Timeline of Govt response to Surgical Mesh Issue in New Zealand

1996: First transvaginal mesh device ProteGen Sling was introduced on the market.

1999: ProteGen was recalled by the manufacturer following reports of serious complications. However, a multitude of devices based on the same prototype and design characteristics had already entered the market, and were not recalled. New mesh devices for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) continued to enter the market through the same FDA 510(k) pathway (loophole), each claiming substantial equivalence to predicate devices such as the ProteGen Sling.

2002: By now surgical mesh devices were being widely used in NZ

2006: First adverse event report to Medsafe for Surgical Mesh.

2008: The U.S. food and Drug Administration (FDA) published a statement warning about an increase in adverse events related to surgical mesh use for POP and SUI, alerting patients and surgeons about the risks.

2008: The first pelvic mesh lawsuit was filed in the US; over 100,000 have been filed to date.

2008: Medsafe conducted its first review of adverse events associated with surgical mesh procedures.

2009: Medsafe wrote to the CEOs of public & private hospitals outlining key points from the review.

2011: The FDA found complications were "not rare" and "no clear benefit over non-mesh repair" for POP, marking a shift in its risk benefit assessment; SUI was also included in broader safety concerns.

2013: Medsafe published its first Adverse Event Report on surgical mesh implants.

Despite the FDA's 2011 warning that complications were "not rare" across transvaginal mesh procedures, RANZCOG guidance in 2013- 2014 continued to support its use for POP as an accepted treatment option, with increasing caution by 2016 and a gradual shift toward formal acknowledgement of risks and adverse outcomes from 2018- 2019. This indicates a broader delay in coordinated system response in New Zealand, with both professional and government action occurring several years after early international safety warnings.

2018: Scotland suspended mesh procedures for SUI and POP in 2014, followed by a wider UK suspension in 2018 amid escalating safety concerns. These suspensions remains in place to date (2026).

2014 - 2016: Early Advocacy and Government Acknowledgement in New Zealand

July 2014: Petition was first submitted by Charlotte Korte and Carmel Berry to the Health Select Committee, calling for an inquiry into surgical mesh harm.

2015: First surgical mesh claims data analysis by the Accident Compensation Corporation (ACC).

June 2016: Select Committee tabled its report in Parliament with 7 recommendations

August 24, 2016: Cabinet accepts all 7 recommendations and tasked the Ministry of Health and Medsafe with implementation.

Early Regulatory Actions and Warnings: 2017- 2018

May 2017: Australia's Therapeutic Goods Administration announced that it would remove transvaginal mesh products used solely for the treatment of pelvic organ prolapse via transvaginal

implantation from the Australian Register of Therapeutic Goods (ARTG), with the decision confirmed on 28 November 2017.

August 2017: MoH undertook NMDS data extraction on surgical mesh procedures for SUI/POP/hernia and rectopexy. Heavy reliance on free text search (no mesh codes). **Result**- inability to collate meaningful information or determine trends of harm due to inadequate, incomplete dataset. A substantial number of surgeries undertaken in private sector but majority of providers did not use NMDS. (less than 5 providers)

December 2017: Following the publication of Australia's review into surgical mesh implants, Medsafe contacted four mesh device manufacturers requesting safety data on products used in New Zealand.

December 2017: The Surgical Mesh Roundtable (SMRT) was created, at the time a coordinated national work programme had not yet been established

January 2018: Medsafe announced that several surgical mesh products, along with one product for stress urinary incontinence, would no longer be available in New Zealand. This did not affect the continued supply of mesh products for stress urinary incontinence. The decision followed the Australian Senate Inquiry, which recommended stronger evidence requirements for transvaginal mesh used in these procedures. Subsequent regulatory action by the Therapeutic Goods Administration required manufacturers to provide evidence of safety; rather than supply this evidence, manufacturers withdrew several products, citing "commercial reasons

New Zealand Government response 2018 - 2023

May 2018: The Director-General of Health reminded DHBs of risks associated with surgical mesh and the need for strengthened oversight of clinical practice.

July 2018: Deloitte undertook a cost-benefit analysis of establishing a national surgical mesh registry.

September 2018: Director-General of Health Dr Ashley Bloomfield directed DHBs to credential practitioners using surgical mesh for urogynaecological procedures against Australian Commission on Safety and Quality in Health Care (ACSQHC) guidance.

2017/2018: ACC undertake further comprehensive surgical mesh claims data analysis.

8 October, 2018: The first Credentialling Committee was convened to develop a New Zealand–specific framework.

June 2019: Ministry of Health initiated a Restorative Justice Project: over 600 survivors, clinicians, and families are heard. Findings highlight harm, poor regulation, lack of informed consent, and agency silos.

