Responding to harm from surgical mesh.

A report for the Ministry of Health

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This report was prepared by a team led by 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. The Collaborating Centre for Safe Healthcare, Faculty of Health, Victoria University of Wellington partnered with the Chair to provide expertise in safe healthcare.

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The wordle on the cover of this document was developed from survey respondents’ comments.
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Executive summary

The Ministry of Health (MoH) is leading a response to harm from surgical mesh which aims to:
- Minimise the risks of mesh use.
- Support those affected by harm from mesh use.

The MoH ran a public survey between November 2018 - January 2019 to hear from people who have been harmed by surgical mesh, and/or their families/whānau, about how they might be supported to tell their story. 423 respondents answered the survey, including patients, families, whānau and healthcare professionals. Independent analysis of the survey was provided by experts in restorative justice and safe healthcare from Victoria University of Wellington. Findings were analysed within a restorative justice framework to identify the harms and needs of those affected by mesh use and how respondents thought wellbeing could be restored.

Many respondents described life changing physical and psychosocial harm from surgery involving mesh use. They reported a loss of trust in healthcare providers and stakeholders, particularly surgeons in private hospitals and the Accident Compensation Cooperation (ACC). Respondents mentioned informed consent as a key issue, with many indicating consent was lacking or risks were insufficiently described. When those affected asked for help, their dignity was not preserved within relationships where they felt seen, heard, acknowledged, understood and treated as if they mattered. Patients and families/whānau reported feeling abandoned within a complex system, turning to other mesh victims for help, support and advice. Together, these conditions have created conflict, with many respondents using angry and adversarial language to describe their experience.

A number of suggestions to restore wellbeing and provide a meaningful apology were provided by respondents. Many spoke of the need for a navigator to help address the harms and needs created, access support from ACC and coordinate care. Respondents also suggested that New Zealand (NZ) based, competent mesh removal surgeons are required to remove mesh and prevent ongoing harm. Other suggestions included minimising or banning mesh use and improving strategies related to informed consent.

Only a few respondents suggested that accountability for mesh harm should be pursued within a legal framework. Most indicated a preference for telling their stories to the responsible parties so that the harms and needs created could be attended to. Identified responsible parties included surgeons, professional colleges, Johnson and Johnson, ACC, the Health and Disability Commissioner (HDC) and the MoH.

Restorative processes are underpinned by relational values, including freedom, respect, truth accountability, empowerment and equal concern and could be an ideal way to support storytelling and restore relationships for all those affected.

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Background

The use of surgical mesh, especially in urogynaecological surgical procedures, has been a matter of local and international concern for some years. The MoH is currently leading a surgical mesh work programme which aims to minimise the risk to patients and support those harmed by its use. As part of this, the Government is committed to providing an opportunity for New Zealanders to share their lived experiences of surgical mesh. Hearing from those injured by mesh is important to help inform what needs to be done to improve patient safety in the future. It will also help inform what else needs to be done to support those already affected.

As a first step, from November 2018 to January 2019 the MoH ran a public survey to hear from people who have been harmed by surgical mesh, and/or their families/whānau. New Zealand’s Chief Medical Officer commissioned the Diana Unwin Chair in Restorative Justice, in partnership with the Collaborating Centres for Safe Healthcare at Victoria University of Wellington to undertake an independent analysis of survey findings.

Respondents consistently described not being heard when they have tried to talk about the harm they have experienced, they also noted how much they appreciated “this opportunity to be heard. It is beyond comprehension that so many lives have been affected”. A restorative approach gives priority to hearing the voice of victims and is aligned with what the MoH wishes to achieve. Therefore, the key focus of this report is to describe the experiences of those affected by mesh use using a restorative inquiry framework.

