Report of the Health Committee

Petition of Sally Walker: Suspend the implantation of mesh sling for stress urinary incontinence

June 2023

Contents

Dr Tracey McLellan
Chairperson

Petition of Sally Walker

Recommendation

The Health Committee has considered the petition of Sally Walker—Suspend the implantation of mesh sling for stress urinary incontinence—and recommends to the Government that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause.

Request to suspend the implantation of mesh sling for stress urinary incontinence

The petition was presented to the House on 1 September 2022. It requests:

> That the House of Representatives suspend the implantation of vaginally-inserted mesh sling for stress urinary incontinence (SUI).

The petitioner explained that mesh midurethral sling (MUS) implantation is a common treatment in New Zealand for stress urinary incontinence (SUI). However, she asserts that severe harm is regularly caused to women by many of the medical professionals who perform the surgery.

The petitioner believes a pause in the practice would stop serious ongoing harm. In her view, surgeons implant mesh incorrectly, and cause further harm removing it, as well as causing injury with non-mesh urogynaecological procedures. The petitioner noted that New Zealand surgeons were assessed against credentialling guidelines in 2018. She submits that they have continued to operate despite most of them not meeting the criteria. The petitioner would like New Zealand to follow the example of the United Kingdom, which paused the use of surgical mesh for SUI. She considers that, although access to treatment may be an issue, the benefit of the procedure does not outweigh the risk.

About our consideration of this petition

During our consideration of this petition, we received written submissions and heard oral evidence from seven submitters: Sally Walker, Charlotte Korte, the Ministry of Health, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australasian College of Surgeons, Dr Wael Agur, and the Physiotherapy Board of New Zealand.

Many of these submitters referred to the suspension of mesh surgery in the United Kingdom, and to two New Zealand reports about surgical mesh that contained recommendations. A brief explanation of each of these matters is set out below.

Petition 2011/0102 of Carmel Berry and Charlotte Korte

In June 2016, the Health Committee of the 51st Parliament presented its report to the House on Petition 2011/102 of Carmel Berry and Charlotte Korte.[1] The petition requested that the House inquire into the use of surgical mesh in New Zealand.

The petitioners had both experienced complications from surgical mesh, a medical device used to provide additional support when repairing weakened or damaged tissue. Surgical mesh is used in urogynaecological procedures to repair pelvic organ prolapse and SUI. It is also widely used for hernia repairs.

The Health Committee made the following recommendations to the Government:

- that it work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry
- that a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications
- that it suggest that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures
- that it encourage health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored
- that it encourage utilisation of the adverse events reporting system as applicable to medical devices
- that it endorse the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery
- that it consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand.

Hearing and responding to the stories of survivors of surgical mesh

In 2018, as part of its surgical mesh work programme, the Ministry of Health conducted a public survey of consumers and families harmed by surgical mesh. The aim of the survey was to determine the level of interest in sharing their stories with health authorities and learn how they could best be supported to do so.

In June 2019, the ministry commissioned the Diana Unwin Chair in Restorative Justice at Victoria University to provide a restorative justice approach to surgical mesh harm. The project aimed to listen to the stories of patients adversely affected by surgical mesh. This was seen as a way of helping to clarify the responsibilities of the ministry and the wider healthcare sector to address the problem, and inform subsequent actions. Between August and October 2019, more than 600 mesh-injured people shared their stories through forums held throughout the country or to an online database. Additional stories were heard from the families of people affected by mesh, and health professionals.

[1] A copy of the report is available on the Parliament website.

During the listening project, consumers and health professionals identified several major needs to address surgical mesh harm. They were:

- credentialling of surgeons
- specialist multidisciplinary mesh services
- informed consent
- safety culture and systems
- acknowledgement of harm
- responding to mesh harm both now and in the future.

The actions needed to address these were discussed at a workshop in November 2019. It was attended by representatives of the main agencies and professional bodies identified as sharing collective responsibility for undertaking reparative and preventative actions. Nineteen action points were agreed at the workshop. A report summarising the themes that emerged from the Restorative Justice process was published in December 2019.[2] We discuss progress on the various action points throughout our report.

Suspension of the use of mesh in the United Kingdom

In 2014, the Scottish Government called for the use of mesh implants to be suspended while an independent safety review was undertaken. The final report of the review was published in March 2017.[3]

In February 2018, the United Kingdom Government announced an Independent Medicines and Medical Devices Safety Review. The review examined how the healthcare system had responded to concerns raised by patients and families about three medical interventions, including surgical mesh. In July 2018, the review Chairwoman, Baroness Julia Cumberlege, recommended that the use of surgical mesh to treat SUI should be immediately paused until a set of conditions were met. The conditions of lifting the pause were as follows:

- Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly.
- They report every operation to a national database.
- A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery.
- Reporting of complications via the Medicines and Healthcare products Regulatory Agency is linked to the register.
- There is identification and accreditation of specialist centres for SUI mesh procedures, removal procedures, and other aspects of care for those adversely affected by surgical mesh.

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2 Wailling, J., Marshall, C., & Wilkinson, J. (2019). *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). Wellington, New Zealand: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington.

3 The *Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women* report is available here.

- National Institute for Health and Care Excellence guidelines on the use of mesh for SUI are published.

The recommendations were accepted by the Department of Health and Social Care and NHS England. The pause allowed for the use of mesh to treat SUI only in prescribed exceptional circumstances and under a high-vigilance regime.

In July 2018, the Chief Medical Officer Northern Ireland and the Welsh Cabinet Secretary for Health and Social Services announced similar pauses in Northern Ireland and Wales.[4]

Comments from the petitioner

The petitioner made a written submission in October 2022 and a supplementary submission in March 2023. We held an oral hearing with her on 15 February 2023.

The petitioner's and other women's experiences of mesh harm

The petitioner, Sally Walker, is a 73-year old woman who told us that her insides were badly damaged after mesh was incorrectly implanted into her body. As a result, her bladder has been removed and her vagina sewn closed. The petitioner said she can only make peace with all that has happened to her by doing everything she can to ensure that no woman ever has to suffer from this procedure again.

The petitioner's experience has connected her to "countless" other women who have suffered just as much as or more than her from what she described as an "avoidable, maiming procedure". Many of these women are much younger than the petitioner and have their whole lives ahead of them. We heard that the petitioner mentors and advocates for other women. Her youngest mesh-harmed consumer was 34 years old when mesh was implanted incorrectly and went into her urethra during surgery. The operation, which was performed seven months after the birth of her second child, changed this woman's life "dramatically". The petitioner said that the woman's surgeon insisted on mesh despite her requesting a fascia sling, and she was not given any other or less invasive options.

We were told that mesh can cause horrific and debilitating complications. Examples of the harm caused by mesh MUS include:

- chronic severe unrelenting pain
- severe chronic fatigue
- regular urinary tract infections and other infections
- multiple surgeries to correct the original surgery and remove the mesh, which can then cause more problems
- losing the ability to carry out routine activities, work, walk, sit, or have sexual intercourse
- devastating emotional and psychological effects
- damaging effects on relationships and families

[4] In July 2020, *First Do No Harm: The report of the Independent Medicines and Medicines Safety Review* was published. A copy of the report is available here.

- significant financial burden due to an inability to work
- loss of identity as a woman.

The petitioner considers that mesh data has been wrongly reported, leading to women continuing to be exposed to unnecessary risk and to suffer major harm. She submits that women have needed to go elsewhere to seek a second opinion and safer care. However, for many reasons, most consumers do not want their original surgeon to be told about this. As a result, the petitioner believes the data is inaccurate.

We heard that, in one year, 50 people put their trust in the petitioner to make a difference. Of these, four have had their bladder removed, and she expects that number to rise this year. The petitioner said that many of these women are suicidal, and are on a "cocktail" of medication, including Valium, Morphine, and Tramadol. This has been prescribed by surgeons who believe the problems are "all in our heads".

Outcomes that the petitioner is seeking

The petitioner referred to the petition of Carmel Berry and Charlotte Korte and the Restorative Justice reports, both of which contain strong recommendations. However, she submits that many of these actions are incomplete or remain "largely ignored".

The petitioner is seeking seven outcomes to address the problems caused by mesh MUS implantation in New Zealand. They are set out in more detail below.

Suspension of mesh MUS implantation

The petitioner requests that mesh MUS implantation be suspended until proper safeguards can be introduced. She maintains that the Government is focusing on reducing mesh harm and safeguards have not been established while this work is ongoing. According to the petitioner, in the meantime, some of the country's most experienced surgeons are causing harm, as well as creating further harm when removing mesh. She urges New Zealand to join Scotland and England in providing protection from mesh harm.

The petitioner recognises that asking for a pause on mesh implantation will restrict access to treatment for many patients. However, she said she cannot, and will not, stand by and not advocate and give her voice for all consumers who have and will continue to suffer the consequences from the effects of these procedures.

We asked the petitioner what her strongest priority would be in regards to improving quality care for women and making informed choices. The petitioner told us that her first priority would be to pause mesh implantation until surgeons are upskilled and have better knowledge of how to properly implant it. She said she does not want it banned and she wants it to be used in future. However, women's safety is paramount to her. We heard that the petitioner wants to know that surgeons are willing to upgrade themselves in a registry, be accountable, and put women first.

