Surgical Mesh Crisis: Why have NZ regulators failed to act to protect patients from harm?

Tamarra Al- Azzawi

Abstract

Mesh in the early 1990s was successfully used for hernia repair. Pharmaceutical companies then modified the device as a promising alternative to the lengthy and costly treatment of vaginal reconstruction surgery for POP and SUI. In turn, the use of vaginal mesh rapidly grew as a treatment for SUI and POP. However, in rushing to fulfil this demand and hit the market, regulators failed to ensure that the device was safe for patients. Consequently, serious health complications from inserting the foreign body became apparent across thousands of women. Over the past two decades, harmed women have collectively triggered extraordinary media coverage calling for awareness and change in the medical field. It has broken many health consumers' trust and confidence due to the accountable bodies omitting to take responsibility for their wrongdoings. Many countries, such as the UK, U.S. and Australia, have been gradually implementing positive changes to prevent harm caused by transvaginal mesh. Yet New Zealand is still behind. This paper addresses why regulators, and the legal framework in New Zealand, have failed to act to protect patients from harm in the context of the mesh crisis. This is an essential question for the legal and medical professions, as they are so tightly intertwined in their role as regulators to devices and practitioners. Therefore, as global advancements in medical devices rapidly develop, it is essential to hold New Zealand regulators accountable to ensure that these devices are, in fact, fit for purpose. This paper explores how the various responsible regulatory bodies have collectively contributed to patient harm by assessing the mesh journey in New Zealand. It also acknowledges and evaluates the actions taken to restore and prevent further injury. Finally, the paper will end at the present day, where this paper will provide recommended reforms necessary to effectively protect women's health related to SUI and POP through the implementation of credentialling and registry systems.

Table of Contents

I. Introduction

Transvaginal mesh devices for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) have significantly impacted women's health globally. The device has been controversial among the medical profession and patients throughout the last two decades. It was rapidly introduced into the market in 1998 as a preferable alternative for surgeons and patients. However, over twenty years later, patterns of severe complications arose across patients internationally, causing irreversible harm to women. Through widespread media coverage, protests, petitions and creating advocacy groups around the world, including the USA, the UK, and Australia, harmed patients have fought for the attention of the public and regulators to acknowledge and address the regulatory failures continuing to take place. In New Zealand, patients continue to come forward, telling their stories of how mesh has caused them lifelong harm and stripped them of their physical and mental health. This paper explores how and why the different responsible New Zealand regulators have enabled the continuation of mesh device implantation, failing to protect patients from mesh harm. It will argue that the approval and surveillance procedures surrounding medical devices and surgeons have not been adequate to prevent patients from harm. Consequently, the 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. These issues need to be immediately addressed as it is an ongoing crisis.

This paper will critically evaluate the consumer's mesh journey from pre-market regulation to the hands of practitioners through to complaints and compensation. Firstly, starting with introduction of mesh into New Zealand through MedSafe's lack of pre-market surveillance, doctors proceeded with implantations without having proper formal training or credentials. Following this, the Medical Council omitted to hold doctors accountable for their medical negligence. When patients sought compensation from ACC, they were provided little to no aid, restrained by the rigid system. Consequently, patients sought justice and prevention for future patients at the Health and Disability Commission (HDC) as their final stop to complain. Yet this ultimately proved to be a dead-end, with 'No further action.

To better inform regulators on how to approach prevention for future patients, reviewing the mistakes made leading up to the crisis and evaluating the efforts to restore harm is an essential task. The next section of this paper critically analyses the initiatives these regulators have taken to mitigate damages and prevent further injury. Firstly, by evaluating the Ministry of Health's intervention through the restorative approach. Then, this paper will evaluate ACC's commitment to reviewing declined claims and improving the informed consent process for patients.

The final part of this paper proposes recommendations to ensure that medical regulators perform their functions effectively. The first section will analyse and recommend adjustments to the credentialing framework that is projected to be implemented by the end of 2022. The second recommendation is the implementation of a registry to improve health outcomes for mesh-injured and future SUI and POP patients. Lastly, a discussion on why regulators must suspend transvaginal mesh in New Zealand and what the associated risks may be. These changes can rebuild the public and patients' trust and confidence in regulators and practitioners.

Note that when this paper refers to mesh, it is specifically referring to the mesh devices used for POP and SUI only, which include polypropylene mesh tape and mid-urethral sling.

II. What is Surgical Mesh

Transvaginal mesh is a net-like device used in urogynaecology surgery to treat POP and SUI. These conditions result from women experiencing pelvic floor dysfunction during childbirth. The average age of patients is 56 years old, with ages ranging from 20 to 84 years.[1]

SUI affects up to a third of women over the age of 40.[2] SUI is caused by weakened muscles or ligaments of the urethra. Prolapse is when the integrity of the tissue holding the organ is dysfunctional or decreased. By inserting the plastic mesh around these muscles, the material provides support to repair and reinforce the weakened connective tissues within the vaginal

[1] *ACC Surgical Mesh Review* (ACC, March 2015) at 4.
[2] Karin S Coyne, Chris C Sexton, Christine L Thompson, Ian Milsom, Debra Irwin, Zoe S Kopp, Christopher R Chapple, Steven Kaplan, Andrea Tubaro, Lalitha P Aiyer and Alan J Wein "The prevalence of lower urinary tract symptoms (LUTS) in the USA, the UK and Sweden: results from the Epidemiology of LUTS (EpiLUTS) study" (2009) 104(3) BJU International 352 at 360.

wall around the mesh.[3] Up to 80% of women with pelvic floor dysfunction have POP co-exist with SUI.[4]

Mesh insertion has proven highly effective with the proper patient selection and the right doctor.[5] However, mesh placed incorrectly can cause the mesh to move and irritate surrounding organs and tissues, such as the bladder. The mesh can cause post-surgery mesh-related symptoms such as chronic pain in the lower body, incontinence and recurrent urinary or vaginal infection, and becoming aware of the mesh during intercourse for both woman and her partner. Foreign body response symptoms occur, which causes the body to reject the foreign body through wound breakdown, causing mesh erosion, fistula formation and inflammation.[6] Consequently, the mesh can cause a worse health outcome than the patient initially had.

III. The Problem: What is the surgical mesh crisis

Before vaginal mesh, colposuspension was the standard surgical treatment for SUI and POP. It is a complicated abdominal procedure that requires an average of 7 days in the hospital, a lengthy recovery period and a high failure rate of initial and revision surgery.[7] Consequently, this created an opportunity for an alternative treatment. Mesh was initially a treatment abdominally to repair the hernia by strengthening surrounding tissues. Ulf Ulmsten, a Swedish obstetrician and gynaecologist, adopted this concept and invented the mesh for the surgical treatment of SUI and transvaginal repair of POP.[8] This appeared to be a new efficient solution for patients.

In 2002, the device was introduced in New Zealand. Sally Walker's story is a prime example of the severe injury caused by transvaginal mesh surgery, from pre-surgery to post-surgery, illustrating the reoccurring regulatory failures.

---

[3] Michelle Llamas "Transvaginal Mesh" (24 September 2021) Drugwatch https://www.drugwatch.com/transvaginal-mesh/.
[4] S. W. Bai, M. J. Jeon, J. Y. Kim, K. A. Chung, S. K. Kim and K. H. Park "Relationship between Stress Urinary Incontinence and Pelvic Organ Prolapse" (2002) 13 Int Urogynecol J 256 at 258.
[5] Interview with Anonymous, Surgeon (Author, 2 September 2022).
[6] Waitemata District Health Board "Managing complications of Stress urinary incontinence and pelvic organ prolapse treatment (with options for mesh removal)" (October 2019) Te Whatu Ora Health New Zealand Waitematā <https://www.waitematadhb.govt.nz/assets/Documents/healthy-living/FPH/Managing-Complications-for-Stress-Urinary-Incontinence-and-Pelvic-Organ-Prolapse-Treatments-10Dec19.pdf>.
[7] Jonathan Gornall "How mesh became a four letter word" (2018) 363 BMJ 1.
[8] Michelle Llamas, above n 3.

