription.

If you are concerned about your identity being known within your own RA, or by the primary researcher, you may decline participation in the project or withdraw from the project as described in the consent form.

What are the costs of participating in this research?

Participation in this research will require commitment to spending the time required to respond.

The expected time required to respond in Phase One is approximately 45 minutes to complete the questionnaire for the two representatives involved.

The expected time commitment for Phase Two is up to an hour for the interview process, plus the time required to review the transcript.

No other costs are expected to be incurred by participants.

What opportunity do I have to consider this invitation?

Please respond to this invitation within four weeks. If we have not heard from you within two weeks, we will send a reminder email. If you do not want to receive a reminder email, please let us know.

Will I receive feedback on the results of this research?

We are happy to provide a summary of findings once these are available. The consent form includes a question asking if you would like to receive results. If this is answered 'Yes', a summary of findings will be sent to the contact details provided.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Assoc Prof. Judith McAra-Couper, *judith.mcara@aut.ac.nz*, (+649) 921 9999 ext. 7193.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, *ethics@aut.ac.nz* , (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:

Tim Friedlander, *qpk4805@autuni.ac.nz*, (+649) 892 7535

Project Supervisor Contact Details:

Assoc Prof. Judith McAra-Couper, *judith.mcara@aut.ac.nz*, (+649) 921 9999 ext. 7193.

Phase 1 approved by the Auckland University of Technology Ethics Committee on 5 November 2020, AUTEC Reference number 20/252.

Participant Information Sheet

Date Information Sheet Produced:

6th March 2022

Project Title

Risk and Regulation in Healthcare: An interdisciplinary enquiry

An Invitation

My name is Tim Friedlander, the primary researcher, and I invite you to take part in a research project being undertaken as a part of my AUT Doctor of Health Science degree. This project involves exploration and description of the beliefs of Responsible Authorities (RAs) regarding the profession-specific risk factors to public safety. This will help us to understand the risks of harm that New Zealand health regulators see as important within the profession they regulate, with a view to comparing these across the disciplines regulated under the Health Practitioners Competence Assurance Act 2003 (the Act).

Although I currently hold the position of Registrar of the Osteopathic Council of New Zealand, please be assured that this study is designed to minimise any potential bias, and that your choice around participation will neither advantage nor disadvantage any relationships in any way.

What is the purpose of this research?

The knowledge gained from this study is expected to both help inform discussion and decision-making around risks of harm in healthcare, as well as identify areas of potential commonality between RAs (and professions), to allow more efficient inter-disciplinary work.

As this is also undertaken as part of my Doctoral studies, the findings of this research may also be used for academic publications and presentations.

How was I identified and why am I being invited to participate in this research?

Your RA participated in Phase One of this research and we have now selected a limited number of RAs to participate in the interviews for Phase Two. We have selected these interview participants from the responses to Phase One, with a view to explore the widest range of beliefs (i.e. the most 'unique' responses).

We will confirm consent before proceeding with the interview phase, and you are welcome to decline participation in Phase Two (the interview) despite participating in Phase One.

It is important to note that participants will be asked to act as representatives of their RA, rather than as individuals, as the focus of the study is on the overall beliefs of the RA as a group.

Please note that the Osteopathic Council of New Zealand will be excluded from the interview phase due to the pre-existing relationship between the primary researcher and this RA.

How do I agree to participate in this research?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

Initial written approval of participation will be required from the RA as a group, from a representative with authority to make such decisions (for example, the CE/registrar or Chair). We then ask that the RA nominate one individual to participate in Phase Two. Individuals who may agree to participate in Phase Two may be different from those who participated in Phase One.

Consent will be sought separately from this nominated individual at the beginning of Phase Two of this research, whether or not they also agreed to participate in Phase One.

Consent forms will be provided to individuals via electronic or hard-copy mediums, and interviews will not commence until these have been received.

What will happen in this research?

Phase Two

We will choose a sample of up to six RAs to participate in Phase Two. RAs who are selected and approve participation in this phase will be asked to nominate one representative to take part in a single interview. While this representative may be one of those involved in Phase One, this is not necessary.

These interviews may occur at your place of work, or an appropriate alternative venue that you suggest. Interview over electronic communication (e.g. videoconferencing) may also be used if preferred.

The interview will be semi-structured, which means that we will use guide questions to steer the conversation, but there is room to explore the ideas you feel are important.

Please note that any information you provide must not contain any details of specific cases in a way that could identify people. While general comments about the nature of a specific case may be acceptable, no details relating to, or that may allow identification of, any individuals should be disclosed

We will record the interview, and this will then be transcribed. Transcriptions of the interview will be sent to you (the representative) to check for accuracy. You, as a representative, may clarify or correct the transcript.

What are the discomforts and risks?

As you are providing opinions on behalf of the RA, it is not expected that there will be any discomfort or risk involved in participation.

There may be potential risk of conflict if your beliefs are different to those of the RA, however the research process has been designed to ensure involvement of multiple views prior to any data being analysed.

There may also be perceived risk in comparing the potential risks and harms of different professions, however the intent of this research is to identify areas of commonality between professions from a regulatory risk perspective and we are not looking to compare any other aspects of these healthcare professions (such as quality or scope of care).

How will these discomforts and risks be alleviated?

Any potential risks involved from differences in belief should be ameliorated through the study design. RAs are asked to nominate representatives that they believe will accurately represent their views, and you (as a participant) will be asked to answer as a representative of the RA rather than with your personal opinion (where these may be different).