We observed that many of the recommendations from the petition of Carmel Berry and Charlotte Korte and the Restorative Justice process have not been implemented. We asked whether the petitioner is calling for a pause because she is not confident in the health system's ability to make changes and protect women's safety without one. The petitioner

said that nothing gives her confidence unless mesh MUS implantation is paused. She submits that nothing has changed nearly 10 years later and a pause is needed to save lives.

In her supplementary submission, the petitioner told us that, less than two weeks after presenting her petition, five more mesh-harmed women had approached her for help. She said that these women were harmed by the country's most experienced surgeons. Two more severely harmed women have come forward to talk about having their bladders removed. According to the petitioner, the Restorative Justice process is not enough. Women do not simply want to share their stories and have others share their anguish. Instead, they want women to stop suffering the same harm.

Mandated credentialling

Credentialling is a process used by health and disability service providers to assign specific clinical responsibilities to health practitioners. This is based on their education and training, qualifications, experience, and fitness to practise within a defined context. This context includes the particular service provided, and the facilities and support available within the organisation.

One of the agreed action points from the Restorative Justice report was to:

> Establish a credentialling committee by the end of January 2020 to recommend national standards for individual practitioners and services commencing with urogynaecology procedures. Minimum standards for insertion, renewal, repair and removal surgery and native tissue repair will be included.

The petitioner considers that this action point has not been addressed. She recognises that proper credentialling ensures that medical professionals are appropriately trained and current in their practice, adhere to clinical guidelines, and report complications. However, in her view, credentialling is "less than ideal" at present. The petitioner has the following concerns:

- The time frame for completion is unknown.
- Credentialling is encouraged in the private sector but there is no means of enforcement.
- Legislation is needed to regulate credentialling.
- Surgeons need to provide safe practice to gain consumers' trust.
- Credentialling relies on the values, priorities, and decisions of future committee members.
- Credentialling for implanting mesh has not commenced and no start date has been advised.

Introduction of a mandatory registry

The petitioner believes a mandatory registry is needed to record all mesh MUS implantations. To enable this, legislation would be needed that would be similar to the Cancer Registry Act 1993, which created the Cancer Registry. The petitioner proposes that an MUS registry would be a statistical record and provide a basis for better data about devices, complications, and prevention, as well as programmes for potential research.

The petitioner considers that an MUS registry would have several benefits, particularly improved quality of care and increased patient safety. A registry would also track long-term safety and performance to establish the best surgical practice for better patient health outcomes.

In the petitioner's view, for an MUS registry to be successful it needs two specific functions, as a minimum. They are: data about surgeries, implantation details, and adverse events; and patient-reported outcomes measures that are separate from the surgeon.

Use of mesh midurethral slings only as a last resort and with proper informed consent

The petitioner believes that mesh MUS implantation should only be used as a last resort when no other option is available. It should be implanted by an appropriately qualified subspecialist in female pelvic medicine and reconstructive surgery who is competent to fix any problems that may arise.

We heard that informed consent is one of the major problems reported by the women who the petitioner mentors or advocates for. She said that many women are at their most vulnerable when seeking medical advice and support. Therefore, they need significant support, and need the risks to be properly explained and understood, and all available choices offered and discussed with them. The choices include pelvic floor exercises, pessaries (a removable device), lifestyle changes, and native tissue slings. The petitioner submits that women are not given other options if their specialist believes that mesh should be used. She emphasised the importance of women having their views heard and having a voice to say what they really want for their bodies.

Categorising mesh injuries as sensitive claims

The petitioner noted that the following action point was agreed under the Restorative Justice process:

> ACC recognises the complex and sensitive nature of mesh claims and intends to use an approach that ensures mesh injured clients are matched to case owners with appropriate background, experience and skills.

According to the petitioner, this has not happened and she urgently calls for this action point to be implemented. She submits that the inaction results in:

- the sensitive nature of mesh claims to ACC not being addressed, causing mental injury
- multiple assessments and delays for treatment causing more complications
- ACC still declining treatment injuries on technicalities
- many people finding the ACC process retraumatising.

Introduce high-vigilance scrutiny for all non-mesh pelvic floor procedures

We were told that the United Kingdom Government implemented mandatory high-vigilance scrutiny of non-mesh surgery, alongside the surgical mesh suspension.[5]

[5] This recognised that surgeons may need to change procedures as a result of the suspension.

The petitioner requests that high-vigilance scrutiny be introduced in New Zealand for all mesh and non-mesh urogynaecological surgery. She said that 50 percent of surgical mesh procedures are undertaken in the private sector, but the Ministry of Health has no legislative mandate over it. The petitioner is also seriously concerned about an increase in non-mesh harm due to a lack of training and current practice in these procedures.

Protection of the urogynaecology subspecialist title

The petitioner would like "urogynaecology" as a subspecialty to be a protected title. She also requests that a generalist should not be allowed to call themselves a urogynaecologist. The petitioner said that the title is protected in Australia and the rest of the world.

Comments from Charlotte Korte

Charlotte Korte is a mesh-injured woman and patient advocate who supports women to get the help that they need. She made a written submission in October 2022. We held an oral hearing with her on 15 February 2023.

In 2014, Ms Korte and Carmel Berry petitioned Parliament requesting that the House inquire into the use of surgical mesh in New Zealand. Ms Korte told us that she is shocked at how many women are still contacting her for help. She submits that not much has changed for mesh-injured women since she began advocating for change in 2012. Ms Korte said that it has been nine years since she last appeared before a health select committee. She considers the fact that she is in front of a committee once again fighting for women not to be harmed as "quite frankly appalling".

According to Ms Korte, women still face a range of barriers. They include receiving acknowledgement of their harm, finding a specialist with appropriate skills to help them, and obtaining support from ACC. She described this treatment as "gaslighting", which adds further psychological trauma to the already "immense" physical effects.

On 30 September 2022, the Accident Compensation (Maternal Birth Injury and Other Matters) Amendment Act 2022 received Royal assent. The Act is expected to extend cover for maternal birth injuries to an estimated 17,000 to 18,000 more women annually. Ms Korte noted that these women will be presenting to specialists for birth and treatment injuries. In her view, this is a "red flag" because not all surgeons are informing patients about the risks of mesh and many patients are not being offered alternative treatments.

Concerns about a focus on harm reduction

Ms Korte said that the Government has a programme of work that focuses on reducing mesh harm. However, she maintains that there are no safeguards in the meantime and harm continues every day. Ms Korte told us that, in her advocacy role, she hears stories about experienced surgeons causing significant injury. This includes implanting mesh incorrectly, causing further harm removing it, and causing injury with non-mesh procedures. She considers that the benefit of continuing with these procedures does not outweigh their risks.

Ms Korte submits that the mesh work programmes have not effected any change. In her written submission, she said that a woman is no safer now than they were when the Restorative Justice process started in 2018. She pointed out that there are still no specialist

mesh centres, no education programmes to upskill surgeons, and no registry or database to measure actions and outcomes.

At her hearing, Ms Korte said that:

> It is no longer good enough to use the excuse that because some women seem fine after having this surgery, it is ok to leave others completely disabled with shattered lives, unable to function in everyday life.

Ms Korte submits that the lived and documented experience in New Zealand demonstrate a significant safety problem that is still not fixed. In her view, there is no clear evidence that patient safety has improved.

Actions in other jurisdictions

Ms Korte highlighted actions taken in other jurisdictions. She noted that the suspensions in Scotland and the rest of the United Kingdom are still in place after nine and five years respectively. We heard that they remain because patient safety cannot be guaranteed.

Ms Korte also referred to a 2020 judgment from the Australian Federal Court.[6] It ruled that several medical devices could not be supplied, distributed, marketed, or promoted in Australia without including certain information in the patient information leaflets and promotional material. The information included that:

- adverse events may occur regardless of the skill of the surgeon
- removal of part of the implant can be difficult
- removal of the whole of the implant may be practically impossible
- adverse events may occur years after implantation, with the risk enduring for as long as the implant remains in the patient.

Ms Korte is a member of the International Continence Society Diagnosis and Treatment of Mesh Complications Committee. That committee noted that there is no long-term data about the problems that mesh can cause and even less about managing mesh complications and the outcomes from treating them. Further, data from the United Kingdom suggests that at least 10 percent of patients have problems and this may be the "tip of the iceberg".

Credentialling of surgeons

Ms Korte observed that consumers need assurance when they have surgery that their surgeon is competent to perform it and fix any problems that may arise. This is provided for under Right 4 of the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996.[7]

Ms Korte noted that surgeons were assessed against Australian credentialling guidelines in 2018. The guidelines require two years of patient-reported outcomes, which she said most surgeons did not provide. She asserts that surgeon did not meet the criterion but continued to operate, with nothing done to stop them.

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6 Gill v Ethicon Sàrl (No 6) [2020] FCA 27.