In 2009, Sally had been experiencing prolapse and incontinence. She went to a specialist who instructed her to undergo mesh insertion surgery. During Sally's appointments, her doctor promoted the surgery as quick and easy. He did not provide any information regarding the risks and complications associated with the mesh implantation, pre and post-surgery, or alternative treatment options. Yet like many patients, she had complete trust and confidence in her doctor that his judgement was in the best interest of her case. Therefore, Sally underwent surgery with little knowledge about the procedure. As soon as the operation happened, Sally recalls feeling something was wrong. The doctor inserted the mesh incorrectly, leaving the plastic mesh poking into her bladder. This caused severe consequences, with continuous sepsis, infection, and bleeding. Moreover, her incontinence continued. Sally's chronic pain continued for years.

In 2017, Sally went to a urogynaecologist, where she finally felt acknowledged and heard regarding the pain she had experienced. The mesh placement and inaction by practitioners to restore the damage for many years led to the mesh eroding in her bladder. Nine operations were attempted to save her bladder, yet this had failed. Eventually, Sally had no choice but to remove her bladder and have her vagina sewn closed. [9]

Throughout Sally's mesh journey, Sally relied on ACC to cover her treatment injury costs for the damage caused by the mesh. They had identified that the vaginal mesh insertion and placement were, in fact, the cause of her chronic pain. Seeking justice and closure for the harm she endured, Walker complained to the HDC. Unlike many, Sally was able to trigger a formal investigation. Yet the HDC had decided to close her case due to her doctor's inability to respond. Concerningly, the HDC refused to release the independent urologist and surgical mesh expert reports in Walker's case.[10] Many, like Sally, are left with much worse health outcomes resulting from mesh and helplessness to a rigid system that deprived them of the natural justice they deserve.

Because of mesh, Sally is one of many women across New Zealand who have been robbed of their livelihood. Many have lost their jobs, marriages, and the ability to have future children and show up to be physically capable parents. The harm this medical device has caused for

[9] Interview with Sally Walker, TVM survivor, (Rachel Smalley, First Light, Today FM, August 19 2022) transcript provided by Rova (Auckland).
[10] Emma Russell "In Her Head women's health: Sally Walker's surgical mesh trauma- 'My body was breaking down'" *The New Zealand Herald (*online ed, Auckland, 30 June 2022).

thousands of women has exposed New Zealand's lack of adequate regulatory checks and balances within the healthcare system that must be addressed.

IV. The Story of Failure- History of the regulatory failures from various Accountable Agencies

A. MedSafe

The story of failure in New Zealand begins at the point that vaginal mesh was introduced through MedSafe in 2002. Medsafe is responsible for regulating therapeutic products in New Zealand, including Medical Devices.[11]

In New Zealand, there is currently no national pre-market assessment or approval process for medical devices to enter the market. Therefore, suppliers are not required to provide documentation of the device's safety and effectiveness.[12] Instead, MedSafe highly depends on overseas research, evidence, and method to inform their decisions on enabling devices to be marketed in New Zealand. Transvaginal mesh cleared under the 510k process, which meant the device was approved for market without any clinical trials to support the device's safety for permanent implantation.[13] The 510(K) mechanism simply provides a shortcut to medical safety due diligence to advance economic efficiency in the US. In 2002, MedSafe relied upon this process and forwent any pre-market surveillance of the medical device's short and long-term effectivity before enabling patients to have the device implanted.

To a certain extent, it is understandable that MedSafe would rely on international research and evidence to inform its decisions. Their constrained resources limit their ability to robustly inquire and research the safety of each medical device coming through the market. Yet some precautionary measures should have been undertaken, especially for devices approved under the 510(k) notification system, as the FDA is legally obligated to use the "least burdensome route" for approval.[14] The benefit of procedural efficiency in the healthcare market cannot

[11] "About MedSafe" (29 June 2020) MedSafe <https://www.medsafe.govt.nz/other/about.asp#device>
[12] Linda Meade *Deloitte Surgical Mesh Registry: Cost Benefit Analysis (*Ministry of Health, July 2018) at 7.
[13] Carmel Berry "Mesh Down Under" (October 12 2019) NZ History < https://nzhistory.govt.nz/women-together/mesh-down-under>.
[14] Richard Rowberg and others *Food and Drug Administration Modernization Act 1997- The Provisions* (1998, CRS Web) at FDMA97.

outweigh the significant risk of harm Medsafe is potentially exposing to patients. Therefore, MedSafe's processes are not fit for purpose in ensuring medical devices are safe for consumers before entering New Zealand as there are little to no barriers to entry.

Following the lack of pre-market approval, 56,508 mesh devices were sold in New Zealand between 1 January 2005 and 31 October 2014.[15] MedSafe omitted to proactively implement post-market surveillance to ensure the device was safe. The FDA in 2008 issued a safety warning in response to increasing complaints. In 2011, the FDA concluded that mesh insertion 'exposes patients to greater risk' relative to the traditional POP repair undertaken before mesh introduction. [16]

Consequently, although one can be critical of the FDA's rapid implementation of vaginal mesh into the market, at the very least, the FDA followed through by issuing warnings concerning the safety of the products. Therefore, MedSafe should have responded to the safety warnings made by the same regulators they relied upon when approving the products used in New Zealand. The alerts, alongside the 1070 adverse events reported to MedSafe relating to mesh devices between 2005-2018[17] should have prompted MedSafe to inquire about the state of vaginal mesh effectiveness in New Zealand. Instead, surgeons continued to offer mesh as the standard option. ACC did not share treatment injury information with Medsafe until 2017. Moreover, there was a clear silo of information amongst MedSafe and other regulatory bodies within New Zealand, which diminished the urgency for MedSafe to initiate safety precautions surrounding using mesh promptly.

Only by late 2017 did MedSafe exercise its power under s38 of the Medicines Act[18] to request information about the safety of their mesh devices from the four suppliers of surgical mesh. By January 2018, MedSafe had announced that all four pharmaceutical suppliers were no longer supplying transvaginal mesh products for pelvic organ prolapse in New Zealand.

---

[15] *ACC*, above n 1, at 21.
[16] FDA *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse* (Center for Devices and Radiological Health, July 2011) at 10.
[17] *ACC*, above n 1, at 21.
[18] Medicines Act 1981, s38 (2).

At that time, the media coverage from major news outlets, such as the Guardian and Skynews[19], had falsely interpreted MedSafe's intervention as New Zealand banning the product. Only the device manufacturers independently withdrew their supply from New Zealand to avoid providing safety information. However, MedSafe and the media outlets' false advertisement regarding the stance of mesh in New Zealand has confused many doctors and health consumers. In actuality, MedSafe's demand for safety information did not hinder the continuation of surgeons implanting mesh. Surgeons have been able to continue using the remaining inventory and individually import the mesh themselves for clinical use.[20] Consequently, MedSafe has enabled the device to continue to be available for surgeons to use for POP and SUI.

B. Practitioners

Once the device had been freely introduced into New Zealand by MedSafe, this put the medical device in the hands of practitioners. 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.[21] Patients should confidently expect their doctors to have the necessary knowledge, training, and experience to provide the medical care they advise their patients to undertake. Especially when women are in a vulnerable position enduring a great deal of pain, patients should be able to trust their practitioner is acting in their best interest.

Yet these patient expectations that arise through the doctor's fiduciary duty had been breached. The first issue with practitioners performing mesh implantation surgery is their failure to accommodate consumers to make an "informed choice and give informed consent" under the Rights Code of Health and Disability Services Consumers Rights 1996.[22] Many women reported not being told adequate information about the risks, complications, and alternative options.[23] A patient needs to know this essential information when making such a permanent decision. During an appointment, it is difficult for the patient to know what to ask and assess areas of concern they may wish to inquire about. Consequently, they rely on their doctor to raise all the relevant information and initiate discussion to raise questions based on that

---

[19] Charlotte Lomas "New Zealand bans vaginal mesh over safety fears" 12th December 2017 Skynews <*https://news.sky.com/story/new-zealand-bans-vaginal-mesh-over-safety-fears-11167897*>

[20] *Adverse Events Report Relating to Surgical Mesh Implants- summary of data received by Medsafe* (MedSafe, October 2019) at 8.