What is restorative justice?
The aim of restorative justice is to clarify accountability for harm suffered, meet the needs of those who have been hurt and restore the wellbeing of all involved in a harmful event. Restorative justice is particularly useful in situations of severe harm, both intentional and avoidable, and in situations of intractable conflict. It aims to meet needs, promote reconciliation and create a future environment of safety and belonging:

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.

Survey findings are presented using a restorative inquiry framework (Figure 1). This helps to maintain a focus on the harms and needs of those affected by mesh, recognising they are best placed to make suggestions about how to mitigate risks and restore wellbeing. A restorative inquiry framework is built around four key questions:

**Figure 1: Restorative inquiry framework**

<table>
<thead>
<tr>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who has been hurt and what are their needs?</td>
</tr>
<tr>
<td>Who is responsible for the harm and what are their obligations?</td>
</tr>
<tr>
<td>How can things be put right again?</td>
</tr>
<tr>
<td>How can we prevent it from happening again?</td>
</tr>
</tbody>
</table>
What happened?

Different mesh procedures have been used to treat varying conditions, each with unique risks and benefits. Surgical mesh products have been demonstrated to be both effective and safe in general, paediatric, orthopaedic, and plastic and reconstructive surgeries. From the late 1990s both synthetic and biological mesh has been used in urogynaecological surgery for prolapses and urinary incontinence due to concerns relating to recurrence following repairs using the surgical techniques of the time.

The evidence and medical opinion supporting effectiveness and safety of mesh for urogynaecological surgery is controversial. Systematic reviews of published reports and large cohort studies have investigated the relative long-term benefits and harms of urogynaecological surgery with or without mesh. Differences have been demonstrated favouring the use of mesh in surgery for incontinence but not for the repair of prolapse. One Cochrane review described the quality of evidence from prospective studies for pelvic organ prolapse as “very low to moderate” with risk of “bias” and “imprecision” and the data on adverse events “scanty.” Other Cochrane reviews have indicated higher rates of complications and post-surgical interventions with mesh compared to native tissue repair. Approximately one in ten patients who have mesh implants will have complications within five years. These rates are based on complications that are severe or require post-surgical interventions; as they do not include complications managed in outpatient or primary care settings, such as chronic pain or depression, the rates could be greater. In addition, there are significant gaps in the materials science knowledge of how these surgical mesh products cause harm or fail.

By 2005 specific urogynaecological mesh products were registered in the USA, UK, Europe, Australia and NZ and were rapidly adopted. In 2008, the United States Food and Drug Administration (FDA) began issuing warnings regarding the use of urogynaecological mesh, further...
advising in 2011 they had “not seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk”.  

The FDA ordered manufacturers to address concerns and resubmit applications to demonstrate effectiveness and safety, only a fraction of these were undertaken and many manufacturers ceased marketing their products or changed the indication for use. In Australia, UK and Europe many, but not all, urogynaecological mesh products have been withdrawn and indications have been changed (i.e. not to be used as the primary surgical treatment), with restrictions (i.e. only to be used by suitably trained surgeons).  

In 2010, New Zealand women’s organisations and consumer groups called for attention to be paid to significant complications in women who had undergone urogynaecological surgery with mesh. The Chair of the New Zealand National Board of the Royal Australasian College of Surgeons wrote to the New Zealand Health and Disability Commissioner in 2014 and described the general use of mesh devices and where “discussion is expected to be more specific”. Qualifying and quantifying specific risks and benefits with certainty for the use of mesh in urogynaecological surgery has not been possible because of the lack of high quality, reliable clinical data and information. In addition, it has been recognised that both patients and clinicians overestimate the benefits and underestimate the harms of treatments.  

The Women’s Health Action Trust requested that the 2016 Health Select Committee take urgent action regarding:  

- The testing and evidence for use of mesh in urogynaecological surgery.  
- The registration of all New Zealand mesh surgeries similar to other surgical implant registers.  
- ACC undertake an independent audit.  
- The Medical Council of New Zealand and Royal Australian and New Zealand College of Obstetricians and Gynaecologists ensure only qualified, experienced surgeons use mesh in urogynaecological procedures with appropriate informed consent processes.  
- The Health Quality and Safety Commission and other agencies share information about injuries and adverse events.  
- A review of the Medsafe approval procedures for medical devices.  