7 Right 4 is the right to services of an appropriate standard.

Ms Korte considers that credentialling of surgeons now is imperative. She understands that the current process is a paper-based exercise that heavily relies on surgeons supplying their own data. Ms Korte said that this is inherently biased. She believes independent data must be included for the process to be scrupulous. Possible sources include the Health and Disability Commissioner, ACC, Medsafe, and independent medicolegal reviews. Ms Korte also submits that patient-reported outcome data is an essential part of the process. This data should be collected independently, without the involvement of the surgeon.

Concerns about harm from non-mesh urogynaecological procedures

According to Ms Korte, there has been a recent resurgence in surgeons undertaking non-mesh surgery. We were told that the recent uptake has resulted in serious adverse events due to a lack of training and experience in non-mesh procedures. Ms Korte acknowledged the mandatory high-vigilance scrutiny in the United Kingdom for non-mesh surgery. She believes similar safeguards need to be introduced in New Zealand to mitigate further harm.

Support for a suspension of mesh slings for stress urinary incontinence

Ms Korte said that the petition is not about taking treatment options away from women, nor is it about trying to reduce harm. Rather, it is about stopping harm, ensuring that the procedures being offered are safe, and that the surgeons who are operating are competent.

Ms Korte submits that mesh-injured women have lost their trust in surgeons, health professionals, and the government. She believes an urgent suspension of mesh sling implantation for SUI will not only protect many women from future harm from mesh procedures. It will also go some way towards restoring faith in the government and its health agencies.

Comments from the Ministry of Health

The Ministry of Health—Manatū Hauora made a written submission in November 2022. We held a hearing with the Chief Medical Officer, Dr Joe Bourne, on 3 May 2023.

The ministry explained that it has a substantial work programme under way to reduce previous harm and prevent future harm resulting from surgical mesh. Its work programme is centred around the recommendations made in two reports: *Report of the Health Committee into Petition 2011/102 of Carmel Berry and Charlotte Korte* and *Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare.* The ministry told us that much of the work programme is also working to address the matters raised in this petition.

In its written submission, the ministry noted that six actions from the Restorative Justice report are considered completed. Nine actions require ongoing monitoring and four remain in progress. The in-progress actions are:

- establishing credentialling for surgeons undertaking urogynaecological procedures involving surgical mesh
- establishing a registry for urogynaecological procedures involving mesh
- designing education packages to ensure that health professionals understand their role in preventing and reducing harm from surgical mesh

- modernising the regulation of medical devices in New Zealand through the replacement of the Medicines Act 1981 with the Therapeutic Products Bill.[8]

The ministry noted that Te Whatu Ora—Health New Zealand is leading work to establish specialist services for people who experience complications from surgical mesh.

Regulating medical devices

Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is a business unit of the ministry, and is the authority responsible for regulating therapeutic products in New Zealand, including medical devices. At present, medical devices are not fully regulated in New Zealand. For medical devices to be legally supplied, the sponsor must notify it to Medsafe's WAND database[9] within 30 days of becoming the sponsor.

On 13 June 2023, we presented our report to the House on the Therapeutic Products Bill. The bill would replace the Medicines Act, and regulate how products are manufactured, tested, imported, promoted, supplied, and exported. It includes the regulation of medical devices, including surgical mesh. If enacted, the bill (excluding section 384) would come into force on a date appointed by the Governor-General by Order in Council, or on 1 September 2026 if not previously brought into force.

The ministry emphasised that issues associated with the use of surgical mesh are not unique to New Zealand. They have also occurred in countries that have comprehensive legislation and pre-market evaluation and approval mechanisms.

The ministry explained that Medsafe began taking action regarding surgical mesh in 2008. At that time, it was concerned enough to conduct its first review of the use and adverse events associated with surgical mesh.

In December 2017, Medsafe used provisions in the Medicines Act to request safety information from four suppliers of surgical mesh products. Consequently, several types of mesh products were removed from supply in New Zealand.[10] As a result of this action, surgical mesh was effectively banned for pelvic organ prolapse. Other products also required amendments to their instructions for use before they could be supplied in New Zealand. The ministry pointed out that New Zealand is one of a small number of countries that have taken regulatory action to remove some surgical mesh devices from the market.

Quantifying the risk of harm from surgical mesh

The ministry described an adverse event as an event with negative reactions or results that are unintended, unexpected, or unplanned. For surgical mesh, they can include negative effects or unintended consequences associated with its use or implantation. Patients, caregivers, healthcare professionals, and suppliers are encouraged to lodge an adverse event report in certain circumstances. They are if an incident has occurred and there is

8 This work is occurring outside the surgical mesh work programme.

9 The Web Assisted Notification of Devices database.

10 Specifically, they were all surgical mesh products for treating pelvic organ prolapse via transvaginal implantation and a single incision mini-sling for treating SUI.

concern about the safety of the device or its use. ACC also submits adverse event reports following a treatment injury claim, where relevant.

In October 2019, Medsafe updated its *Adverse Event Reports Relating to Surgical Mesh Implants* report. It found that 22,195 surgical mesh devices had been supplied in New Zealand for SUI procedures in the period from 1 January 2005 to 30 June 2019. In the same period, 1,325 adverse event reports were received relating to surgical mesh. Of these, 483 related to surgical mesh for SUI, or for pelvic organ prolapse and SUI. This equated to a rate of adverse events of just over 2 percent if supplied devices were used as a denominator.

The ministry acknowledged that there is evidence of harm occurring. However, it is unable to confirm the denominator—that is, how many surgical mesh procedures are being undertaken. Other data sources are evidence that injury is still occurring. Examples include ACC treatment injury claims and complaints to the Health and Disability Commissioner (HDC). However, they do not provide evidence about the extent of harm.

Credentialling

The Australian Commission on Safety and Quality in Health Care leads and coordinates key improvements in safety and quality in health care across Australia. In 2018, the Director-General of Health wrote to district health boards (DHBs) directing them to assess surgeons against the Commission's *Guidance for Hospital Credentialling of Senior Medical Practitioners to Undertake Transvaginal Mesh Surgery for Stress Urinary Incontinence.* As a result, many DHBs stopped using surgical mesh to treat SUI where their surgeons did not meet the standard outlined in the guidance. The ministry noted that procedures involving surgical mesh were only undertaken in 10 districts in the period from 1 January to 30 June 2022.

In May 2022, the ministry published the *National Credentialling Framework: Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures*. We heard that the intended outcome of the credentialling process is to provide confidence that surgeons who are using or removing surgical mesh have the appropriate skills and qualifications. The framework identifies the rationale for adopting a national credentialling standard, defines specific credentialling criteria, and describes a process for the standard and criteria to be implemented. It also identifies the structures needed to support surgeons and health services to become credentialled.

The ministry explained that it has a three-tiered system for credentialling. It said that the first round of credentialling surgeons for tier 3 against the framework was undertaken in late 2022. Tier 3 procedures are the most complex and involve revisions and removal of mesh. Provisional results were made available in February 2023, with surgeons given one month to appeal. The appeals were being considered by a new panel in mid-May 2023. The ministry expected the full results of credentialling from the tier 3 round to be made public by June 2023.

We were told that further rounds for tiers 2 and 1 will occur after the initial process is reviewed. The review aims to ensure that the process is robust and the intended outcomes are realised. It will also consider how to expedite the implementation of credentialling while maintaining confidence in the process.

The ministry said that tier 3 does not include implanting of mesh. It acknowledged that credentialling for tier 1, which includes implanting, will be "some way away yet". We heard that several Australian surgeons who are on the Credentialling Committee have commented on the rigour of the New Zealand credentialling process. However, the ministry pointed out that this rigour means that the process is taking a long time to implement. In recognition that this process will take some time, Te Whatu Ora is asking public hospitals to credential their surgeons against the Australian standard again.

National mesh registry

The ministry explained that it asked DHBs in 2018 to hold and maintain local registers to collect information through the National Minimum Dataset about surgeries involving surgical mesh.[11] This collection aimed to support the ability to identify those most at risk, follow up with patients as needed, and ensure that robust informed-consent processes were being followed.

At its oral hearing, the ministry told us that a national registry was continuing to be developed. It pointed out that it has found it "incredibly difficult" to identify good data that can accurately report the extent of harm that is occurring. The ministry knows through ACC how many women have been harmed by surgical mesh. However, it is very difficult to determine the denominator—that is, the number of mesh products implanted—so it can understand the proportion of women who have been harmed.

The ministry had identified a preferred option, which was a collaboration with a registry operating from Monash University in Australia. The ministry was working with the university to adapt the registry to New Zealand's needs. For example, the Monash register does not record ethnicity, which would be a requirement for any New Zealand register.

The ministry was in the process of handing over responsibility for implementation to Te Whatu Ora. It said that it expected the registry to be introduced by the end of 2023, at the earliest.

Primary care education

The ministry told us that it has collaborated with ACC and consumer groups to develop a series of webinars for people working in primary care. The webinars include information about pelvic organ prolapse, identifying surgical mesh harm, and optimising management of female urinary incontinence. The webinars use case studies to provide information to improve the ability of GPs to identify women who have potentially been harmed by surgical mesh. Their GPs can then refer them to suitable treatments.

The ministry acknowledged the role of secondary and tertiary services in providing care involving surgical mesh. Work is still needed to develop further education packages for health professionals working in these settings. The ministry considers that the relevant surgical colleges need to primarily lead the secondary and tertiary education. It told us that it was meeting with the colleges in late May 2023 to agree a way forward for this work.