[21] Ron Paterson *The Good Doctor: What patients want (Auckland University Press,* Auckland, 2012) at 4.

[22] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, r 7.

[23] Emma Russell "In Her Head: Petition demands halt on surgical mesh for birth injuries" *The New Zealand Herald (*online ed, Auckland, 13 August 2022).

information. However, many patients recalled their surgeons being belittling and passive to their concerns, claiming that their 'only option was mesh', 'with no alternatives being offered'. One woman stated her surgeons told her to 'come back when you agree to have mesh.'[24] Only in retrospect did patients recognise that they were misled and pressured to undergo this treatment. This clearly illustrates how practitioners have abused the power imbalance within a doctor-patient relationship.

At the surgical stage, doctors could conduct the surgery without any formal training or certifications. In turn, many surgeons lacked proper training to perform the treatment, meaning they were implanting the vaginal mesh incorrectly. This breaches the fundamental ethical duty imposed upon surgeons dating back to Hippocrates' oath "to help and do no harm".[25] Yet many practitioners were solely trained by one surgeon who brought the Transvaginal Mesh (TVM) surgery to New Zealand following their overseas training. The surgeon had been negligently inserting mesh. Evident as the surgeon who wrongly implanted Sally Walker mesh into her bladder.[26] Consequently, it is inconceivable that practitioners trained by one surgeon, who himself failed to insert the mesh correctly, could be implanting mesh without any specific training program or system of credentialing. This demonstrates the lack of knowledge surgeons have about the risks and complications associated with the device, as 'Instructions for use' were not provided by the manufacturers. In turn, this creates a great deal of fear and concern for patients undergoing surgery, as they are unaware that their doctor has no specific training to offer or perform the implantation surgery.

C. Medical Council

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. Under the Health Practitioners Competence Assurance Act 2003, their role includes "Making sure doctors have the skills to practise within the scope of how they are registered" and "reviewing doctors when their performance, professional conduct or health is a concern."[27] With the clear lack of credentialled surgeons

[24] Jo Wailing, Chris Marshall and Jill Wilkinson *Hearing and Responding to the Stories of Survivors of Surgical Mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health) (The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington, 12 December 2019)* at 17.
[25] Basil Varkey "Principles of Clinical Ethics and Their Application to Practise" (2020) 30 Med Princ Pract 17 at 18.
[26] Emma Russell, above n 10.
[27] "What We Do" Medical Council of New Zealand <https://www.mcnz.org.nz/about-us/what-we-do/>.

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.[28] 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. By law, when the medical council receive complaints or notifications about a doctor's behaviour or competence, they must be referred to the Health and Disability Commissioner. The Commissioner then manages the notification about the doctor from the patients, family or concerned staff members in the medical practice.[29] Yet the Medical Council omitted to follow up or review the performance of these practitioners, as they were legally obligated to. Instead, the Medical Council continuously resolved many tensions between patients and doctors with the least interventionist approach when regulating the profession.

D. Accident Compensation Corporation

As patients had to undergo many appointments and procedures due to mesh insertion, the ACC system in New Zealand was to provide compensation for those who suffered treatment injuries. Patients were put in a position where they had to give up work, unable to be mothers to their children, and women who were primary income earners had to sacrifice their saving or even their homes.[30] Yet the compensation awarded was modest relative to the life-long damage that occurred. Up to 33% of treatment injury claims were denied.[31] Understandably, claims were declined in earlier years of surgical mesh treatment injury claims due to the lack of medical evidence and knowledge about the device. Therefore, ACC may not have understood the magnitude of harm. However, the ACC claim review process concealed negligent doctors who should not have been performing this surgery. Practitioner cooperation is essential in completing claim forms for injured patients.[32] Yet practitioners breached their responsibility, as it was discovered that inadequate or missing documentation was frequently identified in

[28] Interview, above n 5.
[29] "What We Do", above n 27.
[30] Wailing, Marshall and Wilkinson, above n 24, at 18.
[31] ACC, above n 15.
[32] Ron Paterson, above n 21, at 117.

claims.[33] Consequently, practitioners negligently inserting mesh were providing insufficient treatment injury information. This prevented ACC from being able to prove the causal link between the patient injury and treatment.[34] In turn, it enabled ACC to reject treatment injury claims. This left patients helpless as they were stripped of the compensation they were entitled to, causing many women and their families to face significant financial difficulties.

Moreover, patients could not seek adequate compensation directly from the mesh manufacturers due to the limitations imposed by s317 of the ACC Act.[35] Considering ACC compensation is a social contract, those applying for personal injury must forgo their right to sue for an injury. The Court of Appeal in *McGougan v Depuy International Ltd*[36], in 2018 affirmed this in the context of the hip replacement device scandal. The law does not bar complainants from suing the other party to claim exemplary damages. However, punitive damages are likely to be limited, considering manufacturers have withdrawn supply in New Zealand.

Arguably, patients would have rather waived their right to ACC and brought long-term litigation to set a precedent and increase awareness surrounding the issue, much like the Johnson and Johnson case in Australia. The class action in 2022 has settled at $300 million,[37] which has enabled victims to receive higher and fairer compensation relative to ACC's limited payments. Ultimately, if patients cannot opt-out of the ACC scheme to pursue legal action against the device manufacturers, they should be fairly compensated for giving up this right.

Adequate compensation would have enabled women to receive mesh removal surgery abroad with credentialled surgeons. Women reported battling against ACC's denial of removal surgery for ten years.[38] Not only did this allow for symptoms to continue, but as time went on, this enabled the mesh inside patients to continue to erode. Consequently, undergoing removal surgery at this stage would be much riskier and more complex, with a higher chance of failure. Sally Walker illustrates this, as early intervention could have enabled successful mesh removal by a qualified surgeon overseas and prevented her bladder removal.

---

[33] Wailing, Marshall and Wilkinson, above n 24, at 18.
[34] Accident Compensation Act 2001, s32.
[35] Ron Paterson, above n 21, at 317.
[36] *McGougan v Depuy International Ltd* [2018] 2 NZLR 916, [2018] NZCA 91.
[37] Melissa Davey "Johnson & Johnson reaches $300m settlement over pelvic mesh implants" (12 September 2022 The Guardian <https://www.theguardian.com/business/2022/sep/12/johnson-johnson-reaches-300m-settlement-over-pelvic-mesh-implants>.
[38] At 18.

Aside from ACC's omissions to act, ACC payments for surgical mesh injuries have rapidly increased from $500,000 in 2017 to $5.1 million last year.[39] Moreover, 1,603 claims were made between 2005 and 2020 about surgical mesh[40], which revealed specific doctors or, at the very least vaginal mesh insertion surgery was causing an excessive rate of injury claims. This should have acted as a catalyst for ACC to comply with their statutory obligation under section 284.[41] ACC had a responsibility that if it believed there was a 'risk of harm to the public', to 'report the risk, and any other relevant information, to the authority responsible for patient safety concerning the treatment that caused the personal injury.'[42] The mechanism intended to improve patient safety was only utilised once in the past five years concerning a medical equipment issue, according to an IOA request. Yet following this, ACC did not record any outcome resulting from the risk of harm notification as they leave the responsibility for the referred authority to manage.[43] Agencies handling complaints should have a low threshold for alerting the regulator where there is evidence of a pattern concerning medical behaviour.[44] Yet the failure to adequately warn and communicate to other responsible bodies about the increasing trend of mesh-harmed patients led to the crisis escalating.

E. Health and Disability Commission

HDC is the final stop for patients to complain about harm suffered. The HDC is an independent watchdog, providing health consumers with a voice in the healthcare system by resolving complaints and holding individuals and system providers accountable to initiate improvements in their practice.[45] Therefore, for surgical mesh patients, the HDC provides an avenue to complain to the healthcare providers who have negligently inserted mesh without informed consent or the proper skill and experience.

Yet the HDC has proven ineffective at proactively responding to the collective complaints to initiate restorative and preventive action against reoccurring problems from surgical mesh insertion. When patients complained, HDC rejected most claims with 'No Further Action'.