The research team (the primary researcher and supervisors) are from a multi-disciplinary background, and will consult to ensure that all data is analysed and reported in an appropriate manner that minimises bias and the risk of value comparisons between professions.

What are the benefits?

Benefits to Participants

This study aims to promote the principles of 'right-touch regulation'; specifically, that regulation should be proportionate to the risk posed, and targeted, to minimise unwarranted side-effects from the regulatory process. If the aim of competence assurance is to minimise the risk of harm to the public, and if the risks of harm are not defined or identified, it is difficult to ensure that the competence assurance process is both targeted and proportionate. This, in turn, means that RAs may lack assurance that their processes strike an appropriate balance between minimising the risk of harm and over-regulating health practitioners.

The potential benefits of this study for RAs include both informing current risk mitigation mechanisms (including identifying factors beyond individual competence that may need addressing), as well as identifying areas of commonality or difference between the professions currently regulated by the HPCAA, to help promote better inter-disciplinary regulatory collaboration. Gaining a better understanding of the specific risks of harm to the public across the regulated health professions will both directly help meet the objectives of the HPCAA as well as provide a foundation for future research in this area.

Benefits to the Researcher

As a Registrar of an RA, I will also benefit from this knowledge in my regulatory work. As a practitioner, this will also help me be more aware of the inherent risks in my own practice. Additionally, this research project will contribute towards gaining a Doctor of Health Science qualification.

How will my privacy be protected?

Although the data associated with individual RAs will be identified when reporting the results of this study, no individuals will be personally identified.

Your identity as a participant will likely be known to the members of your RA who are involved in this project and will be known to the primary researcher and supervisors, however your identity will be kept confidential from other people involved in the research project.

Data from all returned interviews will be associated only with the relevant RA, not the individuals involved. All electronic data will be protected in encrypted files, and any hard-copy data will be stored in a locked file in a secure room. Only the primary researcher and project supervisors will have access to these files. Interview recordings will be provided to a transcriber to allow transcription, however they will sign a confidentiality agreement, and keep copies of this data only long enough to complete transcription.

Note: Only limited confidentiality can be offered

Although your identity will be kept confidential in any reporting and external communication, your identity may be known to members of your RA, as well as the interviewer and primary researcher.

In authorising approval of the RA to participate, your RA has agreed to maintain your confidentiality as much as practicable, however this means we cannot guarantee complete confidentiality.

If you are concerned about your identity being known within your own RA, or by the primary researcher, you may decline participation in the project or withdraw from the project as described in the consent form.

What are the costs of participating in this research?

Participation in this research will require commitment to spending the time required to respond.

The expected time commitment for Phase Two is up to an hour for the interview process, plus the time required by the representative to review the transcript.

No other costs are expected to be incurred by participants.

What opportunity do I have to consider this invitation?

Please respond to this invitation within four weeks. If we have not heard from you within two weeks, we will send a reminder email. If you do not want to receive a reminder email, please let us know.

Will I receive feedback on the results of this research?

We are happy to provide a summary of findings once these are available. The consent form includes a question asking if you would like to receive results. If this is answered 'Yes', a summary of findings will be sent to the contact details provided.

What do I do if I have concerns about this research?

Any concerns regarding the nature of this project should be notified in the first instance to the Project Supervisor, Assoc Prof. Judith McAra-Couper, *judith.mcara@aut.ac.nz*, (+649) 921 9999 ext. 7193.

Concerns regarding the conduct of the research should be notified to the Executive Secretary of AUTEC, *ethics@aut.ac.nz* , (+649) 921 9999 ext 6038.

Whom do I contact for further information about this research?