[11] The National Minimum Dataset is a national collection of public and private hospital information about discharges. It includes coded clinical data for inpatients and day patients.

Informed consent

The ministry explained that it worked with the HDC in August 2021 to write to the DHB chief executives and private surgical hospitals. The work aimed to inform their understanding of the informed consent processes where surgical mesh was used. They found that, in most cases, informed consent processes were operating and were audited regularly, but there were select cases where improvements could be made. For these cases, the ministry sent a reminder about appropriate informed consent processes. It also recommended that appropriate patient resources be used to support decision making.

The ministry observed that informed consent is a system-level issue and concerns about it are not limited to the use of surgical mesh. The ministry and the HDC made a joint submission to the National Quality Forum that was held in August 2022.[12] This was in response to an increase in concerns about a lack of or inadequate informed consent practices for patients. The Forum agreed that the ministry will work with the HDC to convene a subcommittee. It will contain representatives from the Health Quality and Safety Commission, Te Whatu Ora, Te Aka Whai Ora—the Māori Health Authority, and the Medical Council of New Zealand. The subcommittee will review the matter in more detail and determine the necessary actions to improve the consistency of informed consent practices.

Considering a pause in the use of surgical mesh to treat stress urinary incontinence

At our oral hearing, the ministry told us that it was investigating a pause in the use of surgical mesh to treat SUI. It was doing so through the Surgical Mesh Roundtable, a committee established to oversee the implementation of recommendations made through the Restorative Justice process. The ministry was considering the scope of a pause, appropriate exceptions to it, and the conditions under which the pause could be lifted.

The ministry was exploring what levers are in legislation that would enable it to implement a pause if needed to best preserve patient safety. However, it noted that New Zealand differs from the United Kingdom. This is because the ministry has been unable to identify any existing regulatory or legislative mechanism for implementing a pause. The ministry would also be unlikely to be able to enforce any pause even if public and private hospitals made an operational agreement to implement one. It acknowledged that it has very good collaboration with both gynaecology and urology colleges. The ministry would work with them and the Medical Council of New Zealand to investigate how it could effect a pause if one were recommended.

The ministry highlighted the benefits and risks of a pause. It noted that a pause would allow the implementation of credentialling, and the establishment of education and upskilling programmes and a registry for pelvic floor procedures. The risks include removing access to a treatment that is potentially valid and, in some cases, the only appropriate option for some women. We heard that, if a pause were introduced, the ministry would want ensure that a range of alternative treatments would be available to help women with their SUI symptoms. It added that a pause could also result in surgeons becoming disenfranchised with restrictions

[12] The Health Quality and Safety Commission hosts the Forum. It consists of representatives from the ministry, Te Whatu Ora, Te Aka Whai Ora, the HDC, ACC, and PHARMAC.

being placed on their practice, and they might exit the workforce. This would further remove access to treatment for women.

The ministry reiterated that medical devices are not fully regulated in New Zealand. We asked whether anything in the Therapeutic Products Bill would allow for a pause. The ministry said it is having discussions with its policy team about the potential to use this legislation in the future. However, we heard that the implementation of the bill would be later than the ministry would want to act if it decided to implement a pause.

Comments from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists

In November 2022, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) made a written submission. On 15 February 2023, we held an oral hearing with Dr Susan Fleming, the Chair of Te Kāhui Oranga ō Nuku; with Dr Sarah Machin, the Chair of New Zealand Training and Accreditation; and with Dr Tim Dawson, a urogynaecology subspecialist.

RANZCOG describes itself as a not-for-profit organisation dedicated to establishing high standards of practice in obstetrics and gynaecology and excellence in women's health. It trains and accredits doctors in Australia and New Zealand in the specialties of obstetrics and gynaecology. RANZCOG also supports research into women's health and advocates for women's healthcare. It does this by developing productive relationships with individuals, the community, professional organisations, and government.

RANZCOG recognised the pain and distress suffered by many women in New Zealand who have experienced complications resulting from pelvic mesh implants. It acknowledged that system-wide failures led to this harm and it accepts its part. RANZCOG said it is committed to enabling the actions agreed by the Restorative Justice process to proceed and is actively involved in them.

We heard that RANZCOG takes its responsibilities seriously as the body responsible for setting standards and providing training in obstetrics and gynaecology. However, it noted that it also has a responsibility to advocate for the care of women with SUI. RANZCOG strongly contends that pausing or banning mesh will disadvantage their care.

About stress urinary incontinence

RANZCOG explained that the problem of female urinary incontinence is common in New Zealand, with estimates varying by age group and ethnicity. SUI is one of the common causes of urinary incontinence in women. It involves involuntary urine leakage with increased abdominal pressure typically associated with coughing, sneezing or exertion. RANZCOG described SUI as an often debilitating and bothersome condition that, like other causes of incontinence, can substantially reduce a woman's quality of life.

RANZCOG noted that non-surgical treatments such as pelvic floor exercises and behavioural modification are helpful in alleviating symptoms in some women. In 2014,

RANZCOG developed a position statement on midurethral slings.[13] The statement was amended in 2022. It states that, as the first line of treatment, all women should be recommended to undertake pelvic floor physiotherapy or see a continence nurse advisor for pelvic floor exercises and bladder retraining.

Surgical management of stress urinary incontinence

RANZCOG highlighted the surgical treatment options that are available to manage SUI: midurethral slings, laparoscopic (keyhole) approaches, and the Pubovaginal Fascial Sling.

Midurethral slings were developed in the early 1990s, and involve a minimally invasive, generally outpatient procedure. The technique uses a 1cm wide mesh strip consisting of monofilament polypropylene. It is placed through the vagina under the mid-urethra exiting from two small sites in either the suprapubic or groin areas. The procedure has essentially replaced open and transvaginal suspension surgeries for uncomplicated SUI.

The evolution of endoscopic surgery has led to the development of laparoscopic approaches to incontinence surgery. For example, the laparoscopic colposuspension does not use mesh. Instead, it uses permanent polypropylene or nylon or ethibond sutures. RANZCOG noted that this procedure is more difficult than the MUS and requires advanced laparoscopic skills that are not widely available. The operation also takes longer.

The Pubovaginal Fascial Sling is a non-mesh operation for SUI that is highly effective and long-lasting. However, it requires an open abdominal incision and the creation of a native tissue sling from a woman's abdominal or thigh fascia. The surgery is painful and recovery is prolonged. The procedure also has a risk of up to 10 percent that women will have to catheterise themselves because of an inability to urinate after surgery.

RANZCOG observed that none of the currently available options are perfect and women considering surgery should take into account the pros and cons of each procedure. It considers that, if women are informed of their options and understand their risks, they should be free to choose whether to have an MUS. RANZCOG believes removing MUS will limit the choices available to women because it removes one of the less invasive surgical choices.

Benefits of mesh midurethral slings

RANZCOG noted that more than 2,000 publications in scientific literature describe and evaluate the MUS for treating SUI. The studies include a wide range of patients and comparisons to other established non-mesh SUI procedures. According to RANZCOG, literature supports the view that MUS surgery is highly effective in the short and medium term for treating SUI.

RANZCOG said there is strong evidence that the MUS is associated with less pain, shorter hospitalisations, a faster return to usual activities, and reduced costs. This is when compared to historic options that were used to treat SUI. As a result, the MUS has become the most common surgical procedure for treating SUI in the developed world and the preferred treatment for uncomplicated SUI. We were told that the MUS is the operation of

[13] RANZCOG. *Position statement on midurethral slings.* Retrieved from https://ranzcog.edu.au/wp-content/uploads/2022/05/Position-statement-on-midurethral-slings.pdf.

choice for treating SUI in Europe, Australia, and the United States. RANZCOG attributed this to the positive safety profile combined with the benefits detailed above.

Risks of mesh midurethral slings

RANZCOG accepts that harm has been caused by MUS surgery. It said it is an inevitable consequence of all surgical interventions that a proportion of those undergoing a surgical procedure will experience a complication or adverse outcome.

According to RANZCOG, the risks associated with mesh used for the MUS have become confused in the broader discussions about surgical mesh. This includes mesh used in gynaecology for pelvic organ prolapse. In 2011[14] and 2014,[15] the Food and Drug Administration (FDA) provided updated communications about serious complications associated with transvaginal placement of surgical mesh used to treat pelvic organ prolapse. RANZCOG strongly emphasised that the US FDA publications clearly stated that mesh for SUI was not the subject of the safety communications.

RANZCOG observed that a limitation of the medical scientific data is a lack of long-term follow-up data that includes patient-defined outcomes. It pointed out that most healthcare systems, including New Zealand's, do not provide for long-term follow-up of surgical care by surgeons. They also do not have medical records or databases that link hospital-based care to primary care.

RANZCOG recognises that a proportion of women develop concerning symptoms in the longer term. This has become clear as issues related to surgical mesh have become widely known and women have been empowered to discuss their experiences. However, at present, there is a lack of prospectively collected long-term data about the MUS, and adverse events are difficult to interpret without a denominator. This makes it difficult to ascertain the frequency of long-term complications related to MUS.