---

[39] Emma Russell "In Her Head: Women's health- Surgical mesh investigation, claims surgeons harmed women" *The New Zealand Herald (*online ed, Auckland, 30 June 2022).
[40] ACC *Summary of 'look back' at declined surgical mesh claims* (ACC, October 2020) at 1.
[41] Accident Compensation Act 2001, s284.
[42] Accident Compensation Act, s284.
[43] "Vaginal mesh risk of harm data" (11 October 2022) (Obtained under Official Information Act 1982 Request to the author).
[44] Ron Paterson, above n 21, at 117.
[45] "Purpose and Vision" HDC <https://www.hdc.org.nz/about-us/purpose-vision/>.

Among 68 surgical mesh complaints made to the HDC, only two crossed into the formal investigation stage.[46] Note that these are cases where the complainant was willing and able to complain to the HDC. This is not the case for many, evident in that elderly or socio-economically deprived women are less likely to complain,[47] and 1 in 200 choose to make an official complaint to the HDC.[48]

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.

Limiting factors to the HDC's complaints process have contributed to the HDC's lack of investigations. Firstly, processing a claim is very disconnected from the complainant. Completed solely through paperwork submissions strips the complainant of the opportunity to make their personal case to the HDC. Complaints cannot always be truly understood when explaining physical injury and psychological trauma through official documentation.

Understandably, assessing each case personally would be timely and resource exhaustive. Moreover, there is a backlog the HDC must manage. Regardless of this human disconnect, when the HDC is processing many similar complaints regarding the same practitioners, medical device and resulting injury, this indicates a great magnitude of collective suffering. This should act as a call for an inquiry into the broader issue. Patients would feel heard and satisfied that they have collectively contributed to changes in the system to prevent future harm. Yet eventually, most women were left with an unjust outcome with "No further action".

Secondly, there is a lack of transparency to the public as the HDC does not publish the reasons for NFA decisions. Only formal investigations are published, which has only been in 2 instances for TVM. However, in Sally Walker's case, the HDC refused to release a report into Walker's case from an independent urologist and surgical mesh expert, Dr Hazel Ecclestone.[49]

---

[46] 2 pers.comm Rose Wall Deputy Health and Disability Commissioner, data provided via email as cited in Petition of Renate Schütte: A right to appeal decisions made by the Health and Disability Commissioner.
[47] Ron Paterson, above n 21, at 26.
[48] At 26.
[49] Emma Russell " 'Rotting' surgical mesh leaves woman without a bladder" (30th June 2022) NewstalkZB <https://www.newstalkzb.co.nz/news/national/in-her-head-womens-health-sally-walkers-surgical-mesh-trauma-my-body-was-breaking-down/>.

Negligent surgeons can escape liability undetected and continue practising negligently. In turn, HDC has not proven to be the trusted regulatory body representing and advocating on behalf of the patient. Instead, it has only caused a loss of trust in HDC creating any positive outcomes. This poses a significant risk to effectiveness of the complaint system. Complaints to the HDC should be encouraged, as they act as a vital mechanism to detect negligence in the medical profession that would otherwise go undetected. However, the HDC's lack of investigations discourages patients from complaining, knowing they will most likely be left with NFA.

Lastly, a limitation of the HDC system is the lack of the right to appeal decisions made by the HDC. Once the HDC decides to close cases with "no further action", there is no alternative avenue for a complainant to bring forward their case based on its equity and hold negligent surgeons accountable. Injured patients are constrained to only two alternative options: firstly, to seek judicial review. For many families, this is not a viable or accessible option due to the very high legal costs, usually from $30,000.[50] The judicial review's purpose is limited to reviewing the fairness of the procedure applied by the HDC rather than the fairness of their decision. Consequently, this leaves the complainant with no place to seek a review of the credit of the HDC decision.

Secondly, the complainant could lodge a complaint to the Ombudsman. Once again, this process would only inquire into the operation of the HDC reaching its decision instead of the outcome itself. [51] Ultimately, injured patients are left to accept the inequitable outcomes from the HDC without holding responsible bodies accountable, severely comprising public trust and reliance on the HDC.

V. Actions Regulators Have Taken

A. Ministry of Health – Restorative Approach

The Ministry of Health had predominantly disengaged in addressing the mesh crisis. Arguably, due to the absence of data collected regarding the use of mesh and adverse outcomes. Consequently, there was little evidence on the magnitude of harm transvaginal mesh was

[50] Renate Schütte "Petition of Renate Schütte: A right to appeal decisions made by the Health and Disability Commissioner." at 8.
[51] At 11.

causing New Zealand patients. By 2018, advocates such as 'Mesh Down Under' were applying the necessary pressure to call for change by addressing the Select Committee, complaints to the HDC and media exposure.[52] Their role in increasing awareness through the media finally alerted the Ministry of Health (MOH) that intervention was necessary.

In June 2019, the Ministry of Health commissioned a restorative justice approach, an encouraging step toward addressing the harm. The project aimed to explore the damage caused by surgical mesh use in New Zealand. Through listening and understanding the stories of 600 people, including patients, their families and practitioners, the Ministry identified the core issues that collectively caused this crisis.[53] Finally, it was an opportunity to acknowledge and validate these women's experience, especially for those who may not have been supported by ACC or have the resources to make a complaint to the HDC, in the presence of the regulatory agencies, practitioners, and the public.

The approach positively acted as a therapeutic exercise to rebuild trust and confidence in the healthcare system and authoritative bodies. Allowing doctors and nurses to speak on their experience outside of a bullying culture allowed them to be genuinely heard within an open and safe environment.[54] The mutual understanding between the different parties has been a crucial starting point for progress.

Until this initiative, there was a severe disconnect between the various agencies. Each agency operated independently, with little information shared amongst them. Although the statutory framework enabled risk of harm notifications between responsible agencies, it was not effectively utilised. The restorative approach was a progressive step to bridge the gap among the agencies by improving communication between the different regulators and informing them of their contribution to the mesh crisis. Moreover, the report helped illustrate the magnitude of suffering patients experienced from vaginal mesh surgery.

The Ministry then provided an evaluation of the project, which assessed whether the restorative approach had satisfied its aims to inform subsequent action. Actively commissioning an

[52] Mesh Down Under "Our Mission" <http://meshdownunder.co.nz/>.
[53] Jo Wailing, Chris Marshall and Jill Wilkinson, above n 24.
[54] Interview, above n 5.

evaluation of their input indicates that the Ministry intended to provide transparency and gain feedback on the work they hoped would serve harmed patients and future patients.

Although a positive step forward, the initiative was difficult to obtain the attention of many patients, who by 2019 had been exhausted and untrusting in the system. Yet five years prior, in July 2014, following a petition, the Health Select Committee made seven recommendations to the government after having presented to the House of Representatives regarding the use of surgical mesh.[55] Therefore, the restorative approach for some appeared to be a repetitive exercise of advocating for the government to implement change.

Following the restorative approach, 19 actions were set to be implemented within the Surgical Mesh Work Programme.[56] The actions positively addressed a wide range of issues, including improvements on informed consent, ACC reviewing cases, promising a credentialing framework, and improving education through professional colleges such as RANZCOG.

Disappointingly, most actions were vague and could not be quantitatively measured. For example, the HDC to "promote the visibility of their national advocacy service."[57] cannot be considered an action that will meaningfully and directly address concerns raised by harmed patients. The reforms needed in the HDC were reviewing the mesh case complaints, looking to implement an appeal process, and improving their assessment processes (as discussed earlier). This did not reassure patients that the relevant agencies would be vigilantly held accountable by the Ministry to meet patient expectations. A credentialling framework was promised to be implemented by January 2020.[58] Yet two years on, the framework has not yet been implemented. However, there have been restraints, such as the Coronavirus pandemic, which has caused a delay. The Ministry should have sought to suspend the use of mesh in the interim until they were certain practitioners were competent and skilled to continue operating on patients. Such action would have affirmed that the Ministry had the serious intention to take an active stance in preventing further harm from occurring.

[55] Health Committee *Petition 2011/102 of Carmel Berry and Charlotte Korte* (1 June 2016).
[56] Ministry of Health *Progress tracker: actions agreed in Hearing and responding to the stories of survivors of surgical mesh* (Ministry of Health, April 2022) at 1.
[57] At 1.
[58] At 1.