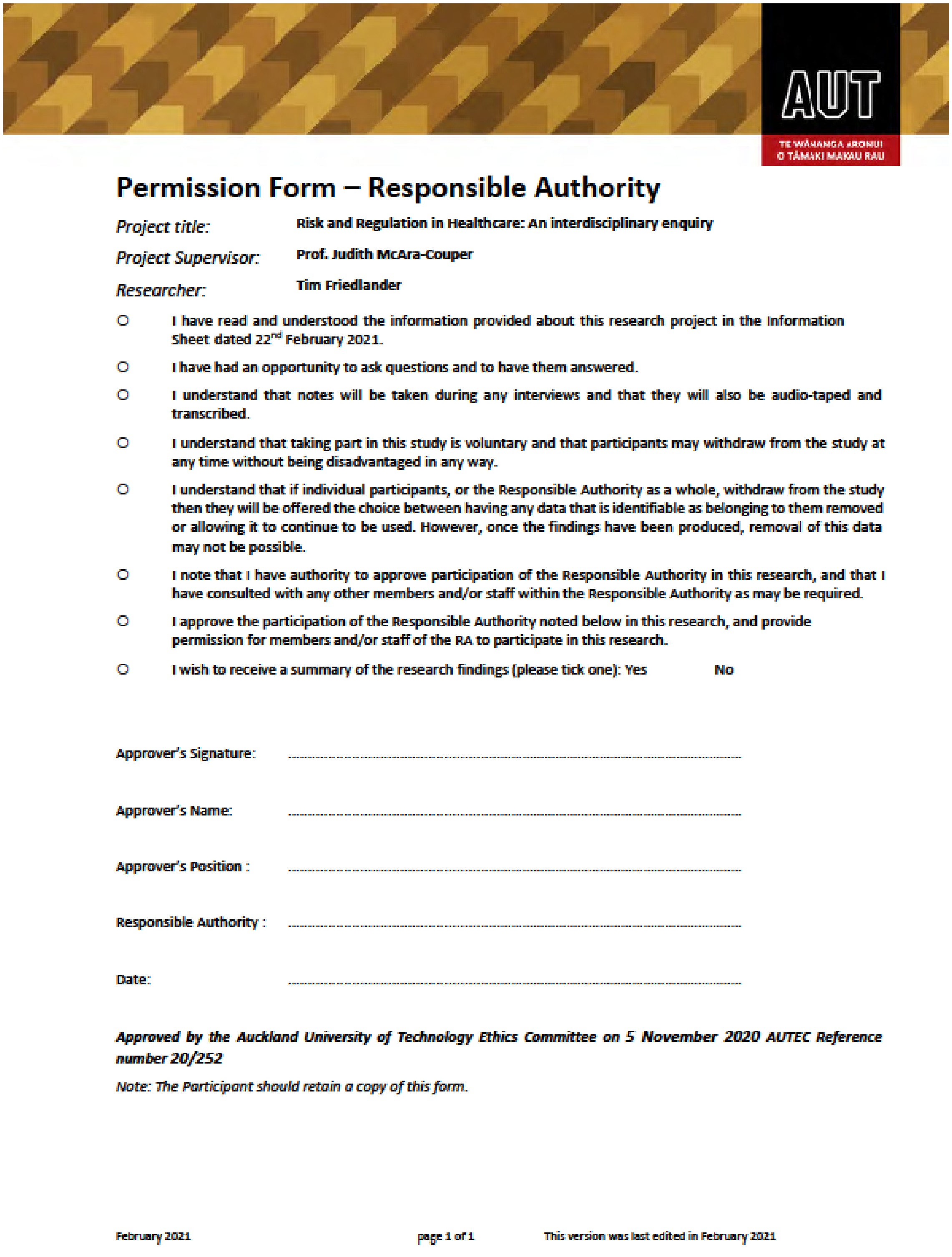
Please keep this Information Sheet and a copy of the Consent Form for your future reference. You are also able to contact the research team as follows:

Researcher Contact Details:
Tim Friedlander, *qpk4805@autuni.ac.nz*, (+649) 892 7535

Project Supervisor Contact Details:
Prof. Judith McAra-Couper, *jmcaraco@aut.ac.nz*, (+649) 921 9999 ext. 7193.

Approved by the Auckland University of Technology Ethics Committee on 13 April 2022, AUTEC Reference number 20/252.

Appendix D – RA Permission/Approval Forms



Permission Form – Responsible Authority

Project title: **Risk and Regulation in Healthcare: An interdisciplinary enquiry**

Project Supervisor: **Prof. Judith McAra-Couper**

Researcher: **Tim Friedlander**

○ I have read and understood the information provided about this research project in the Information Sheet dated 22nd February 2021.

○ I have had an opportunity to ask questions and to have them answered.

○ I understand that notes will be taken during any interviews and that they will also be audio-taped and transcribed.

○ I understand that taking part in this study is voluntary and that participants may withdraw from the study at any time without being disadvantaged in any way.

○ I understand that if individual participants, or the Responsible Authority as a whole, withdraw from the study then they will be offered the choice between having any data that is identifiable as belonging to them removed or allowing it to continue to be used. However, once the findings have been produced, removal of this data may not be possible.

○ I note that I have authority to approve participation of the Responsible Authority in this research, and that I have consulted with any other members and/or staff within the Responsible Authority as may be required.

○ I approve the participation of the Responsible Authority noted below in this research, and provide permission for members and/or staff of the RA to participate in this research.

○ I wish to receive a summary of the research findings (please tick one): Yes No

Approver's Signature: ....

Approver's Name: ....

Approver's Position : ....

Responsible Authority : ....

Date: ....

Approved by the Auckland University of Technology Ethics Committee on 5 November 2020 AUTEC Reference number 20/252

Note: The Participant should retain a copy of this form.

February 2021 page 1 of 1 This version was last edited in February 2021

Approval Form | Phase Two – Responsible Authority

Project title: **Risk and Regulation in Healthcare: An interdisciplinary enquiry**

Project Supervisor: **Prof. Judith McAra-Couper**

Researcher: **Tim Friedlander**

○ I have read and understood the information provided about this research project in the Information Sheet dated 3rd June 2022.

○ I have had an opportunity to ask questions and to have them answered.

○ I understand that notes will be taken during any interviews and that they will also be audio-taped and transcribed.

○ I understand that taking part in this study is voluntary and that participants may withdraw from the study at any time without being disadvantaged in any way.

○ I understand that if individual participants, or the Responsible Authority as a whole, withdraw from the study then they will be offered the choice between having any data that is identifiable as belonging to them removed or allowing it to continue to be used. However, once the findings have been produced, removal of this data may not be possible.

○ I acknowledge that, as the nominated participant is responding as a representative of the RA, the participant should not be identified, except where necessary for the research process. I acknowledge that the Responsible Authority will assure the identity of the participant is kept confidential (both internal and external to the RA).

○ I acknowledge that the responses of the representative may be linked to this Responsible Authority, and that the Responsible Authority is willing to manage any adverse response to these statements.

○ I note that I have authority to approve participation of the Responsible Authority in Phase Two of this research.

○ I approve the participation of the Responsible Authority noted below in this research.

○ I wish to receive a summary of the research findings (please tick one): Yes ○ No ○

Approver's Signature: ....

Approver's Name: ....

Approver's Position : ....