RANZCOG's view about a suspension

RANZCOG said it supports the use of MUS in the surgical management of female SUI by appropriately trained and credentialled surgeons. RANZCOG believes that the evidence of benefit to the population as a whole outweighs the risk. It accepts that individuals considering their options may come to different conclusions about what is right for them. The clinician's responsibility is to support the patient to make the best decision for them.

RANZCOG told us that it does not support the petitioner's request to suspend the implantation of vaginally inserted mesh sling for SUI. It acknowledged that there have been shortcomings in the area of MUS surgery. We heard that a substantial body of work is under way to address these concerns. It includes work on credentialling and improving informed consent. In RANZCOG's view, a ban on procedures is not necessary or appropriate for this progress to continue.

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[14] Food and Drug Administration (FDA). *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*. 2011. Retrieved from: https://www.fda.gov/media/81123/download.

[15] Food and Drug Administration (FDA). FDA Safety Communication: *UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse*, 2014.

RANZCOG said it understands the consumer concerns behind the call for a suspension. It referred to the 2018 pause in the United Kingdom until certain conditions were met. RANZCOG likened these conditions to the recommendations of the Restorative Justice report, which the Surgical Mesh Roundtable is now responsible for implementing. RANZCOG submits that the United Kingdom pause was used to "buy time" for the Independent Medicines and Medical Devices Safety Review to conclude. Time was also needed to implement the various recommendations that had been agreed to reassure the public about mesh.

RANZOG considers that it has strong guidance that addresses many of the concerns that lie within the scope of its professional domain. This includes guidance to its members that they should only operate within their capabilities and the scope within which they are credentialled. The guidance also includes matters that members should discuss with patients to enable them to sufficiently understand their treatment and make an informed decision.

RANZCOG said it has confidence in the governance and oversight processes that are now established in New Zealand. It considers that these, along with the new credentialling framework, will support the availability of a range of options for women with SUI. These processes also ensure robust oversight of the quality of care. RANZCOG believes that suspending the availability of the MUS would adversely affect the lives of New Zealand women. It is concerned that one of the unintended consequences of the mesh controversy has been to stop women from receiving any treatment for SUI.

Dr Dawson is a urogynaecologist working in Auckland. He emphasised the "absolute misery" that women who suffer from SUI can experience. He pointed out that women who have surgery do not have mild symptoms. SUI affects their employment and leisure activities as well as family and intimate relationships. RANZCOG believes that, because of the gravity of these symptoms and the effect that they have, surgeons should be able to offer the best treatment for them. These may be conservative, non-surgical options, or operative management, within which mesh slings have a place. RANZCOG is concerned that implementing a ban or pause on the implantation of MUS would remove an option that is the most used procedure worldwide for this condition. It observed that the United Kingdom is the only place that a pause or ban on these procedures has been implemented.

Dr Dawson is concerned that if MUS were removed in New Zealand, the burden would not be felt evenly by all women. He told us that he has colleagues who practise at Middlemore Hospital in the Counties Manukau region. A large percentage of patients are obese and have co-morbidities such as diabetes. Dr Dawson said that these women are not suitable for other procedures, which either have much higher risks of complication or reduced efficacy. He submits that a pause would leave them without a viable surgical option.

We note that Counties Manukau has a large proportion of Māori and Pacific people. We asked whether there is any data to support the long-term success rate of MUS for them. RANZCOG acknowledged that the success rates in patients with a higher body mass index (BMI) are not as good as those with a lower BMI. It said, however, that the majority of women will have a good outcome regardless of BMI.

We asked how confident RANZCOG can be in the assessment of outcomes given the evidence that complications are not being identified and the lack of long-term research.

RANZCOG acknowledged that the quality of outcome evidence “absolutely could be better”. It considers that this is part of the rationale for establishing a national registry and having standardised outcome measures.

Implementation of a national database or registry

RANZCOG strongly supports clinicians keeping a logbook (or similar) about the surgical care that they provide and documenting data about short- to medium-term outcomes. However, it recognises that this is not sufficient. RANZCOG supports the development of a national database or registry. It would like the registry to contain centralised prospective data and surgical outcome monitoring that is linked to longer-term outcomes measures, including patient-reported outcomes. RANZCOG noted that this work is under way but considers that progress has been “unreasonably slow”.

RANZCOG recognises that finding a solution to data collection and monitoring is complex and is not unique to mesh surgery. It submits that, for most surgeries, there is a lack of reliable national data about surgical outcomes that includes those beyond the immediate surgical period, as well as patient perspectives. The collection of local immediate surgical data also varies greatly across the country. RANZCOG suggested that attention be given to New Zealand’s information systems to ensure that they can provide the level of information needed to assess performance in several areas. The areas are the performance of surgeons, units, and the health system generally. It believes that responsibility for ensuring a consistent system-wide approach rests with the ministry and Te Whatu Ora.

Strengthening the credentialling framework

RANZCOG supports the idea of setting broad credentialling standards at a national level. It agrees that the ministry has an obligation to ensure that a transparent and robust monitoring and credentialling approach is implemented to ensure ongoing safety. This is particularly true given the level of concern and patient harm associated with the use of mesh. RANZCOG said it is committed to working with the Credentialling Committee to ensure that the approach is robust, transparent, and embedded in a learning culture.

According to RANZCOG, its preferred approach would be to embed mesh and urogynaecological procedures within a broader National Credentialling Framework. This would incorporate lessons learned since the 2010 national framework was introduced. RANZCOG is concerned that the focus on mesh, pelvic floor, and urogynaecological procedures is a lost opportunity to prevent similar problems with new procedures or technologies in the future. In its view, the system lessons that were learned from the mesh experience are relevant to the introduction of all new surgical treatments.

Establishment of mesh removal centres

RANZCOG acknowledged that mesh removal requires special skills and training. It supports the establishment of specialist mesh centres where there is expertise in how to treat mesh complications and the most appropriate techniques for mesh removals. RANZCOG generally agrees with the New Zealand Credentialling Framework that mesh removal should be undertaken only in specialty centres that have access to a multidisciplinary speciality team. However, it submits that an operating general gynaecologist can generally perform several procedures. They are acute procedures within the first six weeks of surgery that need sling

adjustments, such as MUS loosening, MUS division, and MUS trimming. The gynaecologist should be appropriately credentialled and supported by a multidisciplinary team or level 3 Mesh Complications Service once established.

Protection of the "urogynaecology" title

RANZCOG explained that it has a clearly defined training pathway for urogynaecological specialists. It also supports appropriately trained and credentialled general gynaecologists to provide urogynaecological surgery to their level of experience. It does not believe that title protection is needed.

We were told that, when a subspecialist becomes certified, they receive a letter from the RANZCOG chief executive. The letter informs them that they are entitled to use the post-nominal "CU" (Certified Urogynaecologist). They are also recognised as being able to use the protected tile "Specialist in Urogynaecology" along with their FRANZCOG qualification. RANZCOG also provides advice to subspecialist trainees in its handbook. It reminds them that they must not identify themselves as a Specialist in Urogynaecology until all training requirements are satisfactorily completed. They must also have been certified by the RANZCOG Board.

Comments from the Royal Australasian College of Surgeons

The Royal Australasian College of Surgeons (RACS) describes itself as the leading advocate for surgical standards, professionalism, and surgical education in New Zealand and Australia. It is a not-for-profit organisation, representing more than 7,000 surgeons and 1,300 surgical trainees and international medical graduates across New Zealand and Australia. RACS supports healthcare and surgical education in the Asia-Pacific region and is a substantial funder of surgical research. It is the accredited training provider in nine surgical specialities, including urology.

We received a written submission from RACS in November 2022. On 15 February 2023, we held an oral hearing with Dr Sharon English and Dr Eva Fong. Both are urologists and represent RACS as members of the Surgical Mesh Roundtable.

Dr Fong explained that she has treated over 300 women with mesh complications from 76 different surgeons in New Zealand. They include from the country's most experienced surgeons and from recent implantations.

RACS noted that a large United Kingdom study found that 3.3 percent of women required MUS removal at nine years. However, it said it cannot be assumed that surgeons in New Zealand have the same results. This is because the lack of a registry means there is no local data. RACS added that the study did not measure the severity of harm. Given that the procedure aims to improve a patient's quality of life, even a small percentage of life-altering complications would be significant.

RACS' views about suspending the implantation of mesh slings

In its written submission, RACS told us that it was neither for nor against the petitioner's proposal to suspend the implantation of mesh MUS to treat SUI. It considers that many improvements are needed to the implantation, assessment, and reporting of anti-incontinence surgery. RACS said it agrees with the points in the petitioner's submission that

argue for a suspension. It believes a pause would buy time but would only be effective if a lot of work was undertaken before surgery recommenced. The work is described in more detail below. At its oral hearing, RACS acknowledged that some of this work was happening "in the background", albeit very slowly.

Arguments for a pause

RACS said that a pause would reduce consumer mesh complications and harm while anti-incontinence surgery is made safer. It also considers that a pause would send a message that something proactive was being done about this important matter that has affected many lives.