Another limitation of the 19 actions was the lack of implementing a registry to gather the information that would clearly illustrate the scale and scope of injuries caused by mesh patients. In countries such as the US and UK, and domestically through the Select Committee[59] and advocates, there had been an emphasis that a registry was necessary to improve data collection to improve the profession's understanding of the device. There is no evidence that the government is currently seeking to implement a registry, which is a solution that has been proven in other areas of health and jurisdiction to improve health outcomes exponentially. This paper will later recommend the implementation of a mesh registry. The Ministry should have taken a bolder stance in utilising the opportunity to impose recommendations that would hold regulators publicly accountable for implementing reforms. Not only would this improve outcomes for mesh patients, but there would be a strong incentive to drive regulators to implement change. It would increase the public's trust and confidence in the Ministry's ability to lead systematic reform where needed.

Ultimately, the difficulty in the actions addressed was that changes needed to be implemented within different regulatory bodies, not by the Ministry. The government making such promises meant harmed patients understandably set high expectations for their efforts and vulnerability in the restorative approach to pay off. Consequently, the restorative approach only acted as the first step in many ways. The approach's efficacy is only evident once recommendations produce positive health outcomes for women suffering from POP and SUI.

B. ACC Reviewing Declined Mesh Cases

As part of the surgical mesh restorative process commissioned by the Ministry of Health, ACC committed to reviewing previously declined ACC surgical mesh claims. 77% of claims between 2005 and 2020 were accepted, and 372 were declined.[60] The review covered claims made between 1 July 2005 and 25 November 2019.[61] A sample reviewing 10% of declined claims for mesh-related injury was rejected based on the reasons that there was no injury, no causal link, or an ordinary consequence of treatment.[62]

[59] Health Committee, above n 56.
[60] ACC, above n 39, at 1.
[61] At 1.
[62] At 2.

ACC must be credited for reviewing previous cases considering the developments in medical knowledge regarding mesh insertion surgery. During the review, positive action is initiated to serve the patients' individualised needs, as many mesh survivors want to feel heard.[63] ACC has ensured patients experience a personalised review, with a dedicated specialist cover assessor to provide support through the process. Patients can choose whether they would prefer a female or male assessor. They have attempted to restore the progressive damage mesh injured patients have faced due to the lack of adequate compensation for their injuries.

Yet the review process firstly has shown the extent of declined claims has dated back to 2005, nearly two decades ago. Consequently, this illustrates the prevalence of the crisis. Moreover, for many the opportunity to remove their mesh effectively that was available at the time of their injury, is no longer an option. This is due to mesh progressively eroding around the surrounding tissues overtime. Consequently, the review is too late for many women who have missed the window to undergo removal surgery, as it only becomes more complex with increased risk of vaginal scarring and damaged tissue. Ultimately, the limited efficacy of reviewing previous claims illustrates that although regulators intend to restore the damage, preventative measures are essential to avoid irreversible damage that can no longer be rehabilitated.

C. Improving Informed Consent

Another development from the restorative approach was the improvement of informed consent to potential mesh patients. A comprehensive patient information resource booklet has been created and distributed to patients with SUI or POP advised to do mesh insertion. It is available on the Ministry of Health's website and provided during patient consultations.[64] This has created a safeguard by ensuring extensive information surrounding mesh complications is provided to the patient, regardless of the lack of disclosure the practitioner may provide. The booklet is an essential tool that can positively inform patients' areas of concern and research to protect their decision-making.

Yet there are concerns with relying on this as a tool to ensure informed consent. This appears to expose the lack of confidence in regulators have in practitioners, as they have taken the

[63] Wailing, Marshall and Wilkinson, above n 24.
[64] Ministry of Health, above n 52.

responsibility to provide information to the patient.[65] There is a risk that will enable practitioners to avoid liability in breaching rights 6 and 7 under the Code of Health and Disability Services Consumers' rights[66] as they can rely on providing the booklet without further input. Moreover, with greater external resources, patients may be confused and anxious about the best course of action to take. For many women who are experiencing prolapse or incontinence, their main priority at the time is for their current symptoms to stop. Patients expect they can rely on their doctor and assume their advice is tailored to the specific patients' medical needs.[67]

Moreover, patients believe that they can trust their doctor to competently perform the surgery if they advise their patients to undergo implantation.[68] Consequently, when patients are in a desperate position, where their doctor advises them to use mesh- their decision is likely to count on their doctor's instructions over eternally. provided information or online research. Furthermore, placing the burden on the patient to do their research can be a daunting task and unrealistic expectation, considering the patient deliberately relies on their doctor to provide the most relevant and reliable information.

Undoubtedly, these booklets have successfully created a safeguard to better inform patients about their decision and the risks of complications, as the information has been presented in a digestible and simple format. However, this information should act as a tool to set-off a discussion with the surgeon to determine whether the patient is suitable to be selected for the procedure. Yet this does not replace the surgeon's responsibility to provide the information a reasonable consumer would expect and correctly insert the mesh.

VI. The Next Steps: What actions need to be taken?

A. National Credentialling:

A National Credentialling Framework is projected to be implemented in New Zealand by the end of 2022. The framework has been long overdue to ensure that surgeons undertaking mesh

[65] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, r 6(b).
[66] Right 7.
[67] Basil Varkey, above n 25, at 18.
[68] Ron Paterson, above n 21, at 6.

surgery are, in fact, skilled and experienced enough to do so. The New Zealand Framework will be led by the National Credentialling committee, which the Ministry will oversee. The Committee will comprise of at least one external surgical expert from a recognised overseas mesh removal centre, an expert from Aotearoa New Zealand, with appropriate surgical experience and acceptable outcomes (once credentialled themselves), consumer representation and Māori health clinical expertise.[69]

A credentialling process is implemented to formally verify a practitioner's license, experience, education, certification, clinical judgement, and technical capabilities. It imposes crucial requirements that set a baseline standard for credentialing is vital to ensure patients receive equal, safe, high-quality patient care.[70] Credentialling systems incentivise an increase in continuing education to maintain proficiency with the latest clinical discoveries around treating POP and SUI. Surgeons should only be able to perform advanced mesh implantation surgery if they have been granted the privilege to do so through official credentialling, certifying the surgeon is skilled and competent to perform the surgery. For New Zealand's credentialling framework to be effective, they must require surgeons to demonstrate a fundamental knowledge of the biology, safety, informed consent, and potential complications associated with mesh implantation.[71] Moreover, they must hold a fundamental knowledge of the techniques and technical competence required for mesh implantation.[72] By patients knowing their doctor has this credentialling, practitioner have a greater expectation placed upon them to provide a higher standard of care.

Another advantage of the framework is that the Ministry of Health will publicly list the credentialled surgeons and accredited services.[73] This is undoubtedly a positive step toward building patient trust. Especially after the increased media and awareness regarding mesh implantation, patients understandably are warier and prefer to verify the surgeon's skill and competence. Providing patients with an accessible list of credentialled doctors can strengthen patients' confidence. Patients can be assured their doctor has gone through a robust process that affirms they obtain a high standard of competence and skill. Moreover, it can provide greater

[69] Ministry of Health *National Credentialling framework – Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures* (May 2022).
[70] J. Christian and others "Credentialling for transvaginal mesh placement- a case for 'added qualification' in competency" (2012) 23 Suppl S27 at S30.
[71] At S30.
[72] At S30.
[73] Ministry of Health, above n 69, at 12.

transparency and accountability to the public as those surgeons are now openly held to credentialling standards.

However, the committee must be wary that doctors who may have had extensive experience with mesh implantation, does not automatically equate to skill and competence, considering the high harm rate resulting from mesh surgery. Consequently, the credentialling framework must be robust enough to correctly capture doctors that need more training to upskill, regardless of whether they have had many years of experience. Understandably doctors may be reluctant to undergo the credentialling process considering they may believe they are entitled to continue their practice without being challenged. This is especially true for many surgeons performing the surgery for years, with little accountability pressed against them. In this instance, it is the medical colleges' and the Ministry of Health's responsibility to create an encouraging culture. One that promotes credentialling as a positive form of improving the patient's experience rather than an exercise of challenging the doctor's skills and competence.