December 2019: The Hearing and Responding to the Stories of Survivors of Surgical Mesh: Ngā kōrero a ngā mōrehu report is published with 19 action points, including:

- Interdisciplinary education
- Surgeon credentialing and training
- Enhanced informed consent practices.
- Multidisciplinary care coordination.
- ACC review of declined claims.

Repeated requests for the Ministry of Health to independently evaluate the outcomes of this process were declined. These requests continue.

January 2020: The second Pelvic Floor Reconstructive Credentialing Committee is established to develop national credentialing standards.

May 2020: First interdisciplinary working group established to develop a Surgical Mesh Education and Harm Prevention Programme.

June 2020: DHBs were interviewed regarding credentialing status against the Australian standard**.**

June 2020: A new Credentialing panel formed to review how DHBs assessed surgeons performing urogynaecological mesh procedures against the Australian standard.

June 2021: June 2021: The Health and Disability Commissioner released a report raising concerns about informed consent processes for mesh procedures, including whether patients had sufficient opportunity to consider information prior to consenting.

July 2021: HDC expressed concerns about ongoing inconsistencies in informed consent across DHBs and private providers.

May 2022: The New Zealand National Credentialling Framework: Pelvic floor Reconstructive, Urogynaecological and Mesh Revision and Removal procedures was finally published.

Sept 2022: Sally Walker presented a petition to parliament requesting a suspension of stress urinary incontinence mesh procedures.

October 2020: ACC announces review of previously declined mesh-related injury claims from 2005-2019. This was not widely advertised. ACC was reluctant to agree to external review, resulting in a 9-month delay before the medico legal panel was established. Few claims were reviewed, with limited transparency, including for the panel. A request for an independent review of the process by the medico- legal panel and consumer representative was declined by ACC.

Dec 2nd 2022: HDC/HQSC send a joint memo to Joe Bourne and SMRT. Key concerns were outlined and recommendations made for action to be taken to reduce the risk of further harm.

March 2023: Goodfellow published 4 webinars on surgical mesh management as part of the Surgical Mesh Education program, this group was subsequently disestablished afterwards.

April 2023: Two mesh clinics were established, one in Christchurch and in Auckland

Escalating Concerns and Nationwide Pause 2023

Pressure via media continued, with countless articles highlighting serious harm and ongoing calls for suspension of mesh use, alongside sustained consumer advocacy from multiple individuals and groups, including Sally Walker's long-standing petition, formal submissions and correspondence with government, broader media advocacy, and formal escalation through letters, press statements, and regulatory engagement.

July, 2023: Health Consumer Advocacy Alliance, alongside the Auckland Women's Health Council, Federation of Women's Health Councils, and Cartwright Collective, sent a joint letter to the Director-General of Health requesting immediate suspension of mesh procedures and calling for high-vigilance scrutiny and transparency of all mesh and non-mesh pelvic

July, 2023: Joint media statement: HCAA joined Auckland Women's Health Council, Federation of Women's Health Councils & the Cartwright Collective to call for an immediate suspension of mesh procedures under Medicines Act. They reference Section 37 of the Medicines Act 1981 as a legal tool for suspension.

***August 23, 2023**: The Director-General Dr. Diana Sarfati announces a time-limited pause on mesh use for Stress Urinary Incontinence (SUI) citing four criteria.

Further concerns raised: Training and education were not required criteria for lifting the pause, despite earlier Medsafe recommendations in 2009. While the Ministry of Health's education programme and the 2018 credentialing process (including subsequent rounds) did not formally identify

lack of training as a "red flag," they revealed concerns about insufficient technical skill, knowledge, and core competencies. With limited visibility of training undertaken, and a similar number of surgeons credentialled to implant mesh as before, these concerns persist.

Very few surgeons are credentialled to perform mesh removal, and limited numbers offer non-mesh alternatives, restricting safe care and informed choice. Concerns about the adequacy of monitoring, despite "expectations" of heightened oversight have been raised and remain ongoing. Concerns also persist regarding the reinstatement of mesh procedures and the lifting of the "pause" without appropriate safeguards in place.

New Zealand Government Response 2024- 2025

2024: New patient information decision aids released by HQSC and Ministry for SUI and mesh surgeries, endorsed by the Surgical Mesh Roundtable. Repeated requests for a patient decision aid for mesh removal were declined due to budgetary constraints.

22 August, 2024: Interim high-vigilance guidelines for non-mesh SUI procedures implemented, regional multidisciplinary meetings established, and exceptions process for mesh cases set up. Concerns remain about visibility, comprehensiveness, and effectiveness of oversight.

***2025:** Progress Tracker update by MOH with 17 of the 19 actions marked as "Completed," with two still in progress. Concerns were raised about the tick-box approach and the extent to which subsequent advice to Ministers reflected what is occurring in practice.