In RACS' view, a pause would also allow time for a number of initiatives to be implemented. They relate to credentialling of surgeons, establishing multidisciplinary teams and a national registry, educating and upskilling surgeons, and gathering data about the success and complications of mesh surgery.

Dr Fong said that every day she continues to see patients with life-altering mesh complications. Doctors are dealing with significant trauma daily and they are significantly secondarily traumatised by seeing patients' suffering. She considers that patients and doctors cannot carry on with the current situation, and harm will continue if the status quo remains. Dr Fong believes a pause would allow urgent remedial actions to be taken.

Arguments against a pause

RACS told us that a pause would reduce access to treatment for some patients and in some regions. It pointed out that the use of mesh is the best and only option for some patients, such as those who are elderly with significant stress incontinence. Patients in regional areas would be disproportionately affected as non-mesh options may be less likely to be offered.

RACS said that practitioners could start performing non-mesh procedures despite not having recent experience or training and being less familiar with them. This could result in higher rates of adverse outcomes and practitioners might not be able to treat these complications. RACS submits that surgeons might become deskilled in mesh MUS implantation and training opportunities might stop. This deskilling could make it difficult to reintroduce MUS procedures after a long period of pause, or the pause could become permanent.

RACS noted that current networks do not allow patients to be referred out of their area for alternative surgery. The workload of non-mesh implanting surgeons could also increase dramatically if patients were referred to them. We asked whether RACS expects that the health reforms will enable patients to be referred outside their district. RACS explained that two mesh complications services were being established in Auckland and Christchurch. At the time of our hearing, the funding and other matters were still being decided. RACS expected the first patients to begin using the service in March 2023. It noted that patients would be directed to their local service. However, if they had a strong reason, such as having a surgeon involved, they could transfer to the other service.

RACS' proposal for a partial pause

RACS proposed an alternative to a total pause on all surgeons using mesh MUS procedures. Under its proposal, MUS implantation could only be performed at mesh

specialist centres by surgeons who were credentialled to remove mesh. This would assure the patient that their surgeon would be capable of treating any complications that developed. The surgery could only be performed after other options had been explored and discussions held within a multidisciplinary team. In its written submission, RACS suggested that any pause would be time limited, ending no later than the end of 2023.

RACS considers it vital that, if a pause were in place, measures to ensure patient safety be introduced and appropriately funded. The proposed measures are:

- developing a national mesh and pelvic surgery registry
- introducing high vigilance scrutiny for all non-mesh pelvic floor procedures
- credentialling medical professionals undertaking mesh MUS implantations
- establishing specialist multidisciplinary centres
- educating and upskilling specialists and trainees.

In RACS' view, the above measures must be implemented promptly and be mandated and enforced in both public and private practice to ensure patient safety.

Development of a centralised pelvic floor surgery registry

RACS said it supports the petitioner's request for the implementation of a centralised pelvic floor surgery registry. It considers that a registry would provide an "arm's length" (independent from the surgeon) collection of data about devices, patient outcomes, and patient-reported outcomes. It would also enable complications and problems to be identified.

RACS explained that there is no formal qualification for treating mesh complications, including surgery, and it is not part of any training scheme in New Zealand. It noted that publications outlining results and treating mesh complications come from overseas centres that have substantial volumes of them. Conversely, volumes in New Zealand, based on Ministry of Health data, appear to be very low. RACS considers that, without a registry of results or patient-reported outcomes, there is no evidence that these low volumes are safe for complex mesh removal surgery.

RACS believes the registry should be mandatory against medical council registration and a prerequisite for credentialling at the provider level. It submits that patients need to be equally safe wherever they access treatment. Accordingly, the same rigour should apply to both public and private practice. RACS would like the registry to be linked to funding and to be mandatory within private practice for the credentialling of private facilities. It would also like the ministry to enforce the use of the registry.

RACS considers that data about patient-reported outcome measures is an important part of a centralised registry. It also suggested that consideration should be given to extending the registry to include all pelvic floor procedures (mesh and non-mesh).

At the oral hearing, Dr English acknowledged the work with Monash University on the registry. She considers that funding is needed for a person to operate and manage the registry in New Zealand.

High-vigilance scrutiny for all non-mesh pelvic floor procedures

RACS explained that the ministry gathered data about non-mesh pelvic floor procedures in 2022, with the results indicating generally low volumes of non-mesh SUI procedures. It recognises that most practitioners have minimal training and recent experience in non-mesh SUI procedures. It referred to a 2014 study that found that, after 2008, more than 98 percent of stress incontinence procedures in the United Kingdom were mesh slings.[16] Similar data has been seen worldwide.

RACS believes this minimal recent experience or training for surgeons in non-mesh SUI surgery creates a significant potential risk to patient safety. It considers that education and upskilling is needed for surgeons who do not have significant recent experience and previous high-level training but wish to undertake these procedures. This should include education, observation, mentoring, and proctoring.[17] Ideally, RACS would like proctoring for these procedures to occur only in specialist mesh centres. In its view, this requirement should be mandated, with a legislative amendment to enable enforcement. RACS would also like non-mesh SUI procedures to be subject to high vigilance-scrutiny and, as previously noted, to be recorded in the national registry.

We heard that surgeons treating mesh complications have consistently seen that informed consent is not truly given. This is because there has been substantial deskilling in non-mesh procedures since 2008. RACS considers that surgeons have a "certain cognitive bias" where they are unlikely to offer a procedure that they cannot perform, making the informed consent unbalanced.

Robust credentialling of medical professionals

RACS highlighted several concerns it has about the credentialling process. It pointed out that the current credentialling process does not include data that is independent of the surgeon. RACS submits that this lack of independent data input reduces trust in the process. It believes this is problematic given the breakdown in trust resulting from mesh complications, which was detailed in the Restorative Justice report.

We were told that the national credentialling framework is being implemented in a "stepwise fashion". Also, a definite time frame has not been provided for the credentialling of mesh implantation. RACS said that, in the meantime, there is no clear evidence that patient safety has improved since the Restorative Justice report. It observed that consumers continue to express concerns about mesh complications while the credentialling process occurs. In RACS' view, a pause, with a defined time frame, may be appropriate until the credentialling of implanting surgeons is completed in 2023/24.

RACS believes that the ministry must have the ability to enforce the requirement to be credentialled to perform this procedure in public and private practices. The ministry should also be able to ensure that the credentialling remains up to date.

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[16] Withington J, Hirji S, Sahai A. *The changing face of urinary continence surgery in England: a perspective from the Hospital Episode Statistics database*. BJU Int. 2014;114(2):268-277. doi:10.1111/bju.12650.

[17] Proctoring is an objective evaluation of a practitioner's clinical competence by a person serving as a proctor.

RACS explained that the credentialling process examines the surgeon. However, for patient safety, it considers that the quality and expertise of multidisciplinary meetings also needs to be evaluated. RACS submits that it is likely that additional education and infrastructure will be needed to make these meetings safer.

Educating and upskilling trainees and surgeons

In 2022, Dr Fong published a study in an international peer-reviewed journal about the quality of clinical evaluation and follow-up in patients who had mesh slings in New Zealand.[18] The study reviewed chart data from New Zealand women who had mesh complications and the quality of their initial history, examination, diagnostic bladder studies, and post-operative follow-up. It identified significant shortcomings in diagnosis and follow-up for MUS surgery. This included surgeons:

- having significant knowledge deficits about what constitutes an adequate clinical history and examination
- often failing to recognise and diagnose problems when they occurred, which adds to patients' suffering
- lacking knowledge or understanding of patients' long-term results and complications, which have implications for their upskilling and ability to provide true informed consent.

We heard that RACS supports a pause so it can properly learn from these shortcomings. It noted that, since the Restorative Justice process in 2018, no substantial educational programmes have been instituted in secondary care for specialists performing urinary incontinence procedures. RACS also pointed out that the ministry's education committee has only started education in primary care.

RACS considers that national funding is needed for ongoing education. Dr English pointed out that, for many surgeons, slings came in after they had trained. The opportunities to learn how to implant them and be proctored were not always available. As a result, people learned "*ad hoc*" and then starting performing the procedures.

RACS offered to contribute to developing educational packages, mentoring, and proctoring for practising surgeons and trainees in gynaecology and urology. It considers that comprehensive upskilling is needed across all aspects of clinical care. In RACS' view, a mandated educational programme with assessment should be completed and linked to funding for providers.

We asked why RACS believes it has taken so long for upskilling to occur given that surgeons have been aware of the problems for some time. Dr English said that one of the reasons is because surgeons are people. They honestly believe they are doing a good job, and if they do not see complications reported back to them, they do not realise what is happening. RACS believes that a national registry that sends regular benchmarked feedback to surgeons about their results will be helpful.

[18] Fong E, Ecclestone H. *Quality of Pre-operative Assessment for Mid Urethral Slings in Women Who Present With Mesh Complications*. Urology. 2022 Oct;168:90-95. doi: 10.1016/j.urology.2022.07.013. Epub 2022 Jul 29. PMID: 35908739.

Education about mesh complications

RACS referred to data that found that only 5 percent of the 300 mesh complications treated by Dr Fong's group were referred by the implanting surgeon. It also noted data that found the average time from implantation to mesh removal surgery was eight years. RACS submits that both of these figures support the view that surgeons implanting mesh are not recognising complications.