Another concern in the credentialling framework is the extensive reliance on practitioners reporting their data and information to the credentialling board. A heavy burden is placed on the practitioner to prove their skill and competence. Practitioners must provide the Committee with essential documentation, such as logbooks that include "indication for surgery, examination findings, diagnostic results, pre-operative PROMs, operation notes, complications and clinical and patient-reported outcomes at six months."[74] This allows the practitioner to control the Committee's understanding of the practitioner practise. Practitioners have proven to not always be reliable in providing full transparency to regulators, in order to protect themselves from exposure to liability for negligent behaviour. This was evident in the ACC claims for treatment injury (as discussed earlier). Consequently, the Committee must impose robust independent direct auditing procedures to capture negligent practitioners, instead of enabling it to be a paperwork exercise by the practitioner applying to be credentialled.

Furthermore, an alarming aspect of the credentialling framework is the lack of legislative or regulatory authority to incentivise practitioners and colleges to implement effective change. The framework only requires the Credentialling Committee to send a copy of the credentialing

[74] J. Christian and others, above n 70, at 34.

report to relevant staff and facilities for consideration. Essentially, this leaves complete discretion to the facilities regarding whether they want to implement the recommendations.

Suppose the Committee has concerns about a specific practitioner's conduct or competence in this practice area. In that case, the Committee may notify the Medical Council under the Health Practitioners Competence Assurance Act 2003. Moreover, the Committee may send a copy of the notification to the relevant professional body, such as RANZCOG or RACS, to provide the practitioner support or advice.[75] Theoretically, this provides safeguards through the risk of harm system. Yet one can be sceptical about the efficacy of this mechanism, considering its failure to protect patients from harm in the past, as it was not exercised during the escalation of the crisis. However, considering there is an allocated committee specifically responsible for issuing risk of harm notifications rather than large regulatory bodies, it may potentially prove to be utilised constructively.

As a recommendation, once a surgeon has fulfilled the criteria to prove they have the knowledge in the biology, safety, informed consent, and managing complications. It would be beneficial that an audit of the first 10-20 cases of the newly credentialed surgeon to ensure the proper safety benchmarks are being adhered to would be ideal.[76] It would assure the industry, medical colleges, and regulatory bodies that the practitioner is proving they meet the skills expected of a credentialled doctor to continue to perform the surgery. One could argue that this next layer of safeguarding can be costly and time-consuming. However, considering the Ministry of Health has declared only five practitioners are performing the surgery in New Zealand, the small scale makes this an achievable requirement.[77]

A significant positive development implemented into the framework is the approach to credentialling mesh removal and non-mesh alternative surgeries as a separate credentialling framework. This considers the future risks that as more awareness grows around mesh implantation, ACC reviewing claims may increase, and the demand for mesh-removal and non-mesh alternative procedures. Moreover, under the Accident Compensation (Maternal Birth Injury and Other Matters) Amendment Bill enacted on 1 October 2022, ACC projects that under the new law, 28,000 women per year will now have access to the support and treatment

[75] Ministry of Health, above n 69, at 16.
[76] J. Christian and other, above n 70, at S30.
[77](5 September 2022) 31266 NZPD (Jan Logie to the Minister of Health- Hon Andrew Little).

needed.[78] This poses a severe risk to more women seeking treatment for birth injuries, as they will be exposed to the dangers of mesh and now non-mesh surgery. Moreover, the risk is heightened, as many surgeons in New Zealand have not had to practise alternative treatments for SUI and POP for years, nor have they been officially trained to do so.

The UK is a case study illustrating these concerns have already manifested. The Independent Medicines and Medical Devices Safety Review triggered the UK's suspension of vaginal mesh for SUI and POP in 2018. The pause on mesh remains present, yet mesh is not banned. It is only used as a last resort in extreme patient cases, with heavy monitoring. The UK Mesh Clinical Advisory Group, comprised of specialists in urogynaecology, found they had few surgeons within the UK who could provide non-mesh procedures to women needing treatment following their mesh suspension in 2018.[79] Due to the lack of training and practise surgeons had after decades of primarily performing mesh implantation.[80] Consequently, following Charlotte Korte's advice, "strict monitoring is essential".[81]A robust credentialling system is necessary to prevent further harm in mesh removal and non-mesh alternative surgeries.

The credentialling framework has done well in treating mesh removal as a separate practice, requiring practitioners to undergo specific sub-speciality training before performing the surgery. Moreover, it also addresses that practitioners undertaking non-mesh surgery are required to:

- "demonstrate supervised and documented training in each specific non-mesh procedure (for example, through logbooks, including volumes and case review of patients) or
- be proctored by a qualified surgeon with currency of experience in specific procedures and
- demonstrate the ability to successfully treat the complications of non-mesh procedures."[82]

[78] Sue Claridge (ed) *Birth Injury, ACC, and Surgical Mesh* (online looseleaf ed, Auckland Women's Health Council) at 17.
[79] Sue Claridge (ed), above n 78, at 18.
[80] At 18.
[81] "Serious Patient Safety Concern Results In Multiple Organisations Calling On the Government To Act Urgently" (29 August 2022) Scoop Health <https://www.scoop.co.nz/stories/GE2208/S00065/serious-patient-safety-concern-results-in-multiple-organisations-calling-on-the-government-to-act-urgently.htm>
[82] Ministry of Health, above n 69, at 32.

For these requirements to successfully credential a doctor that will create the outcomes desired, the Committee must impose a high threshold to satisfy each element. This paper cannot comment on the specific medical skills the doctor must display through this competence tool. Yet from a public safety perspective, the main objective is for these credentialling requirements to be rigidly applied and not simply a tick box exercise. Considering credentialling is set to take place biennially. The framework must be built to adapt to advances in medical research, technology, and surgical methodology to ensure that ongoing training under credentialling is up to date.

Moreover, the framework proposes that multidisciplinary teams for mesh removal are to be formed, which include "specialist urogynaecologists, urologists, a radiologist with expertise in female pelvic floor and reconstructive medicine, potentially colorectal and orthopaedic surgeons, specialist continence and urology nurses, a specialist in pain management with pelvic floor expertise, pelvic health physiotherapists, diagnostic pelvic floor ultrasound capacity, comprehensive urodynamic testing, psychology psychosexual support and consumer advocacy."[83] This would provide extensive support around all aspects of treatment and recovery for each patient's case. However, it was announced by the Ministry of Health in 2022 that there are only five doctors that hold an "Annual Practising Certificate with a subspeciality of urogynaecology"[84] operating in New Zealand. Considering the substantial staffing and resource allocation required, the expectation that such a large specialised team can be assembled could be deemed unrealistically achievable in the near future. Yet the credentialling framework publicising the standards they are expecting themselves to meet allows the Committee and other stakeholders to be held accountable, to achieve these aspirational aims to provide the best patient-centred care.

Following these considerations, a key factor determining the framework's efficacy is its execution into the existing medical systems operating. The framework must be easily integrated into the individual practitioner's workplace and wider hospital or clinic systems and structures. The lower the barriers to implementing the framework, the more efficient data can be collected for the Credentialling Committee to assess the competence and skill practitioners have. The current expectation that facilities must establish a local credentialling process to report to the

[83] Ministry of Health, above n 69, at 43.

[84] (5 September 2022) 31226 NZPD (Jan Logie to the Minister of Health- Hon Andrew Little).

national credentialling committee increases resistance.[85] It burdens each local facility considerably to develop and implement a personal system. This requires a high expenditure of time and resources, which are already limited within these facilities. Instead, the Ministry of Health could invest in a registry. This will be the following recommendation discussed in this paper.

The fundamental purpose of credentialling is to uphold patient safety. Imposing a credentialling framework can potentially restore the trust and confidence in doctors and the healthcare system. For this to be effectively achieved, patients expect the framework to vigorously address the concerns raised over the past two decades, amongst hundreds of complaints made. Patients need a framework to prevent harm from occurring to future patients, as this is ultimately the objective for advocacy groups and individual complainants.

B. Registry

Following the credentialling framework, establishing a registry would go hand in hand as a means of setting up preventative measures by collecting complete data around the use of mesh, mesh removal and non-mesh alternative surgery. Currently, there is a clear silo of information between regulators. In turn, this enabled the poor practice to continue undetected and arguably manifested into the mesh crisis.