Responsible Authority : ....

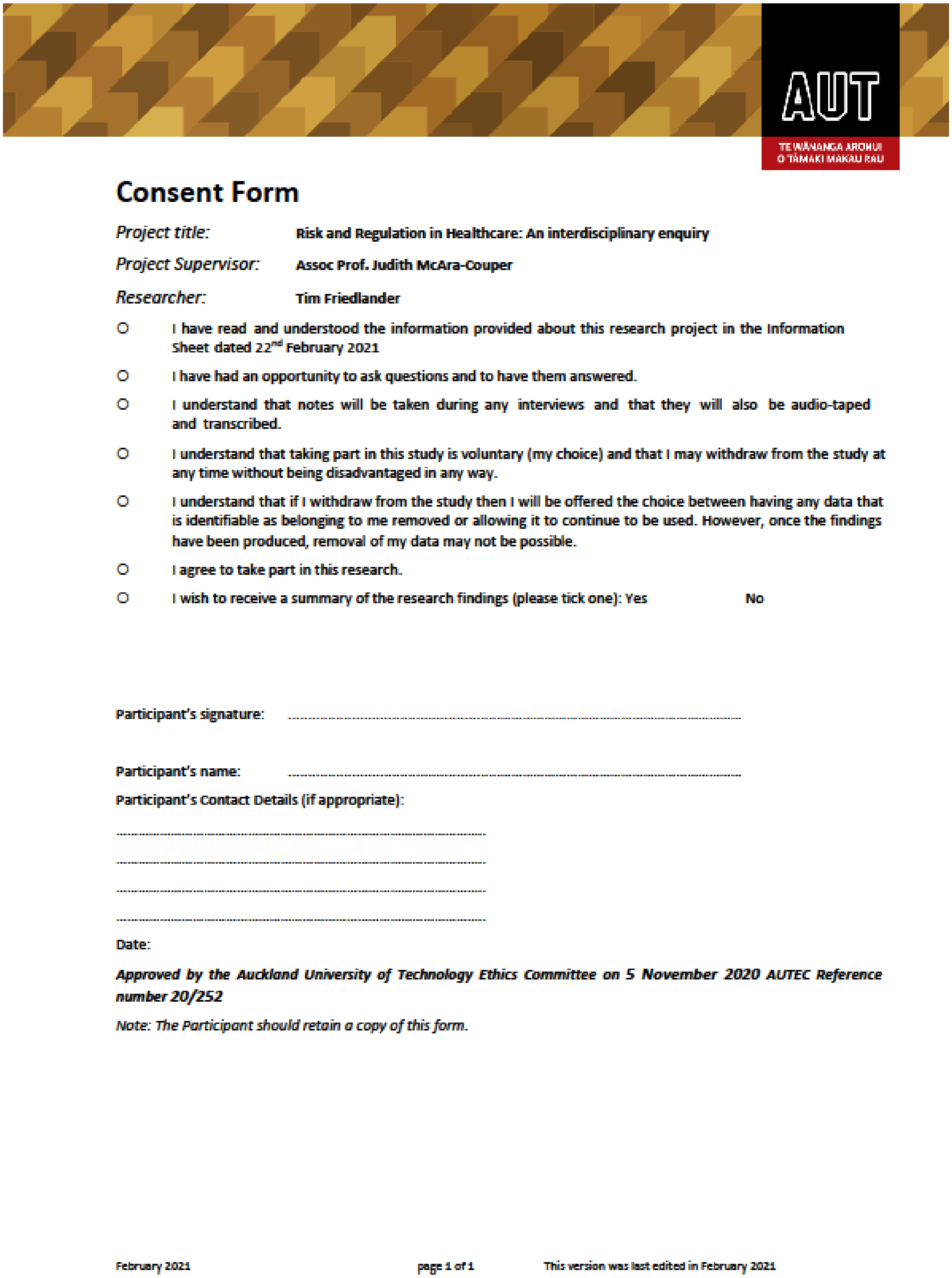
Date: ....

Approved by the Auckland University of Technology Ethics Committee on 13 April 2022 AUTEC Reference number 20/252

Note: The Responsible Authority should retain a copy of this form.

April 2018 page 1 of 1 This version was last edited in April 2018

Appendix E – Participant Consent Forms



AUT
TE WĀNANGA AROHUI
O TĀMAKI MAKAU RAU

Consent Form

Project title: **Risk and Regulation in Healthcare: An interdisciplinary enquiry**

Project Supervisor: **Assoc Prof. Judith McAra-Couper**

Researcher: **Tim Friedlander**

○ I have read and understood the information provided about this research project in the Information Sheet dated 22nd February 2021

○ I have had an opportunity to ask questions and to have them answered.

○ I understand that notes will be taken during any interviews and that they will also be audio-taped and transcribed.

○ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.

○ I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.

○ I agree to take part in this research.

○ I wish to receive a summary of the research findings (please tick one): Yes No

Participant's signature: ....

Participant's name: ....

Participant's Contact Details (if appropriate):

....

....

....

....

Date:

Approved by the Auckland University of Technology Ethics Committee on 5 November 2020 AUTEC Reference number 20/252

Note: The Participant should retain a copy of this form.

February 2021 page 1 of 1 This version was last edited in February 2021

AUT
TE WĀNANGA ARONUI
O TĀMAKI MAKAU RAU

Consent Form | Phase Two

Project title: **Risk and Regulation in Healthcare: An interdisciplinary enquiry**

Project Supervisor: **Prof. Judith McAra-Couper**

Researcher: **Tim Friedlander**

○ I have read and understood the information provided about this research project in the Information Sheet dated 3rd June 2022.

