

Hearing and Responding to the Stories of Survivors of Surgical Mesh

Ngā kōrero a ngā mōrehu –
he urupare

Report for the Ministry of Health

December 2019

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VICTORIA UNIVERSITY OF
WELLINGTON
TE HERENGA WAKA

The Diana Unwin
Chair in Restorative
Justice

Acknowledgement

We would like to express our deepest gratitude to all of the people who have participated in this project.

Thank you for trusting us with your stories; It has been our privilege to listen.

We hope this report presents the story of mesh harm in New Zealand in a way that honours and dignifies each and every one of you.

“There is no greater agony than bearing an untold story inside you”

– Maya Angelou

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This report was prepared by the research team dedicated to the surgical mesh project at the Diana Unwin Chair in Restorative Justice, Victoria University of Wellington. The Chair was established in January 2014 to serve as the focus for collaborative, interdisciplinary research and teaching on restorative justice theory and practice, both within the justice sector and beyond.

The holder of the Chair, Professor Chris Marshall, provides academic and professional leadership to a team of researchers and practitioners and facilitates collaborative engagement between public sector agencies and civil society organisations on restorative justice issues.

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2 Life with mesh¹

My arse is out,
 My arse is in.
 Oh, I don't know where to begin...

Mesh went in,
 It moved about.
 'It's in her head!'
 They were heard to say,
 Fine for them, they don't live this way.

They've cut me here,
 Stitched me up,
 And now really don't give a...

So... Mesh is out,
 It is a dirty word.
 Time for voices to be heard.

Pain so bad it made me shout.
 It's broken many,
 Untied some too.
 Ministry of Health it is now up to you.



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4 Executive summary

1. In June 2019, the Ministry of Health instigated a restorative justice approach to exploring the harm caused by surgical mesh use in Aotearoa New Zealand. The project aimed to listen to the stories of patients adversely affected by surgical mesh as a way of helping to clarify the Ministry's responsibilities, and those of the wider healthcare sector, to address the problem and inform subsequent action.
2. The approach employed is consistent with the principles of resilient healthcare and was continuously refined to adapt to emerging needs.² It was codesigned by the Chief Medical Officer, Chief Nursing Officer and their Principal Advisor, the consumer advocacy group, Mesh Down Under, and the Diana Unwin Chair of Restorative Justice at Victoria University of Wellington. It was comprised of three phases: listening and understanding, planning and acting, and reporting and evaluating.
3. The report builds on the analysis of an initial survey of affected persons conducted by the Ministry of Health in 2018. It provides an analysis of the consumer stories captured in 32 Listening Circles (n=246), eight individual meetings (n=21) and an online story database (n=484) in July-October 2019. It also includes analysis of responses from health professionals gathered from an online database and telephone interviews (n=28).
4. From this data, a complex and nuanced picture of the harms and needs created by surgical mesh has emerged. Mesh injured New Zealanders have described life-changing physical and psychosocial harms stemming from surgery involving mesh. The loss of trust they now have in healthcare providers and institutions cannot be overstated. Their injuries and needs have rarely been acknowledged or validated by those in the health system, leaving them feeling desperate and, in many cases, contemplating suicide. Their dignity has been eroded and they are left grieving losses to their physical wellbeing, relationships, identity, employment and financial status.
5. Mesh injury has also rippled out through the lives of their families and loved ones. It has deeply affected the emotional wellbeing of partners, children, relatives and communities.
6. Health professionals proposed that mesh use is safe for the majority of consumers when certain requirements are met. These include: selecting the right patient; careful assessment and diagnosis, with no contraindications; using the right procedure, the right product and a credentialed surgeon with the appropriate technical skills; and employing a collaborative approach, with fully informed consent, including giving patients the option not to have surgery.
7. Health professionals who have cared for mesh injured patients described their own emotional responses to the impacts of mesh as they learned about their patients' suffering and the lack of acknowledgement they have received. They expressed a desire for services of an appropriate standard for consumers and a healthcare environment characterised by a positive safety culture and collegial support.
8. Results indicate that planning and funding measures to address the needs of those affected will be important. Participants emphasised that a meaningful apology must include acknowledgement of harm and purposeful, timely action that includes compensation. They saw accountability for mesh harm and repair as a shared responsibility. The responsible parties identified include the Accident Compensation Corporation, general practitioners and surgeons, the Health and Disability Commission, the Medical Council of New Zealand, Medsafe, the Ministry of Health, and private and public hospitals.

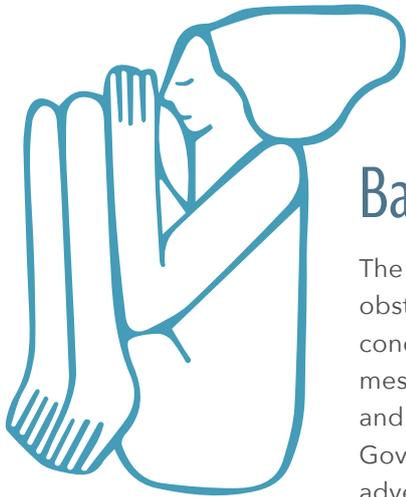
9. An important first step in restorative action is the provision of practical support to meet the substantive needs of patients, families and whānau. Suggestions included: the provision of appropriate support services; greater clarity around the right to make fully informed choices and give informed consent, as well as the right to effective communication and to be treated with respect and dignity; and the right to complain.
10. Practical examples were given to illustrate how such consumer rights could be upheld – such as: the provision of specialist inter-disciplinary mesh services; proactive monitoring of mesh-related surgery; dedicated advocates to navigate the complexities of the health system; and treating mesh-related claims more sensitively.
11. Embedding existing standards such as the New Zealand Code of Health and Disability Services Consumers' Rights and the Choosing Wisely framework into everyday medical practice is essential. Training and credentialling of medical practitioners intending to insert, repair, renew or remove surgical mesh is considered crucially important for future healthcare delivery.
12. Collaboration between all the responsible parties will be essential to meet the needs of those affected by surgical mesh harm. These parties met in November 2019 to discuss the impacts of surgical mesh use and identify actions to promote repair.
13. Including the mesh community in transparent and inclusive dialogue and service design is necessary to rebuild trust. Restoration of relationships characterised by trust and partnership is essential to restore wellbeing. Implementing the actions identified in this report will meet the needs of individuals and communities and prevent future harm.

5 What happened?

Introduction

This report summarises the themes emerging from the Ministry of Health's project "*Listening to the Impact of Surgical Mesh Use and Understanding the Ministry of Health's Responsibilities to Inform Action*". The project has explored the harms and needs created by the use of surgical mesh in New Zealand. It is underpinned by restorative principles and has employed restorative practices.

This report describes the co-design process and findings, illustrated by participants' own words. The harms, needs and reparative actions identified by those impacted by surgical mesh harm, health practitioners and healthcare stakeholders are included. The project will be evaluated in early 2020.



Background

The use of surgical mesh, especially in urology, gynaecology and obstetrics surgical procedures has been a matter of local and international concern for some years. The Ministry of Health is leading the surgical mesh work programme which aims to minimise the risk to consumers and support those harmed by its use. As part of this programme, the Government made a commitment to provide an opportunity for those adversely affected by mesh to share their experiences of living with surgical mesh. This has been an important step in deciding what needs to be done to address their needs and improve patient safety in the future.³

From November 2018 to January 2019, the Ministry conducted a public survey of consumers, family and whānau harmed by surgical mesh. The aim was to gauge interest in sharing their stories with health authorities and find out how they could best be supported to do so. The Chief Medical Officer commissioned the Diana Unwin Chair in Restorative Justice at Victoria University to undertake an independent analysis of survey findings.

In total, 423 respondents completed the survey. They included consumers, families, whānau members and healthcare professionals. Findings were analysed within a restorative justice framework that aims to identify what harms had resulted from mesh use and how respondents thought their needs could be addressed. The report is available on the Restorative Health website.⁴

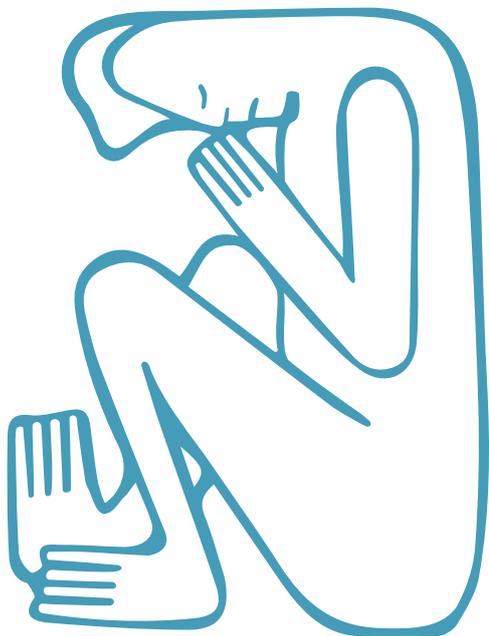
Very few survey respondents thought that the health professionals responsible for mesh harm should be subject to formal penalties. Most indicated a preference for telling their stories to the responsible parties so that their harms could be acknowledged, consequences addressed, and future harm prevented. Survey respondents initially identified the responsible parties as surgeons, General Practitioners (GPs), mesh manufacturers, professional colleges, the Accident Compensation Corporation (ACC), the Health and Disability Commission (HDC) and the Ministry of Health (MoH).

A restorative justice response

After consultation, the Office of the Chief Medical Officer decided that a restorative approach would be an ideal way to begin to address the needs of those affected by mesh harm. Such an approach would enable storytelling, provide validation and help to rebuild trust with harmed parties. In June 2019, the Diana Unwin Chair in Restorative Justice was commissioned to co-design, deliver and evaluate a restorative approach to surgical mesh harm.

Restorative justice involves a voluntary, relational process whereby those with a personal stake in an offence or injustice or harmful episode come together, in a safe and respectful environment, with the help of skilled facilitators, to speak truthfully about what happened and its impact on their lives, to clarify accountability for the harms that have occurred, and to resolve together how best to promote repair and bring about positive changes for all involved.

Marshall, 2019, p. 178⁵



6 The co-design process

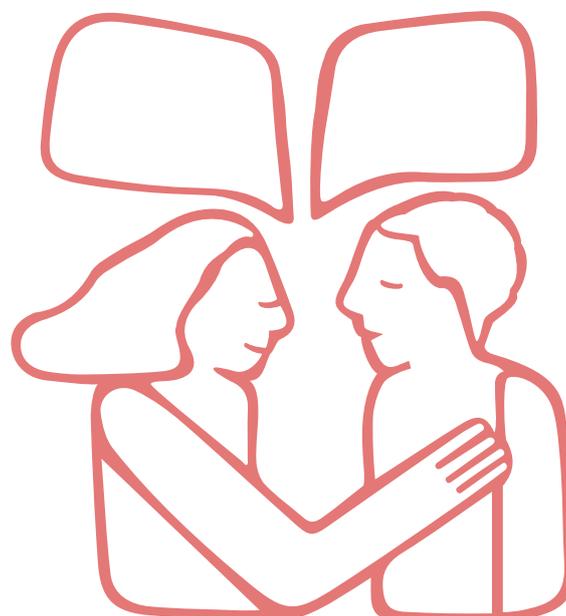
A co-design team was formed in June 2019. It included representatives from the Ministry of Health, the consumer advocacy group Mesh Down Under (MDU), and the restorative justice team at Victoria University (Appendix 1). Planning meetings used restorative circle practices to build connections between people and ensure all voices were heard equally.

Consistent with resilient healthcare principles, the design process was continuously refined to adapt to emerging needs. The design is based on a restorative inquiry framework (Table 1) which seeks to identify and maintain a strong focus on the harms and needs of those directly affected by mesh and to clarify accountabilities for repair. The approach recognises that the immediate parties are best placed to make suggestions about how best to promote restoration and mitigate future risks.

Table 1: Restorative inquiry framework

◆ Who has been hurt and what are their needs?
◆ Who is responsible for the harm and what are their obligations?
◆ How can things be put right again?
◆ How can we prevent it from happening again?

The agreed process incorporated three phases: (i) listening and understanding, (ii) planning and acting, (iii) reporting and evaluating.



