Are Our Medical Harm Reporting Systems Effective?

Are People Safe?

A DISCUSSION DOCUMENT

October 2023

"Safe health care should be seen as a basic human right."

— Global Patient Action Plan 2021-2030, World Health Organization

HEALTH CONSUMER ADVOCACY ALLIANCE
Experts by Experience

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Ki te kotahi te kākaho ka whati, ki te kāpuia, e kore e whati.

Alone we can be vulnerable. Standing together we are unbreakable.

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Preparing a report on harm reporting in Aotearoa New Zealand was not an easy task due to the complexity of our reporting systems, and inability to capture consistent and accurate data from our health entities. This would not have been possible without Jacqueline Morris of FACSNZ and Julie Haggie of TINZ, and we would like to thank them for their contributions; their hard work and the information they provided has been an important factor in the development of this document.

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We wish to acknowledge all the New Zealanders harmed as a result of unsafe care. This discussion document is one step on the path towards improved reporting of harm and safer health care.

How to read this Discussion Document

This document is divided into two main parts. The main body of the discussion document, followed by the appendices that provide *vital supporting evidence* critical for understanding the information in the main body, especially for the case studies.

In the document there are both internal (intra-document) links, which are red; and external links, which are blue.

Foreword

This report is not just about data and statistics, and clinical responses. It is about humanising the harm. People are not just numbers. You cannot – and should not – separate the human factor from the cold, hard data. Behind every number is a person.

What do medically harmed New Zealanders wish for the most?

The most common answer is they want acknowledgement, and for no one else to experience the same trauma, the same harm, and the loss that they have experienced. Their biggest hope is for meaningful change; and to not feel like a lost statistic.

It is one thing to be able to detect harm in our health sector, but responsible health authorities must also take swift action when serious issues have been identified. Responsible health entities should be doing everything possible to ensure that medical harm is stopped. This is why Risk of Harm (ROH) and Severity Assessment Code (SAC) reporting is so important. It acknowledges the significance of harm and demonstrates the need for safer practice.

Our four co-founders have all experienced significant harm in our health system. Every day we are in touch with New Zealanders from all walks of life who have also been harmed when seeking treatment. Although we focus on two case studies in this discussion document, there is ongoing and repeated harm inflicted upon many New Zealanders across the health system in many disciplines. This must stop.

Our Fetal Anticonvulsant Syndrome (FACS) and surgical mesh harmed communities are brave, but have endured so much. The harm that they have experienced is being repeated over and over again; the devastation continues. This harm has not only destroyed the lives of the people who have suffered significant injury, but it has severely impacted on their families, whānau, their friends, and most importantly their children.

When the childbearing person thinks about their legacy, they never think they could possibly harm a future generation because of the harm that was caused to their own children. This harm flows on to their grandchildren if grandchildren are even possible. The compounding intergenerational harm is unacceptable. When you think of the deaths caused by exposure to anti-seizure medicines *in utero*, these babies are not being acknowledged in the way they deserve, and this is beyond heart-breaking. The reality is, for those of us affected, we will never know what our amazing children would have been capable of. This is magnified by the fact that ACC's Loss of Potential Earning pays them only 80% of minimum wage, assuming they would have never been capable of any job greater than minimum wage; that they would never have amounted to anything more than that.

The plethora of reports about ongoing surgical mesh harm are alarming; so many lives have been totally ruined. How has this devastation been allowed to continue for so long? Mesh injured people go on to watch others fall victim to the same harm, powerless to do anything about it. In 2019, the Restorative Justice Process[1] was open to *ALL* mesh sufferers, to hear about their lived experience; this included all New Zealanders harmed by surgical mesh and their whānau who have also been deeply affected. Many health professionals and relevant health agencies who attended the Listening Circles[2] described the stories as "harrowing"[3]. Despite hearing and acknowledging the harm, it took many years for action to be taken to stop it. A 'pause' on mesh procedures was announced in August 2023 following a petition by Sally Walker.[4] Sadly, health entities minimised this action in their

subsequent media comms, inferring the pause would only be for a "number of months' and lifted after four set 'criteria' were met.[5, 6] Although the Restorative Justice Process was inclusive of all those suffering mesh harm, a new female pelvic mesh specialist service being created to help those suffering mesh harm excludes some New Zealanders, including women suffering harm from rectopexy procedures and men harmed by hernia repairs. These people feel totally forgotten, and have been told that they are not within the scope of current actions taken to address harm and are on the 'to do next' list.

Too many people have been harmed or have died due to intractable systemic failures that have not been properly addressed for decades. Robust harm reporting systems ensure that patients are kept safe. However, there is no evidence at all that patient harm is being identified and successfully monitored, with explicit action taken to stop harm when it occurs and to prevent further harm. While some medical harm is being reported there is no consistency in what is being reported, and these reports seem to disappear into the ether, with no transparency regarding follow-up and action. This is exacerbated by a failure of all health entities to identify and track practitioners who are repeat offenders in causing harm to multiple patients. No-one in Aotearoa New Zealand is competently tracking individual practitioner harm.

Multiple health entities talk about working together to make improvements to our harm reporting systems; however, actions to date fall well short of what needs to be done to ensure the public are safe. Incredibly, there is no one with the legislative mandate or enforcement power over the private health sector; there is no doubt that this is perilous. How, in 2023, can this still be a problem? Our health system is meant to protect us but, upon delving into our harm reporting systems, we found the exact opposite – our health system is actually enabling this harm. Not one health entity can confidently say they are doing a good job of protecting our people. Where is the scrutiny, where is the accountability, where is the transparency?

New Zealanders need to know that our health entities will act and do whatever they need to do to ensure we are safe in the hands of our health professionals. Cherry picking individual health issues to focus on without enacting transformative change across the entire system, is just tinkering around the edges; the flaws go beyond individual health issues. Fix the systems, scrutinise the selected measures of reporting, and we can address multiple health issues. We don't need more talk; we need action! We need patient safety to be taken more seriously.

The impact of unsafe care cannot be underestimated, it affects all New Zealanders receiving and providing treatment in Aotearoa. Please read this discussion document and consider 'how can we collectively make the change that is needed, work together, take shared responsibility and ownership to proactively prevent harm?'

Ngā manaakitanga

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The Health Consumer Advocacy Alliance
Experts by Experience

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Executive Summary

Serious harm in both the private and public sectors of our health system is enabled though failures in competency, governance, independence, accountability, transparency, and integrity within and between health entities and organisations. The case studies presented in this discussion document – surgical mesh procedures and anti-seizure medicine(s) *in utero* – represent just a fraction of the harm and life-long devastation caused to New Zealanders by medicines, devices, procedures, individual practitioners, health system culture and institutional providers; but they illustrate the enormity, complexity and severity of the problem of serious medical harm.

The lack of reporting of adverse events is negatively impacting not just consumers and future generations, but also clinicians who are left 'picking up the pieces'. Reporting of adverse events is not mandatory, and the heavy reliance and onus on health professionals is not working. The definition of a "Risk of Harm" event is subjective and what is being reported doesn't reflect the significant harm that is occurring in many cases.

Our case studies of serious harm from surgical mesh and anti-seizure medicines *in utero* highlight that there is limited evidence of co-ordination of harm reporting between health entities. If this is the case for serious harm caused by just two medical treatments, it is not hard to imagine the breadth of harm and the failures across our entire health system.

What evidence is there that shows anyone is effectively monitoring or successfully addressing practitioner competency? Few New Zealand registers track patient outcomes effectively, if at all. Potential competency reviews, authorisation decisions and education are hamstrung because learnings are not available to medical practitioners from the available harm reporting processes. The roles and responsibilities of all health entities to establish effective prevention strategies need to be more clearly defined with transparency a priority.

1. Our case studies show that there is no accurate data on mesh injuries and *in utero* harm from anti-seizure medicine. Repeat medical harm in Aotearoa New Zealand is extremely difficult to identify owing to poor reporting system processes.
2. Our health entities should all be collecting data and monitoring repeat harm caused by individual practitioners, but they aren't. This needs to change, urgently. Collecting 'themed' data is not enough; all health entities should be tracking, monitoring and reporting harm caused by individual practitioners.
3. Our health system relies heavily on health consumers to report harm to both HDC and ACC, or CARM (a system that was never designed to capture fetal harm), and health practitioners rarely report harm or even disclose harm to the patient.
4. Not all health practitioners are fully protected under the new and improved Protected Disclosures Act 2022, so cannot raise the alarm on 'red flag' health professionals without being identified. "The Medical Council or HDC would have a high threshold to meet before being able to identify disclosers, and identification must be essential for the investigation to be effective, meaning there is no alternative. However, a surgeon is unlikely to be protected under the Act when reporting harm caused by a colleague at a different hospital, even if they have reasonable grounds to believe the serious wrongdoing occurred" (see page 40).
5. When considering the surgical mesh and anti-seizure medication harm ROH notifications that have been made in the last decade, it is clear that large numbers of reports have not been made. It may be that health professionals have insufficient knowledge about how to make a Risk of Harm notification, and therefore don't do it.

6. Health practitioners rely on relevant entities to collect and report this data. However, ACC can only collect data from claims lodged, and if a serious harm incident is not lodged as an ACC claim, ACC has no data on the incident so it cannot be notified.
7. Post-marketing surveillance systems are flawed, under-regulated, passive and antiquated.
8. Individual practitioner harm caused through a lack of informed consent is not being identified or reported, even when it is known to be caused by repeat offenders. The health, accident compensation and disability agencies in Aotearoa New Zealand are failing to monitor or track repeat offenders who do not obtain ***informed*** consent or discuss choices in potential treatments, despite increasing complaints to the HDC on failures of practitioners to obtain informed consent.
9. Previous correspondence with health entities regarding harm reporting processes specific to mesh use reveals that multiple health agencies state they have been working together for several years to improve their harm reporting processes: adverse events, Severity Assessment Code (SAC) and Risk of Harm notification reporting. Despite claims of process improvements, these are not able to be verified, owing to a complete lack of transparency about the level of harm occurring, and inconsistency and lack of co-ordination between responsible authorities.
10. From official information requests that are included in this report, it is clear that Medsafe, HQSC, HDC and ACC state they are collecting data (grouped into themes), but once reported there is no transparency about the use of the data.
11. There is a systemic lack of accountability for medical practitioners, especially operating in the private sector. We need comprehensive legislation and an effective authority with the ability to **enforce** professional standards of competency or restrict modes of practice. For example, surgical mesh procedures continue unregulated in the private sector.
12. There appears to be no urgency to address and remedy the multiple failures, the inconsistencies and lack of standardisation of reporting between agencies responsible for monitoring and collecting harm data.
13. The purpose of 2023 National Adverse Events Policy from Te Tāhū Hauora (HQSC) is "to encourage national consistency in the way harm is reviewed and reported."[7] The Health Consumer Advocacy Alliance is extremely pleased with the restorative approach and provider education being included in this report. Educating providers on how to report harm is essential. However, providers are only 'encouraged' to use the newly developed harm reporting templates, and although reporting of adverse events is deemed 'expected', it is not mandatory. Once again, lack of transparency is an issue, and public scrutiny of this reporting format is not possible as these reporting templates are not available in the public domain. Without public scrutiny it is difficult to gauge if this new system will be effective, if health professionals will feel safe enough to proactively report harm, and if reporting rates will improve.
14. Despite recent work by the HQSC, it appears that no one agency or person is 'leading the charge' to effect change to protect patients from further preventable medical harm, including addressing the discrepancies in data reporting and monitoring between agencies. We propose the establishment of a National Patient Safety Commissioner who would focus on preventing patient harm by: truly representing and giving weight to the consumer voice; analysing the structure of the health system and the reporting systems and improving the way in which medical harm is reported and acted upon; and providing a "fence at the top of the cliff" that would reduce the incidence of medical injury and harm. A National Patient Safety Commissioner would help reduce the number of complaints to the Health and Disability Commissioner (the ambulance at the bottom of the cliff) and work in tandem with the HDC to effect cultural change within the health system.

Introduction

This discussion document was written with a focus on the eight health entities that have some responsibility for recording, tracking and responding to patient harm:

- Ministry of Health | Manatū Hauora
- Medsafe
- Centre for Adverse Reaction Monitoring (CARM)
- Accident Compensation Corporation (ACC)
- New Zealand Medical Council | Te Kaunihera Rata o Aotearoa
- Te Whatu Ora | Health NZ
- Health Quality Safety Commission (HQSC) | Te Tāhū Hauora
- Health and Disability Commissioner (HDC) | Te Toihau Hauora, Hauātanga

When it comes to risk of harm reporting, these eight agencies work mostly in silos, 'crunching' the data in different ways. Greater clarity is required regarding their roles and responsibilities, and sharing of data.

Patient harm is not taken seriously enough in Aotearoa New Zealand.

The Health Consumer Advocacy Alliance, when reviewing Aotearoa New Zealand's current harm reporting systems, was shocked to find that not one health entity in Aotearoa New Zealand is identifying and tracking individual practitioner harm competently or effectively.

Patient harm costs the individual, their family/whānau and community and it is a significant financial and productivity burden on the entire country. Research both here and internationally has found that medical harm and treatment injury carries a significant burden for individuals and the health system.[8, 9, 10, 11, 12, 13, 14] (see Appendix 3: The Burden of Medical and Treatment Injury on page 38)

It is unconscionable that patient harm is still a significant issue in this country and inconceivable that, with all the technology available in the 21st century, our health entities do not have a more comprehensive approach to addressing it. The current situation is simply unsustainable on multiple levels. "A safety culture is one where there is accountability, but not blame for mistakes, and harm is reviewed and learnt from, in order to improve systems and processes."[13]

Harm caused by surgical mesh procedures and from the use of anti-seizure medicines during pregnancy continues to highlight the deep-rooted systemic flaws at all levels of our health system. The impact of insufficient adverse event/harm reporting processes in this country has contributed to, and enabled, mesh harm to continue for decades, and harm from exposure to anti-seizure medicines *in utero* for over 50 years. It is important to note systemic flaws do not pertain only to surgical mesh harm and fetal anticonvulsant syndrome (FACS); we use these two serious examples as case studies to demonstrate how unsafe our current health system is, and why urgent changes are needed. If we can't get it right for these two serious harm examples, how can we get it right for less serious ones?