There is no centralised system where regulators can access information regarding a practitioner and possible complaints or concerns about their conduct. Consequently, between ACC, HDC, and the Medical Council, one practitioner displaying a negative behavior pattern may not be detected across different complaint boards. This has enabled incompetent practitioners to go without any accountability or correction. This makes it challenging to provide consistent details on the scale and scope of complications from mesh implants. Establishing a centralised surgical mesh registry that would be mandatory for all surgeons performing mesh implant, alternative, or revision surgeries is the most practical and achievable solution. There is a trade-off considering the expenses and time consumption. Yet without this full commitment, restoring and preventing mesh injuries cannot be successfully achieved. This is evident in the initiatives that have already been taken in New Zealand in previous years (as discussed earlier), that have not taken far enough to be effective.

[85] Ministry of Health, above n 69, at 39.

Due to the high costs associated with establishing and maintaining a registry, there has been continuous resistance to implementing a mesh registry in New Zealand. Establishment costs may involve capital costs, purchasing IT equipment, design and functionality of the register, and labour costs in training clinicians using the register. After a register has been established, ongoing costs may include labour of inputting and cleaning the data by a medical professional and other staff, renting the location of office space where the registry is based, and labour costs involved with analysis and reporting of the data collected.[86]

However, the economic trade-off is arguably worth it in the long run, considering ACC has already paid out $5.1 million.[87] Therefore, it is a stronger investment to obtain and maintain data that will provide information to better inform decisions in allocating resources to best address the mesh crisis. In 2017, a study was conducted to systematically review dementia registries worldwide, which found that registries provided a positive return on investment.[88] Moreover, the registry would initiate low treatment costs for ACC to compensate as there is likely to be a reduced number of revision surgeries required to amend mesh treatment injuries.[89]

It has been proven that registries provide invaluable information feedback to health care providers. A study by Van Den Veer et in 2010 found that out of 43 processes of care measures that evaluated how registries provide feedback to health care providers, 26 measures were positively affected by the feedback.[90] Currently, there is limited feedback regarding the health care providers implanting mesh. Yet with this data, it can inform surgeons and colleges of the areas that are working well and what needs improvement. In turn, implementing a registry provides constructive feedback which serves to ensure health outcomes improve and the quality of patient care increases. In 2017, a study conducted systematically reviewed clinical care registries on the quality of patient care and clinical outcomes. It was found that from 17 studies, 16 demonstrated positive health outcomes after implementing a registry.[91] Moreover, the

[86] Linda Meade *Deloitte Surgical Mesh Registry: Cost Benefit Analysis (*Ministry of Health, July 2018) at 7.
[87] Emma Russell "In Her Head: Women's health- ACC payouts for harmful treatment $27 million" (7 May 2022) NZ Herald <https://www.nzherald.co.nz/nz/in-her-head-womens-health-acc-payouts-for-harmful-treatment-27-million/J62G5EZCZDGZ4KHL7Y2NVXGHMM/>.
[88] Karolina Krysinska and others "Dementia registries around the globe and their applications: A systematic review." (2017) 13(9) Alzheimers Dement. 1031 at 1047.
[89] Linda Meade, above n 86, at 7.
[90] Sabine N van der Veer "Improving quality of care. A systematic review on how registries provide information feedback to health care providers" (2010) 79(5) 305 at 323.
[91] Dewan Md Emdadul Hoque and others "Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review" (2017) 12(9) PloS one e0183667.

registry can provide information when advising patients and their families about the current results in specific institutions, enabling patients to access better information regarding their practitioners and confidently provide informed consent.[92]

The UK serves as a positive example where a mesh registry has been established to address the siloed information issue. In July 2018, the House of Commons Health Secretary announced their department would invest 1.1 million pounds in developing a comprehensive database for vaginal mesh.[93] The registry includes historical data from 2017 and will collect data over time following follow-up appointments. Moreover, data will be collected for removal and non-mesh alternative procedures to provide complete data that enables comparison and complications between the different procedures.[94]

Considering there are many registries already established in collecting mesh-related data, there is little research and development required for New Zealand to commit to. The Ministry could invest in a database that all practitioners must report to, with implemented reminders for follow-ups on patients. This could be a tool that can be simply integrated into existing practitioner systems to reduce establishment costs. Moreover, it would collect reports to gather longitudinal information on each practitioner's skill. It will easily enable surgeons to be held accountable to the credentialling framework, which requires practitioners to collect PROMs at baseline (before the surgical procedure), then 6 and 12 months after surgery and annually after that for up to five years, or longer if indicated. Therefore, it would simplify data collection through a unified system that can easily be tracked, accessed, and updated over time.[95]

Ultimately, for the registry to be successful, all the key stakeholders, such as practitioners, surgeon colleges, the credentialling Committee, the Mesh Roundtable, ACC and HDC, must effectively interact and communicate their proportional involvement in supporting the establishment and maintenance.[96]

---

[92] Willian G. Williams "Uses and Limitations of Registry and Academic Databases" (2010) 13(1) Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 66 at 69.
[93] (21 February 2018) 636 GBPD HC 166.
[94] NHS "National Perioperative Data Standard Programme" (August 2022) NHS Digital< https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme>.
[95] Ministry of Health, above n 69 ,36.
[96] Bogdan Pop and others "The role of medical registries, potential applications and limitations" (2019) 92(1) Med Pharm Rep. 7 at 14.

C. Suspension

One must consider the future of SUI and POP treatment, with or without mesh. It cannot be denied that many patients have seen permanent advantages in the use of mesh implantation, with the right selected patient and the competent doctor. In New Zealand, there has yet to be this guaranteed successful combination. Therefore, until a robust credentialling system and effective data collection is in place, the usage of mesh needs to be suspended. New Zealand regulators should prioritise prevention of harm over the chance of successful mesh treatment considering the risks associated with mesh treatment is much harsher. This has proven to be an effective short-term solution in the UK in the interim, until credentialling and a registry is fully in place.

Moreover, suspension is deemed appropriate considering the Ministry of Health has admitted to obtaining no knowledge of the number of accredited urologists operating in New Zealand, who has an overseas certification to take on advanced female pelvic medicine and reconstructive surgery. Te Whatu Ora does not hold information on the subspecialist training completed by urologists, nor do they have information on how many physicians are engaged in specific surgical tasks. [97] Consequently, there is clear ambiguity surrounding how many specialists in New Zealand are qualified to perform mesh implantation, removal, or alternative mesh surgeries. This makes it very difficult to identify practitioners that need to be held accountable, which with robust credentialling and a registry can solve. There

VII. Conclusion

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. In turn, women were not protected from the harms of transvaginal mesh by the regulators they relied upon.

[97] (9 September 2022) 32232 NZPD (Jan Logie to the Minister of Health- Hon Andrew Little).

Moreover, international warnings and harmed patients' complaints to the Medical Council, ACC and HDC have indicated the need for regulatory intervention throughout the crisis. Regulators failing to respond to complaints means the processes solely set up to capture signs of harm to the public, by medical devices or negligent surgeons, will go undetected and uncorrected. Moreover, the silo of information has made the risk of harm notification mechanism redundant, as authoritative bodies have little access to shared data of the surgeons and procedures causing harm. Therefore, although authorities such as the MOH and ACC made efforts to restore and prevent harm, they were not implemented rigorously enough to stop patient harm from continuing.

The best step forward to prevent further harm in the current state of our system is to suspend mesh. New Zealand is not ready to continue with mesh implantation until rigorous credentialling is done alongside complete data collection to track longitudinal changes through a registry. Understandably, practitioners in New Zealand may be resistant to the implementation of robust safeguards placed upon them. Yet this should not influence the moral duty placed upon regulators to ensure patients are compensated and protected from harm.