Phase 1: Listening and understanding

Storytelling is a very personal experience, so multiple options were provided for people to share their stories of mesh harm and injury. From July-October 2019, the following options were available:

- 1. Listening Circles:** Facilitated meetings of between 10-20 participants where those harmed by surgical mesh could share their stories verbally with each other and with the Chief Medical Officer (CMO), Chief Nursing Officer (CNO) and their Principal Advisor. From August-October, representatives of other agencies identified by consumers as having a share in the responsibility for the harm were also invited to attend. Organisations that agreed to participate included ACC, Royal Australasian College of Surgeons (RACS), Royal Australia & New Zealand College of Obstetricians and Gynaecologists (RANZCOG), Royal New Zealand College of General Practitioners (RNZCGP) and the Medical Council. In light of the number of patient safety issues involved, the Health Quality & Safety Commission (HQSC) was also invited to attend.

Circles were provided in all the major centres identified by survey respondents. ACC provided financial support for participants' travel and accommodation. Stories were transcribed by a Victoria University researcher.

Participants were advised that the Circle process was not a ministerial inquiry, nor a complaints process, and that no specific actions regarding their individual case would be directly addressed. The purpose instead was to provide an opportunity for people to share their experiences and give their opinions on appropriate remedies.

Emotional support was provided before, during and immediately after each Listening Circle. Participants were provided with information about how to make a formal complaint to ACC and HDC. They were also given details on how to access ongoing support, which were repeated in a follow up email. Further details can be found at the Restorative Health website.⁶

- 2. Individual Conferences:** Individuals identified in triage or by MDU as being too unwell to travel, or those with complex needs, were offered a facilitated meeting with the CMO, CNO or their Principal Advisor. Such meetings occurred in a hospital or the person's own home. Stories were recorded and transcribed.
- 3. Online reporting:** Two bespoke story databases using the survey design software Qualtrics were developed to capture stories in written, audio or video format. The consumer database opened in July and closed at the end of October, while the database for health professionals was open throughout October. Some health professionals shared their stories in telephone or zoom interviews.

Phase 2: Planning and acting

Phase 2 brought people from the organisations identified as "responsible parties" – those that share some level of accountability for what has happened – together for an impacts and action planning workshop on the 20th of November 2019. Consistent with the principles of restorative justice, the workshop relayed the learnings about the impact of surgical mesh from the storytelling phase and invited the parties, in accordance with restorative philosophy, to "*clarify accountability for the harms that have occurred, and resolve together how best to promote repair and bring about positive changes for all involved*".⁶

Phase 3: Reporting and evaluating

The reporting and evaluating phase includes several steps:

- Researchers undertook a descriptive analysis with the aid of qualitative data analysis software (NVivo 12 plus) to identify themes across the data gathered. Where appropriate, the themes have been triangulated with international research evidence, recommendations from international inquiries into surgical mesh harm, and New Zealand policy.
- Initial findings were provided in a report as a basis for the Phase 2 workshop.
- This final report will be delivered in December 2019, which the Ministry has agreed will be made publicly available.
- A PhD candidate will evaluate the strengths, limitations, outcomes and wider significance of the whole undertaking, drawing on the views of all the key participants. Demographic data will be collected to understand if the needs of Māori and non-Māori participants were met.

Capturing people's stories

Over 600 consumers told their stories in Listening Circles, individual conferences or the database (Table 2). Nearly every story in the database was provided in writing, and 140 consumers told their stories on the database and registered for a Listening Circle. Further information on the location of the Listening Circles and the participants is in Appendix 2.

Most participants in the project self-identified as being mesh injured. Some identified as being a family or whānau member or a friend of a mesh injured person, and the remainder did not identify with either category (Table 2). Participant quotes in this report are identified by these three categories, followed by a code representing the context in which their story was told (e.g., 'Mesh Injured, LC' or 'Family, SD').

Approximately two thirds of Listening Circle participants were women. Of the men who attended, around two-thirds were mesh injured, and the other third came in a support capacity.

Table 2: Consumer participants

Category	Mesh injured	Family/whānau of mesh injured	Other or self-described
Listening Circles (LC)	223	26	n/a
Story Database (SD)	414	48	23
Individual Meetings (IM)	7	7	n/a

When people provided their story through the online database, they were asked where they had learned of the opportunity to participate. The purpose of this question was to assist the Ministry with ongoing communication with participants throughout the project. Results indicate that a mixture of communication methods will be required (Appendix 3).

Respondents were also asked why they chose to tell their story in written, audio or video format rather than attend a Listening Circle. Work pressure was a key reason given, as well as struggling with injuries or pain that prevented travel. Another reason was a lack of understanding about what a restorative process would entail. Some were concerned about talking in a group setting or felt they needed an advocate to tell their story. Many said they wanted to give others *"worse off than me"* the opportunity to attend instead.

7 The impact of surgical mesh use

A restorative framework first explores what happened and the impact on people. This section describes the experiences of mesh injured and harmed consumers and health professionals using surgical mesh.

“Mesh might have saved my life in the moment, but the long-term impacts are devastating.”

(Mesh injured woman/LC)

The impact of surgical mesh on consumers

Circle participants and database respondents were asked the following question:

What, from your experience with surgical mesh, would you like others to know or understand, and also, importantly, what has been its impact on you?

The harm described was extensive and significant, frequently encapsulated in the phrase “life changing”. People who had elective procedures for mild stress urinary incontinence or prolapse often indicated their quality of life was better before the procedure than afterwards:

“I had a house, steady job, caring sexual relationship, good salary, a racing bike, was a triathlete. I ran half marathons. I had a really nice life. By 2001... all of it was gone.” (Mesh injured woman/LC)

“I have lost my occupation as a farmer, lost my farm, lost many jobs due to frequent hospital admissions. I have lost my physical fitness which was important to me as a farmer but also as a keen hunter, tramper and kayaker. I have lost intimacy with my wife due to the pain. These things are impossible due to my daily pain.” (Mesh injured man/SD)

Mesh-related harms were predominantly attributed to:

- **Mesh erosion:** Participants spoke of how mesh had “broken down”, “shrunk” “migrated” or “eroded” into organs, nerves or body structures. In urology, gynaecology and obstetrics procedures, mesh erosion into the bladder, vagina or other pelvic structures was repeatedly mentioned. For major abdominal surgery, side effects could be catastrophic. One man spoke of a cardiac arrest attributed to “the screws used to fasten the mesh”. He explained how, “my heart eroded from the screw near the pericardium”.
- **Technical competence of the surgeon:** Mesh was described as being “too tight”, “in the wrong position” or “with the hooks in the wrong places” when complications arose. Surgeons were said to have underestimated the complexity of the procedure and skills required for mesh insertion or removal or for dealing with additional complications related to removal. A lack of informed consent, repeated mesh insertion and “patching” behaviours were also commonly cited.⁷
- **Physical injuries:** As well as the physical disabilities created by mesh erosion, people described chronic pain from nerve damage as “excruciating”, “constant” and “ongoing”.



- **Inflammation and chronic infection:** People perceived mesh to have contributed to autoimmune diseases (AID). Following full mesh removal, some people indicated that AID symptoms resolved or significantly improved.
- **Psychosocial impacts:** People spoke of outcomes and experiences that were “traumatic”, “overwhelming” and had penetrated “every part of my life”. Many participants had contemplated or attempted suicide.

Tables 3 and 4 summarise the physical and psychosocial harms attributed to surgical mesh. Participants often shared photographs, documents, medical notes, correspondence with ACC, and other artefacts detailing the harm, with a key concern being that “you won’t believe us”.

For most people, the harm had extended over many years and for many it is ongoing. The “relentless” nature of mesh-related injury, coupled with the lack of acknowledgement by health professionals and providers, had led to “feeling invisible” and unheard. For these reasons, most stories featured severe mental distress and complex traumatic grief. Many stories heard in Listening Circles featured suicidal ideation or suicide attempts.

Trauma and grief

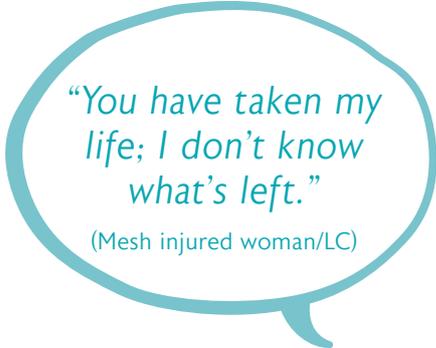
Participants typically described psychosocial impacts as being equal to, or more harmful than, physical complications. The severity of such impacts cannot be overstated. Many referred to themselves, or were observed as, being deeply traumatised and spoke of profound grief over what had been lost. Many indicated they had contemplated or attempted suicide. Participants indicated that the support available to help them adjust to the psychosocial impacts of mesh injury is inadequate.

A significant source of anguish for many men and women was a loss of their identity as spouse or partner, mother, father, carer, worker, employer or professional:

“My husband and I had no intimate life and our relationship has ended. My children are anxious about my health, I can’t work as a senior teacher and I had to stop my degree.” (Mesh injured woman/LC)

The ripple effect of such trauma was particularly evident in one woman’s account of her son’s suicide, which she attributed to the impact of mesh on her whole family. Two participants attended to speak of a family member whose death they attributed directly to surgical mesh. They described their struggle to gain acknowledgement from the coroner or HDC that the death was mesh-related, whilst caring for the young children and family left behind:

“I can’t move on. My daughter isn’t coming back. I want to see mesh banned. I don’t want to read that someone else has lost their daughter, their mother. I am forever going to look at my grandsons with no mum. Until it is banned you will feel us jumping up and down, because she is not here to do that for herself.” (Family member/LC)



“You have taken my life; I don’t know what’s left.”

(Mesh injured woman/LC)

Table 3: The physical harms described by those injured or harmed by surgical mesh

Physical harms described by those injured or harmed by surgical mesh
Chronic debilitating pain unresolved by opiates, anticonvulsants (e.g. gabapentin), tricyclic antidepressants (e.g. amitriptyline) or surgical interventions.
Mesh erosion into other structures commonly the vagina, bladder or nerves, but also examples of abdominal and other organs.
Side effects of medications, particularly analgesics and long-term antibiotic use and resistant bacteria.
Nerve damage e.g. pins and needles, shooting pains, clitoral damage.
Unable to urinate/defecate requiring manual evacuation or self-catheterisation.
Constant urge to urinate.
Incontinence: Urinary, faecal or both.
Prolapse.
Multiple surgical interventions with additional common complications e.g. bleeding, infection.
Loss of overall physical wellbeing: Unable to exercise/undertake physical activity which has negative impact on cardiovascular, muscular and overall health.
Physical disability: reduced mobility, unable to walk without aid, unable to sit or stand for long periods wheelchair bound, pain on movement/daily tasks.
Multiple hospital admissions for mesh-related issues e.g. septicaemia, abscess, wound debridement, VAC (vacuum) pump.
Autoimmune disease/inflammation.
Abscesses: Often recurring, requiring drainage or other treatment.
Treatment where initial phase was authorised by ACC, then second phase declined. Treatment required to reverse initial intervention.
Patient harm event (adverse event) e.g. cut through blood vessel, theatre swab left inside consumer, medication errors (multiple), fall.
Infection: Often multiple, recurring and resistant with long term antibiotic use.
Nephrectomy.
Cancer.

Table 4: The psychosocial harms described by those injured or harmed by surgical mesh

Psychosocial harms described by those injured or harmed by surgical mesh
Re-traumatised from having to repeatedly tell story, especially if previous trauma evident e.g. sexual abuse, sexual assault, family violence.
Suicidal ideation.
Suicide attempts.
Mental illness/suicide (self-harm, post traumatic stress disorder (PTSD), anxiety, depression) in mesh injured.
Addiction to pain medication, sometimes requiring inpatient treatment.
Mental illness/ suicide (self-harm, anxiety, depression, PTSD) in family/ whānau and children of mesh injured.
Profound guilt.
PTSD from intensive care stay. Seen in most consumers who had complex abdominal or trauma surgery.
Sexual dysfunction.
Body dysmorphia.
Sleep disorders: Often related to chronic pain.
Loss of earnings, career, unable to work.
Loss of protective factors e.g. hobbies, exercise.
Loss of home/savings/pension.
Financial cost of unfunded treatment.
Other financial costs e.g. travel, scans, psychological support, home support.
Emotional and physical burden on carers (partner, children, friends).
Break down of relationships (marriage, friendships, children).
Arrested for using alternative pain treatment (cannabis).