The impact of unsafe care cannot be underestimated; it affects all New Zealanders receiving and providing treatment in Aotearoa New Zealand. We have no doubt that individual practitioners,

medical professional bodies, and government agencies believe they are putting consumer safety first. However, there needs to be more transparency and public visibility of the actions taken to measure, review, identify, and address practices that are causing harm.

Aotearoa New Zealand is not alone on this issue. However, despite knowledge of the problem, refusal on the part of authorities and individuals (individually and collectively) to apply rigorous data gathering/monitoring/sharing and review, to fix the problem, makes them culpable.

This discussion document focusses on the lack of systemic competency, and the lack of transparency of monitoring and reporting (individual, inter-agency and public), and how these factors contribute to continued and unacceptable patient harm within the health system.

We present two case studies – harm caused by surgical mesh and anti-seizure medicines *in utero* - to highlight precise examples of under reporting, discrepancies in inter-agency reporting, and the ongoing harm resulting from these deficiencies.

In light of the current health reforms in Aotearoa New Zealand, now is the perfect opportunity to analyse, reflect and reconsider what needs to be done to ensure patient safety, and ascertain how our health entities are addressing these embedded flaws. Drawing out key themes from both examples, we illustrate the wider systemic failures and changes that need to occur.

Agencies Responsible for Collecting Patient Safety Harm Data

A number of agencies claim to take responsibility for patient/consumer safety, including those responsible for collecting data on, monitoring and responding to/reporting on adverse events and patient harm that occurs in the health system.

The following agencies describe their roles and responsibilities as presented below. Are these agencies living up to their claims?

Health Agency	Roles and responsibilities as described by the agency
Ministry of Health | Manatū Hauora	Regulation of the health and disability system is required to ensure that health service providers and products are safe, and that providers operate in an ethically acceptable way.[15] The Ministry has a key role in administering, implementing and enforcing legislation and regulations. Through this work it seeks to improve and manage sector regulation so that patient health is protected while minimising compliance costs.[15]
Medsafe	To enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit. It currently regulates the use of medical devices. It collects adverse event data on medical devices in retrospect. The most recent surgical mesh report is for data collected up to June 2019.[16]

Centre for Adverse Reaction Monitoring	The CARM database provides New Zealand-specific information on adverse reactions to medicines and vaccines. CARM monitors and analyses the database for the identification of new signals, or important patterns, clusters or unusual events or practices that could have significance for medicine safety and prescribing practices in New Zealand. These findings are considered by Medsafe and/or the Medicines Adverse Reactions Committee (MARC). This may result in further investigation and/or formal review which can lead to emphasising or changing relevant prescribing advice or other regulatory actions aimed at ensuring the safety of medicines registered in NZ.[17]
Accident Compensation Corporation (ACC)	Receives and responds to claims of harm and gathers data on Risk of Harm notifications.[18] Under Section 284 of the Accident Compensation Act 2001[19], if ACC believes from information gathered in the course of processing a claim that there is a risk of harm to the public, ACC must report the risk. ACC's assessment of the risk of harm is based on the MoH Severity Assessment Code (SAC).
New Zealand Medical Council	Role is to protect the health and safety of patients by ensuring doctors are competent and fit to practice. The Health Practitioners Competence Assurance Act 2003 is the legislation that defines Council's responsibilities and powers. Health Practitioners Competence Assurance Act 2003 No 48 (as at 01 July 2022), Public Act Contents – New Zealand Legislation.[20]
Te Whatu Ora	Is responsible for improving services and outcomes across the health system and working in partnership with Te Aka Whai Ora. Te Whatu Ora manages all health services, including hospital and specialist services, and primary and community care.[21]
Health Quality Safety Commission (HQSC) | Te Tāhū Hauora	Role is to promote a nationally consistent approach to reporting, reviewing, and learning. Their 2023 National Adverse Events Policy[22] sets out local organisational roles and the Commission's national role in reporting, reviewing, and learning from adverse events.
Health & Disability Commissioner (HDC) | Te Toihau Hauora, Hauātanga	Is an independent watchdog, providing people using health and disability services with a voice, resolving complaints, and holding providers to account for improving their practices at an individual and system-wide level.[23]

With these eight agencies claiming to have some responsibility for either collecting and monitoring patient harm data, or patient safety, where is it all going wrong?

It is important to re-emphasise that reporting of adverse events is not mandatory in Aotearoa New Zealand, all reporting systems are passive, and there is no comprehensive and centralised means by which patient safety data is collected and monitored or can be queried. Each agency "crunches" the raw data in different ways, so comparing data from different agencies is impossible.

There are serious inconsistencies in data collected and what is available from different agencies on the same medical harm, notwithstanding that not all harmed consumers lodge complaints with HDC or are aware of their right to lodge claims with ACC. Similarly, consumers often don't know they can

report adverse events and medical injury to CARM and Medsafe. An example of the incomplete data sets can be seen in the responses to Auckland Women's Health Council OIA requests (2022) for information from ACC, HDC and MoH/Medsafe on reports of harm from endometrial ablation; the data held by each agency was vastly different. ACC had received 61 claims to the 30th of June 2021 (47 claims were accepted and 14 were declined) with a total of over $1.2 million paid out.[24] The HDC found 9 complaints from the 1st of January 2012 to the date of the OIA.[25] The MoH responded that it "does not hold reports relating to endometrial ablation… and there are no grounds for believing [the information] is held by another agency,"[26] even though a medical device is used for the procedure.

It is extremely difficult for health agencies or the public to obtain relevant data or any information from private sector practitioners and organisations. The private sector does not report procedural data to the NMDS (National Data Monitoring System) and rarely report harm.

> *"The evidence is incontrovertible—we are inadvertently harming an unacceptable number of our patients by the very healthcare intended to help them."*
>
> *— Mary Seddon and Alan Merry* [8]

There is a focus and reliance on ACC data to substantiate rates of medical harm and treatment injury. However, ACC data is an inconsistent and incomplete data set. ACC has said that it engages with relevant health entities to share information and data with authorities for treatment and patient safety. The harm reporting process was looked at in 2012, but in reality, in over a decade, nothing has changed.

> *"From a public viewpoint, it is inconceivable that a statutory claims agency could sit on information indicating a risk of harm to patients from an individual practitioner, without bringing the matter to the attention of the relevant registration board".*
>
> *"ACC has made relatively few reports to registration boards under the mandatory risk reporting provisions. Comparative information at individual practitioner level is not available. Even at service level, hospitals and district health boards do not receive detailed information comparing their treatment injury rate for particular procedures compared with other hospitals or boards. The high hopes that ACC "treatment injury" data would be a catalyst for patient safety improvements appear not to have been fully realized".*
>
> *— Ron Paterson 2012*[27]

Case Studies

Case Study One: Surgical Mesh

(see also Appendix 1 on page 24)

The Historical Context

Surgical mesh was first used for hernia repairs in the 1960s, then in the 1990s mesh was adopted in Aotearoa New Zealand for pelvic organ prolapse, stress urinary incontinence and rectopexy procedures. Patients began experiencing severe complications, and over time, increasing reports of significant complications began to surface. Surgical mesh devices have caused significant injury and irreversible harm to thousands of patients worldwide. In response, patient advocacy groups around the world sought justice and started to voice their concerns and seek accountability for the harm caused.[28]

Inadequate regulatory processes globally resulted in surgical mesh implants being marketed and sold without undergoing rigorous premarket testing, thorough clinical evaluation, or having met stringent safety and efficacy standards. Key findings from multiple international lawsuits show that mesh manufacturers knew well before market launch of each product, that they were aware of the risks associated with surgical mesh devices, but they did not disclose this.[29, 30]

The surgical mesh issue is extremely complex and multifactorial. A more comprehensive history and timeline (pages 25 and 31) that covers significant events and actions taken to address the mesh issue globally and in Aotearoa New Zealand is provided in Appendix One starting on page 24.

In Aotearoa New Zealand, Medsafe substantially relies on the decisions made by overseas regulatory bodies. While some post-market action can be taken when safety issues become apparent, Aotearoa New Zealand does not have a nationally based premarket assessment and approval process.[28] In future the newly passed Therapeutics Products Act will enable our yet to be established Therapeutic Products Regulator to regulate how products are manufactured, tested, imported, promoted, supplied, and exported.[31] However, the Health Consumer Advocacy Alliance are extremely worried about the transitional provisions in the bill, which stipulate a six and a half year wait before sponsors of implantable medical devices are held accountable for the lack of safety of their products. This includes medical devices already known for, and identified as, causing significant harm.

Medsafe has faced strong criticism for their inadequate pre- and post-market surveillance process and their inability to effectively regulate medical devices that enter the market. While there is criticism of the FDA's rapid implementation of vaginal mesh into the market (see page 24), the FDA did issue warnings concerning the safety of the products. Medsafe should have responded to the safety warnings made by the same regulators they relied upon when approving the products used in New Zealand.[28]

Despite a Parliamentary petition in 2014 asking for a formal inquiry to be undertaken into mesh use in Aotearoa New Zealand (see page 25), and to bring an end to the harm being caused, there had been no acknowledgement from the medical sector that mesh surgery was causing any issues, even though there was a significant body of evidence internationally documenting concerns from both the medical community, regulatory bodies, and patients.

Since then, mesh surgery has been under significant scrutiny and several countries have removed some surgical mesh devices from the market. In England, surgical mesh procedures for pelvic organ prolapse and stress urinary incontinence repairs were suspended, and in Scotland there has been a permanent suspension of the same mesh procedures.

The surgical mesh situation illustrates the failure of many in the medical community to understand the outcomes of care provided to patients, or the severe trauma and harm that has been experienced. "When patients are at their most vulnerable, to feel their experiences are at best being downplayed and at worst disbelieved by the health professionals who are caring for them, is hugely concerning"[32]. The ongoing dismissal of patient concerns and downplaying of the risks associated with mesh procedures is apparent even after the Restorative Justice Process undertaken by the Ministry of Health in 2019, in which the lived experience of mesh harmed New Zealanders were listened to and subsequently reported on.[3]

Despite an increased global awareness of this crisis over decades, there has been limited progress in Aotearoa New Zealand on developing a data system to track mesh related surgery prospectively or retrospectively. Improving the regulatory aspects of medical device surveillance is important, but there is also "an imperative to develop robust prospective data monitoring of all surgical interventions."[33]

Patients should be identified, contacted and closely monitored when "red flags" on particular therapeutic products or concerns about specific procedures have been raised. Aotearoa New Zealand must follow the lead of other countries where comprehensive registries that obtain quality outcome measures have been established.

The recently published Medical Device Outcome Registry platform (MDOR) in the UK is a good example of a comprehensive database. This register will "capture data on over two million medical device procedures and more than 10 million unique devices used on patients each year across the NHS and independent healthcare sector."[34] MDOR will use "the data to actively detect, predict and prevent patient harm, and improve outcomes for patients".[33] New Zealanders deserve to have similar robust tracking and monitoring systems, and patient safety should supersede financial constraints.

General Harm Reporting Systems – Surgical Mesh Adverse Events

At which point is the harm reporting system failing?

Evidence of ongoing and repeated harm demonstrates that the harm reporting system is failing. There is a lack of transparency and lack of accountability, and a lack of clear lines of responsibility and communication (see page 26).

The ongoing increase in mesh claims "should have acted as a catalyst for ACC to comply with their statutory obligation under section 284, yet their failure to adequately warn of and communicate with other responsible bodies about the increasing trend of mesh-harmed patients has led to the crisis escalating."[28]

In 2017, the Ministry of Health stated that ACC and Medsafe would improve and streamline their surgical mesh adverse event reporting.[35] This was a positive step and for a while it seemed that the reporting process between these two agencies had been improved. Both ACC and Medsafe claim improvements have been made to their combined reporting processes.

However, recent correspondence from an OIA request reveals that data no longer marries (see page 27), the reporting processes are once again inadequate, and identification, tracking and monitoring of surgical mesh harm is not occurring.

How is this possible?

Medsafe blames ACC for this data discrepancy — but what has been done since to rectify this issue?

Prior to 2019, Medsafe reported individual surgical mesh adverse events in an annual report on their website, and although this report wasn't perfect (as not all adverse events were included in this dataset), it was easy to identify how many reports had been made to the agency. In 2019, the report that Medsafe provided had changed: Medsafe had moved from reporting adverse events on an individual basis, to themed reporting. They have not provided a report since 2019.

Mesh harm is still occurring, rates of injury are still increasing, and our completely inadequate harm reporting processes are ensuring that it does. Information provided to the Surgical Mesh Roundtable (SMRT) shows that surgical mesh claims to ACC have risen significantly, with an increase of **915 new surgical mesh claims in only two years,** from August 2020 to August 2022. Since then, in a new update to the SMRT claims have increased again (new statistics are not publicly available).

While complaints about surgical mesh procedures to the HDC have risen significantly over a similar time period, they substantially trail the numbers of ACC claims lodged (only 35 in the two and a half years to November 2022).

There **must** be a lower threshold for alerting relevant health entities and regulatory authorities when there is evidence of an emerging pattern regarding harmful procedures, and/or unsafe medical care or incompetency. The way ACC report their data makes it difficult for individuals and cross sector agencies to obtain any consistent data from the datasets that ACC provides.