***August 2025:** Progress update confirmed by MOH in a briefing to Associate Health Minister, Casey Costello, *"All the steps required to lift the pause have been implemented except a female pelvic registry."*

However, this statement by the MOH presents an overly simplified view of progress and does not fully reflect what is occurring in practice, particularly in terms of how consistently these measures are being implemented across services. This is supported by Health and Disability Commissioner findings highlighting ongoing variability in informed consent and the implementation of mesh safety requirements across providers.

Further Context and Links to relevant information:

2008: Medsafe surgical mesh adverse event report Surgical Mesh Adverse Event Reports

2009: Letter outlining action taken by Medsafe, surgical expertise and training noted "as an issue", recommendation for a training program to be established. ActionsTakenByMedsafe2009.pdf

Medsafe Conclusions
The Director-General of Health may only take action if a medical device is believed to be unsafe (refer Section 38 of the Medicines Act 1981). When used in accordance with the manufacturer's DFU by appropriately trained surgeons Medsafe has concluded that surgical mesh devices do not present an unreasonable safety risk to patients. As the Medicines Act 1981 does not require the effectiveness of a medical device to be evaluated prior to its supply in New Zealand no determination has been made of the effectiveness of these devices.

The MDIRC committee agreed there appeared to be a training issue and recommended that an appropriate training program be put in place by the manufacturers in cooperation with professional organisations such as the RANCOG to manage problems.

2013: Medsafe Adverse Event report- Surgical Mesh Adverse Event Reports

2014: Scotland immediately suspended transvaginal mesh procedures for SUI and POP. Halt in use of transvaginal mesh - gov.scot

2017 May: TGA undertakes regulatory actions after review into urogynaecological surgical mesh implants. "45 devices have been removed from urogynaecological use by the TGA - 43 cancelled from the ARTG and a further two have been limited to non-urogynaecological procedures (see Table 2 of

Devices Cancelled below). Additional devices have been removed from the ARTG by sponsors of the device, due to commercial reasons." TGA actions after review into urogynaecological surgical mesh implants | Therapeutic Goods Administration (TGA)

TGA actions after review into urogynaecological surgical mesh implants | Therapeutic Goods Administration (TGA)

2018: Medsafe: "All four companies contacted have responded and have confirmed that all products removed from the Australian register are no longer supplied in New Zealand,". Urogynaecological Surgical Mesh Implants

2018: Deloitte's cost benefit analysis report: Surgical Mesh Registry: Cost Benefit Analysis

2018: Jan Medsafe update Urogynaecological Surgical Mesh Implants

2018: Sept Govt Directive: Govt announced intended safeguards to restrict surgical mesh use. DHBs were advised to stop use in urogynaecological surgery unless credentialing standards and robust informed consent (including risks) could be met. This signalled expectations to assess surgeons against Australian guidance, limit use to appropriately trained practitioners, review services, and consider local registers, with a national registry also proposed, without clear oversight or enforcement. "We all expect the health care system to keep us safe, yet too many women have suffered harm from surgical mesh. These safeguards are intended to give women greater confidence in the health care system." New surgical mesh safeguards put in place | Beehive.govt.nz

2018: The UK introduced a wider suspension of mesh procedures in response to escalating safety concerns, later reinforced by the Independent Medicines and Medical Devices Safety Review (Cumberlege Review). https://www.gov.uk/government/news/government-announces-strict-rules-for-the-use-of-vaginal-mesh

ACC surgical mesh data analysis: 2015: surgical-mesh-report.pdf 2018: surgical-mesh-data-2005-2018.pdf The 2017 ACC surgical mesh claims analysis covering 1 July 2005 to 30 June 2017 was released but is no longer publicly accessible as a standalone report.

2019: RJ Process Report: Healing from harm- Hearing and Responding to the Stories of Survivors of Surgical Mesh

June 2020: Key findings of credentialling panel. Hearing and Responding to the Stories of Survivors of Surgical Mesh - December 2021 update

August 2022: Sally Walker presents petition to parliament Petition of Sally Walker: Suspend the implantation of mesh sling for stress urinary incontinence

2023: Regulatory Escalation and Continued Advocacy

July 2023: HCAA Joint letter to Dianna Sarfarti- Joint-letter-to-Dr-Diana-Sarfati-re-HSC-Mesh-report-10-7-23.pdf

July 2023: HCAA Joint Press statement: Medicines Act Enables Suspension Of Harmful Surgical Mesh Procedures But Will The Ministry Of Health Act | Scoop News

***2023 August:** Director General of Health announcement regarding the mesh pause- Surgical mesh statement from Director-General of Health | Ministry of Health NZ

***August 2025:** Briefing to Minister Costellow: https://www.health.govt.nz/system/files/2025-11/H2025068938-Briefing-Update-on-the-surgical-mesh-work-programme.pdf

***August 2025 Article:** Risks associated with lifting mesh suspension Article-CKorte-re-Potential-lift-of-Mesh-Suspension.pdf