Loss of dignity and trust

Many participants indicated that symptoms of mesh injury were humiliating and degrading, especially those relating to sex or incontinence. A number spoke of having to leave work due to “flooding my knickers”, “constantly pooing my pants and stinking” or having to take pain relieving medications that “meant I was out of it for years”. The indignity was exacerbated by the personal nature of medical investigations and procedures:

“Imagine lying still while a gynaecologist uses a speculum to open your scarred, narrowed vagina, and then introduces an inches long dental needle to inject [local anaesthetic] deep into your vagina. Not pleasant.” (Mesh injured woman/SD)

“It’s not all in your head.” (Mesh injured man/LC)

Most participants indicated that such humiliation was compounded over many years. Many spoke of their symptoms being dismissed or minimised by the parties responsible for helping them, especially the surgical profession and ACC.

A common complaint was that when psychological symptoms were disclosed, medication was usually offered as the primary treatment despite the patient stating, “I don’t want to take any more pills”. Women were often advised they were just “menopausal”.

Participants repeatedly questioned the integrity and motivations of the professionals and institutions that “are supposed to protect us”. They suggested official reports supporting ongoing mesh use had the effect of denying the validity of their experience. Many considered their relationship with health authorities to be marked by disrespect and mistrust, and several felt “completely abandoned by the systems meant to help us”. Some perceived conflicts of interest within the system:

“Our government departments like Medsafe, Health and Disability [Commissioner] and our MP’s are not set up to help you, they are set up for you to fight to prove yourself.” (Mesh injured woman/IM)



Role of the medical profession

Participants recognised that a key facet of a doctor’s role is “to do no harm” and therefore believed surgeons should be held accountable for harmful outcomes and answerable to the consumer and to regulatory authorities, such as the Medical Council. Although some participants perceived mesh-related injury to be unintentional or unpredictable, most questioned the technical expertise or integrity of their initial surgeon. They asked, “how can you put mesh in without knowing how to take it out?” and questioned whether “surgeons are paid by the sales companies to put mesh in”.

A related theme was that surgeons “lied to us over and over”. A lack of understanding in the medical community about what constitutes surgical mesh may have exacerbated this perception. For example, a common response from GPs was, “you don’t have mesh, you have tape”.

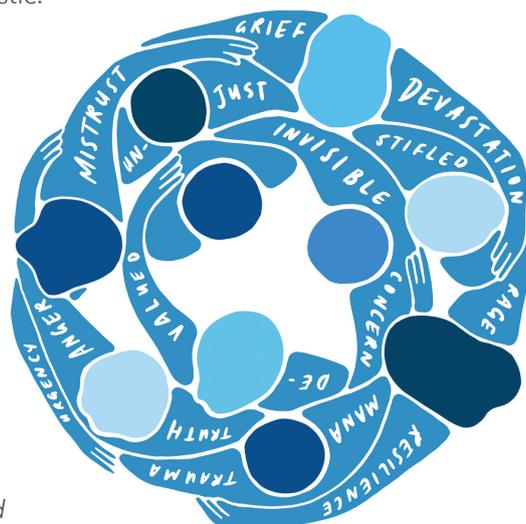
“Someone is lying, and no one is taking responsibility.”

(Family injured man/LC)

Many viewed their doctors as patronising, arrogant and paternalistic. They said their right to be fully informed and to make choices on the basis of informed consent, as outlined in the Code of Health and Disability Services Consumers' Rights 1996⁸, had not been upheld. A number of participants said they had been advised by surgeons that, "my only option was mesh". Alternative options were not offered, and they were told to "come back when you agree to have mesh".

Some commented on how advocacy on their behalf by other medical professionals had been important to uphold their rights:

"My GP has just written to [the surgeon] and told him off and said, 'Don't you put mesh in her; she's had enough mesh'. The surgeon replied that he would not agree to that and wanted to keep HIS options open! I have said NO! I have rights."
(Mesh injured woman/IM)



One surgeon was repeatedly praised for their advocacy skills, which had overturned declined treatment injury claims. Many mesh injured travelled to this doctor, proposing the "compassion of [NAME] is amazing and they make me feel there is still hope." (Mesh injured woman/LC)

Positive descriptions of surgical professionals were otherwise infrequent, and some doctors were described both positively and negatively by different participants. Positive accounts were limited to those who had provided successful follow-up treatment for poor outcomes or had demonstrated empathy by listening and respecting the consumer's dignity and choice.

More commonly, participants spoke of feeling belittled and disbelieved. When common investigations, such as ultrasound, were not able to pick up mesh degradation and damage, medical professionals repeatedly attributed symptoms to a psychological problem.

Statements frequently ascribed to surgeons included, "you don't have mesh, it's not in your notes", or "it can't be the mesh". Such dismissal led them or family members to question "was I really suffering or was it all in my head?". Many participants described feeling abandoned, "degraded and disgusted" when they contacted their surgeon and were told "he wouldn't touch me again".

A small number of participants indicated their doctor had apologised after finally deciding their symptoms were attributable to surgical mesh, while others indicated the doctor had "given up":

"What I couldn't understand was that no one believed me. They not only didn't believe my words, but I went through so many invasive exams - they could feel the sharp mesh growing through my vagina with their own hands. Even then they didn't believe me, 'That shouldn't hurt'; 'You're probably just anxious'; 'Give it 6 months to heal'; 'Have you tried losing some weight?' It was that attitude that really messed with me and totally blocked me from getting treatment for two years of pain. It could have been fixed so early." (Mesh injured woman/SD)

Participants frequently described trust as fundamental to patient safety. But many questioned "how can you trust someone to help you when you have been lied to so many times?" They spoke of living "a horrible life" and being "in fear of having the surgery I need to get well".

Participants who had travelled abroad for mesh removal maintained that the surgical care they received in Australia or the United States was superior to New Zealand, both in terms of technical skills and in terms of "the compassion that was finally shown to me".

The role of ACC

ACC featured in most people's stories. Speaking for many, one described ACC's default response as *"deny, defer, defend"*. Many were frustrated and angry that ACC frequently denied treatment injury claims, suggesting, *"In the US [the manufacturers] have paid millions, but I can't sue because of the existence of ACC"*.

Once again, many felt abandoned by a system that *"our taxes pay for"*. Some contrasted the ease with which they had accessed *"phenomenal support"* from ACC after an accidental injury to the fight, extending over many years, to *"get help I am entitled to"* for mesh injury. Those that had treatment claims accepted called themselves *"lucky"*, describing ACC as supportive and helpful.

Many told of pursuing costly legal processes over a number of years to get help because *"It's not just the surgeons, my battle with ACC is worse"*. One explained:

"I had to fight ACC for 10 years. Twice in Fairway court. ACC did everything in their power to prevent me getting this mesh out." (Mesh injured woman/SD)

Several described treatment assessment processes as *"dehumanising"*, with a small number expressing rage. Participants spoke of feeling *"defeated"* and *"exhausted by the fight"*. Many attributed their lack of mental wellbeing or suicidal ideation to the indignity and protracted nature of ACC processes:

"I had suicide attempts and a 6 week stay in a mental health unit because of the 2 years of pain ACC put me through." (Mesh injured man/LC)

"I am at the end of the road, is this my fault? I relied on [ACC], there is no contact with [ACC] and my life is over." (Mesh injured woman/LC)

The expert review processes of ACC (and also of HDC) were seen as an opportunity to *"cover up"* for fellow doctors. Inadequate or missing documentation were frequently cited as barriers to procuring the evidence required for a treatment injury claim:

"[The surgeon] took photos and I asked for it to be detailed. He said, 'No I won't do that, he is a colleague of mine.'" (Mesh injured woman/LC)

Many attributed this behaviour to *"the Old Boys Club situation"*. Several women noted that ACC reviewers were predominantly male, which they found humiliating and did not consider the sensitive nature of claims:

"... not a nice thing to do to a rape victim, especially when ACC know that I can't let a male near me without distress." (Mesh injured woman/SD)

Repeated investigations to prove an ongoing need to ACC case managers, such as for incontinence pads, left participants feeling *"humiliated"* and *"degraded"*. Many felt retraumatised by the need to *"tell my story over and over, and to start at the beginning"*. The need to do so was often attributed to administrative failures within ACC, such as missing notes, high staff turnover and changes in assessment or case management requirements. Some spoke of return-to-work interviews that were too short to appreciate the full complexity of the injury:

"He said, 'You look fine' to me, but couldn't see the pain I was in every day. They don't know me at all." (Mesh injured man/LC)

Some people had asked their employers or GPs to be their advocates. Many explained how the financial compensation available to them was inadequate to meet their immediate needs proposing *"compensation is no good in 6 or 12-months' time, I need treatment and living costs now"*. Those with permanent disabling injuries who had to give up even part-time work, young mothers, and main income earners were in desperate need of financial assistance. Many had lost all their savings and/or their home.

Numerous people wanted mesh injured New Zealanders to have the opportunity to sue the manufacturers of mesh products:

"We, the injured, hear all the time about massive pay-outs that people overseas have received, and yet we have to fight our way through ACC's bullshit, and hope for a lump sum, which is a pittance in comparison. My life as it was is over, I can't get it back. All I can do is try and make the most of what my body is now able to do, and money would most definitely help with this." (Mesh injured woman/SD)

The role of HDC

The HDC was frequently described as *"not upholding my rights"*. Participants stated there was *"no point"* in pursuing the HDC process as the mesh community knows *"they don't do anything"*. This perception is particularly evident in the following story:

"This doctor had kept no handwritten notes about the surgery, he was under review by the Medical Council at the time I had the initial surgery in 2002 (which I didn't know) and was also doing research on mesh at the time. So today he is still out there doing harm, HDC didn't do their job to protect the public." (Mesh injured woman/SD)

Participants who had experienced an HDC investigation found it deeply distressing. Outcomes, such as *"no further action other than Dr M being advised to write more detailed notes"* were perceived to lack genuine accountability.

Some participants who had complained to HDC that their right to make an informed choice and give informed consent had been breached were told, *"I had informed consent because I signed the form"*. Participants did not think a signature amounted to informed consent, especially when the issues outlined in Table 5 were present.

Many participants wanted *"the HDC to step up, encourage people to make complaints and actually act on them in the patient's interest"*. They also wanted an approach based on dialogue and discussion rather than letters and documents. Many found the need to *"do my own investigation"* due to missing or lost medical files to be debilitating. When Circle participants were asked if they would like an HDC information leaflet, they often declined, stating they were *"already exhausted by ACC"*.

The role of Medsafe

A common perception was that Medsafe has contributed to the harm by allowing medical devices *"into this country without a proper process"* and by the *"grandfathering"* of products. Many expressed the view that consumers have more protection for common household products than for medical devices.

On *"finally tracking down my notes"*, some discovered the batch numbers on their mesh were from a banned device and questioned why *"illegal banned mesh was put in me"*. Two people shared documents with their Listening Circle team to support their claim that mesh had been used in their surgery after the product had been prohibited.

There was a widely voiced view that *"the government is responsible for this product"* and should *"sue mesh manufacturers under consumer protection laws"* to fund removal and provide compensation. Consumers also held Medsafe accountable for not notifying them that there was a concern about mesh:

"I was able to find [via the internet] that the Mesh inside me... had been recalled in 2015 from the FDA. Yet no one has ever called me to say I have a recall mesh living inside me. You would think somewhere in our medical system this would have been looked at and researched and all patients should have been notified. To me this is total negligence." (Mesh injured woman/SD)

Concerns about informed consent

A significant number of stories featured concerns about informed consent (see Table 5). A widely held view was that consent practices did not meet the standard expected in the Code of Consumers' Rights. Many claimed mesh had been implanted without their consent, saying they only became aware of *"this foreign toxic plastic in my body"* when complications arose.



"We have been treated like guinea pigs."

(Mesh injured woman/LC)

The consent process for initial surgery was frequently described as a sales pitch: *"This is a quick and easy fix", "I've done thousands of these with no problems"* and *"You will be back on your feet in no time"*.

In many elective cases, no information was given about the other options available, such as a native tissue repair or pelvic floor physiotherapy, nor any assessment of the expected risks, side effects, benefits and costs of each option:

"Based on the information given, I was led to believe there were no other treatment alternatives and that surgical mesh was safe, so I agreed." (Mesh injured woman/SD)

Many participants commented, *"I would never have had mesh put in me if the risks were fully explained"*. Some indicated feeling pressured into surgery with mesh. One said, *"He held open the door and said come back when you agree to have mesh"*. Only later did she learn that alternatives were possible. Others noted that their concerns were dismissed:

"I went to my surgeon; I mentioned the risk around mesh as I had heard it in the news and was shown a brochure and told, 'you will be sweet mate!'" (Mesh injured man/LC)

Participants often referred to mesh treatment as *"experimental"*. They spoke of being *"treated like guinea pigs"*, equating their experiences to those documented in the Cartwright Inquiry.⁹ Some expressed guilt for trusting their doctor and not questioning the evidence base for mesh use. Others questioned how surgeons go to a conference or speak to a sales representative, then implant *"a new product that is perfect for you"* without evidence or a proper credentialing process.