What needs to change in their data capture systems to ensure they can appropriately contribute to preventing further harm? Is the type of data that ACC selects to report on appropriate? If not, what changes should be made to ensure that it is?

The Health Consumer Advocacy Alliance recommends an **independent** body look at what specifically needs to change in ACC's data capture systems to ensure they can appropriately contribute to preventing further harm.

It is imperative the ACC Risk of Harm notification process is looked at more closely (see page 27), yet at the end of that process, after ACC sends out Risk of Harm notifications, it is unclear what happens to the information.

Given that surgical mesh claims are still increasing and the severe nature of surgical mesh injury that has occurred, one would expect a similar increase in Risk of Harm notifications. Yet few RoH notifications have been made, which is concerning.

The reality is health professionals rarely report Risk of Harm events because they rely on ACC and patients to do this.

Health professionals rely on ACC to:

- Identify and report risk of harm (serious injury).
- Identify and report repeated harm that is occurring.

- Identify and report 'red flag' surgeons who repeat the same harm.

The Health Consumer Advocacy Alliance does not believe this current process is effective, or even working at all, especially when one considers recent research undertaken by Drs Eva Fong and Hazel Ecclestone involving 122 women with significant mesh complications. This study analysed the pre- and post-operative process of 76 surgeons across Aotearoa New Zealand.[36] The results of this study showed repeated harm from individual doctors and poor compliance with available standards, quality indicators and guidelines for preoperative and post-operative clinical evaluation (see diagrams on page 28). In the majority of these cases a significant departure from acceptable standards was clearly highlighted.

As a safeguarding mechanism, the Medical Council of New Zealand | Te Kaunihera Rata O Aotearoa are supposed to take action to hold doctors accountable for their actions. Consumers rely on the Medical Council to uphold its regulatory role as an independent body. The Medical Council failed to uphold their protectionist function when surgeons who did not meet the Australasian credentialing standard performed procedures in Aotearoa New Zealand. Legally the Medical Council did not possess the power to stop the procedures from happening, yet they should have ensured that the surgeons completing the procedure were, in fact, adequately trained and competent to do so.[28]

From information gained under the OIA (see page 29), ACC confirms that it "does not identify repeat offenders or collect adverse event/harm data on individual practitioners." ACC also relies on External Clinical Adviser reports to determine when RoH notifications are made.

There needs to be more transparency about what is being collected by ACC regarding surgical mesh harm. ACC say they are monitoring the surgical mesh issue, but also confirm that they are not collecting data on individuals who are causing repeat harm.

Interagency RoH Harm Reporting: a closer look at the ACC surgical mesh RoH notification process

Public awareness of how the Risk of Harm process works is limited. There is scant information from relevant health entities regarding whether the system is effective, so it is difficult to determine what improvements have been made, if any. The Health Consumer Advocacy Alliance believes more scrutiny needs to be applied to determine the robustness of existing harm reporting processes, both from the public and health entities themselves.

ACC Surgical Mesh RoH Data Reporting to Medsafe and the Ministry of Health

ACC has said that it engages with relevant health entities to share information and data with authorities for treatment and patient safety.

On several occasions (during ongoing correspondence between ACC and Charlotte Korte) ACC has stated that they have streamlined and 'improved' their RoH reporting process with Medsafe in 2017, and again "refreshed" their surgical mesh adverse event reporting process after meeting and working with all relevant health stakeholders from 2020-2022.

ACC Surgical Mesh RoH Data Reporting to HQSC

Information obtained from HQSC via email to Charlotte Korte (31st Jan 2023) during the same period was much worse; only one report was made (page 29).

The Health Consumer Advocacy Alliance would like to see more transparency about what improvements have been made to this process, and question why ACC Risk of Harm notifications for surgical mesh harm have reduced significantly over the last decade.

If there were 915 new surgical mesh claims reported by ACC over two-year period to August 2022, which did include serious adverse events and significant harm, why is this not reflected in the RoH data provided by ACC (see table below). With so many claims, regardless of whether these were historical, why were there so few Risk of Harm notifications?

What, if anything, did ACC do as part of their monitoring processes to address the discrepancies between higher claim numbers and extraordinarily low RoH notifications to the MoH and Medsafe? If all health entities are working together to enhance reporting systems, why were other agencies not contacting ACC to make them aware of this and taking steps together to remedy the problem?

ACC believes that the *"2019/2020 "refresh of our risk of harm reporting policy ensured we provide our partner organizations with the right information when we report a risk of harm to them."* However, this is not evident in the table supplied by them.

Table 1: Risk of harm notifications under section 284 of AC Act by authority

Year	Ministry of Health	Medsafe
2013/14	<4	<4
2014/15	29	29
2015/16	34	33
2016/17	10	6
2017/18	5	5
2018/19	-	-
2019/20	-	-
2020/21	-	-
2021/22	<4	<4

Note: no other responsible authorities have been identified for notification of risk of harm for cases relating to surgical mesh.

Source: ACC OIA Ref GOV 007232

From the ACC data above:

	ACC to Medafe	ACC to Min of Health
2017/18	5	5
2021/22	<4	<4

The data supplied by ACC for the years 2018/19 to 2020/21 is inadequate; there is no explanation for the lack of data in those years, even though surgical mesh claims were increasing, as were complaints to the HDC.

Over the Last Decade, What Has Improved?

Transparency International NZ sent an OIA request to ACC regarding the surgical mesh Risk of Harm Notification reporting process to see how comprehensive it was; to determine how effective it was, and to gain clarity on what improvements had been made.

In their 14th of November 2022 response to the TINZ OIA request (see page 30), ACC did not identify:

- any specific improvements made to their RoH reporting process;
- any positive impacts from these changes;

other than:

> *"Following the refresh of ACC's risk of harm policy in March 2020, we have routinely reported all surgical mesh claims under Section 2019/20, including a retrospective notification covering all claims received by ACC…."*

In October 2020, ACC said (ref GOV- 007232):

> *"ACC is currently working with key health agencies, for example Ministry of Health, Health & Disability Commissioner, regulatory and professional health bodies, medical indemnity insurers, and clinicians to update the Risk of Harm reporting process."*

ACC had previously declared they would report all surgical mesh claims, not just serious and sentinel events to Medsafe in 2017, so it begs the question "what updates or improvements did ACC make to the RoH process in 2020?"

There is no transparency regarding what improvements have been made to the RoH process by any health entities of Aotearoa New Zealand!

Our regulators have failed to act to protect patients from harm (page 30):

"Ultimately, the question of why New Zealand regulators failed to act to protect patients from harm has proven to be multi-faceted. When mesh was introduced to New Zealand, they did not practice robust protectionist measures from the medical device regulators to the practitioner regulators. Regulators responsible for acting as a check and balance against each other, such as Medsafe, the Medical Council, ACC and HDC, did not hold each other accountable in the interest of patient safety."[28]

Case Study Two: Fetal Anticonvulsant Syndrome (FACS)

(see also Appendix 2: Additional Information and Context for the Fetal Anticonvulsant Syndrome Case Study on page 33)

Overseas, exposure to sodium valproate *in utero* has been named as the new thalidomide, with the Hon. Prof Peter Turnpenny, Clinical Geneticist, University Exeter, stating "Everyone knows about thalidomide but awareness of fetal valproate syndrome is very poor despite it being a far bigger problem."

Historical Information

Throughout the 1960s, 70s and 80s, a number of case reports were published in the medical and scientific literature, which described children who had been exposed to one or more anti-convulsant drugs and had one or more major birth defects. These case reports described children who had been born with a range of defects, including spina bifida, cleft palate, heart defects and limb malformations. Some of the children in these case reports were also reported to have what was then labelled as

'mental retardation' (now referred to as intellectual disability), neurodevelopmental delay or a learning disability, while others were too young for such conditions to be diagnosed. Congenital malformations occur for a number of reasons and individual case reports are not enough to show that the malformation in that child was likely to have been caused by the exposure in the womb to the anticonvulsant/anti-seizure medicine. However, when a number of case reports detailed the same type of malformation in the children, this indicated that closer investigation was required, particularly when the research in 2013 showed cause for concern due to the growing numbers of children with neurodevelopmental difficulties and diagnoses of Autistic Spectrum Disorders where the mother had taken valproate during the pregnancy.

Very recently (May 2023) Medsafe issued an alert on "Sodium valproate (Epilim) use in people who can father children..."[37] stating that there is "...a potential risk of neurodevelopmental disorders in children whose fathers were treated with Epilim at the time of the child's conception...".

Aotearoa New Zealand had begun to look into anticonvulsants and congenital abnormalities prior to 1968. In a letter written in March 1968 by E.G. McQueen, on behalf of the New Zealand Committee on Adverse Drug Reactions, to Dr D A Cahal in London, McQueen stated: "We have recently had several cases drawn to our attention and there seems reason to believe that these constitute only a small proportion of such cases, the majority probably escaping attention."[38] Little did the author know that seven years after that letter sodium valproate would come into Aotearoa New Zealand and cause so much harm to babies exposed *in utero*.

During this time period in Aotearoa New Zealand, congenital abnormalities and deaths were being reported to the New Zealand Centre for Adverse Reactions Monitoring (CARM), yet what changes occurred?

Sodium valproate is only one of approximately 19 anti-seizure medicines that are available in Aotearoa New Zealand. Currently sodium valproate carries the highest risk to an unborn baby where up to 40% of babies exposed will have developmental delays. In saying this "It is clearly established that anti-seizure/mood stabilising medicines are associated with congenital malformations (such as spina bifida, cleft palate, and heart defects), and cognitive impairment and behavioural difficulties (such as Autism Spectrum Disorder)."[39]

How Has This Occurred?

There are a number of reasons why this situation has arisen:[40]

- Data sheets were not required for medicines until the Medicines Act 1981 came into effect (see page 33).
- Consumer Medicine Information (CMI) sheets not legislated and provide only limited information (see page 33).
- Sodium valproate was removed from Intensified Adverse Drug Reaction Reporting Scheme (see page 33) even though in February 1979 the sponsor, Reckitt, had reported to the Department of Health 6/34 abnormal babies born to mothers taking valproate.
- Multiple reports were dismissed by Department and Ministry of Health and Committees under their jurisdiction (see page 33).
- A delay of two and a half years in getting Prescriber Updates written by Medsafe (see page 34).
- Delays in getting acknowledgement on current issues with medicines (see page 34).

- When advised of issues from other government bodies, such as the Neurological Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC), recommendations were not followed through by Medsafe (see page 35).
- Centre for Adverse Reaction Monitoring (CARM) numbers differ and are not monitored (see page 35). Reported numbers increased by 14 in three years, including five deaths and this did not raise concern.
- Strategies employed to inform women of reproductive potential and ensure informed consent have been limited and not effective (see page 36).
- Epilepsy blamed for problems occurring until 2009 (see page 36).
- Antiepileptic medicines were not closely monitored, even when known to be teratogenic (see page 36).
- Studies that were meant to be done were not done (see page 37).

It is unknown how many babies have been harmed or have died during the time periods covered by the above issues, nor the extent of the devastation inflicted on the families/whānau who are impacted by such injury and death.

CARM Reporting

During the period 1 April 1965 to 31 March 2017 there had been 25 reports to CARM, and five out of the 25 were neonatal deaths in which babies were exposed to sodium valproate *in utero*.[41]

Between 1 April 1965 and 31 December 2019 there had been one neonatal death out of 10 reports to CARM, of exposure to carbamazepine, lamotrigine, or topiramate *in utero*. This death occurred in 1969![42]

On the 12th of August 2022, the Minister of Health, stated "...there have been no reports to the Centre for Adverse Reactions Monitoring of congenital malformations consistent with those described for foetal anticonvulsant syndrome (FACS) for other anti-epileptics thought to cause FACS in the last 10 years..." However, it is clear from the CARM reports that there have been, highlighting inaccurate collection and/or dissemination of information.[43]

CARM was not designed to capture this information and is a passive form of post-marketing surveillance.

ACC/HQSC Failure to Accurately Report

As of 18 February 2023, ACC has accepted 49 out of 69 claims for FACS, a number that is substantially higher than the number of CARM reports.

ACC state "...Of 69 decided treatment injury claims for foetal valproate syndrome, 33 have been reported for a risk of harm. We know that all notifications were sent to the Ministry of Health, the majority to Medsafe and fewer than four have been reported to the Ministry of Health, Medsafe and the Medical Council..."[44]

Why have only 33 out of the 69 treatment injury claims for fetal valproate syndrome been reported for a risk of harm? There is no reason given for this discrepancy, no transparency and no accountability.

In an email from ACC to Denise Astill, FACSNZ, when discussing the Severity Assessment Code, Denise was advised: "Accepted Fetal Valproate claims are now also notified as a Severity Assessment Code (SAC) event to the Health Quality and Safety Commission. These notifications are non-identifiable." Yet the Health Quality and Safety Commission state "…Following a search of our adverse events database we do not have a record of any SAC events for Foetal Anti-convulsant Syndrome (FACS) reported to HQSC…"[45] (see page 37)

The question remains, why did ACC only start to report SACs from 2020, when the first known ACC claim for FACS was back in 2008? Who is defining what is a SAC and risk of harm event?

"We must exercise vigilance to make sure that adverse events are never reduced to numbers and that we listen to consumers and whānau during the review process. We hold a duty to those who are harmed to listen to their stories, to learn from our mistakes and to work to prevent harm to others."[13]

Minister of Health

The Minister of Health wrote a letter dated 5 April 2022 to Denise Astill that stated "I am writing to acknowledge the concerns you raised in your petition entitled "*Inquiry into the numbers harmed by antiepileptic medicines during pregnancy*"[46]. I apologise for the time it has taken me to respond to you since the Select Committee report. I assure you that all possible measures have been taken since receiving your petition to ensure future harms to pregnant women and their children are minimised.