In August 2016 the Health Select Committee made the following recommendations to the Government that were supported by the Minister of Health:  

- Investigate options for establishing and maintaining a centralised surgical mesh registry, consistent with international recording of surgical mesh complications.  
- Communicate with medical colleges to review best practice around informed consent for surgical mesh patients.  
- Encourage health providers to ensure coding information is consistent and patients with mesh complications can be identified and monitored.  

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- Encourage utilisation of the adverse events reporting system as applicable.
- Endorse ongoing education for surgeons on the use of surgical mesh and mesh removal surgery.
- Consider expanding the role of Medsafe to assess the quality and safety of medical devices.

In 2017, Medsafe required suppliers of mesh implants to provide safety information and limited the supply of mesh for urogynaecological surgery. In 2018 the Director General for Health wrote to all NZ DHB Chief Executives outlining the MoH actions in response to mesh, which were delivered in partnership with health sector stakeholders and the consumer group Mesh Down Under (MDU). In order to hear from those affected by mesh use, patients and/or their families/whānau, the MoH also ran a public survey from November 2018 to January 2019.

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What are the harms and needs created by mesh use?

Respondents
Survey respondents (n=423) were predominantly patients, families and whānau. Comments indicate that some responses were also provided by healthcare professionals concerned about harm from surgical mesh.

Harms
Harm from surgical mesh was described as “life changing”, with the exception of three comments that described positive experiences. Respondents described both physical and psychosocial harms (Table 1), with many indicating that their harm experience has compounded over many years from multiple interventions intended to restore wellbeing. Multiple respondents described psychosocial impacts as more harmful than physical complications, consistent with evidence that surgical complications are a significant, often long-term predictor of post-operative psychosocial outcomes.

Figure 2: Respondent demographics

### Table 1 Physical & Psychosocial harms.

<table>
<thead>
<tr>
<th>Physical Harms</th>
<th>Psychosocial Harms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic pain</td>
<td>Break down of relationships (marriage, friendships, children)</td>
</tr>
<tr>
<td>Chronic pain unresolved by multiple medications</td>
<td>Suicide</td>
</tr>
<tr>
<td>Side effects of medications</td>
<td>Mental illness (PTSD, anxiety, depression)</td>
</tr>
<tr>
<td>Multiple surgical interventions</td>
<td>Loss of sex life</td>
</tr>
<tr>
<td>Complications of multiple surgical interventions</td>
<td>Loss of earnings, career, unable to work</td>
</tr>
<tr>
<td>Physical disability e.g. immobility</td>
<td>Loss of protective factors e.g. hobbies, exercise</td>
</tr>
<tr>
<td>Multiple hospital admissions</td>
<td>Loss of home</td>
</tr>
<tr>
<td>Autoimmune disease/inflammation</td>
<td>Financial cost of unfunded treatment</td>
</tr>
<tr>
<td>Infection</td>
<td>Other financial costs e.g. travel, scans, psychological support, home support</td>
</tr>
<tr>
<td>Cancer</td>
<td>Emotional and Physical burden on carers (partner, children, friends)</td>
</tr>
<tr>
<td></td>
<td>Arrested for using alternative pain treatment (cannabis)</td>
</tr>
</tbody>
</table>

#### Loss of dignity

A sense of dignity comes from participating in “*Relationships where we feel seen, heard, acknowledged, understood and treated as if we mattered.*”

Multiple respondents reported a perceived a loss of dignity stemming from:

- Disempowerment in their relationships with healthcare providers (Surgeon or GP)
- Abandonment by the healthcare system when requesting acknowledgement of harm and/or support to restore wellbeing (ACC, HDC).