Even after a mesh injury was diagnosed, interventions intended to repair the damage were often described as *"the beginning of the worst part of my journey"*. The original surgeon often underestimated the risks involved during the consent process or did not disclose their intentions. Some participants indicated they had consented to full removal, only later to discover the surgeon had *"cut the edges of the tape and left it in me"*, or implanted additional mesh. Some were told their mesh had been fully removed, only to find out later it was still in place when complications arose.

The few examples given of acceptable consent processes related to surgery where *"I would be dead without mesh"* or to emergency procedures where the doctors *"had to just get on with it"*.

Two surgeons were frequently praised for their consent processes around mesh removal. In instances where the consent process was deemed to be acceptable, surgeons were depicted as equal partners in the decision process. They investigated all options, presented them to the patient and *"finally listened to me and gave me choices"*.

Table 5: Concerns raised about consent processes

Concerns raised about consent processes
Non-invasive options e.g. physiotherapy not discussed/offered.
Not advised that a medical device (i.e. mesh) would be implanted during surgery.
One conversation about consent usually in hospital on day of surgery, no time to consider options.
An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option was not provided.
Alternative surgical options not discussed/offered e.g. native tissue repair (pelvic sling, hernia)
Only risks of operation disclosed were bleeding and infection.
Participants indicated they felt pressured into surgery after being advised that mesh was the only option available to them.
Consent requested after the consumer had been administered pre-medication or in the anaesthetic room.
Consent requested by someone other than the operating surgeon (e.g. a junior doctor).
Non-medical personnel in the operating theatre without consent (e.g. sales and training representatives).
Trainees performing surgery without knowledge or consent until after the operation.
Opportunistic surgery i.e. <i>"while I was in there, I fixed your hernia"</i> .
Operating surgeon discussed wrong operation or thought they were a different patient/consumer during consent process.
Not advised that surgeon had minimal or no experience of using product for this specific surgery.
Consumer not told that they could decline experimental treatment.
Painful procedures in consulting rooms undertaken without analgesia or anaesthetic e.g. cutting tape and <i>"I hit the roof"</i> .
Two instances of treatment video recorded without consent.
Options presented driven by financial motivation rather than consumer choice.
One instance of pig-based product used on Jewish patient.

Concerns about equality

Both men and women have been affected by mesh and described significant losses. However, the harm experienced by women included unique features. Women spoke of feeling deeply humiliated when symptoms were age or gender specific:

"I said, 'I know I have a mesh'. 'He said, I think its menopause:'" (Mesh injured woman/ LC)

"ACC wouldn't cover my treatment injury because they said it was related to when I gave birth years ago." (Mesh injured woman/ LC)

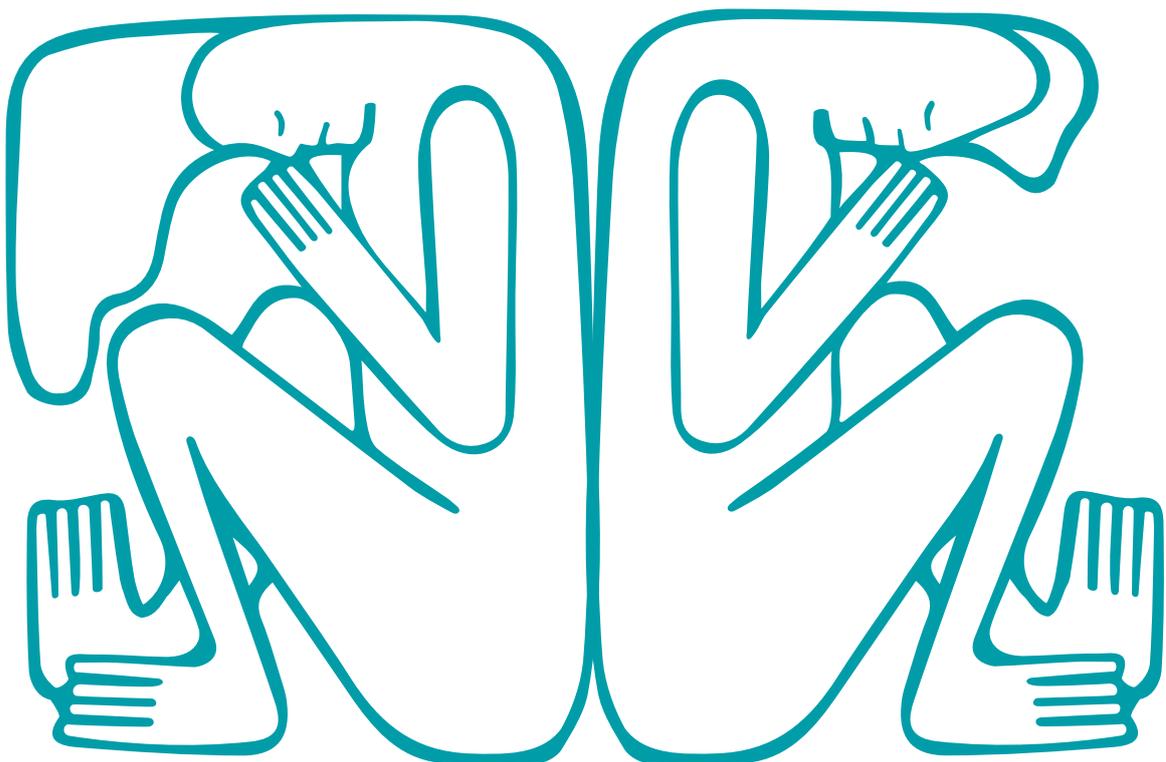
Many women described the distress they experienced when mesh eroded through their vagina, or damaged their partner's penis, stating *"I can't have sex now; it has changed my life"*. Some compared the traumatic nature of this loss to *"medical rape"*. Often women had been abandoned by their partners or described the guilt or shame of not being able to meet their partner's needs. They spoke of having to give up on sex *"because of the pain"* or because of *"the mesh cutting his penis"*. One spoke *"the nerves to my clitoris [are] damaged and it's like having a vibrator inside me every day"*.

Women described feeling humiliated by doctors: *"She told me I should buy a vibrator"* or *"he talked to my husband about our sex life while I was sitting right there"*. One woman was so deeply distressed when a young male doctor suggested *"I should masturbate"* that she sat in the road contemplating suicide:

"I was watching the cars to see when I could run out and end it, but I couldn't do it to my children. I sat in the gutter and people just walked past me. I sat in the car and I cried and cried. I rang ACC and told them that the pain specialist had told me to play with myself because I couldn't have sex and I felt so downgraded, so disgusted." (Mesh injured woman/LC)

The sensitive nature and extended impact of such personal loss was particularly evident in women who had previously experienced sexual assault, and where *"anyone talking about my vagina is traumatic"*. Some described ACC processes as *"like being surgically raped"*. Another commented:

"Why do I need to tell my story over and over again to get ACC to pay for my incontinence pads more now than I did 18 years ago?" (Mesh injured woman/LC)



The loss of identity for women who were mothers or carers was described as “traumatic”. Many described the guilt and agony of everyday life in which they balanced “caring for my children and laying on the floor for hours in pain from a procedure I chose to have”.

The impact on children, which was described as “significant” and “unfair”, ranged from anxiety and depression to self-harming and suicide:

“My son has missed out on his mother in his most formative years, he has had to witness me writhing on the floor in pain and then crying because I cannot get up; he has had to help clean me up after the pain makes me vomit; he has had to miss out going on adventures outdoors, on holidays, out for dinners or to the movies; we can’t go on road trips or plane trips; he has missed out on me buying him things because I could not work enough to afford it. Instead of bright and bubbly active he has dealt with grumpy, sullen and tired. He has been denied the mother he deserved.”
(Mesh injured woman/SD)

“I have a 27-year-old son who can’t remember me ever being well. I have been on morphine all sorts for years... couldn’t do a lot... thank God I am so positive about things.” (Mesh injured man/LC)

On the other hand, many women described their children or grandchildren as a protective factor that had kept them from following through on suicidal thoughts.

Adverse events

In addition to the themes already discussed, a number of other adverse events were disclosed. The Health Quality & Safety Commission defines adverse events as “events with negative reactions or results that are unintended, unexpected or unplanned”.¹⁰ Consumers disclosed several such events relating to the insertion, repair, renewal or removal of mesh:

- **Medication-related events:** Death or injury from anaphylaxis or allergy from medications patient had disclosed they were allergic to; side effects from opiates requiring hospitalisation; events relating to polypharmacy.
- **Infection related events:** Delayed diagnosis of infection, multi-resistant drug infections or scalpel injury to bowel or bladder leading to severe sepsis.
- **Allergic reaction to latex:** Used despite the patient disclosing the allergy.
- **Surgical swabs left inside the patient:** Discovered during a later surgery.
- **Readmission to hospital within 24 hours of discharge:** Particularly due to pain, swelling, discharge or fever.
- **Unexpected complications of surgery:** such as cutting into a major blood vessel or other structure.

Feedback on the restorative approach

Feedback from consumers, MDU, representatives of the Ministry of Health and wider health sector stakeholders attending Listening Circles was extremely positive. Participants indicated that the Circle process allowed them safety to talk about issues they had never shared before: *"I never imagined I would be talking to strangers about such personal details"*. Many indicated that the community setting was *"healing"*:

"I have been living with this for so long now it has become 'the norm', to be with this group, under controlled conditions, has enabled me to speak freely without feeling judged."
(Mesh injured woman/LC)

Many participants swapped contact details in order to stay connected to local people who *"really understand each other"*:

"We were all in the toilet having a hug, because that's where we always end up. I came here as a stranger and am leaving with friends." (Mesh injured woman/LC)

Some Circle participants indicated they initially found storytelling a *"traumatising experience"* as they re-lived their experience but were also grateful for the opportunity. Similar sentiments were expressed by people who provided their story in written, audio or video format:

"Writing this is particularly difficult as I have had to revisit several traumatic events."
(Mesh injured man/SD)

At the end of Circles, participants expressed gratitude, cautious optimism and a demand for action from Ministry representatives. These views were also expressed in stories provided in the database:

"I hope the restorative justice process will raise more awareness about the complications mesh causes and enable health professionals to understand the broad effects it has on people's lives."
(Mesh injured woman/SD)

"I believe this restorative thing is another stalling tactic by NZ Ministry of Health as I have been asking for help a long time. Are they stalling till we all die? None of us should be suffering like this and we get an insult payment for injuries and nothing for pain and suffering which is a major problem."
(Mesh injured woman/SD)

Let me be who I was¹¹

On a plane going home after a day,
Of hearing stories from men and women,
About harm from surgical mesh.
Mostly women sharing,
Such courage and clarity,
Sometimes years of pain and sorrow.

They took the option of surgery,
With hope in their hearts it would get better.
Not really knowing, as others have
Come to know,
That mesh entangles the body, the brain,
the heart, the liver.

Not believed, accused of being mad and sent
to mental health services.
Struggling to keep friends and families who
didn't understand, couldn't...
But who hoped and wanted their former,
Mother, sister, friend, aunt, grandmother,
back again.

"Take it out, it's eating my body away!"
Bowel, bladder, vagina functions torn
to shreds,
Feeling fragile and intimacy dead.
Relationships torn apart,
Or bought together,
But who would know which way it went?

Questioned and bullied,
"how many pads did you say?"
And "who is going to pay?"

Jobs lost; careers crushed,
Children unable to feel a mother's warmth,
Hug, lifting and playing,
Or a grandmother caring and chasing.

Telling their stories over and over again
to health 'healers'
This is what happened and how.
But not who I am,
And what I need.

Give me hope and healing,
Give me strength,
Let others see me for who I am,
Not what I have become ...
Surgical mesh.

For some of us, sadness and shame,
At what has been done to me.
Not who I am.
Or should be,
Let me be who I was.

The impact of surgical mesh use on health professionals

The database for health professionals was opened in October 2019. Twenty-two stories were completed in the database, and five health professionals made contact to provide their stories in telephone or zoom interviews. The sample size is small and therefore should be interpreted cautiously, but most respondents were experienced professionals from diverse specialities (Table 6). To maintain anonymity, quotes are attributed to generic groups, e.g., registered nurse, surgeon.¹² The phrase clinician is used to describe quotes attributed to registered health professionals and includes the views of doctors, nurses and physiotherapists.