Dr Fong explained that her study found that 60 percent of people had "red flags" at the time of the surgery. Examples include a mesh exposure or inability to urinate. They were taken back for a small procedure and discharged from the surgeon's care by three months. We heard that Dr Fong's study suggested that patients need to be fully followed up by five years.

Establishment of specialist multidisciplinary centres

RACS submits that specialist multidisciplinary centres need to be established to enable appropriate treatment for patients with mesh complications. It explained that these are complex patients who require input from a range of clinicians so that all aspects of their quality of life are addressed. The clinicians include physiotherapists, psychologists, pain specialists, and surgeons. RACS said that the centres would enable experts to develop educational and proctoring opportunities. They could also enable high-quality data to be collected about mesh removal surgeries. It emphasised the importance of auditing the multidisciplinary centres to ensure that they are following best practice and providing high-quality services.

RACS considers that the multidisciplinary teams need substantial investment, as well as sufficient time to recruit staff, and establish patient pathways, protocols, and procedures. It also requests adequate funding to ensure that appropriate centres are established. RACS provided the Queensland Pelvic Mesh Service as an example. It told us that the service serves a population of about 5 million with annual funding of $5 million.

Protection of the "urogynaecology" title

RACS noted that urogynaecology is a protected title in Australia but not in other countries. It considers that a protected title is not a useful surrogate for several factors. They are adequate training, and being able to demonstrate acceptable clinical outcomes and patient reported outcomes, as well as resolve their own surgical complications.

According to RACS, urologists should also be recognised as having training in managing pelvic conditions, as well as gynaecologists. It pointed out that urologists undertake extensive training in diagnostic aspects and simple and complex pelvic surgery.

RACS observed that urologists in New Zealand have been the predominant specialty involved in treating mesh complications, including complex mesh removal surgery. They have not been the predominant specialty involved in mesh implantation. RACS considers that urologists involved in removing MUS have unique insights into aspects of patient care that should be part of educational targets to prevent future problems. In its view, experienced urologists should be encouraged to lead these educational efforts.

Comments from Dr Wael Agur

Dr Wael Agur is a subspecialist and lead urogynaecologist at the NHS Ayrshire and Arran in Scotland. He is also an Honorary Clinical Associate Professor at the University of Glasgow. We received a written submission and heard oral evidence from him in May 2023.

Dr Agur noted that New Zealand is not the only country dealing with the mesh problem. On the morning of our hearing on 3 May 2023, he had joined a panel giving evidence to the Health, Social Care and Sport Committee of the Scottish Parliament. The matters discussed included:

- how to help mesh-affected women
- the interface between GPs and secondary care and between secondary care and the mesh complications centre in Scotland
- the national helpline for women to phone for initial advice
- the composition of the multidisciplinary teams, which address mesh complications
- the importance of having a urologist on these teams.

Mesh complications

Dr Agur pointed out that chronic pain is one of the most serious and life-reducing mesh-related complications. He explained that understanding about the incidence of chronic pain has consistently increased over the last two decades, as have the reported risks of it. Dr Agur said he expects the reasons for the increased reporting are improved knowledge, better ability to attribute chronic pain to the mesh device, and the longer-term follow up.

Dr Agur referred to RANZCOG's statement that complications are "an inevitable consequence of all surgical interventions". However, he said he expected the statement to acknowledge the fact that the use of mesh devices has added new mesh-related complications. These are over and above the risks associated with surgical interventions in this field.

Dr Agur recognised that the 2011 FDA update focused on the use of mesh devices for pelvic organ prolapse, rather than mesh MUS for SUI. He noted, however, that the update's executive summary referred to 2,874 reports of injury, death, and malfunction. Of these, 1,503 were associated with pelvic organ prolapse repairs and 1,371 were associated with SUI repairs.

Dr Agur observed that prolapse surgery uses a larger sheet of mesh compared to the slim tape MUS. Accordingly, the incidence of mesh-related complications with prolapse is "inevitably" higher than with mesh MUS. However, he submits that the range of mesh-related complications is very similar, regardless of the amount of mesh used and whether it is implanted to treat prolapse or incontinence. Dr Agur added that the FDA changed its description of mesh-related complications from "rare" in 2008 to "not rare" in 2011.

Scientific evidence about the safety of MUS procedures

Dr Agur acknowledged that there have been more than 2,000 publications about the use of pelvic mesh devices to treat SUI. He told us that he reviewed most of them while conducting

two large systematic reviews of the scientific evidence in 2013 and 2019. Dr Agur explained that more than 90 percent of the publications were “low-level evidence”—that is, expert opinion or relatively small cohort studies. The evidence from just over 100 of the 2,000 publications came from randomised controlled trials and their systematic reviews. Further, none of the trials were powered to adequately report on the safety of the mesh devices, and only a few studies followed women up for five years or more. Dr Agur considers that the lack of long-term follow up to identify safety issues is a serious drawback that affected even the higher-quality studies.

Dr Agur noted that real-world data could generally offer an alternative method of determining the long-term safety of interventions. However, he is unaware of any health system that has been able to accurately code the necessary data in a prompt and prospective way that would enable reliable retrospective reporting. This includes information about emerging mesh-related complications and the developing surgical corrective procedures.

The role of surgical skill in reducing mesh complications

In Dr Agur’s view, the risk of chronic pain and most other long-term complications are because of the device itself rather than surgical skill. He emphasised the importance of surgical experience but noted that it is not associated with reductions in device-related chronic pain and other long-term conditions. Dr Agur explained that an inadequate surgical technique by people who are not credentialled is mostly associated with intraoperative complications, such as bladder injury. However, he said that this type of injury does not appear to have long-term complications because it can be diagnosed and repaired during surgery.

Dr Agur noted that the United Kingdom pause on mesh remains despite it having a robust surgical training programme in urogynaecology and female urology. The United Kingdom has also established that mesh MUS surgery should only be performed by credentialled and experienced surgeons. According to Dr Agur, the pause is partly based on the understanding that improving surgical skills could not adequately mitigate the device-related risks.

Colposuspension procedures

Dr Agur explained that the Burch colposuspension was the gold standard continence procedure before mesh MUS was introduced. He said that moving from the more invasive open abdominal approach to the keyhole approach was the natural progression for the procedure 20 years ago. However, the introduction of mesh MUS halted this evolution.

Dr Agur noted that the main advantages of the mesh MUS procedure for patients are related to recovery. He pointed out that the keyhole colposuspension also has these advantages. However, the mesh MUS is technically much easier to perform because it does not require advanced surgical skills. In Dr Agur’s view, the continuation of mesh procedures is likely to keep surgeons’ laparoscopic skills “relatively low in this context”. He said that, as a result of the mesh suspension, an increasing number of surgeons in the United Kingdom are leading the development of the laparoscopic colposuspension procedure. Dr Agur described the procedure as being “back on track” to return to the “gold standard status”.

Dr Agur observed that no scientific studies have reliably compared the risk of chronic pain between the colposuspension and mesh MUS procedures. However, he said that there have

not been consistent reports about chronic pain with the colposuspension procedure, nor have there been calls for its pause. This is despite it being the gold standard between the 1970s and 1990s.

Dr Agur told us that if chronic pain develops after colposuspension, the condition can be cured or treated by removing the stitches. He described this as “relatively easy” from a surgical perspective. Dr Agur compared this to mesh removal surgery, which is technically more difficult to perform and is not always successful.

We asked how much quicker it is to implant an MUS sling than undertake a laparoscopic colposuspension. Dr Agur explained that an MUS sling takes about 15 to 20 minutes. The open colposuspension procedure takes about 60 to 75 minutes, and the laparoscopic approach takes about 90 to 120 minutes. We heard that surgeons get quicker as they improve. At Dr Agur’s hospital, surgeons can perform a laparoscopic colposuspension in 45 to 50 minutes.

The effect of the suspension in the United Kingdom

Dr Agur explained that the national focus naturally moved following the suspension of mesh procedures in Scotland in 2014 and the rest of the United Kingdom in 2018. The focus shifted towards supporting women who suffered mesh-related complications and improving skills in complex mesh removal surgery. It also shifted towards consolidating skills in non-mesh and native tissue surgery to improve outcomes for women suffering from urinary incontinence. Consequently, non-mesh and native tissue procedures (open and laparoscopic colposuspension, autologous fascial sling, and urethral bulking agent injections) became routine practice in many United Kingdom units.

Dr Agur told us that he has only performed non-mesh or native tissue continence surgery since the suspension in 2014. He said he has not witnessed any disadvantage to women, nor has he faced a situation where only mesh MUS would be suitable. We note that New Zealand has unique geographical challenges regarding the provision of healthcare. We asked whether Dr Agur’s comments about not witnessing any disadvantage could be transferred to a New Zealand context if a pause were implemented. Dr Agur acknowledged that he had not worked or lived in New Zealand so was unaware of any significant demographic or geographical differences. However, he suggested that the population size and geographic challenges are not much different between New Zealand and Scotland. Further, Scotland also has an increasing number of women with co-morbidities, including high BMIs. We heard there has been a prompt to address these co-morbidities, such as behavioural interventions or surgery for obesity.