I am very concerned about the harm that has been brought to my attention due to improper warning of contraindications for pregnant women. This is the result of systemic issues that I am taking very seriously."[47]

The petition went into Parliament in 2018, yet the advice from Government only came out in 2022. During those years we simply do not know how many more babies would have been permanently harmed, given the absence of data reporting.

So, the question remains, how are the "…systemic issues" being taken "…very seriously"?

Manatū Hauora | Ministry of Health/Medsafe

Safer Prescribing and Dispensing hui and workstreams

The Minister of Health stated in a response to a Parliamentary Written Question, that "…Due to the collective responsibility to ensure that the health system is delivering safe and person-centred care there are a number of cross-agency workstreams to progress agreed areas for system improvement. These include exploring standardisation of prescribing competence standards, improving digital platforms for sharing medicines information with health professionals, improving understanding of consumer medicine information needs and appropriate communication channels, workforce integration and, medicines risk of harm intelligence. Furthermore, Manatū Hauora hosts a quarterly forum to share updates and progress on the agreed activities."[48]

"If it is not safe, it is not care"[49] is a quote from Dr Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization, at the Patient Safety, 5th Global Ministerial Summit, 2023, in Montreux, Switzerland. It is also the title of Denise Astill and Jacqueline Morris' report after attending the Summit.

It is notable that there were originally no consumers at all at the first hui or on any of the work-streams. Denise Astill, FACSNZ, had to advocate to get herself, another consumer, and an organisa-

tion included. By the time it was agreed that they could be part of the hui, and the medicines risk of harm workstream only, the designs were already in place, and nothing was able to be changed. Unfortunately, the Code of expectations for health entities' engagement with consumers and whānau/ Te tikanga mō te mahi tahi a ngā hinonga hauora ki ngā kiritaki me ngā whānau, was clearly not being complied with. It was very disappointing that HQSC did not insist that consumers be part of this work right from the beginning. Particularly when the Minister of Health stated in an answer to a written question that "I am advised there is a system-wide work programme coordinated by Manatū Hauora to support safer person-centred prescribing and dispensing of medicines. Work regarding foetal anticonvulsant syndrome and anti-epileptic medicines is reflected in this programme."[48] FACSNZ is concerned that, because consumers were not part of this programme right from the beginning, there will be little or no reduction in the harm that is being caused.

Topiramate

The Minister of Health stated in a response to a Parliamentary Written Question "...Medsafe continues to monitor the safety of all medicines in pregnancy and communicates regularly about new safety information when identified through our international regulatory networks..."[50] However, FACSNZ have found this to be an inaccurate representation as it was FACSNZ who alerted Medsafe in May 2019 that the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK had contraindicated topiramate in pregnancy for migraine use. Additionally, it was FACSNZ who notified Medsafe in July 2022 that MHRA were doing a safety review into topiramate after a study found an increased risk of neurodevelopmental difficulties with exposure to topiramate *in utero*. Medsafe raised an alert about this on 11 April 2023, a year after FACSNZ had raised the neurodevelopmental aspect with Medsafe, and four years after FACSNZ had first raised concerns about topiramate with Medsafe. How much harm has been done during those four years while Medsafe were not following international responses?

Information supplied in response to an OIA request shows that 93 babies were born between 2016 and 2019 whose mothers were dispensed topiramate during pregnancy (see page 37).

Considerations for Addressing Harm Caused by FACS

There have been systemic failures that our FACS community has experienced and is continuing to experience. These systemic failures are causing permanent disability or, sadly in some cases, death, to people in our community. Fetal Anticonvulsant Syndrome has been labelled as the new thalidomide. If we have truly learned anything from the past, then why are the responsible agencies still allowing FACS harm to continue?

Since the introduction of anti-seizure medicines into Aotearoa New Zealand we simply do not know how many babies have been permanently harmed, and how many whānau lives changed forever. There have been many reasons given, but one vital reason remains today: the clinicians and people assessing those harmed state that knowledge of harm from anti-seizure medicines in pregnancy simply wasn't known. This highlights that our wāhine or people of childbearing potential on anti-seizure medicines have never had, and continue to not have informed choice, and cannot provided fully informed consent.

While the wāhine or childbearing person is pregnant, a midwife or Lead Maternity Carer should be collecting all information on *in-utero* teratogenic exposure, such as medicines, alcohol, drugs and inhalants, with dose and duration, which is transferred onto the babies NHI as soon as the baby is born. This ensures that if health concerns arise with the baby as they grow, historical health information is available and relevant factors can be identified. A pregnancy register for the collection

of such data needs to be created as this will proactively reveal trends of potential harm that need to be red flagged earlier, instead of waiting generations for them to be revealed.

The Centre for Adverse Reactions Monitoring (CARM) is the Aotearoa New Zealand database that provides information on adverse reactions to medications and vaccines. It is a purely voluntary reporting system, therefore it has significant inherent limitations. It is a passive post-marketing surveillance system and, for example, was not designed for reporting of adverse medication events for babies exposed *in utero*.

Internationally, some "countries are moving to active post-marketing surveillance. These ...[systems] are designed specifically to use real-world data to generate medication safety information and do not rely on individuals to initiate adverse event reports. The United States FDA Sentinel Initiative is one such programme. It is a national electronic system for monitoring medical products, including medicines, vaccines and medical devices. It gathers information from multiple sources (i.e. eHR systems, administrative data and insurance claim records). The Sentinel programme is now expanding, for example to studying the effects of switching between branded and generic medicines, and to the surveillance of the safety of medical devices. "[49]

Having an agency with a teratogenic department tasked with thorough, accountable and transparent work that identifies appropriate interdisciplinary and cross-sector action is essential. It ensures: a proactive rather than reactive approach; ensures fewer people are harmed; is more economically sound; and early red flags can be brought into workstreams that come from the active post-marketing surveillance. It can also provide a lifelong (if not intergenerational) approach to those already harmed by teratogenic agents, whether it be medicine, device, environmental, drug, or alcohol exposure.

Denise Astill and Jacki Morris from FACSNZ attended the Fifth Global Ministerial Summit on Patient Safety in 2023 which was held in Montreux, Switzerland from 23-24 February, 2023. There were more than 600 participants, with over 80 countries represented (including ministers of health, or their representatives), as well as representatives from the OECD, NGOs, patient groups, tertiary providers and various medical professionals to enable continued dialogue, and to carry the ministers of health's message. Some of the countries in attendance were third world countries, yet Aotearoa New Zealand has never had governmental representatives at this summit. Aotearoa New Zealand has signed up to the Global Patient Safety Action Plan 2021-2030, yet what exactly has been done on the Framework for Action?

It is essential for New Zealand to advance towards zero harm occurring, and the Framework from the Global Patient Safety Action Plan is the way forward.

The Crunch!

There is no doubt that quality incident reporting systems enhance patient safety, and that identifying, acknowledging, and reporting medical errors help to prevent future harm, improve quality of care and future practice. Often preventable errors, even small mistakes, can lead to serious consequences for patients and "reported errors should not be limited to serious reportable and adverse events; rather, they should also include near misses and good catches."[51] When effective reporting systems are not in place, health practitioners are unable to learn from adverse events to ensure they are not repeated.

Critically analysing the complexity of our harm reporting system, rather than perpetuating the "current improvement paradigm" is important. Health agencies and individual practitioners accountable for collecting and reporting medical harm must ensure that that harm is reported in ways that identify future risks. Individual practitioners, agencies (including professional bodies), stakeholders and decision makers must prioritise patient safety over professional and privacy boundaries.

Adverse events in health care occur more often in pressurised health systems and continue when harm is under reported, or in many cases not reported at all. The obstacles that prevent health care professionals from reporting medical errors are well documented internationally. "Common human factors that are barriers to safety event reporting include liability concerns; time constraints; physician autonomy; self-regulation; collegiality; the lack of listening, language training, and/or feedback regarding reported events; unclear responsibilities within safety teams; and a high reporting threshold."[51] Regardless of barriers that hamper harm reporting, in order to ensure patient safety it is imperative to have the systemic infrastructure and mechanisms to identify or quantify safe and unsafe practices, and practitioners. Currently, this is not possible in Aotearoa New Zealand; with our current safety reporting systems, especially at an individual practitioner level, medical harm is extremely difficult to identify.

It is inconceivable that our health authorities and entities continue to state they are monitoring serious issues like surgical mesh and anti-seizure medicinal harm when our harm reporting systems are inadequate at best. "The avoidance of harm to patients should not need financial justification: its importance has been enshrined in healthcare since Hippocrates stressed that we should first do no harm."[52]

Health entities in Aotearoa New Zealand should be applying, and formally requiring, practice standards, yet surgeons and health practitioners continue to repeat harm with only occasional, and often delayed, accountability for the harm caused. Poor safety measures result in health consumers making treatment/care decisions for themselves and their dependents in the absence of informed consent or informed choice. Competency is an equally important issue, where interlinking intransigent approaches hamstring safe care. Efforts to lift professional standards are fundamentally undermined by a lack of legal authority and by entrenched professional views. The problem of surgical mesh harm and fetal anticonvulsant syndrome is so intractable that the Director General of Health should have intervened much earlier, and must now step in to finally stop this devastating harm from continuing.

Aotearoa New Zealand must follow the lead of other countries where comprehensive registries that obtain quality outcome measures have been established, as previously mentioned in this document. Patients should be identified, contacted and monitored when "red flags" on particular therapeutic products or concerns about specific procedures have been raised internationally. Patient safety should supersede financial constraints.

The 2023 Therapeutics Products Act formally requires appropriate monitoring. The new Therapeutic Products Regulator is expected to have in place a post-marketing surveillance and response system. The Regulator will be responsible for carrying out surveillance, and when necessary, respond to safety, quality, efficacy, or performance issues in accordance with the system.

The creation of this new legislation is an opportunity for our health entities to take responsibility and be accountable for enacting system reform that will improve consumer outcomes. Transparency is essential, and the actions taken to improve our patient safety reporting systems must not be hollow gestures. However, consumers should not have to wait for the establishment of the new Regulator to have a safer health system.

To ensure tangible improvements are made, consumers should be involved at every level of the health system and contributing to improving harm reporting systems. The time for 'back-room' meetings without consumer input and little transparency has gone and is not acceptable. Harm information should be shared widely and publicly. Patient safety must be a priority, not demonstrated by words alone, but must be visible in actions. It is time for much more comprehensive scrutiny of our harm reporting systems, to ensure cohesive meaningful data and information is collected and patients are safe.

Absence of evidence is not evidence of absence!

Sir Liam Donaldson, Patient Safety Envoy, WHO, stated at the 5th Global Ministerial Summit on Patient Safety, "We need to acknowledge that no news is not necessarily good news, meaning that just because there aren't adverse effects/harm being reported does not mean it isn't occurring. In fact, we can go further by saying that not only is history repeating itself, but the same harm is happening to different people in different places."[49]

Despite recent work by the HQSC, it appears that no one agency or person is 'leading the charge' to effect change to protect patients from further preventable medical harm, including addressing the discrepancies in data reporting and monitoring between agencies. We propose the establishment of an independent National Patient Safety Commissioner who would focus on preventing patient harm.

A Patient Safety Commissioner would truly represent and give weight to the consumer voice. He or she would analyse both the structure of the health system and the harm/adverse event/medical injury reporting systems and ensure improvement in the way in which medical harm is reported and acted upon, providing a conduit between health agencies – effectively removing the siloing that still occurs today, especially in sharing of reports of harm data – and also between the health system and health consumers.

An independent National Patient Safety Commissioner would act as the "fence at the top of the cliff", over time reducing the incidence of medical injury and harm. They would reduce the number of adverse outcomes, and medical injury and harm complaints to the Health and Disability Commissioner (effectively the ambulance at the bottom of the cliff), freeing up HDC resources to investigate other breaches of patient rights, and work in tandem with the HDC to effect cultural change within the health system.

Returning to our initial questions, are our current medical harm reporting systems effective? Are people safe?

The answer is NO!

We need patient safety reform.