Table 6: Respondents: Health Professionals

Occupational group	Number	Specialities	Years of experience
Doctor	16	General Practice (GP) Medicine General Surgery Colorectal surgery Orthopaedic surgery Obstetrics and Gynaecology Urology surgery Sexual Health	1=0-5 years. 1=5-10 years 5=10-15 years 9= 15 years or more
Registered Nurse (RN)	8	Theatre Nurse Practice Nurse Clinical Nurse Specialist Peri Operative Nurse	7 = more than 15 years 1= 5-10 years
Physiotherapist	3	Pelvic Floor	15 years or more
Acupuncturist	1	Acupuncture	15 years or more

Perceived impacts on patients

Health professionals were asked to describe in their own words:

Can you tell us about the impact surgical mesh has had on your patients?

In response, many indicated mesh had made a significant contribution to “improving the quality of life” of consumers. It was a minimally invasive procedure and had a small re-operation rate. Some said it could be life changing for their patients, indicating there were many patients they could not treat if the product were not available:

“The Mid-Urethral Sling (retropubic TVT [Tension-Free Vaginal Tape]) has had an overwhelmingly positive affect on many hundreds of women. It has allowed them to resume work, sport, increased confidence, allowed single women who were too ashamed and shy to find a partner. It has allowed mums to jump on the trampoline with their children. For some women their leakage was so bad they slept on newspapers with a bath towel between their legs, sleeping on the sofa as the squabs were easier to wash than the mattress.” (Surgeon)

The views of clinicians varied about which procedures required mesh and the complication rates associated with each procedure or product:

“Mesh repair for abdominal wall hernia repair is proven to be safe with less pain and less risk of recurrence. Sure, mesh is a foreign body and it has very occasional problems (infection) but compared to the old suture-repairs it is a much, much better option. Using mesh in the female pelvic floor is a different story - the female pelvic floor has different mechanics and dynamics to the abdominal wall - personally I would never use mesh in a female pelvis.” (Surgeon)

Surgeons agreed that the decision to use mesh should take into account complication rates for specific procedures. Two surgeons proposed patients should be provided with the complication rates of surgeons to meet the threshold for informed consent.

Some surgeons cautioned against a rush back to traditional surgeries, suggesting they were abandoned worldwide for very good reasons, including cost, increased recovery time, or suitability. The need to base any Government decision regarding mesh use on *“evidence and not emotion”* was viewed as of key importance.

Most respondents thought that complications from mesh use occurred in a minority of consumers. However, those who had regular contact with mesh injured patients (GPs, medical doctors, surgeons, registered nurses and physiotherapists) stated that when complications arose, the harm was significant and severe, and was exacerbated when health professionals or ACC failed to acknowledge it. The following comments were typical:

“They have been told ‘it’s in their heads’ or that because they are a female they are overreacting. Medical professionals have discounted the severity of their conditions, many have been told they have nothing wrong with them and that the pain, discomfort, scarring, mesh erosion, incontinence, psychological effects are minor and to ‘just get on with your life’. ACC provides a further layer of frustration, distrust, fear, failure and the feeling that no one cares, no one listens, no one admits fault.” (Physiotherapist)

“These women go somewhere, and no one believes them, but they are labelled as mad, belittled, ridiculed and they think they are crazy. They see ten doctors before they see [someone who helps them]. To go through that must be devastating.” (Surgeon)

Health professionals with a lot of exposure to mesh injured consumers indicated that mesh injuries were ongoing and could on occasion be related to an unnecessary procedure. They indicated there was significant variability in patient assessment, investigations, mesh placement and technical competence. These clinicians described their disappointment in colleagues whose practice they considered to be irresponsible or inadequate:

“As surgeons we try to do our best. When we cause problems, I would expect that you would feel bad and follow through; to tell your patient, ‘this is a journey we are on together’. This is the biggest part of what is missing. There is dissonance between wanting what is best for your patients and dismissing them as a problem.” (Surgeon)

Perceived impact on health professionals

Health professionals were also asked:

Can you tell us about the impact that surgical mesh use has had on you as you have cared for patients?

Surgeons who advocated for mesh use noted they had had few or no patients with complications and so described little or no personal impact. Clinicians working with multiple consumers with mesh injuries (e.g., pain specialists, clinicians investigating or treating injuries) or those who had long term relationships with mesh injured patients (e.g. GPs) described feeling “helpless”, “powerless” and needing very special skills to “cope with your own self-care so you do not burn out”.

Some doctors and nurses reported they had attempted to raise concerns about mesh harm through various avenues, including:

- Feedback to individual doctors about an initial surgery after complications or regarding concerns about complication rates or technical skills
- Talking or writing to local managers or clinical leads
- Talking or writing to professional or regulatory bodies or ACC
- Presenting data at conferences or in their place or work
- Informal discussion with surgical colleagues.

Most indicated a “lack of acceptance [in the health sector] that there are issues regarding consumer safety and mesh injuries” which was “frustrating” especially when they observed unsafe practice. For example:

“I know a doctor who was buying mesh from India, cutting it into individual pieces and he only works in private... One lady consented for a hysterectomy and woke up with a bladder sling, that’s not right... One surgeon I know has done many surgeries with many impacts, but he said, ‘I am not using mesh [and having] lots of complications.’ There is a lack of understanding and accountability for practice.” (Registered nurse)

Others indicated that when they raised concerns to a private hospital provider, they were not listened to:

“I found a whole stack of mesh products sitting on the shelf on my private hospital that my google search said were banned. I emailed the manager a carefully worded email and received a response saying someone else was across it, and these products had been previously banned but had been reapproved: don’t worry about it. There was no attached information to confirm this. It was quite clear that my enquiries weren’t welcome. A recent check of the same stock shelves found that most of those mesh products have now been removed.” (Registered nurse)

Surgeons suggested that the culture of the surgical profession was not always supportive of open discussion and interdisciplinary collaboration. Nurses said they had witnessed people being “thrown under the bus.” Doctors described behaviours towards female surgical colleagues who spoke up about mesh as “massive bullying” that could significantly impact wellbeing:

“There was bullying from the outset when I spoke up, they ridiculed what I was saying or doing, and [someone] started an investigation because it was so bad. They were scared I was going to commit suicide.” (Surgeon)

The existence of these behaviours meant that some surgeons feared retributive action and were unwilling to provide feedback to their colleagues relating to technical competence.

8 Needs – How can we make things right?

This section describes the needs consumers and health professionals perceive to be important in order to repair harm, restore wellbeing and ensure patient safety in the future. Responses reflected three types of ‘justice need’ that people often have in the wake of serious harm: the need for repair of substantive losses, the need for a fair and transparent process of resolution, and the psychological need for acknowledgement, respect and empathy (Table 7).¹³



Table 7: Categories of justice needs

Justice Need	Definition
Substantive	The actual harms that need to be remedied.
Procedural	The process of interacting, communicating and making decisions about how to address harms.
Psychological	The way one is acknowledged, respected and treated throughout the process, ensuring those affected can honestly communicate differences, concerns and potential similarities with each other in a safe way.

1. The needs of consumers

Consumer participants were asked to describe in their own words:

What do you need now to enable you to move forward?

One recurring theme to emerge was the need for acknowledgment and empowerment. The Code of Consumers’ Rights also centres on the need for empowerment, and the rights listed in the Code are a helpful way of summarising the expectations of mesh injured parties.

“More than anything else, the success of the Code [of Consumers’ Rights] lies in its empowerment of patients and consumers. They are empowered by it to know that they have rights, to ask that they be respected, and to request information about their condition, proposed treatment and options.”

*Manning & Paterson, 2009, p. 152
The Cartwright papers¹⁴*

The right to services of an appropriate standard

Participants expressed a strong desire for specialist mesh removal clinics. Ideally such centres would be used to “put mesh in and take it out”. Consistent with advice from the RANZCOG¹⁵ and recommendations from the Australian Senate Inquiry,¹⁶ these centres should have an interdisciplinary focus and technical expertise to investigate and remove mesh (Table 8). The inclusion of pain specialists was viewed as essential, since there is a well-established link between chronic pain and mental wellbeing. One participant envisaged:

“A specialist treatment centre for men and women injured by mesh - a one-stop shop fully funded with access to counselling, social work, pelvic physiotherapy, occupational therapy and [surgeons] with specialist mesh complication knowledge and skills.” (Mesh injured woman/SD)

“I need an empathic multidisciplinary team to help me through the process. We need social workers who understand how to deal with ACC... We need mental health workers to help us with depression and anxiety and the recognition that all these things are connected to [the] surgery. I need someone to acknowledge all these things are linked. I need an empathetic multidisciplinary team that I am confident in.” (Mesh injured man/LC)

a) Credentialed surgeons

Participants considered it essential to have New Zealand surgeons trained and credentialed in mesh surgery and removal. A small number of participants had accessed full mesh removal procedures overseas at their own expense. Many others, especially those requiring complex surgical interventions, were waiting for expensive treatment abroad to be authorised by ACC or the Ministry of Health, due to the lack of technical skills in New Zealand. The desperation experienced by those who had self-funded complex treatment abroad was evident in this story:

“I had to kiss my daughter goodbye before, kiss her and give her a letter in case I died. ACC wouldn't pay for me to be fixed but they would pay for me to come back in a box.” (Mesh injured woman/IM)

In the same way that the insertion of mesh was described as life changing, mesh removal in the US and Australia (and occasionally in New Zealand) was also described as “life changing”. Symptoms vastly improved “as soon as the mesh was out of me”. Many consumers expressed the view that the New Zealand Government should be responsible for ensuring the same standard of care here:

“With ACC legislation denying funding for overseas treatments and no New Zealand surgeons having the experience or ability to undertake full mesh removal, the government is denying access to adequate health for all of the men and women mesh sufferers who are unable to fund overseas treatment themselves.” (Mesh injured woman/SD)

In addition to mesh removal, specialist clinics should also provide ongoing support for those affected with chronic symptoms, as life “would never be the same” after mesh.

Replacing outdated medical models with a holistic approach to healing was also thought to be essential, though findings indicate this may be challenging in elective surgical settings. The desired approach is that the patient is seen as a whole person, not a diagnosis, and that their individual physical, mental, spiritual and social needs are addressed as they heal. The need for such an integrated approach was one of the findings of He Ara Oranga¹⁷ and is also aligned with the established Māori health model, Te Whare Tapa Whā.¹⁸



b) Advocacy support

Participants recommended the appointment of specially trained and empathetic ‘navigators’ to help harmed parties navigate the complexities of the healthcare system. Navigators would help consumers to access care proactively and would prevent them getting lost in the journey between care providers and ACC case management systems. Considering the sensitive nature of the issues involved with mesh, navigators may help prevent re-traumatisation from having to tell stories over and over again. They would also help ensure closer co-operation between health professionals and providers, better sharing of information among providers, and would enhance the overall quality and continuity of services. Such an advocacy role has proven successful with cancer patients in New Zealand in improving access to treatment and patient experience and could be extended to mesh patients.¹⁹

c) Psychosocial support

Participants considered the provision of better psychosocial support for individuals and their families as essential. Surgical complications are known to be a significant predictor of negative post-operative psychosocial outcomes²⁰ and traumatic grief has a long-term impact on morbidity, though it is not always considered within medical models of treatment.²¹

Many expressed a desire for a community where they could meet regularly for peer support. Many indicated that participating in the Listening Circles had “unburdened” them, and that the opportunity to be in the presence of “*all these amazing people who understand me, when I thought I was the only one*” had been profoundly healing and supportive. The desire for ongoing support through such meetings was frequently mentioned.

d) Mesh register

A mesh register was considered highly desirable, with many people questioning:

“Why is it so difficult to have a register in NZ? Who is being affected, why and how? We need on record what is happening”. (Family member/LC)

The argument for a mesh register is consistent with safety approaches that advocate anticipating and remaining vigilant to risk and adapting accordingly.²² It is also consistent with patient safety research that has concluded clinicians fix-and-forget patient safety problems rather than fixing-and-reporting them, which is better in the long term for patient safety.²³

Participants saw Medsafe and the Ministry of Health as being responsible for anticipating and remaining vigilant to risk to prevent “*another mesh disaster with a medical device*”, asking “*how does Medsafe let this stuff in?*” Medsafe currently collects adverse event data on medical devices in retrospect. It has recorded 1070 adverse events relating to surgical mesh and stress urinary incontinence devices between 2005-2018.²⁴ Participants wanted a proactive approach, questioning why data measuring harm from surgical mesh is collected in retrospect by multiple agencies that do not appear to share information.