We observed that there has been a suggestion that a pause could undermine confidence in practitioners and surgeons. This could result in them stopping practising from a sense of intrusion into their decision making. We asked whether these types of discussions were seen ahead of the suspensions in Scotland and the rest of the United Kingdom. Dr Agur agreed that there had been concerns, which he said were natural. We heard that there was strong opposition from surgeons who were unable to perform non-mesh alternatives or introduce them at that stage in their career. There was little opposition from younger surgeons and consultants who realised the issues with mesh procedures and wanted to reintroduce non-mesh and native tissue surgeries earlier in their practice.

Comments from the Physiotherapy Board of New Zealand

In January 2023, we received a written submission from Te Poari Tiaki Tinana o Aotearoa—the Physiotherapy Board of New Zealand. On 3 May 2023, we held an oral hearing with James Dunne, Registrar, and Damon Newrick, Professional Advisor, at the Board.

The Board is a responsible authority constituted under the Health Practitioners Competence Assurance Act 2003. Its main functions in relation to the physiotherapy profession are:

- registering physiotherapy practitioners
- issuing annual practising certificates to practitioners
- setting scopes of practice for practitioners
- accrediting physiotherapy training institutions
- setting professional and practice standards for practitioners
- recertifying and continuing professional development for practitioners
- ensuring appropriate systems and processes relating to the health, competence, and conduct of the profession.

The Board explained that it does not have a position regarding the issues the petitioner raised about the use of MUS for SUI. This is because mesh implantation does not form part of the physiotherapy scope of practice. However, it acknowledged that a number of submitters have identified that physiotherapy can play a role in managing pelvic health issues. Physiotherapy can also form part of a conservative management strategy for issues that do not involve the use of a mesh MUS.

The Board noted that there are about 6,000 practising physiotherapists in New Zealand. All practising physiotherapists are enrolled in the general scope of physiotherapy practice, which incorporates practice in the area of pelvic health. Under the Board's Practising in a Defined Field Standard, all practitioners must ensure that they are competent and appropriately trained to practise in the area of physiotherapy in which they have chosen to work. This aims to ensure that practitioners who choose to practise pelvic health or any other area of physiotherapy are competent to do so. The Board does not accredit or prescribe particular qualifications or training for physiotherapists to practise in this area. This recognises that there are a number of different pathways to competence.

Specialist and advanced scopes of practice

The Board also has specialist and advanced scopes of practice. These scopes indicate to referrers and patients that physiotherapists have advanced skills that may be more suitable for their complex needs. Physiotherapists with a specialist scope manage the most complex, difficult, or critical presentations in their area of practice. The Board described the standard as high, resulting in only a small number of registered specialists.

At present, the Board has registered one physiotherapist as a specialist in the area of pelvic health. The Board also has a special interest group, convened by Physiotherapy New Zealand (the membership organisation). The group represents and brings together the physiotherapists who practise pelvic health. We heard that international guidelines from the International Continence Society recommend four to six months of supervised conservative

management before considering surgery. This involves a pelvic health physiotherapist. The Board noted that the success rate for avoiding surgery is between 74 and 80 percent.

The Board explained that the advanced scope is only a year old. At present, no physiotherapists are registered in this scope because people are still applying for it. The Board noted that the specialist scope was introduced in 2012 and experienced quite a long lag before people were registered.

We asked whether the Board plans to increase the number of physiotherapists with a specialist scope. The Board said that it would love to see more people working in the specialist and advanced scopes. It added that that this was just a matter of time. The Board pointed out that this does not prevent physiotherapists in the general scope from practising in the area of pelvic health. We heard that there are some physiotherapists in this scope doing “amazing” work.

Our response to the petition

We thank Sally Walker for her courage in sharing her experience and for acting as a voice and mentor to women who have been harmed by mesh. We acknowledge Charlotte Korte for her advocacy over many years. We commend both women for their efforts to stop other women suffering the same harm as them.

The petitioner requests that mesh MUS implantation be suspended until surgeons are upskilled and have better knowledge of how to properly implant mesh. We note that submitters had differing views on whether a pause is necessary. We also recognise that a pause could reduce access to a treatment that works for many women.

We note that the ministry was already considering whether a pause should be implemented. We recommend to the Government that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause. We agree with RACS that any pause should be time-limited.

The petitioner is concerned that the action related to credentialling from the Restorative Justice process has not been addressed. She would like specialist training for all medical professionals performing MUS to be mandated. We note that progress is being made on credentialling but we encourage this process to be prioritised.

The petitioner requests the introduction of a mandatory registry to record all MUS implantations. We were pleased to hear that progress is being made on the registry but urge it to be prioritised and ensure that it reflects the needs of the affected communities. We also encourage the ministry and Te Whatu Ora to consider whether non-mesh urogynaecological procedures should also be included.

We were concerned to hear that women are still reporting that they are not having the opportunity to give true informed consent, and that the ministry has expressed concerns about the informed consent process more generally. We also note RACS’ comments that, because of the deskilling in non-mesh procedures, informed consent is not truly being given. We were interested to hear about the ministry’s work with the National Quality Forum to improve the consistency of informed consent practices.

The petitioner requests that high-vigilance scrutiny be introduced for all mesh and non-mesh urogynaecological surgery. We note that in the United Kingdom, the high-vigilance process involves ensuring the necessity and appropriateness of any procedure and ensuring that all appropriate treatment and surgical options have been fully explained and offered, including where secondary referral would be required. The high-vigilance process must provide assurance to the trust or hospital Medical Director that a multidisciplinary team has agreed the appropriateness of the procedure for that patient, and the need to proceed within the pause period. We encourage the ministry to consider an approach that is suitable for Aotearoa.

The petitioner considers that ACC is not recognising the complex and sensitive nature of mesh claims. We urge ACC to work with the mesh injured to progress the recommendation from the Restorative Justice process.

The petitioner would like "urogynaecology" as a subspecialty to be a protected title. We note that both colleges do not consider that a protection of title is needed. We also acknowledge the role that urologists have played in treating mesh complications.

We acknowledge the harm that some people have experienced from mesh complications. We also recognise that, although this matter predominantly affects women, it can also affect transgender men, and non-binary and intersex people.

Green Party of Aotearoa New Zealand differing view

The Green Party supports a stronger direction to suspend the implantation of vaginally inserted mesh sling for stress urinary incontinence (SUI). We are concerned the recommendation that the Ministry of Health work with the relevant colleges and the Medical Council of New Zealand to investigate how it could effect a pause essentially gets the same body which has procrastinated for so long to make the final decision.

We note that we were told concerns that a pause could reduce access to a treatment that works for many women were also raised in Scotland ahead of the decision to implement a suspension, and the adverse impacts were not realised. The Greens believe the potential for adverse impacts could be mitigated with high-vigilance scrutiny and proactive engagement and promotion of physiotherapy. We also believe there is sufficient acknowledgement of serious harm to necessitate a suspension.

Progress towards credentialling has been very slow and credentialling of those implanting mesh is still "some way away". We have been unable to obtain any information at all regarding how long it will take to credential surgeons nationally, or when this process is expected to be completed.

Recent reporting on the first round of assessments reported only 12 surgeons applied to be credentialled, for the removal of mesh implants, and only six of them were found to meet the minimum standards. This suggests that surgeons have been practising for the last few years without the requisite competencies despite surgeons being assessed against Australian credentialling guidelines in 2018. We are also concerned that there appears to be nothing to stop non-credentialled surgeons in the private sector from continuing to work. This means we are not confident patient safety can be assured.

The Green Party believes the Government needs to follow England and Scotland and step in and prioritise patient safety until there is a nationwide system of rigorous credentialling that has been completed, and high vigilance scrutiny placed on all non-mesh pelvic floor procedures. The harm that is being caused is not acceptable.

Appendix

Committee procedure

The petition was referred to us on 24 November 2022. We met between 7 December 2022 and 28 June 2023 to consider it. We received written submissions and heard oral evidence from the petitioner, Charlotte Korte, the Ministry of Health, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal Australasian College of Surgeons, Dr Wael Agur, and the Physiotherapy Board of New Zealand.

Committee members

Dr Tracey McLellan (Chairperson from 15 February 2023)
Tangi Utikere (Chairperson and member until 8 February 2023)
Matt Doocey
Dr Elizabeth Kerekere
Dr Anae Neru Leavasa
Marja Lubeck (from 8 February 2023)
Debbie Ngarewa-Packer
Sarah Pallett
Soraya Peke-Mason (from 3 May 2023)
Dr Shane Reti
Toni Severin
Lemauga Lydia Sosene (until 3 May 2023)

Jan Logie also took part in the consideration of this petition.

Evidence received

The documents we received as evidence in relation to this petition are available on the Parliament website.

Recordings of our hearings can be accessed at the following links:

- Hearing of evidence with the petitioner, Charlotte Korte, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Royal Australasian College of Surgeons (15 February 2023).
- Hearing of evidence with Dr Wael Agur, the Ministry of Health, and the Physiotherapy Board of New Zealand (3 May 2023).