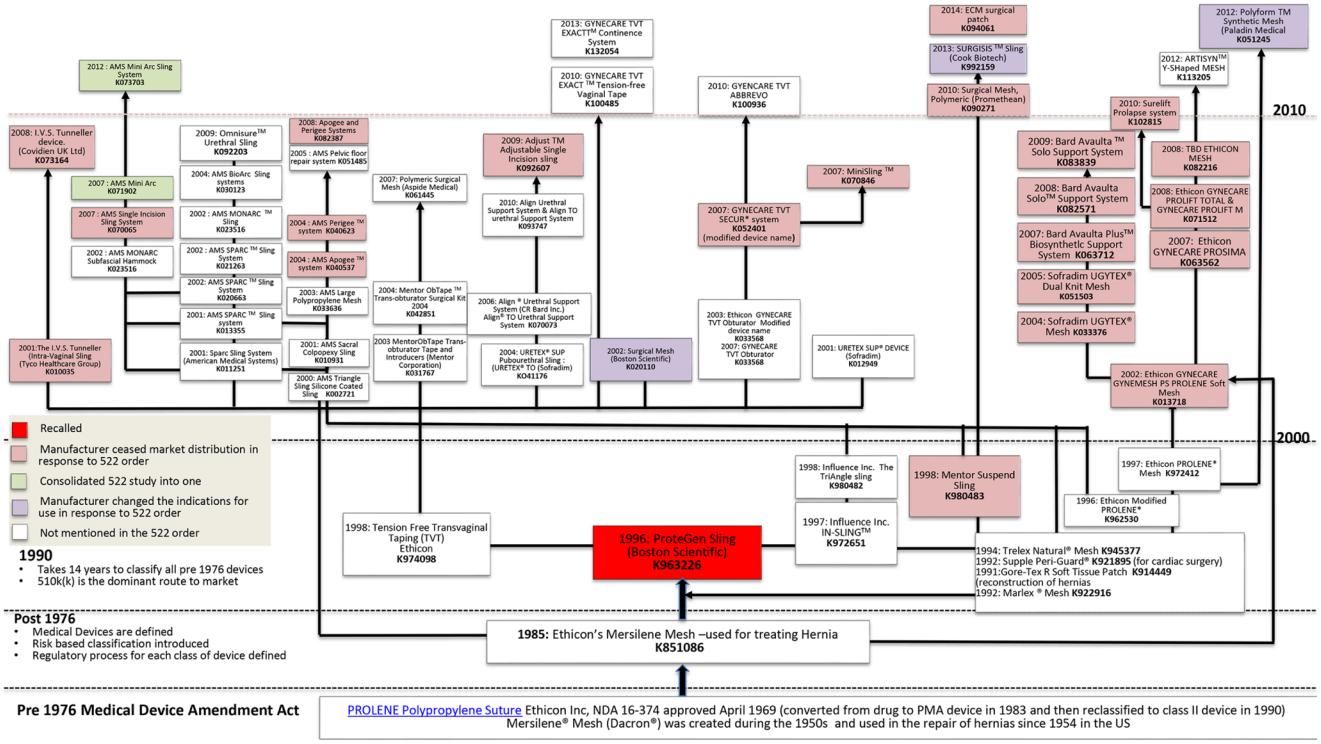
Appendix 1: Additional Information and Context for the Surgical Mesh Case Study

The surgical mesh issue is extremely complex and multifactorial. In order to make clear the extant of the safety issues surrounding the use of surgical mesh in Aotearoa New Zealand and the crisis that arose from the harm caused by mesh, additional information is provided in this appendix. The information provided here is critical to a complete understanding of the surgical mesh case study. However, the broader information is included here to ensure greater clarity for those who have a limited understanding of the mesh issue in their first reading of the case study starting on page 11.

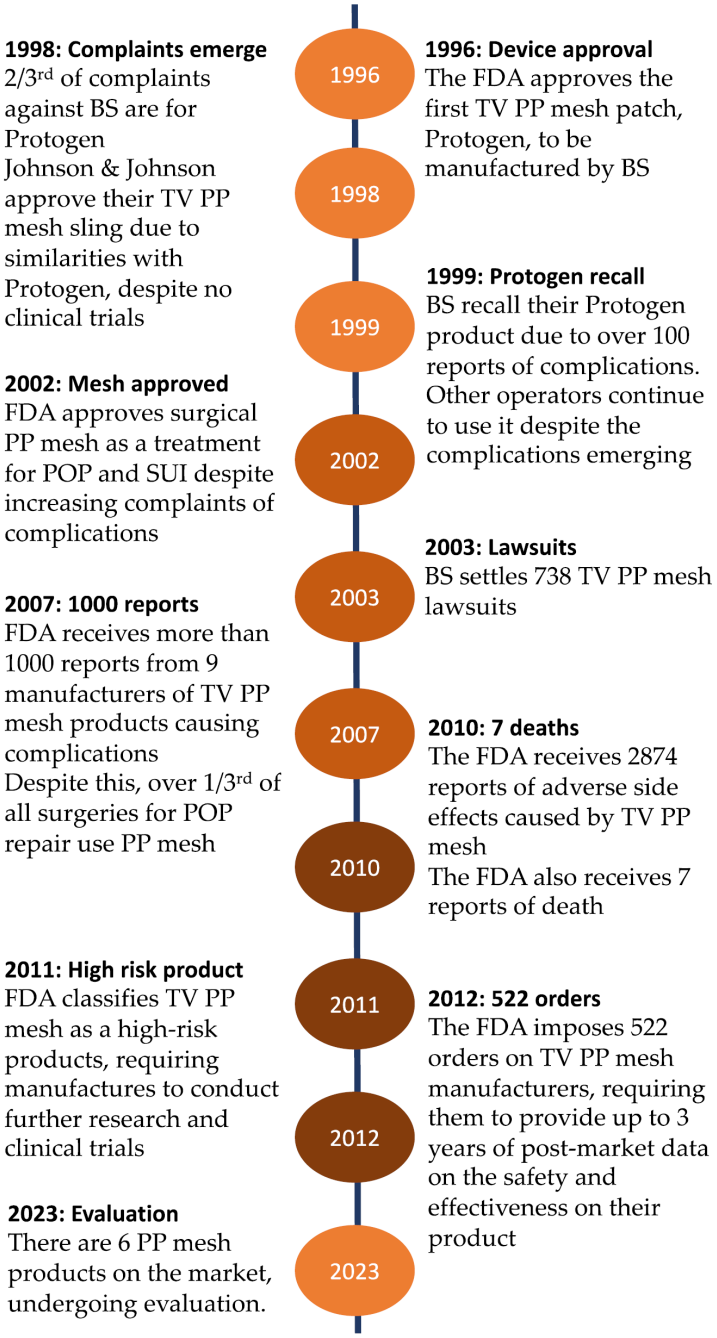
Regulation

Most surgical mesh devices were cleared under the expedited Food and Drug Administration (FDA) 510k process; these devices were approved for market release without any clinical trials to support the device's safety for permanent implantation. The approval process diagram (see below) shows the plethora of mesh devices that were approved on the first predicated device, the Protogen. The Protegen mesh device was recalled by Boston Scientific Ltd in 1999 due to safety concerns, while all other mesh devices based on this predicate device were allowed to stay on the market for sale.

After serious concerns emerged, in 2012 the FDA asked device manufacturers to provide evidence of safety. The brief timeline on page 25 illustrates key dates in the regulation and investigations of PP vaginal mesh.[53]



Food and Drug Administration device chain approval for transvaginal mesh.[54]



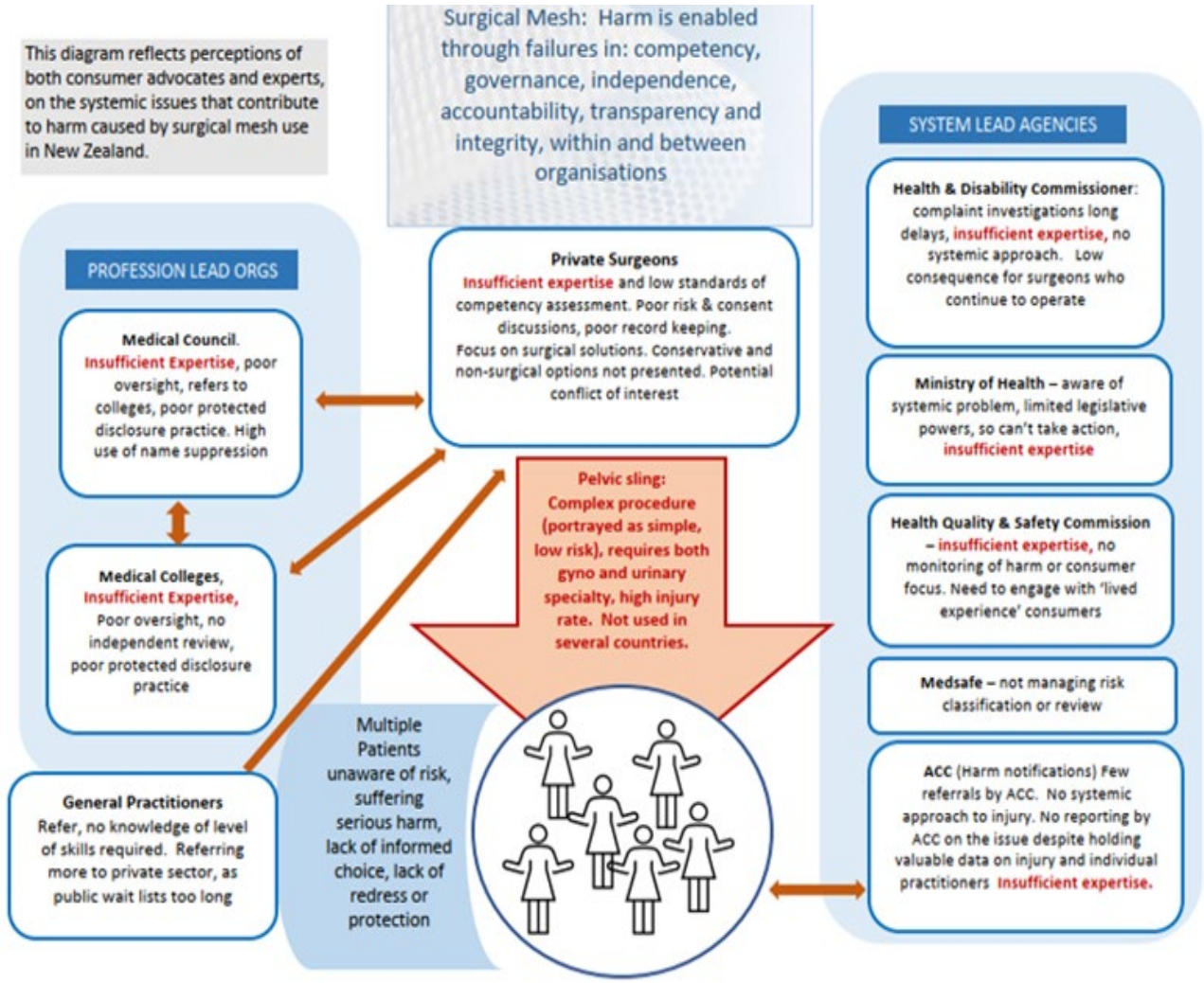
Timeline depicting major events that have taken place since the first introduction of the polypropylene pelvic mesh. Boston Scientific (BS), Polypropylene (PP), transvaginal (TV). (Source: Seifalian A, et al.[53])

Petition to Parliament

A petition was brought before the Government in 2014, asking for a formal inquiry to be undertaken into mesh use in Aotearoa New Zealand, and to bring an end to the harm being caused. This petition did not focus on women only; it included those experiencing harm from hernia repairs, rectopexy procedures, pelvic organ prolapse and stress urinary incontinence surgery. At this stage there was no acknowledgement from the medical sector that mesh surgery and the devices themselves were causing any issues, even though there was a significant body of evidence internationally documenting concerns from the medical community, regulatory bodies, and patients.

At Which Point is the Harm Reporting System Failing?

The systemic issues that contribute to the overall failure are described in the diagram below. However, the diagram below focuses on the systems and processes and the lack of regulation. The underlying product characteristics that contribute to the harm must be addressed; there must be more focus on products that are inherently harmful.



Lack of transparency = Lack of accountability

General Harm Reporting Systems — Surgical Mesh Adverse Events

ACC/ Medsafe adverse event reporting: for a procedure that is meant to improve the health and quality of life of consumers, mesh surgery has caused an excessive rate of severe injury. The ongoing increase in mesh claims "should have acted as a catalyst for ACC to comply with their statutory obligation under section 284, yet their failure to adequately warn and communicate to other responsible bodies about the increasing trend of mesh-harmed patients has led to the crisis escalating."[28]

A statement was published by the Ministry of Health in their 2017 Health Surgical Mesh Update, regarding action taken by ACC and Medsafe to improve and streamline their surgical mesh adverse event reporting.

"Agreement with ACC that additional information is to be supplied from 1 March 2017 in relation to all surgical mesh treatment injury claims received by ACC".

"Information on all treatment injury claims received by ACC has now been supplied to Medsafe and is included in the updated Medsafe Adverse Event Report."

— Implementation of Government Response to Report of the Health Committee on Petition 2011/102[35]

This was a positive step and for a while it seemed that the reporting process between these two agencies had been improved. Both ACC and Medsafe claim improvements have been made to their combined reporting processes. Yet, there is no evidence of this; in fact, their respective surgical mesh data reports still do not match up.

From recent correspondence through the OIA it seems that this data no longer marries, the reporting processes once again are inadequate, and identification, tracking and monitoring of surgical mesh harm is not occurring.

"Since the last Medsafe report was published, the Accident Compensation Corporation (ACC) has been through several restructures. The most recent information provided to Medsafe is now in a different format to that provided earlier and uses different descriptors."