○ I have had an opportunity to ask questions and to have them answered.

○ I understand that notes will be taken during any interviews and that they will also be audio-taped and transcribed.

○ I understand that my responses may be linked to the RA I represent and that, although my details will be kept confidential, my identity may be known by individuals with the RA.

○ I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without being disadvantaged in any way.

○ I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible.

○ I agree to take part in Phase Two of this research.

○ I wish to receive a summary of the research findings (please tick one): Yes○ No○

Participant's signature: ....

Participant's name: ....

Participant's Contact Details (if appropriate):

....

....

....

....

Date:

Approved by the Auckland University of Technology Ethics Committee on 13 April 2022 AUTEC Reference number 20/252

Note: The Participant should retain a copy of this form.

Appendix F – Phase 1 Questionnaire

RISK AND REGULATION IN HEALTHCARE: AN INTERDISCIPLINARY ENQUIRY

INTRODUCTION

This questionnaire has been designed to determine the beliefs of New Zealand Responsible Authorities (RAs) towards the risks to public safety that may exist within the health professions. Factors leading to increased risk include contributing factors, medical error and practitioner misconduct.

Please note that we are asking you to answer as a representative of the Responsible Authority rather than your personal opinion. To this end, we have asked that each Responsible Authority nominate two representatives to complete one questionnaire collaboratively. Answers should reflect the overall beliefs of the RA as a whole as much as possible.

This questionnaire is in four parts:

1:- **Overall Levels of Risk and Harm** – This section includes questions to determine overall how likely the RA would consider risk factors are to occur, and how severe the potential harm could be, within the profession

2:- **Contributing Factors** – This section includes questions to determine how likely the RA would consider particular contributing factors are to exist in the profession, and the potential harm they may create.

3:- **Practice Errors** – This section includes questions to determine how likely the RA would consider particular errors are to occur in the profession, and the potential harm they may create.

4:- **Misconduct** – This section includes questions to determine how likely the RA would consider particular types of misconduct are to occur in the profession, and the potential harm they may create.

DEFINITIONS OF HARM:

No harm: Any incident that ran to completion but no harm occurred to the patient

Mild harm: Incident in which: (i) patient was harmed, with mild and short term impact, on physical, mental or social functioning, that was expected to resolve in a few hours; (ii) patient was harmed but required no or minimal intervention/treatment, e.g. anti-emetic, oral antibiotic or repeat of a minor procedure such as vaccination or insertion of contraceptive implant; and/or (iii) patient or their loved ones experienced transient emotional distress but no long-term consequences and incident report contains words, e.g. angry, anxious, confused, distressed, frightened, frustrated, humiliated or upset, that might describe a feeling that occurs at the time of the incident but soon passes

Moderate harm: Incident in which: (i) patient was harmed, causing a medium term impact on physical, mental or social functioning that was expected to resolve in days; (ii) patient required medical intervention in the form of treatment, e.g. antibiotics or intravenous fluids; (iii) patient required short-term hospitalization for assessment and/or minor treatment in either ED or a hospital ward; and/or (iv) patient or their loved ones experienced psychological difficulty of a more longstanding nature but not requiring formal treatment, e.g. as indicated by evidence in the report of more longstanding anxiety, insomnia, or low mood

Severe harm: Incident in which: (i) patient was harmed, causing a major long-term or permanent impact on physical, mental or social function or shortening of life expectancy; (ii) patient was harmed and required major medical or surgical intervention that, most often, was delivered in a hospital setting, e.g. cardioversion, any major surgery; (iii) patient was harmed and required prolonged hospitalization or admission to CCU, HDU and/or ICU; and/or (iv) patient or their loved ones experienced enduring psychological difficulty that required specialist treatment, e.g. as indicated in the report by evidence of chronic anxiety or depression or psychosis

Death: Incident in which, on the balance of probabilities, death of the patient was caused or brought forward in the short term by the incident

The definitions of harm in this questionnaire have been adapted from:
Cooper, J., Williams, H., Hibbert, P., Edwards, A., Butt, A., Wood, F., Parry, G., Smith, P., Sheikh, A., Donaldson, L., & Carson-Stevens, A. (2018). Classification of patient-safety incidents in primary care. Bulletin of the World Health Organization, 96(7), 498–505. https://doi.org/10.2471/BLT.17.199802

1: OVERALL RISK

Before considering the individual risk factors and incident types in Sections 2-4, please indicate by ticking the boxes how likely a risk to public safety is to exist, and how severe the potential harm could be, within the practice of the profession regulated by the RA.

1A: LIKELIHOOD OF RISK

How likely are the following issues to be present in the profession regulated by the RA?

	Highly Unlikely	Unlikely	Neither Likely nor Unlikely	Likely	Highly Likely	Unsure
1. Likelihood that underlying risk factors exist in normal practice						
2. Likelihood of practice errors						
3. Likelihood of practitioner misconduct						

1B: IMPACT ON HARM

How severe is the harm that could occur to patients in the following situations?

	No harm	Mild harm	Moderate harm	Severe harm or Death	Unsure
1. Due to underlying risk factors that are present during normal practice					
2. A practice error occurs					
3. Practitioner misconduct occurs					

2A: CONTRIBUTING FACTORS – LIKELIHOOD

Please read the contributing factor descriptions on the left and indicate by ticking the boxes how likely these are to exist within the practice of the profession regulated by the RA.