Table 8: Desired mesh services

Need	Description
Credentialed Surgeons	Surgeons who: <ul style="list-style-type: none"> • Practice within a holistic model of care. • Are trained in the use of the specific device. • Have the technical expertise to perform the specific procedure, both implanting and partial or full removal of mesh. • Are trained in surgical alternatives e.g. native tissue repair (e.g. hernia and pelvic slings). • Monitor and report patient outcomes and complications on a surgical mesh register.
Technology	Access to equipment that can support the identification and removal of mesh e.g. 3D scans and to explore alternative options to surgery e.g. urodynamic testing.
Interdisciplinary teams	Access to alternative options to improve wellbeing and (a) prevent the need for surgical intervention e.g. physiotherapy (b) improve overall wellbeing when living with mesh-related injury e.g. physiotherapy, social worker, occupational therapy, complementary therapy.
Pain Specialists	Specialist in chronic pain management, to include both invasive interventions (e.g. nerve blocks/machines) and other therapies (e.g. meditation, complementary pain therapies).
Advocates	To proactively identify and assist with: <ul style="list-style-type: none"> • Financial and psychosocial supports. • ACC treatment injury claims. • Access to the high cost treatment pool when surgical options are not available in NZ. • The Code of Consumers' Rights. • HDC or other complaints process. • System navigation.
Psychological support	Counselling and psychological support for traumatic grief. A focus on mental wellbeing rather than pharmacological intervention alone. Face to face support groups with other mesh injured. Recognition of partners and children as a protective factor and access to psychosocial support for the whole family/whānau.
Sex therapists	Access to sex therapists for couples or individuals.

e) Regulating mesh use

The strength of feeling expressed about ongoing mesh use in New Zealand cannot be over-stated. Many participants called on the government to *“BAN this plastic shit. We are taking it out of the ocean, but we are putting it into our bodies”*. Other participants wanted mesh use to be minimised, or only used as a last resort.

A handful of consumers indicated that mesh was an essential tool for surgeons, as it had been used in their case during lifesaving treatment, such as in complex gastrointestinal surgery. Although regulatory action has been taken by the Ministry of Health resulting in the removal of some or all products of four suppliers of mesh implants for urology, gynaecology and obstetrics surgery, some participants' stories, and other informal discussions, indicate that product removal may not have been fully implemented by all providers.

f) Further research

Participants called for research to explore the efficacy and impact of mesh use and treatments intended to alleviate symptoms. The research should include:

- Understanding the prevalence and impact of this *“emerging issue”* in New Zealand. Other countries have also undertaken research to inform individual and national decision making.²⁵
- Appreciating the psychosocial impact of mesh harm on individuals and families, as well as focusing on procedural failure rates.
- Further investigation of the link between mesh and autoimmune disease.²⁶
- Effectiveness of non-traditional pain therapies for surgical mesh nerve pain, especially medical cannabis.

The right to be fully informed, make informed choices and give informed consent

Participant feedback shows that current consent practices, in both private and public hospital systems, are not meeting consumer's needs and in some cases appear to be violating consumers' rights. The improvements they called for align closely with the Medical Council position statement,²⁷ the Code of Consumers' Rights, and RANZCOG advice that patients should be able to access transparent information about the technical competence of their surgeon and provider.²⁸ The need to embed the principles of the Choosing Wisely framework (Figure 1) in elective surgery practice was also particularly evident in people's stories.²⁹

A meaningful consent process was described as consultation with more than one party, in person, with time to consider options, and with follow-up discussion. Some participants suggested that collaboration between surgeons and other specialists involved in their care would ensure all risks were accounted for. They also indicated that a collaborative, well documented process would ensure they were provided with appropriate advice regarding post-operative symptoms and support options. Consistent with systematic reviews that have considered consent processes,³⁰ participants also expressed the need for additional written information, audio-visual interventions and extended discussions.

Comments indicated that consultation processes designed by consumers and other healthcare professionals are more likely to provide informed consent for surgical mesh procedures. The use of these principles is not unusual in healthcare³¹ and the development of co-designed patient leaflets and informed consent processes for mesh patients was agreed to by MDU and the professional colleges in 2017.³²

Figure 1: Choosing wisely: Four questions for patients to ask³³

4 QUESTIONS FOR PATIENTS TO ASK

Some tests, treatments and procedures provide little benefit. And in some cases, they may even cause harm. These questions can help you make sure you end up with the right amount of care – not too much and not too little. As each situation is unique, a discussion with your health professional can help you develop a healthcare plan for you.

1. Do I really need this test or procedure

Tests may help you and your doctor or healthcare professional determine the problem. Procedures may help to treat it. Understanding why your doctor is considering a test and weighing up the benefits and risks – is always advisable, and is every patient’s right and responsibility.

2. What are the risks?

If you have – or don’t have – the test or procedure, what is likely to happen? Are there potential side effects. What are the chances of getting results that aren’t accurate? Could that lead to more testing or another procedure?

3. Are there simpler, safer options?

Sometimes all you need to do is make lifestyle changes, such as eating healthier foods or exercising more. Or an alternative test or treatment that might deliver useful information, while reducing any potential negative impacts for you.

4. What happens if I don’t do anything?

Ask if your condition might get worse – or better – if you don’t have the test or procedure right away.

The right to complain

Participants were not generally acquainted with regulatory actions relating to mesh taken to date or perceived them as failing to meet the needs of those affected by mesh harm. There was a strong desire for government to sue the manufacturers of mesh products under consumer protection laws. Participants cited Federal prosecutions underway in the United States and were hopeful that a positive result would help New Zealanders to access adequate financial compensation.

As noted earlier, there was cynicism about complaining to HDC. It is worth noting that in the period 2014/15 - 2018/19, the HDC recorded 45 complaints relating to surgical mesh.³⁴ This appears to be a small number given the scale of the problem evident in consumers stories. Of the 2,682 claims that had risk of harm notifications in the last six financial years, only 76 related to injuries caused by surgical mesh.³⁵

It has been noted that participants regarded the creation of an independent advocacy service as essential. The advocacy services MDU provided through Facebook, web pages and lobbying were highly regarded. In every Circle, at least one participant identified MDU as the “source of truth”. Many people praised MDU, saying “those ladies have given hope where there is no hope and have suffered so much”.

The right to effective communication and to be treated with respect

A key need expressed was for respectful partnerships with medical professionals in therapeutic relationships in which the dignity and choice of individuals are respected:

“It’s our right as New Zealanders to be heard, not told it’s in our head.” (Mesh injured woman, LC)

It is essential that consumers, health providers and stakeholders communicate transparently, openly and effectively. The need for a *“timely”* and *“human”* approach was also evident in stories that involved ACC and the HDC. More *“in person conversation”*, with people who *“know me and who I am, not just what [doctors] have written about me in my notes”*, is important to dignify and validate people’s experiences.

Although a small number of respondents wanted those responsible for causing harm to be held to account and punished, most indicated a preference for an apology. Some people expressed a desire for a public apology from the Minister of Health or the Prime Minister. A meaningful apology would include an admission of responsibility and steps to meet the needs of those injured, including compensation:

“Health professionals and health organisations, including government agencies to be held accountable for breaches of the Code of Rights. Women with surgical mesh complications have not been treated with respect, they have not been treated fairly, they have not been treated with dignity. They have not been communicated with, they have been lied to and coerced, they have been part of a massive uncontrolled experiment (not unlike the Unfortunate Experiment at National Woman’s) and their complaints have not been given a fair hearing.” (Mesh injured woman/SD)

2. The needs of health professionals

In order to understand the needs of health professionals, they were asked to report on what they wanted others to know or understand about their involvement in mesh use and their hopes concerning change in the future.

In general terms, health professionals said they wanted to meet consumers’ needs within a safe healthcare environment. This requires putting patients first; interdisciplinary teamwork, collaboration and trust; supportive leadership and governance; and a learning culture.³⁶

Most considered the ongoing use of mesh in minimally invasive procedures, with low complication rates, to be both extremely important and safe for the majority of consumers:

“A ‘ban’ on mesh would harm a lot more people who would now have to revert to obsolete forms of repair.” (Surgeon)

Mesh should continue to be available when healthcare providers meet the following criteria:

“The right patient, the right assessment, the right diagnosis with no contraindications, the right procedure, the right product, a surgeon with the right technical skills and a team at the right place and time with fully informed consent, including the option to decide not to have surgery.”

(Registered nurse)

Credentiailling

Clinicians working with mesh injured patients recognised there is considerable variation in technical competence and device placement in current practice. They therefore thought that mesh insertion, repair and removal surgery should be performed within credentialled, interdisciplinary mesh centres on *“a smaller number of people by doctors who do high volume surgery”*. Credentialling supports patient safety and is *“also beneficial in terms of practitioner protection, provider accountability and consumer confidence in the health system.”*

When doctors raised credentialling, their view was consistent with the Ministry of Health’s national framework.³⁷ They emphasised that the credentialling of doctors, nurses and health professionals is a responsibility delegated to professional peer groups, in co-operation with professional bodies:

“We need to acknowledge our unconscious incompetence. There needs to be a willingness to listen to those of us who do know more and acknowledge that where we have been and where we are at is not OK for the patient.” (Surgeon)

Clinicians involved in urology, gynaecology and obstetrics mesh insertion, renewal or repair proposed a national framework was required for these procedures. Gynaecological procedures involving mesh are already defined as a *“suggested example of extension from standard scope of practice”* by some private providers and requires special credentialling, though mesh injury has still occurred.³⁸ Clinicians indicated that specially trained experts should assess technical competence within these frameworks and the need to make such assessment mandatory was worthy of consideration.

Clinicians stressed that credentialling should involve more than an assessment of a surgeon’s technical ability to perform surgery. It should also encompass holistic models of care, patient experience and collegial behaviours, and be incorporated into professional standards that were regularly assessed:

“There should be training in both the surgical techniques and the medical and mental issues patients experience. There should be a holistic model and practitioners must respect the moral and ethical obligations under the Code of Rights. There appears to be a lack of competence in the basic principles of medicine. You learn your skills from listening to your patients.” (Surgeon)

Informed consent

The responsibility for ensuring a patient is fully informed of a mesh procedure was described as the responsibility ultimately of the surgeon. Doctors and nurses working in surgical specialities indicated that a detailed assessment, investigation and diagnosis before deciding on a surgical intervention is an essential prerequisite for informed consent. Subsequent discussion with the patient should also include the risks and benefits of alternative options, including native tissue repairs, and the option of not having surgery at all.

If nurses are to check whether the patient understands the procedures relating to mesh described on the consent form, they need to have access to the information. However, as one nurse explained:

“... nurses are usually not party to the consenting process when a surgeon speaks to a patient: we do not know what is discussed or whether mesh specifically is part of the conversation (it’s supposed to be).”

Surgical nurses expressed a desire to be fully involved in the consent process, so they could discharge their responsibility to safely care for patients undergoing mesh procedures:

“We need to know if mesh is safe to use. ... WHICH mesh, WHICH procedures? We need really clear guidelines and protocols we can use in our everyday practice. We need to know the procedures we are participating in will not cause harm to the patient. We need to know if we can choose to opt out of assisting with a procedure if there’s a chance it will harm a patient. We need stats and data. We need management to openly talk about mesh.” (Registered nurse)

A number of suggestions were made to address knowledge gaps, including health sector-wide education about mesh injury, improving foundational training for surgical doctors and training overseas of a small number of mesh specialists with *“additional diagnostic and technical skills”*, particularly for mesh removal surgery which is considered particularly complex. The need for ongoing research on the effectiveness of specific devices and procedures was also mentioned. Research trials would enable clinicians to learn *“which types of mesh are safe and how we can improve the benefits gained whilst minimising the complications that can occur”*.

Safety culture

Health professionals proposed that harm from mesh occurs within a complex system influenced by professional or personal viewpoints, regulations, financial considerations in private practice and a concern to maintain a public image. These conflicting demands are often unhelpful, and the focus should always remain on *“what is best for the patient”*.