Bibliography

A. Cases
    a. *McGougan v Depuy International Ltd* [2018] 2 NZLR 916, [2018] NZCA 91.
B. Legislation
    a. Accident Compensation Act 2001.
    b. Medicines Act 1981.
    c. Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.
C. Books and Chapters in Books
    a. Ron Paterson *The Good Doctor: What patients want (Auckland University Press,* Auckland, 2012).
D. Journal Articles
    a. Basil Varkey "Principles of Clinical Ethics and Their Application to Practise" (2020) 30 Med Princ Pract 17.
    b. Bogdan Pop and others "The role of medical registries, potential applications and limitations" (2019) 92(1) Med Pharm Rep. 7.
    c. Dewan Md Emdadul Hoque and others "Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review" (2017) 12(9) PloS one e0183667.
    d. D. Karmakar and L. Hayward "What can we learn from the vaginal mesh story?" (2019) Climacteric 22 (3) 277-282.
    e. FDA *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse* (Center for Devices and Radiological Health, July 2011).
    f. J. Christian and others "Credentialing for transvaginal mesh placement- a case for 'added qualification' in competency" (2012) 23 Suppl S27.
    g. Karin S Coyne, Chris C Sexton, Christine L Thompson, Ian Milsom, Debra Irwin, Zoe S Kopp, Christopher R Chapple, Steven Kaplan, Andrea Tubaro, Lalitha P Aiyer and Alan J Wein "The prevalence of lower urinary tract symptoms (LUTS) in the USA, the UK and Sweden: results from the Epidemiology of LUTS (EpiLUTS) study" (2009) 104(3) BJU International 352.
    h. Karolina Krysinska and others "Dementia registries around the globe and their applications: A systematic review." (2017) 13(9) Alzheimers Dement. 1031.
    i. Jonathan Gornall "How mesh became a four letter word" (2018) 363 BMJ 1.

j. Linda Meade *Deloitte Surgical Mesh Registry: Cost Benefit Analysis (*Ministry of Health, July 2018).
k. Richard Rowberg and others *Food and Drug Administration Modernization Act 1997- The Provisions* (1998, CRS Web) at FDMA97.
l. Sabine N van der Veer "Improving quality of care. A systematic review on how registries provide information feedback to health care providers" (2010) 79(5) 305.
m. S. W. Bai, M. J. Jeon, J. Y. Kim, K. A. Chung, S. K. Kim and K. H. Park "Relationship between Stress Urinary Incontinence and Pelvic Organ Prolapse" (2002) 13 Int Urogynecol J 256.
n. Willian G. Williams "Uses and Limitations of Registry and Academic Databases" (2010) 13(1) Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu 66.

E. Parliamentary and government materials

a. Health Committee *Petition 2011/102 of Carmel Berry and Charlotte Korte* (1 June 2016).
b. Renate Schütte "Petition of Renate Schütte: A right to appeal decisions made by the Health and Disability Commissioner." at 8.
c. "Vaginal mesh risk of harm data" (11 October 2022) (Obtained under Official Information Act 1982 Request to the author).
d. (21 February 2018) 636 GBPD HC 166.
e. (9 September 2022) 32232 NZPD (Jan Logie to the Minister of Health- Hon Andrew Little).
f. (5 September 2022) 31266 NZPD (Jan Logie to the Minister of Health- Hon Andrew Little).

F. Reports

a. *ACC Surgical Mesh Review* (ACC, March 2015).
b. ACC *Summary of 'look back' at declined surgical mesh claims* (ACC, October 2020) at 1.
c. *Adverse Events Report Relating to Surgical Mesh Implants- summary of data received by Medsafe* (MedSafe, October 2019).
d. Australian Government *Final Report on the Australian Government Response to the Recommendations of the Senate Community Affairs References Committee Report: The number of women in Australia who have had transvaginal mesh implants and related matters (July 2021).*

e. FDA *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse* (Center for Devices and Radiological Health, July 2011).
f. Julia Cumberlege *First Do No Harm (*Independent Medicines and Medical Devices Safety Review, July 2020).
g. Jo Wailing, Chris Marshall and Jill Wilkinson *Hearing and Responding to the Stories of Survivors of Surgical Mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health) (The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington, 12 December 2019).*
h. Linda Meade *Deloitte Surgical Mesh Registry: Cost Benefit Analysis (*Ministry of Health, July 2018).
i. Ministry of Health *Progress tracker: actions agreed in Hearing and responding to the stories of survivors of surgical mesh* (Ministry of Health, April 2022).
j. Ministry of Health *National Credentialling framework – Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures* (May 2022).
k. Ministry of Health "*Surgical Mesh Roundtable: Terms of Reference"* (July 2022).

G. Dissertations
a. Jade Frances du Preez "Developing New Zealand Regulation: Lessons from Pelvic Mesh Devices" (LLB (Hons) dissertation, University of Auckland, 2018).

H. Internet Resources
a. "About MedSafe" (29 June 2020) MedSafe <https://www.medsafe.govt.nz/other/about.asp#device>.
b. Carmel Berry "Mesh Down Under" (October 12 2019) NZ History < https://nzhistory.govt.nz/women-together/mesh-down-under>.
c. Charlotte Lomas "New Zealand bans vaginal mesh over safety fears" 12th December 2017 Skynews <*https://news.sky.com/story/new-zealand-bans-vaginal-mesh-over-safety-fears-11167897*>.
d. Emma Russell "In Her Head women's health: Sally Walker's surgical mesh trauma-'My body was breaking down'" *The New Zealand Herald (*online ed, Auckland, 30 June 2022).
e. Emma Russell " In Her Head: Petition demands halt on surgical mesh for birth injuries" *The New Zealand Herald (*online ed, Auckland, 13 August 2022).

f. Emma Russell " In Her Head: Women's health- Surgical mesh investigation, claims surgeons harmed women" *The New Zealand Herald (*online ed, Auckland, 30 June 2022).
g. Emma Russell "In Her Head: Women's health- ACC payouts for harmful treatment $27 million" (7 May 2022) NZ Herald <https://www.nzherald.co.nz/nz/in-her-head-womens-health-acc-payouts-for-harmful-treatment-27-million/J62G5EZCZDGZ4KHL7Y2NVXGHMM/>.
h. Emma Russell " 'Rotting' surgical mesh leaves woman without a bladder" (30th June 2022) NewstalkZB <https://www.newstalkzb.co.nz/news/national/in-her-head-womens-health-sally-walkers-surgical-mesh-trauma-my-body-was-breaking-down/>.
i. Michelle Llamas "Transvaginal Mesh" (24 September 2021) Drugwatch https://www.drugwatch.com/transvaginal-mesh/.
j. Melissa Davey "Johnson & Johnson reaches $300m settlement over pelvic mesh implants" (12 September 2022 The Guardian <https://www.theguardian.com/business/2022/sep/12/johnson-johnson-reaches-300m-settlement-over-pelvic-mesh-implants>.
k. Mesh Down Under "Our Mission" <http://meshdownunder.co.nz/>.
l. NHS "National Perioperative Data Standard Programme" (August 2022) NHS Digital< https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme>.
m. "Purpose and Vision" HDC <https://www.hdc.org.nz/about-us/purpose-vision/>.
n. "Serious Patient Safety Concern Results In Multiple Organisations Calling On the Government To Act Urgently" (29 August 2022) Scoop Health <https://www.scoop.co.nz/stories/GE2208/S00065/serious-patient-safety-concern-results-in-multiple-organisations-calling-on-the-government-to-act-urgently.htm>.
o. "Transvaginal Mesh" RANZCOG <https://ranzcog.edu.au/og-magazine/transvaginal-mesh/>.
p. Waitemata District Health Board "Managing complications of Stress urinary incontinence and pelvic organ prolapse treatment (with options for mesh removal)" (October 2019) Te Whatu Ora Health New Zealand Waitematā <https://www.waitematadhb.govt.nz/assets/Documents/healthy-living/FPH/Managing-Complications-for-Stress-Urinary-Incontinence-and-Pelvic-Organ-Prolapse-Treatments-10Dec19.pdf>.

q. “What We Do” Medical Council of New Zealand <https://www.mcnz.org.nz/about-us/what-we-do/>.

I. Other Resources

a. Interview with Sally Walker, TVM survivor, (Rachel Smalley, First Light, Today FM, August 19 2022) transcript provided by Rova (Auckland).

b. Interview with Anonymous (Surgeon), (Author, 2 September 2022).

c. Sue Claridge (ed) *Birth Injury, ACC, and Surgical Mesh* (online looseleaf ed, Auckland Women’s Health Council).