— GOV Ref H2022010669

ACC Risk of Harm (RoH) Reporting Systems: Surgical Mesh

How the Risk of Harm notification process works

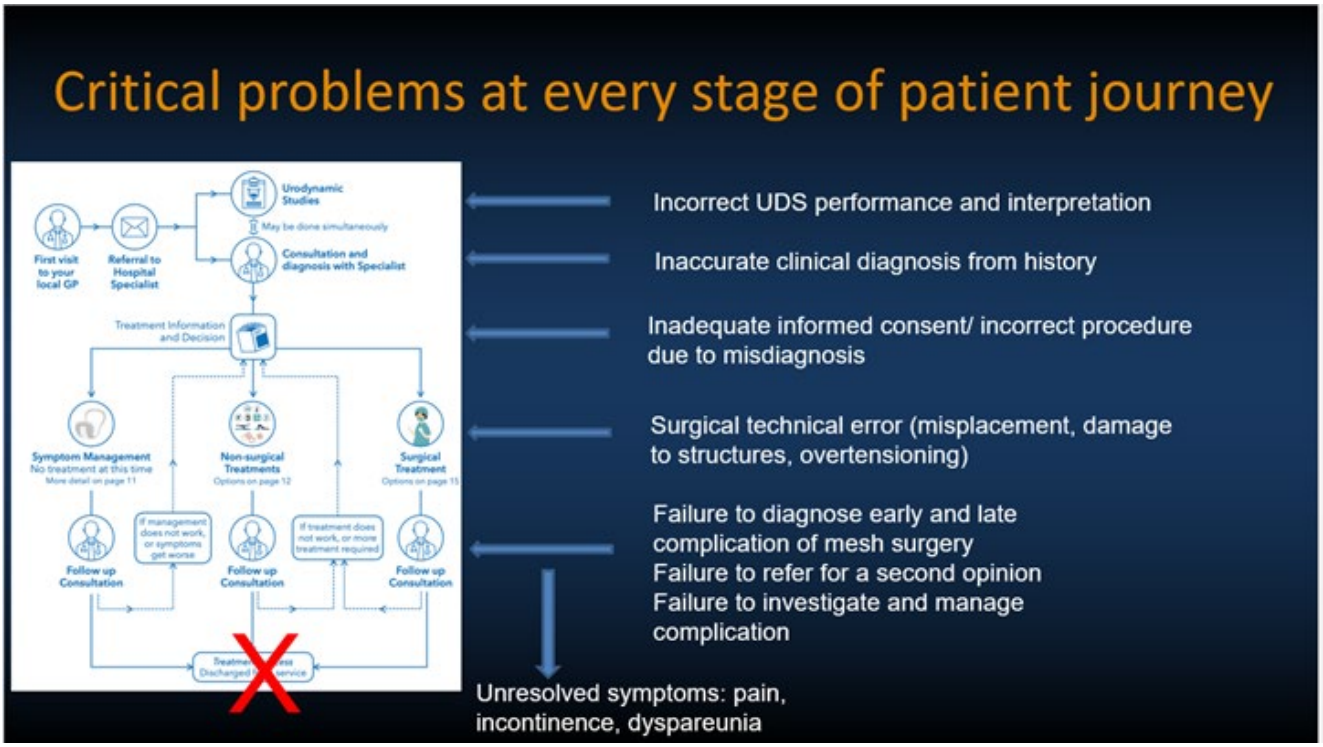
"Under Section 284 of the Accident Compensation Act 2001, if ACC believes from information gathered in the course of processing a claim that there is a risk of harm to the public, ACC must report the risk."[55]

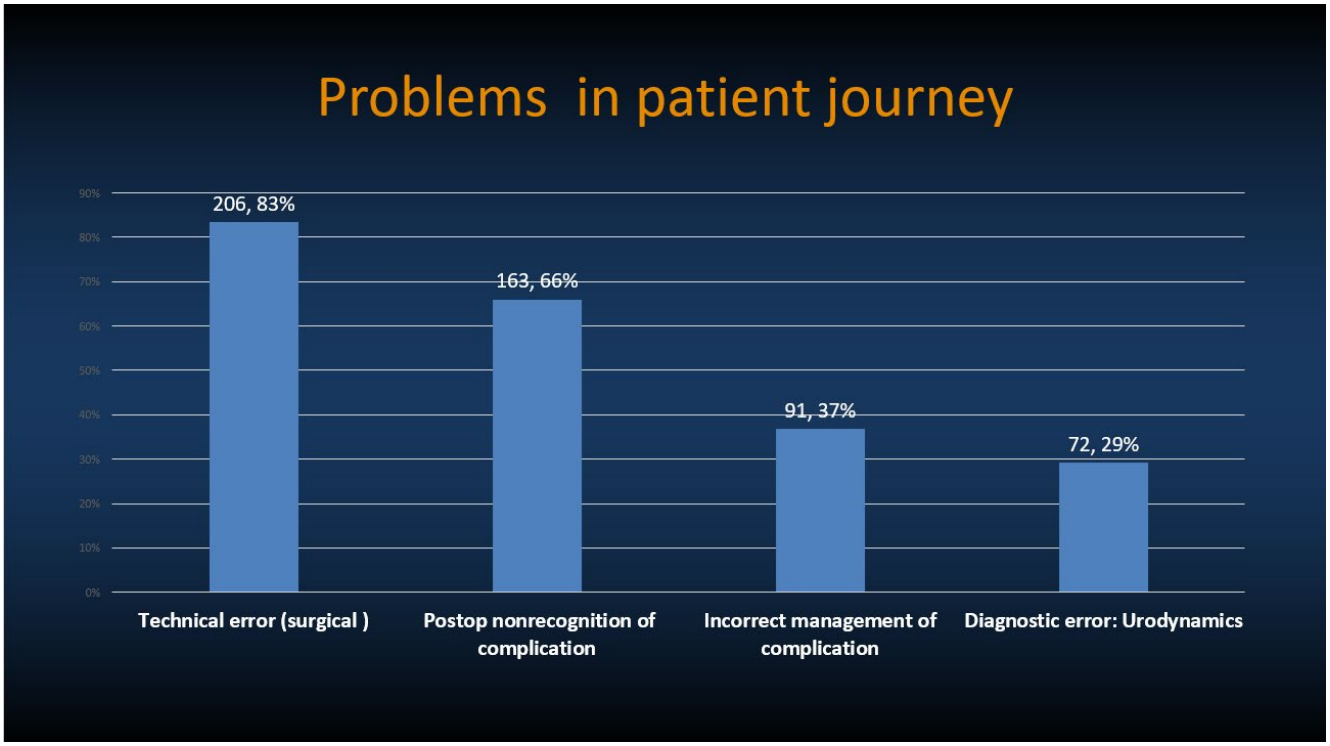
ACC's assessment of the risk of harm is based on the MoH Severity Assessment Code (SAC).

1. Health authorities collect data on serious and fatal injuries that occur during and/or because of treatment from health professionals.
2. ACC is one of the key health agencies that collect data on adverse events.
3. Whenever someone is hurt during their treatment, the injury is classified as a "treatment injury" by ACC. Common treatment injuries include wound infections, and reactions to medication or medication errors.
4. The most serious adverse events receive a "Risk of Harm" notification.
5. A Risk of Harm notification is required because assessment of the treatment injury shows there is potential for the same mistake to occur again and cause injury in someone else (systemic problem).
6. ACC then forwards notifications onto authorities like the Ministry of Health | Manatū Hauora, Director General of Health, and the Medical Council of New Zealand | Te Kaunihera Rata O Aotearoa.
7. After ACC sends out Risk of Harm notifications, it is unclear what happens to the information.

Recent Research by Drs Eva Fong and Hazel Ecclestone

Recent New Zealand research involving 122 women with significant mesh complications was undertaken by Drs Eva Fong and Hazel Ecclestone. This study analysed the pre- and post-operative process of 76 surgeons across Aotearoa New Zealand.[36] The results of this study showed repeated harm from individual doctors and poor compliance with available standards, quality indicators and guidelines for preoperative and post-operative clinical evaluation. In the majority of these cases a significant departure from acceptable standards was clearly highlighted, and this can be seen in the diagrams below:





Recent Information from OIA Requests

From information gained under the OIA (see below), ACC confirms that it "does not identify repeat offenders or collect adverse event/harm data on individual practitioners." ACC also relies on External Clinical Adviser reports to determine when RoH notifications are made.

GOV-007232

How many Risk of Harm Notifications need to be submitted against an individual health professional before they are deemed a 'frequent flier', or investigated further because they are of concern?

ACC manages each notification on an individual basis. The authority responsible looks at notifications against individuals and will have their own processes for managing this. As mentioned above, ACC has no additional process for repeat notifications against providers.

Please confirm the total number of health individuals who have had repeated Risk of Harm notifications made against them that specifically involve Surgical Mesh adverse events and procedures -more than one notification.

Between 1 July 2005 and 9 October 2020, there have been 111 risk of harm notifications related to surgical mesh, sent to the Director General of Health. Of these, fewer than four were notified to the Medical Council of New Zealand (MCNZ). Which organisation/s ACC notifies is considered based on the individual circumstances. An example of when MCNZ might be notified is when an External Clinical Advice report indicates a departure from the expected standards of care.

The notifications made to the Director General of Health do not name specific health professionals, while the notifications made to MCNZ contain the names of specific health professionals but due to the small number of individuals involved (<4), no further information can be provided.

2. *Can you please confirm the total number of Risk of Harm notification reports received from ACC, adverse event SAC reports, and identify the names of any other health entities/authorities you have received adverse event data (SACs) from that specifically relates to surgical mesh harm, dating from 1 July 2013 to 1st Dec 2022.*
    - *Please provide the request (at 2 above) broken down per financial year, from July 2013 to 1st Dec 2022.*
    - *For each year, please include surgery type, as in whether the notification pertains to a POP, SUI, Rectopexy or hernia procedure.*

The Commission has received 1 anonymised event reported in 2019 by Southern DHB that pertains to the use of surgical mesh. This event is not related to the surgeries listed above.

Transparency International NZ OIA Request

In an OIA request (response number OIA GOV-021271) TINZ asked for:

1. The total number of Risk of Harm notifications ACC have reported to relevant authorities relating to surgical mesh harm, from 1 July 2013 to 1st August 2022.
2. Please provide the request at 1 above broken down per financial year (from July 2013 to 1st August 2022).
3. For each year, please include surgery type, as in whether the notification pertains to a POP, SUI, Rectopexy or hernia procedure.
4. For each year, please advise the authorities reported to.
5. Please also provide commentary on the following questions:
   a. Have there been any positive impacts due to policy changes around risk of harm notification process, if so, what?
   b. Is there more that can and/or will be done to improve the risk of harm notification process?
   c. Within the current risk of harm notification reporting process, does ACC identify individual practitioners who have repeat notifications?
   d. Previously ACC have grouped their reporting into themes of harm, as opposed to individual practitioner harm. Has this changed as a result of the improvements made to this process?

Surgical Mesh Crisis: Why have NZ regulators failed to act to protect patients from harm? A paper by Tamarra Al-Azzawi

The summary[28] below succinctly explains how the failure to act to address surgical mesh harm pertains to Aotearoa New Zealand.

Many countries, such as the UK, U.S. and Australia, have been gradually implementing positive changes to prevent harm caused by transvaginal mesh [and also other surgical mesh procedures]. Yet New Zealand is still behind. It has broken many health consumers' trust and confidence due to the accountable bodies omitting to take responsibility for their wrongdoings.

Healthcare system regulatory bodies set up to act as a check and balance to other regulators have collapsed, holding no one accountable. This has been caused by individual regulators failing to uphold their purpose by ignoring clear indications of patient harm. The lack of cross-collaborating between authoritative bodies has collectively enabled harm to continue in New Zealand. Although systematic failures placed patients at risk of harm, the competence of the individual doctors physically operating on patients is a crucial factor that must be questioned.

As a safeguarding mechanism, the medical council were supposed to take action to hold doctors accountable for their actions. Consumers in New Zealand rely on the medical council to uphold its regulatory role as an independent body.

With the clear lack of credentialled surgeons incompetently performing the mesh surgeries, the Medical Council failed to uphold their protectionist function. Legally they did not possess the power to stop the procedures from happening, yet they should have ensured that the surgeons completing the procedure were, in fact, adequately trained and competent to do so. They did not react to concerns about poor performance, as there is no evidence that doctors were questioned or held accountable for being incompetent to conduct the insertion surgeries.

Instead, the Medical Council essentially passed on the responsibility to the HDC. Over the past decade, the accumulation of complaints indicated a risk of harm to the public. Yet the HDC system did not act as the overseer it was trusted to be. The lack of disciplinary action against negligent practitioners dilutes the incentive for practitioners and medical service providers to diligently uphold the consumer rights of mesh-

injured patients. Disappointingly, most actions were vague and could not be quantitatively measured. This did not reassure patients that the relevant agencies would be vigilantly held accountable by the Ministry to meet patient expectations.

Ultimately, the question of why New Zealand regulators failed to act to protect patients from harm has proven to be multi-faceted. When mesh was introduced to New Zealand, they did not practice robust protectionist measures from the medical device regulators to the practitioner regulators. Regulators responsible for acting as a check and balance against each other, such as Medsafe, the Medical Council, ACC and HDC, did not hold each other accountable in the interest of patient safety.

— Tamarra Al-Azzawi[28]

Surgical Mesh Timeline

- 1950s – Hernia mesh introduced.
- 1990s – SUI and POP transvaginal mesh kits – cleared by FDA with NO clinical trials (510K loophole), aggressively marketed, rapid uptake by surgeons and quickly replaced traditional surgery.
- 1990s – mesh adopted in New Zealand for POP, SUI and rectopexy procedures.
- 1999 – Boston Scientific recalled the very first mesh device (Protegen), because serious complications were identified. All subsequent mesh devices had used the Protogen as a 'predicate device' to achieve market clearance, being "substantially equivalent" in design. All subsequent mesh devices released onto the market for sale were not recalled.
- 2003 – By this time 230,000 TVT procedures worldwide and NO mesh registers, despite recommendations and warnings given by health bodies.
- 2005, 2007 – Cochrane reviews on SUI and POP mesh – need for longer term studies to determine safety.
- 2008 – FDA public health notification – serious complications with POP and SUI mesh.
- 2011 – FDA update – serious concerns and adverse events NOT rare for POP.
- 2012 – FDA orders 34 manufacturers of surgical mesh for transvaginal repair of POP to conduct new post-market safety studies.
- 2014 – NZ Petition to Parliament asking for a formal inquiry into mesh use, Scottish Petition to Parliament and subsequent suspension of SUI and POP mesh procedures.
- 2015 – First ACC Surgical Mesh Review: [Retrospective] Analysis of Treatment Injury Claims – 1 July 2005 to 30 June 2014.
- 2016 – FDA re-classifies surgical mesh from Class II to higher risk Class III.
- 2016 – Governments response to surgical mesh Health select committee report with recommendations for action.
- 2017 – Australian Senate Transvaginal Mesh Inquiry and subsequent removal of POP from sale, New Zealand followed suit and removed all mesh devices used (using the transvaginal approach to surgery) for POP off the market.
- 2017 – Johnson and Johnson Transvaginal Mesh Class Action Australia.
- 2018 – surgical mesh for POP and SUI was suspended in UK, Wales, N. Ireland, Scotland – as part of The Independent Medicines and Medical Devices Safety Review (IMMDS). Non mesh surgery was also put under high vigilance scrutiny. The suspension remains.
- 2018 – Medsafe Announcement on the outcomes of regulatory action taken on POP surgical mesh products in New Zealand, all products using transvaginal approach to surgery to be removed from

market, no longer available for use. Mesh using the laparoscopic approach to surgery (via the tummy) not affected and remain available.