Health professionals working with mesh injured patients expressed a strong desire for an interdisciplinary working environment characterised by a strong safety culture, where they could raise safety concerns without fear of personal consequences. But this environment was rare:

“Theatre nurses work in a culture of silence. Even when we work with surgeons who we’ve worked with for over a decade and have a great working relationship with, no surgeon wants their surgical technique questioned, especially at the operating table, and especially by a scrub nurse. No surgeons welcome questions about mesh.” (Registered nurse)

“We need to address the issues in surgical culture that relate to pride, ego and male dominance and the focus on money. My female colleagues have experienced massive bullying and sexism and it’s been well described by the College, but things need to start changing.” (Surgeon)

“There was little understanding, empathy, or support shown towards the surgeon. This surgeon spoke of feeling very persecuted and stressed.” (Registered nurse)

“I am sick of being bullied by [the surgical speciality] community and could only speak out because my colleagues support me. It was brought home to me recently what a traumatic experience this has been for me. I feel traumatised, disillusioned and disappointed.” (Surgeon)

Clinicians believed that regulatory action was required in cases where patients’ rights had been breached:

“The problem with medical culture is that we have no civil liability and you would think this would open people up. We need accreditation and this needs to be brought to the forefront of regulation.” (Surgeon)

Clinicians working with mesh injured patients expressed distress at the lack of acknowledgement and ownership of the problem by some of their colleagues. They believed responsibility rested with the original surgeon. Two respondents suggested that accepting responsibility for treatment injury should be mandated in professional standards. Others thought that would be unnecessary, as it was simply a matter of *“doing the right thing”*.

Some respondents noted that formal reporting pathways are not being utilised to raise concerns. One clinician, who had experienced *“severe bullying”* when raising concerns, commented:

“All this damage was being created by mesh and not one incident form was written. If you don’t report it, you don’t only fail the patient, you also fail the practitioner. People are told they are good when they are not. This impacts on the patients.” (Surgeon)

Access issues

Health professionals indicated that it was important to *“listen to patients and believe them when they say they are having trouble”* so they could offer or advocate for the right assessment, diagnosis and support.

Current ACC requirements are viewed as *“a difficult road, unnecessarily so”*. The processes are *“labour intensive”*, with requirements and terminology constantly changing. This adds time and complexity to an already pressured workload and delays getting the treatment consumers are entitled to receive under the Code of Consumers' Rights:

“To get ultrasound or MRI women are having to fight, having to pay out of pocket, to prove to a doctor and others (such as ACC or MoH) that they have issues. The complexity of these women, the lack of funding, the paperwork. All of this on top of dealing with very stressed, frustrated, upset, angry or depressed women.” (Physiotherapist)

“I have one patient - elderly lady - had trouble with first mesh so had it replaced and ended up with a persistent draining wound. She needed a year of antibiotics which she struggled with, lost weight and became quite frail as a result. This affected her independence and ability to socialise - she had a smelly wound she was very conscious of for years. We tried to do an ACC claim, but it was declined, I was very cross about that.” (GP)

9 Repair and prevention

A day-long workshop was convened on 20 November with the representatives of key agencies and professional bodies identified as sharing collective responsibility for undertaking reparative and preventative action with respect to surgical mesh harm. The Minister for Women and Associate Minister for Health, Hon. Julie Anne Genter, attended the opening session of the workshop and expressed her support for the aims of the project. MDU leaders also attended to represent harmed consumers and to ensure that meaningful action was taken to address their needs. A full list of the agencies and professional bodies, including where to find more information about their role, can be found in Appendix 4. The workshop was conducted on a restorative basis.

Weight of the stories

Most participants in the workshop had previously attended at least one Listening Circle and all invited parties were provided with Sections 1-8 of this report a week before the workshop. This was done both to clarify the severity of the harm under consideration and to allow time for the relevant stakeholders to have internal organisational discussions about their obligations.

At the commencement of the day, hundreds of small stones representing each person who had shared their personal story of mesh harm were ceremonially placed in a central kete (basket). One larger stone representing each Listening Circle was engraved with a word that the facilitation team thought best captured the predominant mood or shared experience of that particular Circle.



Throughout the day, the kete remained in the centre of the room, symbolising the weight of the tragic stories shared through the project. Several people spoke of the need to shift the burden of responsibility for these stories from the patients and advocates to the political, professional and organisational parties with collective responsibility for the health system.



Responding to the harm

In the opening circle of the day, attendees were first asked to respond to the following question:

What's sitting heavily with you from your experience in the Listening Circles or from reading the report? How is your organisation impacted?

All attendees explicitly acknowledged the seriousness of the harms created by surgical mesh. Many articulated a sense of horror, frustration, trauma, deep sadness, disappointment and even shame over the indifference, arrogance and lack of compassion injured parties had encountered in the system:

“The report seems to apply across the health system. The indifference was perhaps the hardest thing to take. It is systemic, built into many different layers. Our system is focused on the needs of the services rather than the needs of the people using them.”

Also acknowledged was the remarkable *“bravery, courage and perseverance”* of those impacted by surgical mesh harm and the *“burden”* MDU had carried over many years.



Restoring trust and confidence in clinicians and the healthcare system was considered a major priority. But this is dependent on “seeing tangible progress” in rectifying the problems created by surgical mesh.

This, in turn, is dependent on greater interdisciplinary and interagency collaboration. Several participants indicated that the complex and fragmented nature of the health system had contributed significantly to the harmful experiences of individuals and families:³⁹

“The system didn’t respond well, it didn’t acknowledge [consumers]. ‘I can’t do something for you, perhaps someone else can’. I’ll minimise it, I’ll package it up and pass it on. For the people harmed, it hasn’t worked well at all.”

A team approach, characterised by collaboration, mutual trust and with clear roles and responsibilities, was thought to be essential to responding adequately to the problem and preventing future harm.⁴⁰

“Collectively, we have the opportunity for us to make a difference. To respond in a way that says we value your openness and honesty. ... We will do what we can. We will work alongside you. ... How do we honour the gift we’ve been given?”

“Surgical mesh is only one harm, the World Health Organization says that treatment injury is a leading cause of harm in the world. ... If we don’t collaborate and transcend the agency boundaries, then that pile of stones is going to get larger.”

Some attendees indicated that straightforward actions to respond to immediate suffering, such as providing free GP visits, could make all the difference to harmed parties. Other attendees reflected on what sort of swift purposeful responses would be realistic and achievable for their agencies.

“There’s a sense of urgency. We have to stop talking and get some action.”

One participant noted that harm from surgical mesh is “not just a DHB problem; we know that 51% of this occurs in private hospitals”. There were comments about how the considerable work already underway in the public system could be replicated, enhanced, supported and funded within the private system as well.

Following the Circle, attendees worked together in groups to consider strategies that would help to repair and restore wellbeing, promote trust and cooperation and improve safe practices in the future.



Responding to needs

Throughout the listening project, consumers and health professionals had identified several major needs to address surgical mesh harm. For the workshop, these were gathered into six categories or workstreams:

- **Credentialling of surgeons**
- **Specialist multidisciplinary mesh services**
- **Informed consent**
- **Safety culture and systems**
- **Acknowledgment of harm**
- **Responding to mesh harm both now and in the future.**

Participants divided into separate workstreams and discussed the kinds of actions required from health agencies and providers to address the need. Following the session, the facilitation team presented a detailed summary of the proposed actions as a basis for plenary discussion about next steps. Several common themes emerged from this discussion.

- There was discussion about how successful approaches already underway in local centres, such as a District Health Board's credentialling and information services that were co-designed with patients, could be replicated more widely.
- There was agreement that additional funding was essential to develop specialist mesh centre(s), credential practitioners, provide sector-wide education on mesh, and meet the needs of consumers, both now and in the future.
- Political support is also critical to ensure a joined-up response to surgical mesh harm. In addition, each workstream will require a governance group, including representatives from the Ministry of Health, to ensure it delivers on agreed actions. Transparent reporting and regular communication with the public will be necessary to establish and retain trust.
- Attendees stressed the need for open disclosure by health practitioners and providers when responding to identified harm.⁴¹
- It was agreed that the severity of mesh harm and the failings of the system to adequately address the needs of those injured must be clearly acknowledged in press releases accompanying public release of this report.
- A distinction was made between *acknowledgement* and *apology*. MDU conveyed the preference of their members that a formal apology from the government should come at the end of the process, after a commitment to reparative actions has been taken.
- It was noted that a free, nationwide health and disability advocacy service already exists and could be better utilised to support the mesh injured consumers to achieve early resolution of complaints, such as through a facilitated conversation with their surgeon. When low level resolution is not possible, complaints should be submitted to the HDC or Medical Council.⁴²
- There was widespread agreement that the establishment of specialist mesh services is essential. Such a service should embrace a holistic model of care that considers diagnosis and treatment options other than surgical intervention as well. It must also provide access to credentialled providers and multi-disciplinary services for the insertion, repair, renewal or removal of mesh. Psychological assistance and peer support groups should also be available.

- There was much discussion about the need for, and the sheer complexity of providing, a national framework for assessing and credentialling the technical competence of surgeons to insert, repair, renew or remove mesh. A working group will be needed to make recommendations on how this may be achieved. Such a framework should include data tracking of longer term patient outcomes and experience with individual surgeons.
- Despite explicit statements in the Code of Consumers' Rights concerning the requirement for informed consent, it is clear that existing practice is inconsistent and often inadequate. Workshop participants proposed that a tailored process of consent for the surgical insertion of mesh products, incorporating the Choosing Wisely principles, should be co-designed with consumers as part of the credentialling workstream.
- Attendees agreed that a comprehensive information pack about mesh products should be co-created with consumers for use by consumers.⁴³ Consumers should also have access to information about their potential surgeon, such as their technical training and skill, the number of procedures completed, and data about known patient outcomes and experience.
- It was agreed that a system-wide approach is required to report and respond to harm from surgical mesh in the future. Attendees discussed the potential of a mesh register as a key mechanism for anticipating problems, measuring harm and remaining vigilant to risk.
- Many attendees pointed out that there are broader systemic issues relating to safety that extend beyond the specific issue of mesh harm. While the Ministry of Health is charged with overall responsibility for the health system, a safe healthcare culture can only be created and maintained by healthcare professionals and consumers working together as equal partners.

Proposed actions agreed

Stakeholder representatives at the workshop discussed what organisational commitments could be made at the meeting to undertake concrete reparative and preventative actions. In some cases, high-level commitments were possible on the day; in other cases, agreement was conditional on wider internal decision-making procedures or securing inter-agency cooperation. The following action points were agreed:

1. The severity of the harm from surgical mesh should be acknowledged when the report is released publicly.
2. The Ministry of Health was identified as the coordinating agency for each workstream.
3. A collaborative approach is required to respond to harm from surgical mesh, and groups that should collaborate, were identified for each workstream.
4. The HDC will promote the visibility of their national advocacy service.
5. Attendees will share the final report with their professional members/within agencies.
6. The surgical mesh round table is considered an appropriate group to oversee the delivery of the workstreams. To restore trust, there was an expectation of transparent reporting and regular public updates to communicate progress.
7. Consumers will be reimbursed when participating in the co-design of each workstream.
8. Specialist multi-disciplinary centre(s) are required. A group will meet in January 2020 to advise: the number of specialist centres required to ensure equity of access, the model of care and team required. This may be informed by learning from successful models elsewhere.
9. 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.

10. The Ministry of Health will lead, supported by ACC, interdisciplinary education and build capability of the required technical skills to prevent future harm, and reduce the severity of existing harm. This action intends to also support the provision of removal surgery.
11. Professional colleges will inform and educate their members about their role in preventing and reducing harm from surgical mesh.
12. ACC will partner with consumer representatives to design an approach for looking back through declined mesh-related treatment injury claims. Recognising that claim outcomes may not change; the process will also aim to learn where improvements can be made to the consumer experience.
13. ACC will explore the potential to provide support services, such as counselling, while cover decisions are pending.
14. 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.
15. ACC will continuously improve the collation and sharing of information on injuries caused by surgical mesh with key stakeholders and agencies under its Risk of Harm reporting framework to support prevention of future harm.
16. National standards of practice and the code of rights for informed consent are already in place. Credentialling and training will support these to be embedded in everyday clinical work.
17. National information resources for mesh related procedures should be created with consumers and include informed consent processes. Information should incorporate the product safety profile, outcomes and risks, alternative treatments available, and the informed consent process.
18. The Ministry of Health and Medsafe will support the Government in modernising the regulation of medical devices in New Zealand, including the development of new legislation (Therapeutic Products Bill) to improve device safety.
19. The Ministry of Health will identify the actions and supports required to meet the need for a collaborative approach to safety systems and culture.

10 Conclusion

Almost all the consumers in the listening project described the physical and psychosocial harms they had suffered from surgery involving mesh as life changing. Many individuals and families continue to suffer from significant disabilities in their everyday lives. A clear picture of the harms and needs created by surgical mesh has emerged and an important list of suggested remedies.