The issue of informed consent was widely discussed. Many patients and families/whânau proposed that consent for mesh use had not met the standard outlined in the NZ Code of Rights – as quoted by one respondent:

> “Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer’s circumstances, needs to make an informed choice or give informed consent”

Multiple respondents indicated that mesh was implanted without their knowledge and/or risks were not fully explained, in other words “*downplaying the consent process and rushing through it by saying the risks are the same as for any surgery*”. Others indicated they had specifically asked for mesh not to be used, but were advised that surgery could not proceed without it.

Many respondents described being disregarded when they spoke up about post-operative symptoms and were “*dismissed as neurotic by some in the medical profession.*” When healthcare stakeholders were unresponsive to the needs expressed, respondents sought help elsewhere,

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including from support groups, healthcare providers abroad and lawyers - often at significant financial cost. Loss of dignity led to anger, with many respondents using adversarial language. The following story summarises the common themes:

Case Study

Five years ago, I went to go and see my mother after her surgery. She was so funny, especially since they had given her some morphine...makes everyone a little bit funny. Little did I know that that would be the last bit of laughter I’d hear from my mum for five long years. During this time, her mental health began to deteriorate, as did her physical health.

For 18 months the doctors told her that it was all in her head and that she was delusional. How on earth would you feel if you were told that, after you had an operation that used an unsafe product and you knew full well what the adverse effects were? The reason she knew that was due to her extensive research after surgery about her pains, she knew that she wasn’t alone, she couldn’t be. She was able to find others that had been through the same surgery and they came together as one in search of answers.

Why on earth would such a disastrous product be allowed to be used on humans? I had to watch my mother die in front of me, as the government and the health ministry did nothing. The amount of times she told me she wanted to kill herself is ludicrous. You made her feel like this and you should be held accountable for your actions. This product needs to be banned ASAP to prevent future damages and deaths. My mother was lucky; I know of so many people that have died because of this. This is absolutely disgusting.

Loss of trust

Loss of trust in the medical profession, healthcare providers, healthcare stakeholders and in the MoH was repeatedly described. Multiple respondents questioned the competence of NZ surgeons to safely insert and remove mesh and also questioned the integrity of the surgical profession.

Respondents questioned the competence and integrity of surgeons who:

- Advertised services in the yellow pages and received payment for mesh use perceived to be used without evidence and informed consent.
- Did not listen and/or respond to concerns about post-operative symptoms/complications.
- Continued to use of mesh with an awareness of the harms created by its use.
- Refused to comment on a colleague’s surgical competence when removing mesh, described as “covering up” for colleagues.
- Did not share information that would make it easy to meet their needs e.g. poor documentation in surgical notes, lack of information sharing between private and public sectors.

It is incredibly disappointing to trust your surgeon has your best interests at heart and find out later he had another agenda.
Of note, two respondents indicated they were medical professionals and wanted to speak out about concerns they had about mesh and how it was introduced into practice:

“This technique was designed to make me feel "old fashioned, out of date" and I would lose patients unless I immediately started using the mesh. No training was offered to me.”

Raising concerns about mesh use was described by patients and families/whānau as being challenging, unresolved and characterised by conflict. Respondents perceived that stakeholders, such as District Health Boards, were “not really interested”. Many suggested the Health and Disability Commissioner and MoH would not enforce providers to take responsibility for the harms and needs created by mesh use.

Significant conflict was described with ACC. Multiple respondents indicated they were in “dispute”, or had been in lengthy conflict before claims were approved. Conflict was exacerbated by the approach taken by ACC, which was not perceived to be kind or respectful in nature, or addressing of individual needs.
Needs

Recognising the distinct but interrelated interests for all those involved in mesh harm, including patients, families/whānau, providers and the MoH, it is helpful to distinguish three types of ‘justice needs’ that must be addressed in order to resolve conflict and restore wellbeing24 (Table 2). The justice needs of respondents affected by mesh are summarised in five themes, providing insight as to how harm could be meaningfully repaired.