- 2018 – ACC Treatment Injury Claims Surgical Mesh Related Claim Data Retrospective Review From Jul 2005-30 Jun 2018 (13 fiscal years).
- 2019 – Ministry of Health Restorative Justice Mesh Forums – Restorative Justice Process and publication of report.
- 2019 – TGA Australia, regulatory action taken regarding Boston Scientific mesh products – requiring removal of any remaining mesh products from the Australian market, including stockroom products.
- 2020 – ACC undertook to review declined mesh claims.
- 2020 – Publication of IMMDS report First Do No Harm.
- 2020 – ACC undertook an internal review of mesh claims with a 'declined decision' for cover, "to learn where improvements could be made to the customer experience".[56]
- 2021 – Johnson and Johnson federal court lawsuit appeal dismissed.
- 2021 – New ACC guidelines on mesh injury were established for POP, SUI and hernia repairs, however colorectal repairs using mesh (rectopexy surgery) were not included. ACC developed these guidelines for their cover assessors to determine where mesh injury fits into the legislative parameters of ACC policy.
- 2022 – Sally Walker's petition to Parliament, for a suspension for Stress Urinary Incontinence mesh procedures.
- 2023 – In response to Sally's petition the Health Select Committee requested that Manatū Hauora/ Surgical Mesh Roundtable/Medical Council and medical colleges move from "investigating whether a suspension should be implemented", to "***how it could*** effect a time limited pause".
- 2023 – Sally Walker's petition resulted in the Director General of Health announcing a 'time limited' suspension for Stress Urinary Incontinence mesh procedures.

Appendix 2: Additional Information and Context for the Fetal Anticonvulsant Syndrome Case Study

The Factors Contributing to FACS in Aotearoa New Zealand

The following information has been taken from the written submission that FACSNZ put forward to the Health Select Committee, 6 June 2018[57]. Please note that all of the quoted references can be found in the submission, and where [ ] has been used, this means FACSNZ has made a change from the submission (some information has been removed from the submission for this document).

- Data sheets not legislated until 1981

  "Data sheets were not required for medicines until the Medicine Act 1981 came into effect. This means that the sponsor did not have to provide data sheets prior to this date. The data sheets are owned and maintained by the sponsor, therefore there is no real restrictions, merely a format of how they should be set out, and recommendations from Medsafe or Medicine Adverse Reaction Committee (MARC) when an update should be done. There should be enforceable changes, which include having full information about use of medicine during pregnancy. It should not rely on self-assessable change notification (SACN) from the sponsor, where "Data sheets amended via a SACN are not routinely assessed by Medsafe."

- Consumer Medicine Information (CMI) sheets not legislated and limited information

  "…sponsors may volunteer to provide Consumer Medicine Information (CMI) for publication on the Medsafe website. This scheme has been in place since the 1990's." There are several issues here in the fact that it is on a volunteer basis, so not legislative, and the information the sponsor is providing should be a simplified version of the data sheet, which is also not happening adequately. An example of Medsafe not checking the information going into this volunteer scheme is when the 28 November 2003 Epilim CMI lacks to mention the effect on a foetus, but in the 30 March 2006 Epilim CMI it states:

  "Epilim may affect your developing baby if taken in the first trimester of pregnancy, as it is suspected of causing an increased risk of malformations in the exposed foetus." I am uncertain whether it had mentioned in previous Epilim CMIs about the risks, however if it did there is over a two year period where there was no mention. So even if a consumer was to get an Epilim CMI it was lacking any information regarding effects to a foetus.

- Sodium valproate removed from Intensified Adverse Drug Reaction Reporting Scheme

  Sodium valproate remained on the Intensified Adverse Drug Reaction Reporting Scheme from March 1977 – January 1983. It was removed off the reporting scheme even when the sponsor (Reckitt) in February 1979, had reported to the Department of Health 6/34 abnormal babies born to mothers taking valproate.

- Reports being dismissed by Department and Ministry of Health and Committees under their jurisdiction.

  Using one example from each decade.

New Zealand had begun to look into Anticonvulsants and Congenital Abnormalities prior to 1968, in fact stating in a letter "We have recently had several cases drawn to our attention and there seems reason to believe that these constitute only a small proportion of such cases, the majority probably escaping attention."

The sponsor (Reckitt) in February 1979, had reported to the Department of Health 6/34 abnormal babies born to mothers taking valproate. Reckitt & Colman advised the Department of Health on 8 July 1983 of a Current Problems document, which stated "Although the major structural 5 abnormalities are induced in early pregnancy there is some evidence that treatment in later pregnancy also affects development." Also that "The most frequently occurring defect in 2285 children exposed to anticonvulsant therapy in utero were cleft lip with or without cleft palate..., skeletal anomalies..., congenital heart disease..., CNS defects..., anomalies of the gastro-intestinal tract..., facial and ear abnormalities..., mental retardation..., genitourinary anomalies...". In the Committee on Adverse Drug Reactions (CADR) meeting on 13 July 1983, that document was noted in the minutes.

On 27 June 1989, the Department of Health received a report of "? [querying] Sodium Valproate Syndrome"

On 18 March 1998, MARC, "Sodium valproate and autism. A 4-year old girl whose mother took sodium valproate and folic acid during the first trimester of pregnancy has clinical signs suggestive of autism. Comment: Members commented that there is unlikely to be a causal connection between sodium valproate and autism. No action was recommended."

After a watching brief was recommended on valproate and foetal abnormalities by MARC in December 2004, [and] after a report came in of a "...child born with probable foetal valproate syndrome." "Prior to initiation of the watching brief there were seven reports of foetal disorders with valproate in the Centre for Adverse Reactions Monitoring (CARM) database." MARC reviewed the watching brief in December 2005 and decided that, "As this issue had been adequately explored they agreed that it should be removed from the watching brief list."

On 14 September 2017, MARC did a review on use of sodium valproate in pregnancy.[58] On page 78 of this report CARM report that they had received "...27 cases of Epilim exposure during pregnancy." Of these 27 cases there were 24 cases of "Congenital malformations (often coded as fetal valproate syndrome)..." 13 children with behavioural/neurodevelopmental problems, and 5 deaths.

- <u>Delay in getting Prescriber Updates written by Medsafe</u>

  During a MARC meeting on 14 December 2006 (under 4.1.5.1.[59]) it was recommended "That an article is written for publication in Prescriber Update on anticonvulsants and risk of congenital malformations, and the importance of pre-pregnancy counseling for all women of child-bearing age taking anti-convulsants." That Prescriber Update was published in February 2009[60].

- <u>Delays in getting acknowledgement on current issues with medicines</u>

  An example of delay is the use of sodium valproate in pregnancy, was the acknowledgement of Foetal Valproate Syndrome. In Medsafe's "Use of Sodium Valproate in pregnancy"[61] published on 15 December 2014, it states that "The term fetal valproate syndrome (FVS) was suggested in 1984." Also on 27 June 1989, the Department of Health received a report of "?Sodium Valproate

Syndrome" yet the alert was published 30 years later mentioning FVS. To this date a lot of healthcare professionals have never heard of FVS.

Another example is when the sponsor, Reckitt & Colman advised the Department of Health on 8 July 1983 of a Current Problems document, which stated "Although the major structural abnormalities are induced in early pregnancy there is some evidence that treatment in later pregnancy also affects development." Also that "The most frequently occurring defect in 2285 children exposed to anticonvulsant therapy in utero were cleft lip with or without cleft palate..., skeletal anomalies..., congenital heart disease..., CNS defects..., anomalies of the gastro-intestinal tract..., facial and ear abnormalities..., mental retardation..., genitourinary anomalies...". Medsafe finally acknowledged reduced IQ, congenital malformations, cognitive impairment and behavioral issues in December 2014.[61]

The Epilim data sheets had noted congenital abnormalities, facial dysmorphia, neural tube defects and multiple malformations, in August 1993, developmental delay in January 2003, and verbal IQ delays in August 2005. No longer, or has it been for a long time, just about neural tube defects, or spina bifida that are risks for babies that have been exposed to sodium valproate during pregnancy.

Which then raises the point of the most prescribed antiepileptic medicine in 2016 for females, gabapentin. On 11 December 2001, MARC had a report of a women having an abortion after her fetus had multiple malformations. MARC decided that "...the association with use of gabapentin was coincidental, and hence, the causality was designated "unlikely".[62] (under 3.1.5.1) So in the MARC meeting on 27 March 2002, "The committee recommended no additional action at this time."[63] (under 2.1.6). How carefully is this being monitored?

- <u>When advised of issues from other Government bodies, recommendations not followed through</u>

  On 31 August 2009 "...the Neurological Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC)..." wrote to Medsafe "...requesting that Medsafe strengthen the warning information on the sodium valproate datasheet regarding its teratogenic risk." "...members considered that the datasheet does not appear to fully address the key issues...it does not state that sodium valproate should not be prescribed in woman of child-bearing age if there is a suitable alternative. The Subcommittee felt that the Medsafe regulations were inadequate..." This letter got addressed over 8 months later on 11 May 2010, but correspondence remained happening until 18 February 2011, when Medsafe advised PTAC that "...it is Medsafe's opinion that a contraindication for sodium valproate treatment in women of child-bearing potential, if there is a suitable alternative, is not supported by the evidence.

  PTAC initiated dialogue again about this on 11 August 2013 when "The Subcommittee considered that the datasheet be amended to read 'sodium valproate is contraindicated in women of child-bearing age, unless there is no other suitable alternative'. Medsafe responded by stating "...that there is insufficient evidence to justify contraindicating this medicine from all women of child-bearing potential." Where Medsafe also advised PTAC that "Should the Subcommittee be concerned that prescribers are not following the advice in the data sheet they should contact the professional college(s) to address the issue."

- <u>Centre for Adverse Reaction Monitoring (CARM) numbers differ and not monitored</u>

  New Zealand Pharmacovigiliance Centre prepared a report on "Sodium valproate and Foetal valproate syndrome" in October 2014, where it states that there were "...13 cases of Foetal Valproate Syndrome" 30, however on 14 September 2017, MARC did a review on use of sodium valproate in

pregnancy where on page 8, of this report CARM [state] that they had received "…27 cases of Epilim exposure during pregnancy." Of these 27 cases there were 24 cases of "Congenital malformations (often coded as fetal valproate syndrome)…" 13 children with behavioural/neurodevelopmental problems, and 5 deaths.

How is it possible to [increase] 14 reports in 3 years, including 5 deaths and this not raise concern?

- Strategies that have been employed are limited and not effective

Using MARC's review on the Use of sodium valproate in pregnancy from 14 September 2017, on page 3 where it states what has previously been done for sodium valproate we can summarise the following:

- Reviewed many cases
- A watching brief December 2004 – December 2005
- Published Prescriber Updates
- Trans-Tasman alert

http://www.medsafe.govt.nz/safety/EWS/2015/sodiumvalproate.asp

If these different methods were effective sodium valproate would not have been the second most prescribed antiepileptic medicine for females, or females in childbearing age in 2016.

It is concerning when the antiepileptic medicine that carries the most risk to an unborn baby only has limited and ineffective methods to ensure females have informed consent, what hope is there for all the antiepileptic medicines?

- Epilepsy blamed for problems occurring until 2009

On 11 June 2009, MARC after receiving a case report of twin babies being diagnosed with foetal valproate syndrome at birth, where the mother was on sodium valproate for psychiatric reasons states "The Committee considered that the number of women of child bearing age being treated with valproate was increasing. The Committee noted that the warnings section in the product datasheet focused primarily on the use of valproate for the treatment of epilepsy."

- Antiepileptic medicines not closely monitored, even when known to be teratogenic

Just some examples are when New Zealand had begun to look into Anticonvulsants and Congenital Abnormalities prior to 1968, in fact stating in a letter "We have recently had several cases drawn to our attention and there seems reason to believe that these constitute only a small proportion of such cases, the majority probably escaping attention."

A letter to Medical Practioners on 7 May 1973 from the Department of Health states "In recent years several reports have indicated that anticonvulsant drugs may be teratogenic." Of particular mention in this letter was phenytoin.

Epilim's datasheet from November 1976 states "Sodium valproate, like certain other anticonvulsants, has been shown to be teratogenic in animals."

- Studies that were meant to be done were not done

  From what [FACSNZ] have obtained at the archives [we] can see that on 2 September 1983 there was going to be a "Study of fetal disorders in association with valproate" done. [FACSNZ] can see that it was last mentioned with MARC on 28 March 1984, but [we] cannot find anywhere where this research was actually done.

ACC/HQSC Failure to Accurately Report

Official information request for SACs received for Foetal Anticonvulsant Syndrome HQSC, 2022:

Official information request for SAC's received for Foetal Anticonvulsant Syndrome

1. *How many SAC's have been received for FACS, or the relevant individual syndromes relating to exposure anti-seizure medication(s) during pregnancy, between 2017- current date?*
2. *Who has been lodging these SAC's?*
3. *What has happened to these SAC's since HQSC have been notified of them?*

Following a search of our adverse events database we do not have a record of any SAC events for Foetal Anti-convulsant Syndrome (FACS) reported to HQSC for this period.