To begin to address these needs and remedies, further planning and funding will clearly be required. An important first step for any meaningful repair, is the provision of practical support to meet the substantive needs of patients, families and whānau. The design of specialist services for mesh surgery and the related complications is also seen as a proactive step for safer healthcare in the future.

Other recommendations focus on the training and credentialling of medical professionals, further work on informed consent and effective communication and improvement of complaint processes. In general, participants consider that responsibility for mesh harm and accountability for repair is shared between surgeons, ACC, GPs, HDC, the Medical Council, Medsafe and private and public health care providers. The Ministry of Health is viewed as the leader of all these agencies on behalf of the New Zealand Government. The loss of trust that has occurred in the New Zealand healthcare system is significant. A meaningful apology must include acknowledgement of the harm and a commitment to purposeful and timely action, that includes compensation.

All participants consider it critically important to include the mesh community and clinicians in transparent and inclusive dialogue in order to rebuild trust and secure lasting change. It is only through the restoration of institutional relationships characterised by trust and partnership that wellbeing can be restored, actions implemented, and future harm reduced or prevented.

11 Appendix

Appendix 1: The co-design team

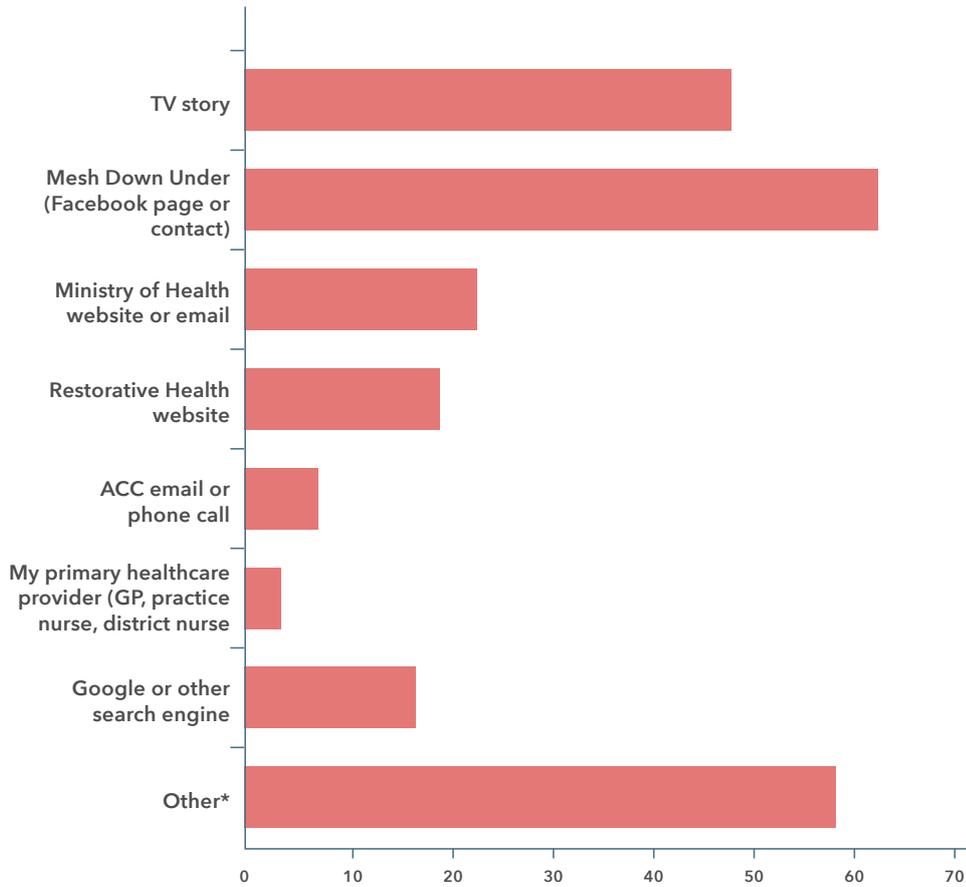
Organisation	Role
Diana Unwin Chair in Restorative Justice. Victoria University of Wellington	Arran Culver, Psychiatrist, Associate & emotional support Jon Everest, Senior Consultant Haley Farrar, Programme Development Advisor & Lead Facilitator Gerard Hoffman, Facilitator Chris Marshall, The Diana Unwin Chair in Restorative Justice Sarah Roth Shank, PhD candidate. Circle facilitator, research & emotional support Jo Wailling, Research Associate & PhD candidate. Project Lead research and evaluation. Facilitator, co-design Jill Wilkinson, Research Fellow Alex Zuur, Research Fellow. Project lead operations & emotional support. Facilitator Circles and co-design
Mesh Down Under	Carmel Berry, Consumer Advocate Charlotte Korte, Consumer Advocate Patricia Sullivan, Consumer Advocate
Ministry of Health	Margareth Broodkorn, Chief Nursing Officer Clare Possenniskie, Principal Advisor & Manager, Office of the Chief Clinical Officers Andrew Simpson, Chief Medical Officer

Appendix 2: Listening Circles

Date	Location	Participants	Mesh impacted	Family/whānau	Support people
23 July AM	Wellington	9	9	0	6
23 July PM	Wellington	9	9	0	6
25 July AM	Auckland Ellerslie	7	7	0	4
25 July PM	Auckland Ellerslie	8	8	0	4
26 July AM	Auckland Henderson	10	9	1	5
26 July PM	Auckland Henderson	10	9	1	3
30 July AM	Christchurch	10	9	1	4
30 July PM	Christchurch	10	9	1	5
2 August AM	Wellington	9	9	0	3
2 August PM	Wellington	9	9	0	3
6 August AM	Dunedin	5	4	1	3
6 August AM	Dunedin	9	7	2	4
9 August AM	Auckland Ellerslie	7	7	0	5
9 August PM	Auckland Ellerslie	9	9	0	7
10 August AM	Auckland Ellerslie	10	9	1	7
16 August AM	Christchurch	8	7	1	3
16 August PM	Christchurch	9	7	2	4
20 August AM	South Auckland	10	9	1	6
20 August PM	South Auckland	10	8	2	7
18 September AM	Wellington	4	4	0	3
18 September PM	Wellington	6	4	2	3
20 September AM	Auckland Henderson	7	5	2	4
20 September PM	Auckland Henderson	5	4	1	4
24 September AM	Auckland Ellerslie	6	6	0	3
3 October AM	South Auckland	6	4	2	5
3 October PM	South Auckland	6	6	0	7
10 October AM	Christchurch	5	5	0	3
10 October PM	Christchurch	9	8	1	5
16 October AM	Christchurch	9	9	0	7
16 October PM	Christchurch	7	4	3	3
24 October AM	Wellington	7	6	1	3
24 October PM	Wellington	4	4	0	4

Appendix 3: Communication strategy

Responses to the survey question, where did you hear about the opportunity to tell your story?



* Respondents who chose the option 'other' cited sources (in order of prevalence) as friends and family/whānau, newspaper/magazine, radio, Medsafe. One person cited their lawyer, one their physiotherapist.

Appendix 4: Organisations invited to the impacts and action planning workshop

Organisation	Role and website
<p>Accident Compensation Corporation (ACC)</p>	<p>ACC is a Crown Entity set up under the Accident Compensation Act to deliver New Zealand's accident insurance scheme. The purpose of the Scheme is to deliver injury prevention initiatives and no-fault personal injury cover for everyone in New Zealand, including overseas visitors. Under the Scheme, individuals forego the right to sue for compensatory damages following injury, in exchange for comprehensive accident insurance cover and compensation. This includes treatment injuries - those sustained through medical treatment. ACC has a treatment injury prevention programme, and provides treatment, rehabilitation, and compensation for those with treatment injuries.</p> <p>https://www.acc.co.nz/</p>
<p>Health and Disability Commission (HDC)</p>	<p>The purpose of the Health and Disability Commissioner is to promote and protect the rights of consumers as set out in the Code of Health and Disability Services Consumers' Rights (the Code).</p> <p>HDC is an independent watchdog, providing health and disability services consumers with a voice, resolving complaints, and holding providers to account for improving their practices at an individual and system-wide level.</p> <p>https://www.hdc.org.nz/</p>
<p>Health Quality & Safety Commission (HQSC)</p> <p>The HQSC were not identified as a responsible party by consumers or health professionals involved in this project and were invited to attend the action planning workshop because they have a role in supporting repair.</p>	<p>The HQSC is a Crown entity charged with:</p> <ul style="list-style-type: none"> • providing advice to the Minister of Health on how quality and safety in health and disability support services may be improved • leading and coordinating improvements in safety and quality in health care • identifying key health and safety indicators (such as events resulting in injury or death) to inform and monitor improvements in safety and quality • reporting publicly on safety and quality, including performance against national indicators • sharing knowledge about and advocating for safety and quality. <p>https://www.hqsc.govt.nz/</p>
<p>Medical Council of New Zealand</p>	<p>The Medical Council of New Zealand is a regulatory authority under the Health Practitioners Competence Assurance Act 2003 responsible for:</p> <ul style="list-style-type: none"> • registering New Zealand doctors • keeping a register of all doctors • setting standards for the way New Zealand doctors practise medicine • making sure doctors have the skills to practise within the scope of how they are registered • promoting continuous learning for doctors so their skills are kept up to date

<i>continued</i>	<ul style="list-style-type: none"> • reviewing doctors when their performance, professional conduct or health is a concern. <p>https://www.mcnz.org.nz/</p>
The New Zealand Medicines and Medical Devices Safety Authority (Medsafe)	<p>Medsafe is a business unit of the Ministry of Health and is the authority responsible for administering the Medicines Act 1981 and Regulations 1984.</p> <p>https://www.medsafe.govt.nz/</p>
<p>New Zealand Nurses Organisation (NZNO)</p> <p>The NZNO were not identified as a responsible party by consumers or health professionals involved in this project and were invited to attend the action planning workshop because they have a role in supporting repair.</p>	<p>The NZNO is the leading professional body of nurses in Aotearoa New Zealand. The NZNO negotiates salary and conditions for nurses, midwives and hospital aides working in the public and private sectors, other health professionals and health sector workers. They provide professional support and leadership for nurses and midwives and clinical development through special interest sections and colleges.</p> <p>https://www.nzno.org.nz/</p>
<p>Nursing Council of New Zealand</p> <p>The Nursing Council were not identified as a responsible party by consumers or health professionals involved in this project and were invited to attend the action planning workshop because they have a role in supporting repair.</p>	<p>The Nursing Council of New Zealand is a regulatory authority under the Health Practitioners Competence Assurance Act 2003 responsible for:</p> <ul style="list-style-type: none"> • Registering nurses • setting ongoing competence requirements and issuing practicing certificates • setting scopes of practice and the qualifications required for registration • accrediting and monitoring education providers and setting the state examination • providing guidelines and standards for practice • receiving and acting on notifications of health and competence concerns • receiving and acting on complaints about the conduct of nurses • promoting public awareness of the Council's responsibilities. <p>https://www.nursingcouncil.org.nz/</p>
New Zealand Private Surgical Hospitals Association (NZPSHA)	<p>The NZPSHA is a membership organisation established to represent the interests of, and promote and connect, the private surgical hospital sector in New Zealand. The NZPSHA currently has 27-member hospital groups located over 39 private surgical hospital sites throughout NZ. NZPSHA member hospitals undertake over 50% of all elective surgery carried out in NZ.</p> <p>https://www.nzpsha.org.nz/</p>
Royal Australasian College of Surgeons (RACS)	<p>RACS is a non-profit organisation training surgeons and maintaining surgical standards in New Zealand and Australia.</p> <p>https://www.surgeons.org/</p>

<p>The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)</p>	<p>RANZCOG is a not-for-profit organisation dedicated to the establishment of high standards of practice in obstetrics and gynaecology and women's health. RANZCOG also trains and accredits doctors throughout Australia and New Zealand in the specialties of obstetrics and gynaecology.</p> <p>https://ranzcof.org.au/</p>
<p>The Royal New Zealand College of General Practitioners (RNZCGP)</p>	<p>The RNZCGP is the professional body and postgraduate educational institute for general practitioners (GPs). The College sets and maintains education and quality standards, and supports members to provide competent, equitable care to their patients.</p> <p>https://www.rnzcgp.org.nz/</p>

12 Endnotes

- 1 This poem was well received in a Listening Circle. It captures many of the sentiments expressed throughout the country.
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