Likelihood of potential risk from:	Highly Unlikely	Unlikely	Neither Likely nor Unlikely	Likely	Highly Likely	Unsure
1. Individual patient characteristics (e.g. personality, behaviour)						
2. Communication errors						
3. Individual practitioner characteristics (e.g. personality, behaviour)						
4. Poor training or education						
5. Performance of high risk clinical procedures/tasks						
6. Issues with team dynamics (e.g. poor teamwork)						
7. Social issues in the workplace (e.g. workplace culture, professional/personal respect)						
8. Poor working conditions (e.g. lack of clear policies/procedures, workload issues)						
9. Lack of suitable or sufficient equipment and resources (e.g. poorly maintained equipment)						
10. Uncontrolled or unsafe working environment (e.g. solo home care)						
11. Poor health infrastructure and/or access to care						

2B: CONTRIBUTING FACTORS – IMPACT ON HARM

Please read the contributing factor descriptions on the left and indicate by ticking the boxes the likely severity of patient harm, should an incident occur due to that factor (i.e. how much harm could an issue in this area create?)

Potential harm from:	No harm	Mild harm	Moderate harm	Severe harm or Death	Unsure
1. Individual patient characteristics (e.g. personality, behaviour)					
2. Communication errors					
3. Individual practitioner characteristics (e.g. personality, behaviour)					
4. Poor training or education					
5. Performance of high risk clinical procedures/tasks					
6. Issues with team dynamics (e.g. poor teamwork)					
7. Social issues in the workplace (e.g. workplace culture, professional/personal respect)					
8. Poor working conditions (e.g. lack of clear policies/procedures, workload issues)					
9. Lack of suitable or sufficient equipment and resources (e.g. poorly maintained equipment)					
10. Uncontrolled or unsafe working environment (e.g. solo home care)					
11. Poor health infrastructure and/or patient access to care					

3A: PRACTICE ERRORS – LIKELIHOOD OF INCIDENT

Please read the medical error descriptions on the left and indicate by ticking the boxes how likely these are to occur within the practice of the profession regulated by the RA.

Likelihood of:	Highly Unlikely	Unlikely	Neither Likely or Unlikely	Likely	Highly Likely	Unsure
1. Communication errors						
2. Diagnostic errors (e.g. poor clinical reasoning)						
3. Inappropriate management/ treatment plan						
4. Errors in a clinical, technical or procedural task						
5. Medication errors (e.g. provision or advice)						
6. Acquired infection (as a result of the healthcare interaction)						
7. Administrative errors (e.g. financial or organisational errors)						
8. Equipment failure, or lack of access to equipment						

3B: PRACTICE ERRORS – SEVERITY OF HARM

Please read the medical error descriptions on the left and indicate by ticking the boxes the likely severity of patient harm, should an incident occur (i.e. how much harm could an issue in this area create?)

Potential level of harm from:	No harm	Mild harm	Moderate harm	Severe harm or Death	Unsure
1. Communication errors					
2. Diagnostic errors (e.g. poor clinical reasoning)					
3. Inappropriate management/ treatment plan					
4. Errors in a clinical, technical or procedural task					
5. Medication errors (e.g. provision or advice)					
6. Acquired infection (as a result of the healthcare interaction)					
7. Administrative errors (e.g. financial or organisational errors)					
8. Equipment failure, or lack of access to equipment					

4A: PRACTITIONER MISCONDUCT – LIKELIHOOD OF INCIDENT

Please read the misconduct descriptions on the left and indicate by ticking the boxes how likely these are to occur within the practice of the profession regulated by the RA.

Likelihood of:	Highly Unlikely	Unlikely	Neither Likely nor Unlikely	Likely	Highly Likely	Unsure
1. Disruptive practitioner behaviour						
2. Boundary violations (e.g. inappropriate touching or relationships)						
3. Inappropriate or unnecessary medical care						
4. Unlawful use or supply of medication						
5. Improper use or management of health information						
6. Unfair costs or misleading advertising						
7. Non-compliance with administrative, contractual or regulatory requirements, or fraud						

4B: PRACTITIONER MISCONDUCT – SEVERITY OF HARM

Please read the misconduct descriptions on the left and indicate by ticking the boxes the likely severity of patient harm, should an incident occur. (i.e. how much harm could an issue in this area create?)

Potential level of harm from:	No harm	Mild harm	Moderate harm	Severe harm or Death	Unsure
1. Disruptive practitioner behaviour					
2. Boundary violations (e.g. inappropriate touching or relationships)					
3. Inappropriate or unnecessary medical care					
4. Unlawful use or supply of medication					
5. Improper use or management of health information					
6. Unfair costs or misleading advertising					
7. Non-compliance with administrative, contractual or regulatory requirements, or fraud					

Appendix G – Phase 2 Interview Guide

Semi-structured Interview Guide

Introduction

Thank you for agreeing to participant in this interview. We are interviewing you as a representative of the Responsible Authority to provide us some insight into how each RA sees the risks to public safety within their respective professions. As much as possible, please answer these questions how you feel the RA would respond, as opposed to your personal opinions. Where their views may be unclear, or you are unsure of how the RA would answer, please let me know.

Please note that any information you provide must not contain any details of specific cases in a way that could identify people. While general comments about the nature of a specific case may be acceptable, no details relating to, or that may allow identification of, any individuals should be disclosed

Participation in this study is voluntary and you may withdraw from the study at any time without being disadvantaged in any way. If you withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of the data may not be possible.