Table 2: Categories of justice needs

<table>
<thead>
<tr>
<th>Justice Need</th>
<th>Definition</th>
</tr>
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<tbody>
<tr>
<td>Substantive</td>
<td>The actual harms that need to be remedied.</td>
</tr>
<tr>
<td>Procedural</td>
<td>The process of interacting, communicating and making decisions about how to address the harms.</td>
</tr>
<tr>
<td>Psychological</td>
<td>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.</td>
</tr>
</tbody>
</table>

Mesh response pathway

Many respondents suggested a pathway is required that focuses on restoring physical and psychosocial wellbeing. Many recommended creating a “navigator” role to support those affected through the complexities of the healthcare system. Such roles have proven successful in NZ, improving access to treatment and patient experience25. A navigator would be a kind, respectful communicator, with an understanding of the harms created by mesh and “help us deal with all the various agencies” because “the whole process is soul destroying”. A navigator was described as of particular importance to gain access to ACC funds and support around mesh removal. However, respondents indicated that “mesh removal does not make the nerve damage and pain complications go away” and that supporting those affected with chronic issues is as important as accessing mesh removal.

Mesh removal specialists
Respondents noted that it was essential to have specialists in mesh removal who could relieve suffering from ongoing harm. Many respondents had travelled abroad for mesh removal and others indicated a lack of competent NZ providers, or funding issues, prevented or delayed swift mesh removal. Respondents suggested that it would be advantageous to fund experts to come to NZ to deal with complex cases and/or to train NZ surgeons to increase local capability in this area. The Royal Australasian & New Zealand College of Obstetricians and Gynaecologists also states that doctors should be credentialled to competently perform mesh surgery and manage complications, indicating there are credentialled providers in NZ. However, many respondents indicated that they did not have trust and confidence in NZ surgeons, proposing a special fund is required so that patients with particularly complex issues can seek specialist treatment abroad.

Suspend or ban mesh use
Many respondents said they wanted the government to ban or minimise mesh use in NZ, although a small number of comments related to positive experiences. Respondents suggested that official reports and comments from the HDC and other bodies supporting the ongoing use of mesh had the effect of denying their harmful experience. The Director-General of Health commented publicly on surgical mesh in terms that acknowledge the harmful experiences of patients as “a significant women’s health issue” in September 2018.26 The MoH has also taken regulatory action resulting in four suppliers of mesh implants for urogynaecological surgery removing some or all products from NZ.27 Respondents comments indicate regulatory actions are not widely known, or are not perceived to adequately meet the needs of those affected by mesh harm.

Informed consent
Respondents considered a meaningful consent process requires consultation with more than one party, in person, with time to consider options and have a follow up discussion. Some suggested that collaboration between surgeons and other specialists involved in their care would ensure all risks were accounted for and that they were provided with appropriate advice regarding post-operative symptoms and support options. The desired approach is aligned with the Medical Council NZ

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position statement on information, choice of treatment and informed consent\textsuperscript{28}, the NZ code of patient rights\textsuperscript{29} and the Choosing Wisely campaign.\textsuperscript{30}

Conversely, multiple respondents described the consent process they experienced as occurring in the hour before surgery, without time to think through options and risks. Many indicated that they were angry and/or distressed and would not have agreed to surgery if the risks had been adequately explained. The desire to explore individual experiences relating to informed consent with those perceived to be responsible was stated by a number of respondents.

Comments indicate that consultation processes designed with 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 healthcare\textsuperscript{31} and the development of co-designed patient leaflets and informed consent processes for mesh patients was agreed by MDU and the professional colleges in 2017\textsuperscript{32}.

