

Summary of progress to address harm from surgical mesh

May 2022

Background

In 2019, more than 600 people chose to share their stories of surgical mesh harm with the Ministry of Health, through a restorative process that aimed to listen to, understand and address those harms.

In response, the Ministry of Health committed to 19 actions on behalf of the health system, which formed a Surgical Mesh work programme. The actions were published in the **Hearing and Responding to the Stories of Survivors of Surgical Mesh** report.

Health agencies have finished six actions and are continuously delivering a further nine, while four actions are in progress. The Ministry of Health has provided detailed public information about progress on the 19 actions **on its website**; however, many people who took part in an evaluation of the restorative process said they were largely unaware of this.

The Ministry recognises the significance of people's decisions to share their stories of surgical mesh harm. In response to the evaluation finding, this factsheet provides a high-level summary of progress. Q&A

Q. Who's responsible for actions to address harm from surgical mesh?

- A. The Ministry of Health coordinates the New Zealand health system's response to surgical mesh harm and works with health organisations and consumer groups on the Surgical Mesh Roundtable to deliver the work programme. **More information about the Surgical Mesh Roundtable is available on the Ministry's website.**

The surgical mesh work programme is led by Chief Medical Officer Robyn Carey at the Ministry of Health, and the Ministry's Office of the Chief Clinical Officers.

Q. More than 600 people told their stories of surgical mesh harm. What difference did it make?

- A. These stories were the catalyst for further action. People who shared their lived experiences of surgical mesh harm helped the Ministry of Health and other health organisations understand the extent and severity of harm many people were suffering. These are some of the changes already made:

- **Surgical mesh harm recognised publicly by health organisations**

Press releases were issued by the Ministry of Health, the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and ACC. The Ministry of Health and other health agencies shared *Hearing and Responding to the Stories of Survivors of Surgical Mesh* widely, so health professionals involved with surgical mesh would have the chance to read about and understand these experiences. However, while this met the commitment, an evaluation of the restorative process found many people did not consider that this sufficiently recognised the harm from surgical mesh. The Ministry aims to reflect the lived experience of people harmed by mesh in its ongoing public information.

- **ACC reviewing previously declined claims**

ACC designed a process to reassess previously declined claims and recognised the complex and sensitive nature of mesh claims. This reassessment opportunity is still available to anyone who had a surgical mesh claim declined before 28 October 2020 – **more information is available on ACC's website.**

Since 2019, ACC has received 115 requests for reassessment, of these 60 have been accepted, 16 have been declined or their original decision did not change, while the remaining 39 are currently being considered. These figures include both historical and more recent injury claims. ACC also changed how it managed claims in response to feedback. Claims are handled by a small and dedicated cover assessment team who are committed to minimising any further trauma.

- **Improvements to informed consent processes**

In 2018, the Director-General of Health wrote to DHBs requiring them to implement rigorous informed consent processes for surgical mesh procedures. Following the restorative process, resources for consumers to understand their rights around informed consent were more widely available, such as *Considering Surgical Mesh to Treat Stress Urinary Incontinence* (www.health.govt.nz/publication/considering-surgical-mesh-treat-stress-urinary-incontinence).

The **Health and Disability Commissioner (HDC)** has also written to all DHBs and the Private Surgical Hospitals Association to improve understanding of informed consent processes in relation to mesh surgery.

Q. What is the Ministry currently doing?

A. The Ministry is working on establishing a process to credential surgeons undertaking pelvic floor procedures. We're also working to establish specialist service centres for mesh complications and designing education packages to ensure health professionals understand their role in preventing and reducing harm from surgical mesh.

Q. What does credentialling mean?

A. Credentialling gives everyone greater assurance. It means a committee of experts checks that surgeons have the right skills, experience and education to be performing complex surgeries such as those using surgical mesh.

From 2018, DHBs were directed by the Director-General of Health to use the Australian credentialling framework to assess surgeons undertaking urogynaecological surgery involving surgical mesh.

The Ministry, the Pelvic Floor Reconstructive Medicine and Uro-gynaecological Procedures Credentialling Committee, and Mesh Roundtable members have agreed on the New Zealand credentialling framework, which will be finalised and published on our website in May 2022. The next step is for the Ministry to establish the national credentialling committee. This will be made up of international experts, professional colleges and Ministry staff members.

Q. What's the benefit of the education packages?

A. The education packages will provide further support to health professionals. We are currently finalising education packages for primary care health professionals such as GPs and nurses. The information will help practitioners identify if a person is experiencing harm from surgical mesh and what support is available. The resources will also help practitioners to consider different options for treating a pelvic organ prolapse (POP) or Stress Urinary Incontinence (SUI) injury early so surgery and mesh aren't needed.

Q. What information is available on the specialist service centres?

A. We have committed to establish specialist mesh complication services in Christchurch and Auckland, operating as one service with two hubs so the service is consistent. The centres will have a focus on pelvic floor procedures. A person experiencing mesh harm can be referred to one of the centres or can self-refer. The centres will offer wrap-around services – physiotherapy, pain specialist, psychological help – as well as the option of mesh removal by credentialled surgeons. We're currently working on the final details, and the centres are expected to be established incrementally during the second half of 2022.

Q. Why are the credentialling, education packages and specialist service centres not yet completed?

A. For the specialist service centres, this is due in part to the scale and complexity of the work. Proposals were fully co-designed with consumers and health professionals, including physiotherapists and nurses, and this robust process took a year. In part, it's also due to the current context for the health system: COVID-19 and the health reforms have meant progress has not been as swift as we intended.

For the education packages and credentialling – these are significant undertakings that require co-design with health professionals and consumers, and it takes some time for consensus to be reached. In some cases, the work is dependent on other components – for example, it is logical to work on the secondary and tertiary education packages after the credentialling framework is published.

Q. Was the restorative process the first time the health system had taken action to address harm from surgical mesh?

A. No. In 2014, a Health Select Committee report led to the Ministry of Health and Medsafe committing to act on seven recommendations to improve the safety of surgical mesh. These actions are being delivered by the Ministry of Health and the Mesh Roundtable, and a

summary is available on Medsafe's website: **Implementation of Government Response to Report of the Health Committee on Petition 2011/102** (medsafe.govt.nz).

Q. Has regulatory action been taken in response to surgical mesh harm?

A. Yes. In 2017 Medsafe took action which restricted surgical mesh products for use in stress urinary incontinence and resulted in no surgical mesh products for pelvic organ prolapse being supplied in New Zealand.

Medsafe has also been monitoring adverse event reports associated with surgical mesh and has provided information and guidance to support its use. Medsafe's website (www.medsafe.govt.nz/devices/Surgical%20Mesh/ActionsTakenByMedsafe.asp) has more information on their actions so far.

Q. What help is currently available for people who have suffered surgical mesh harm?

A. If you have surgical mesh and it causes pain, or you have concerns, contact the surgeon who implanted the mesh. Alternatively, you can contact your GP if you would like to be referred to another specialist in the use of surgical mesh.

Consumers and health professionals are urged to report any adverse events experienced from surgical mesh to Medsafe. Further information, including reporting forms, is available on the **Medsafe website**.



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