With your permission, I would like to audio record this interview as I don't want to miss any of your comments. These audio recordings and any transcripts will only be accessed by myself and my supervisors, except as where necessary for transcribing.

Your identity will be kept confidential in any reporting. We may use selected quotes in our reporting; however, these will not be attributed to you as an individual. We will supply you with a copy of the interview transcript so that you may correct any misunderstandings.

You may decline to answer any question or stop the interview at any time for any reason. Do you have any questions about what I have just explained?

Are you happy for me to proceed with the interview?

I will now start the digital recorder.

Establishing Rapport

Before we begin, could you please tell me a little about your role at the [RA]? How long have you been working in this position?

1. *Overall understanding of risk in profession*
   How well are the risks to public safety in [profession] are understood by your RA?
      Prompt: Why might the RA have a good/poor understanding of the risks?
      Prompt: What information has your RA used/ what actions has the RA taken to understand this risk?

   Overall, how large does your RA believe the risks to public safety that exist within the profession are?

Prompt: Why might the risk be so high/low?

Prompt: Does the RA see the practice of [profession] is inherently high/low risk? Why?

Have there been discussions within the RA as to what the term 'harm' represents? What is the general understanding of this term within the RA?

Prompt: What are the different types of harm that might exist in [profession]?

What does your RA see as the most serious risk of harm to the public from the practice of [profession]?

What does your RA see as the likelihood that a patient could suffer some harm under the care of a [professional]?

Prompt: Does your RA consider that patient harm can be entirely prevented in the practice of the profession? Why/why not?

2. *Contributing Factors*

What does the RA see as the most significant underlying factors when considering the risk to public safety?

Prompt: Why are these seen as the most significant?

Prompt: How much of the risk is seen to relate to the individual, compared to the way they work or the environment they work in?

How widespread are these underlying factors seen to be?

Prompt: Does the RA expect that most [professionals] face the same issues?

Prompt: Has the RA looked at how these factors may be mitigated? How much work might it take to mitigate these factors?

3. *Errors*

Has the RA seen any patterns or themes around mistakes or errors that practitioners or other staff could make in the practice of [profession].

[Clarification: By mistakes or errors I mean things that might unintentionally go wrong, such as not performing a procedure correctly, communicating/understanding something incorrectly or equipment failure]

Prompt: Does the RA consider that the risk of mistakes or errors occurring is high/low? Why?

Prompt: What are the particular errors the RA is most concerned about/watchful for? How significant can the outcomes of these errors be for the patient/client?

Prompt: How might the environment the [professional] works in aggravate/mitigate these outcomes?

4. *Misconduct*

Has the RA seen any patterns or themes around practitioner misconduct amongst [professionals]?

Prompt: Does the RA see a lot of misconduct occurring?

Prompt: Are there particular types of misconduct that the RA sees a lot of? Is there any current thinking or information that might explain this?

How much does the RA consider misconduct to be a factor in the overall risk of harm to the public, compared to, for example, medical error?

Prompt: Does the RA see a lot of misconduct cases, compared to competence concerns?

Prompt: Do the misconduct cases the RA sees tend to be serious, or is there the potential for misconduct to cause significant harm?

5. *Specific Questions (where appropriate)*

The response of your RA to Phase One suggested that [x] is seen as a higher risk for your profession. Are you able to describe why this may be the case?

The response of your RA to Phase One suggested that [x] is seen as a lower risk for your profession. Are you able to describe why this may be the case?

Phase One of this study suggested that it may be difficult to judge the degree of harm that might be caused by contributing factors, errors or misconduct. Do you find this in your work? Why do you think that is the case?

6. *Overall impressions*

Overall, as a regulator, what is the RAs biggest concern regarding public safety within [profession]?

What would be considered as the main type of harm that patients are at risk of?

How much does the competence of an individual [professional] seem to relate to the overall risk of harm to a patient in their care?

7. *Conclusion*

Given the topics we have discussed, are there any areas you would like to comment on further?

Beyond what we've talked about today, are there any other comments you would like to make regarding risk of harm to the public, that we haven't already discussed?

Thank you very much for your time, and the information you have shared today.

Appendix H – Transcriber Confidentiality Agreement

Confidentiality Agreement

Project title:	*Risk and Regulation in Healthcare: An interdisciplinary enquiry*
Project Supervisor:	***Prof Judith McAra-Couper***
Researcher:	***Tim Friedlander***

- ○ I understand that all the material I will be asked to transcribe is confidential.
- ○ I understand that the contents of the tapes or recordings can only be discussed with the researchers.
- ○ I will not keep any copies of the transcripts nor allow third parties access to them.

Transcriber's signature: ....

Transcriber's name: Judith Mogamog

Transcriber's Contact Details (if appropriate):

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44 Tehama St., San Francisco,
CA 94105,United States
Tel: +1 866 941 4131

Date: June 17, 2022

Project Supervisor's Contact Details:

Prof Judith McAra-Couper

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Email: jmcaraco@aut.ac.nz

Approved by the Auckland University of Technology Ethics Committee on 13 April 2022 AUTEC Reference number 20/252

Note: The Transcriber should retain a copy of this form.