**Storytelling**

Respondents were pleased that “now, their story can be heard”, perceiving the length of time it has taken for the MoH to respond to mesh and take action as unsatisfactory. Findings suggest that any opportunity for storytelling must include responsive involvement from parties identified as accountable for meeting the needs of those affected by mesh.

Although a small number of respondents wanted someone to be held to account within a legal framework, most indicated a preference for telling their stories to the responsible parties so that the harms and needs could be attended to. Responsible parties identified included surgeons, surgical colleges, Johnson and Johnson, ACC, HDC and MoH.

Multiple options for storytelling were described (Figure 3). Those who wished to tell their story in person indicated that they would expect support with travel and other financial costs. Only a small number of respondents (9%) were unable to travel to one of the locations offered. Respondents indicated that it would take between 10 minutes to half a day to recount their story, with most indicating it would take approximately 30-60 mins. Of note is the fact that many said they could not travel due to physical disabilities relating to harm from mesh.


\textsuperscript{30} https://choosingwisely.org.nz/


For those who wished to tell their story in person, the majority were comfortable in a community setting with others present (92%). Of the 8% who were not comfortable to share their story in person, comments indicate this is because of privacy concerns. For a small number of individuals, this included fear of the consequences of speaking up, and many requested that any process must ensure their dignity is protected. Those who did not want to tell their story in person indicated a preference for written communication, with follow up by telephone to clarify details.
How can we make things right?

Many respondents indicated that a sincere apology is important to rebuild trust with healthcare providers and stakeholders and uphold the founding principle of healthcare providers to “do no harm”. A genuine apology is recognised as being more than saying the words “I am sorry”, but reflects the desire to be seen, heard, listened to and treated fairly:

“Apologies have the power to heal humiliations and grudges, remove the desire for vengeance, and generate forgiveness on the part of the offended parties. For the offender, they can diminish the fear of retaliation and relieve the guilt and shame that can grip the mind with a persistence and tenacity that are hard to ignore. The result of the apology process, ideally, is the reconciliation and restoration of broken relationships.”

Aaron Lazare

Only a small number of respondents wanted a written apology from the Government (n=2). However, the majority indicated that they wanted Government to “compensate for the harm we have suffered as a result of having a mesh implant”.

Findings indicate that receiving a written apology is less important than actions that address the harms and needs described in this report. This view is consistent with international research that has found that patients and families/whānau prefer to have their individual wishes and needs met following healthcare harm, often including a desire to meet with those involved in the incident.

Findings indicate that an important first step is meeting immediate substantive needs of those affected by surgical mesh. Recognising the complexities involved in minimising the physical symptoms of post-operative complications, respondents have identified a number of issues that are potentially easier to resolve. These include creating a navigator role; greater sharing of information about the MoH response, including, for example, involvement in a review of informed consent practices and giving clarity regarding medical device use in NZ, with a focus on understanding all perspectives.

Respondents comments also indicate that an inclusive and facilitated restorative process could help to meet their procedural and psychological needs. Such a storytelling process aims to clarify what happened in the past, its impact in the present and how repair can be achieved in the future. Using a restorative process is more likely to restore trust to relationships and uphold the dignity of all those affected, because such processes are underpinned by relational values, including freedom of choice, respectful communication, truth-telling, accountability, empowerment and equal concern. It is possible to use restorative processes to capture data in person, by telephone and by written communication.

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Conclusion

Many respondents described life-changing physical and psychosocial harms from surgery involving mesh. This has led to a significant loss of trust in NZ healthcare providers and stakeholders. There is therefore a need to both restore the wellbeing of those affected by mesh use and to repair relationships of trust with providers.

The provision of practical support to meet the substantive needs of patients and families/whānau is an important first step. A second step would be the provision of a restorative process to address the procedural and psychological needs of those affected by mesh, whilst maintaining the dignity of all stakeholders. Restoration of relationships characterised by trust and partnership between the MoH and those harmed by mesh is essential to meet the aims of the surgical mesh programme and prevent future harm.