Please note that the Commission publishes some of its OIA responses on its website, after the response is sent to the requester. The responses published are those that are considered to have a high level of public interest. We will not publish your name, address or contact details.

Babies Born Who Were Exposured to Selected Anti-Seizure Medicine(s) *In Utero*

The table below is from information supplied in response to an OIA request, and provides an indication of how many babies were born following topiramate exposure during 2016 – 2019.[64]

Table 1. Number of liveborn infants whose mothers were dispensed selected anti-epilepsy drugs during pregnancy

Year of birth	2016	2017	2018	2019
Māori				
Carbamazepine	19	22	16	17
Clobazam	<5	0	<5	<5
Lamotrigine	25	31	32	31
Phenytoin sodium	<5	<5	<5	0
Topiramate	9	9	7	5
Non-Māori				
Carbamazepine	38	22	30	30
Clobazam	6	<5	10	7
Lamotrigine	76	73	85	92
Phenobarbitone	<5	0	0	<5
Phenytoin sodium	<5	0	0	0
Topiramate	18	30	26	19

Appendix 3: The Burden of Medical and Treatment Injury

Medical error, treatment injury and harm caused to consumers/patients in the course of receiving health care and medical treatment, imposes a significant financial and productivity burden on individual consumers, their family/whānau and community, as well as on the health system.

In reviewing this issue over the last twenty or more years, it is evident that little has changed to improve harm reporting processes, and there has been scant reduction in medical error, treatment injury and harm caused to consumers/patients in the course of receiving health care and medical treatment.

In a New Zealand study published in 2006, Auckland University School of Population Health lecturers Mary Seddon and Alan Merry found more than 1500 people were killed or permanently disabled annually in this country through ***preventable*** medical error. They wrote:

"The evidence is incontrovertible—we are inadvertently harming an unacceptable number of our patients by the very healthcare intended to help them."[8]

An earlier New Zealand study[9] found that "up to 30% of public hospital expenditure goes toward treating an adverse event", and that does not take into account the cost to individuals in both direct and indirect costs, loss of quality of life etc., and to the community in loss of productivity and participation. Brown *et al.* found in 2002 that "adverse events are estimated to cost the medical system $NZ870 million, of which $NZ590 million went toward treating preventable adverse events."[9]

For example, "FACS has a life-long impact on affected children and their family/whānau. It can cause physical malformations such as heart defects, cleft palate, and spina bifida, as well as learning and behavioural difficulties. The average lifetime cost to ACC of a single FACS claim is estimated at $7 million. A single severe claim is estimated to cost ACC between $5 million and $25 million, which is an indication of the impact on the person."[10]

One must also remember that the number of accepted ACC claims is increasing, so financially speaking, on that measure alone, the cost is significant.

Focusing on the ACC cost per individual, of harm from medical injury for issues such as FACS and surgical mesh, grossly underestimates and understates the total financial burden of that harm, which must consider the financial burden on families/whānau, loss of productivity, loss of quality of life, disability-adjusted life years (DALYs), years lived with a disability (YLDs) and years of life lost due to premature mortality (YLLs).

While in the past the total burden of injury in Aotearoa New Zealand has been calculated[11] including treatment and rehabilitation costs, lost economic contribution and human costs (including the cost of pain and suffering, it appears that no such investigation of the total burden of medical harm and treatment injury has been carried out.

In 2021/22 the Health and Disability Commission (HDC) received 3,413 complaints — an unprecedented increase of 25% on the previous year. The Advocacy Service received 2,971 complaints.[12] The total number of adverse events reported to the Health and Safety Commission (HQSC) in 2019/20 was 975 (916 in 2018/19).[13]

ACC treatment injury data is available from 1 July 2005, when treatment injury provisions came into law. In 2019/20 ACC made a cover decision on 16,604 claims for treatment injuries and accepted 11,285 claims. Each of these claims represent a person who was harmed during treatment.[14]

Davis *et al*. found that in New Zealand adverse events were associated with 12.9% of hospital admissions, of which approximately 35% were classified as highly preventable.[65] In their paper, Davis *et al*. cite research from the US and the UK, published in both governmental reports and in the peer reviewed medical literature. Despite there being an acknowledgement in some quarters that medical harm is an issue, there is little evidence that the issue is being adequately addressed.

A New Zealand study into incidence of harm within general practice, published in 2021, which involved 9076 study patients with 115,797 unique general practice visits, 212,963 prescriptions of 833 different pharmaceuticals and 2,578 hospital admissions, found 2,972 harms experienced by 1,505 patients.[66] The researchers found that while most harm was considered minor, general practice records reveal the extent of severe harms, including preventable deaths.

A 2017 OECD report found that "adverse events are estimated to be the 14th leading cause of morbidity and mortality in the world. This puts patient harm in the same league as tuberculosis and malaria, and makes it a genuine global public health concern."[67] The report also found that "many adverse events are preventable. Furthermore the costs of prevention are dwarfed by the cost of failure."

In 2016, Makary and Daniel estimated that medical error is the third biggest cause of death in the US, and that medical error leading to patient death is under-recognised in many other countries including Canada and the UK.[68] Makary and Daniel call for better reporting, saying that problem of medical error should not be exempt from a scientific approach and that there should be more appropriate recognition of the role of medical error.

The World Health Organisation[69, 70] states that:

- Around 1 in every 10 patients is harmed in health care and more than 3 million deaths occur annually due to unsafe care. In low-to-middle income countries, as many as 4 in 100 people die from unsafe care.
- Above 50% of harm (1 in every 20 patients) is preventable; half of this harm is attributed to medications.
- Some estimates suggest that as many as 4 in 10 patients are harmed in primary and ambulatory settings, while up to 80% (23.6–85%) of this harm can be avoided.
- Common adverse events that may result in avoidable patient harm are medication errors, unsafe surgical procedures, health care-associated infections, diagnostic errors, patient falls, pressure ulcers, patient misidentification, unsafe blood transfusion and venous thromboembolism.
- Patient harm potentially reduces global economic growth by 0.7% a year. On a global scale, the indirect cost of harm amounts to trillions of US dollars each year.
- Investment in reducing patient harm can lead to significant financial savings, and more importantly better patient outcomes. An example of a good return on investment is patient engagement, which, if done well, can reduce the burden of harm by up to 15%.

The burden of medical and treatment injury is a global problem. A paucity of recent and comprehensive scientific research into the scale of medical harm in Aotearoa New Zealand must not be taken as evidence of absence, and it must be assumed that we have as significant a problem as those countries that we habitually compare ourselves with (US, UK, Canada and Australia).

As a first step, New Zealand's visibility at the 6th Global Ministerial Summit on Patient Safety[49] would be a clear indicator that patient safety is being taken more seriously. To build consumer and health practitioner confidence, our health entities must be more vocal in the public domain and be more transparent about the improvements being made on a micro/macro level.

Appendix 4: Statement from Christian Poland[71]

Research Assistant University of Auckland| BSc/LLB(Hons) student

"The Protected Disclosures (Protection of Whistleblowers) Act 2022 (the Act), which came into force on 1 July 2022, can protect surgeons when making disclosures about serious wrongdoing in or by their organisation. It should almost always protect them from being identified if they make their disclosure to their organisation, Ministry of Health and the Health or Disability Commissioner. It seems likely that the Act would also protect them if they disclosed to the Medical Council — but this would turn on whether they can be considered an "appropriate authority" under s 25 of the Act. This is unlike the previous Protected Disclosures Act 2000, where, normally, protected disclosures could initially be made only to the organisation itself.

The Act applies regardless of any conflicting or overlapping responsibilities under the Medicines Act or any other Act. Therefore, even if there are loopholes in the Medicines Act, the protections under the Whistleblowers Act would take precedence.

However, a surgeon (A) is unlikely to be protected under the Act when reporting harm caused by a colleague at a different hospital, even if they have reasonable grounds to believe the serious wrongdoing occurred. This is because, in order for a disclosure to be "protected", the serious wrongdoing must be "in or by the discloser's organisation": s 9(a). However, any discloser that confidentially informs surgeon A of the serious wrongdoing for the purpose of seeking advice is protected under the Act (see s 11(4)(d). Surgeon A would also be protected by encouraging a relative or associate at the other hospital to make a protected disclosure themselves: s 22.

Definition: Is the person a "discloser" disclosing "serious wrongdoing"?

The discloser must fit within the section 8 definition. This includes current or former employees, contractors, managers and volunteers, so it will include surgeons whenever they encounter unsafe medical practises.

The concern must then be about serious wrongdoing, defined in section 10. The wrongdoing must be in or by the organisation; and can include serious risks to public health, public safety, or the health or safety of any individual: s 10(b). It can also include any "grossly negligent" act, omission or course of conduct, as well as gross mismanagement, by a person in the public sector: s 10(e). Unsafe medical practises would be "serious wrongdoing" either under s 10(b) as a serious risk to someone's health, or under s 10(e) as gross negligence or mismanagement when in the public sector.

Definition: Who can the disclosure be made to?

The discloser only has protections under the Act if they disclose the wrongdoing "to their organisation or to an appropriate authority": s 11(1).

Meaning of "organisation"

The "organisation" is the body of persons in which the serious wrongdoing took place: s 4. This would likely be the medical practice or hospital itself.

Meaning of "appropriate authority"

Section 25 of the Act defines an "appropriate authority" broadly. The Act is quick to emphasise that the meaning of the term is not limited under the Act. However, it can include the Ministry of Health, the Health and Disability Commissioner (see Schedule 2), as well as "the membership body of a particular profession … with the power to discipline its members". It would seem possible that the Medical Council would fall under the broad definition of an "appropriate authority".

The Court of Appeal in 2014 saw "no indication of error" in an Employment Court judgment which impliedly found that the Medical Council of New Zealand could be an appropriate authority. The case concerned a community support worker who alleged that one of the clients was being allowed by the organisation and DHB to engage in abusive prostitution. Her disclosure to the Medical Council would have been protected, but her disclosure to the client's family and to journalist were not.

Scope: When is protection available under the Act?

The discloser must have reasonable grounds to believe there is, or has been, serious wrongdoing in or by the organisation: s 9(a). They cannot disclose in bad faith: s 9(c).

Disclosure to organisation

If the disclosure is made to their organisation, in must be made in accordance with any internal procedures or to the head/deputy head in order to be protected: s 11(2). All public sector organisations are required to have appropriate internal procedures: s 29(1). The internal procedures must not be inconsistent with the Act: s 24.

Disclosure to appropriate authority

A disclosure made to an appropriate authority will result in protection "at any time … whether or not the discloser has also made the disclosure to their organisation or to another appropriate authority": s 11(3).

Extensive nature of the protection under the Act

Protection applies where the discloser "substantially complied" with these requirements: s 11(4)(c). They are protected even if there is no serious wrongdoing, and also protected even where they disclose to another person in confidence and for the purposes of seeking advice about whether or how to make a protected disclosure: s 11(4)(a) and (d).

Confidentiality: What protections are available under the Act?

The receiver of the disclosure "must use their best endeavours to keep confidential information that might identify the discloser": s 17(1).

Circumstances where the discloser may be identified

However, the discloser may consent to being identified: s 17(2). Alternatively, there may be "reasonable grounds to believe that the release of the identifying information is essential for the effective investigation of the disclosure; or to prevent a serious risk to public health, public safety, the health or safety of any individual, or the environment; or to comply with the principles of natural justice …": s 17(2)(b). But, the receiver must normally consult the discloser about releasing identifying information: s 17(3).

The Medical Council or HDC would have a high threshold to meet before being able to identify disclosers. Identification must be essential for the investigation to be effective, meaning there is no other alternative. It seems unlikely that not identifying the discloser would result in "a serious risk" to health or safety. If a discloser is making a disclosure against another individual, they may argue that natural justice requires that the discloser be identified. However, it must be essential for natural justice and natural justice can normally be assured without identifying the discloser.

Other protections available under the Act

Employees must not be retaliated against (s 21) and people must not be treated less favourably (s 22) because they intended to make, or they made, a protected disclosure. The discloser, their relatives and associates also cannot be treated less favourably if they encourage someone else to make a protected disclosure or gave information relating to a protected disclosure: s 22(1)(a)(ii)–(iii).

Conflicting or overlapping responsibilities

Importantly, disclosers can make protected disclosures even if they would normally be prevented "under any legislation, rule of law, agreement, contract, internal procedure, oath, or practice": ss 23(2), 24(1). Absolutely no liability or discipline can come from making a protected disclosure: s 23(1). The only exception is for information protected by legal professional privilege (attorney-client privilege): s 39.

Therefore, even if a surgeon had conflicting or overlapping responsibilities under the Medicines Act, or some other Act, the protections under the Whistleblowers Act apply "despite any prohibition of or restriction on the disclosure of information under any legislation": s 23(2).

What is the effect of disclosure?

The receiver of the disclosure should, within 20 working days, acknowledge receipt, consider whether an investigation is warranted, check if the discloser has disclosed elsewhere, deal with the matter, and inform the discloser (with reasons) about the outcome of the disclosure: s 13(1). If this process will take longer, it should inform the discloser of this and appropriately update the discloser about the progress: s 13(2).

The organisation may refer the disclosure to an appropriate authority, or an appropriate authority may refer it down to the organisation or to a different appropriate authority: ss 16(1)–(2).

Assistance about protected disclosures

If a discloser notifies an Ombudsman that the discloser has made, or is considering making, a protected disclosure, an Ombudsman must provide information and guidance to the discloser: s 30(2). More generally, Ombudsmen can provide any information and guidance to any person about the Act: s 30(1)."

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