April 2018 page 1 of 1 This version was last edited in April 2018

Appendix I – HPDT Charge Coding

Category	Charge Characteristic
Disruptive Behaviour	Acknowledgement of colleagues - inadequate/inappropriate
	Assault and/or inappropriate force
	Behaviour inappropriate
	Behaviour inappropriate
	Communication inadequate/inappropriate
	Communication inadequate/inappropriate (2)
	Legislation – breach of Crimes Act 1961 (2)(behaviour)
	Legislation – breach of Crimes Act 1961 (3)(behaviour)
	Legislation – breach of Crimes Act 1961 (behaviour)
	Legislation – breach of Summary Offences Act 1981 (behaviour)
	Legislation – breach of Summary Offences Act 1981 (non-clinical)
	Professional standards inadequate
	Theft and/or Burglary
Boundary Violations	Legislation – breach of Crimes Act 1961 (Boundary Violation)
	Legislation - breach of Customs and Excise Act 1996
	Legislation – breach of Films Videos and Publications Classifications Act 1993
	Legislation – breach of Films Videos and Publications Classifications Act 1993 (2)
	Possession of objectionable material
	Possession of objectionable material
	Professional boundaries breached
	Relationship inappropriate
	Relationship inappropriate use of
	Sexual misconduct - inappropriate relationship
	Sexual misconduct - inappropriate touching
	Sexual misconduct - indecent act
	Sexual misconduct - indecent assault
	Sexual misconduct - sexual relationship with patient or former patient or partner of patient
	Sexual misconduct - sexual relationship with patient or former patient or partner of patient
	Sexual Violation
	Financial - relationship inappropriate
Inappropriate Care	Allowed an unqualified person to undertake task
	Assessment - inadequate/inappropriate
	Assessment - inadequate/inappropriate
	Attendance inadequate
	Care plan - inadequate
	Codified professional standards breach
	Codified professional standards breach
	Competence - lack of
	Confer - failed to
	Consultations - inappropriate/inadequate
	Crown inadequate
	Informed consent - inadequate
	Instructions - inadequate/inappropriate
	Legislation - breach of Contraception, Sterilisation and Abortion Act 1977
	Partnership – failed to end
	Physical restraint - inappropriate
	Planning not carried out appropriately
	Procedure - inappropriate
	Proceeded without adequate skill/expertise
	Public safety compromised
	Referral - inadequate
	Response – inadequate/inappropriate
	Root canal therapy inadequately performed
	Safety of patient put at risk
	Specimen - failure to have examined
	Staff - allowed unqualified person to undertake task
	Staff - failure to provide adequate levels
	Staff - training/supervision inadequate/inappropriate
	Supervision - inadequate
	Tests - failed to perform
	Tests - inappropriate
	Treatment - altered without consultation
	Treatment - care inadequate/inappropriate
	Treatment - care inadequate/inappropriate
	Treatment - followup inadequate/inappropriate
	Treatment - inadequate

Category	Charge Characteristic
Medication/Drugs	Alcohol - under the influence of
	Dispensing - error/inappropriate
	Driving with excess breath alcohol
	Drugs - dispensing inadequate/inappropriate
	Drugs - inappropriate administration and/or misuse of
	Drugs - inappropriate possession/unlawful use
	Drugs - manufacturing inappropriate
	Drugs - packaging/labelling inappropriate
	Drugs/medication - inappropriate administration
	Drugs/medication - inappropriate storage
	Legislation – breach of Crimes Act 1961 (fraud/drugs?)
	Legislation – breach of Land Transport Act 1998
	Legislation – breach of Land Transport Act 1998 (non-clinical)
	Legislation – breach of Medicines Act 1980
	Legislation - breach of Medicines Regulations 1984
	Legislation – breach of Misuse of Drugs Act 1975
	Legislation – breach of Misuse of Drugs Act 1975 (2)
	Legislation - Misuse of Drugs Regulations 1977
	Prescribing - inappropriate/inadequate
Health Information	Confidentiality - breach of
	Failure to record
	Note taking - inadequate/inappropriate
	Privacy - breach of
	Privacy - breach of
	Records - altered/attempt to alter
	Records - inadequate
	Records - inadequate/inappropriate
	Records - inadequately maintained
	Records - inappropriate access
	Records - inappropriate storage
Costs/Advertising	Advertising inappropriate
	Financial gain - inappropriate
	Claiming - inappropriate
Regulation / Fraud	Authority - failed to engage
	Authority - failed to engage / comply
	Authority - Lied/misled
	Conditions on scope of practice - failure to comply
	Controlled Drugs Register - failure to maintain
	Documents - dishonest use of/intent of obtaining pecuniary gain
	Documents/Communications - falsification
	Forgery/fraud
	Legislation – breach of Corrections Act 2004 (fraud)
	Legislation – breach of Crimes Act 1961 (2)(fraud)
	Legislation – breach of Crimes Act 1961 (3)(fraud)
	Legislation – breach of Crimes Act 1961 (Fraud)
	Legislation – breach of Criminal Code Act 1924 (fraud)
	Legislation - breach of Education Act 1989 (fraud)
	Legislation – breach of Injury, Prevention and Rehabilitation and Compensation Act 2001 (Dishonesty)
	Legislation - breach of Social Security Act 1964 (fraud)
	Lied/misled
	Lied/misled - attempted to involve others to authority
	Lied/misled - attempted to involve others to authority
	Misled
	Money Laundering
	Order – breach of
	Practicing without APC
	Practising outside conditions or outside scope of practising certificate
	Practising while suspended from practising
	Practising without a current practising certificate
	Professional Development - failure to comply with requirements
	Title or scope - misrepresentation of

Appendix J – DHSc Research Outputs

1. Preliminary data from this study has been presented at a combined meeting of Responsible Authorities held Monday 19 February 2024