Briefing

Surgical Mesh

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To:	Hon Casey Costello, Associate Minister of Health		
Consulted:	Health New Zealand: ☒ Māori Health Authority: ☐		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Surgical Mesh Delegation

Purpose of report

1. The purpose of this briefing is to provide you, as the responsible Minister for surgical mesh, with information on the issue and the work currently underway across the health system. This is a joint briefing from the Ministry of Health | Manatū Hauora (the Ministry) and Health New Zealand | Te Whatu Ora (HNZ).

Summary

2. The use of surgical mesh is a complex issue and there are a number of stakeholders who are actively engaged with the surgical mesh work programme.
3. There is currently a system wide recommendation by the Director-General of Health to pause the use of mesh in the treatment of stress urinary incontinence (SUI)
4. You will meet with Dr Joe Bourne, Chief Medical Officer on 27 March for a deep dive on surgical mesh delegation.

We recommend you:

a) **Note** the contents of this briefing **Yes/No**

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Deputy Director-General
Clinical, Community and Mental Health | Te Pou Whakakaha

Date: 27/02/2024

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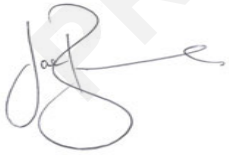

Date: 27/02/24

Dr Joe Bourne
Chief Medical Officer
The Ministry of Health | Manatū Hauora

Surgical Mesh Delegation

Background / context

Surgical Mesh

5. Surgical mesh is a net-like fabric or tape that can be introduced as part of surgery to help repair weakened structures in the human body. It can be used in the treatment of hernias and stress urinary incontinence (SUI), and historically was also used in the treatment of pelvic organ prolapse (POP).
6. The use of surgical mesh in urogynaecological procedures, including the treatment of SUI, has been a matter of local and international concern for more than 10 years. In 2014 Scotland, followed by the rest of the United Kingdom in 2018, introduced a period of 'restricted practice' and a 'High Vigilance Restriction Period', otherwise referred to as a 'pause', in the use of SUI and pelvic organ prolapse surgical mesh.
7. The cross-government surgical mesh work programme is led by The Ministry of Health and guided by the 2016 Select Committee Report on the Petition of 2011/102 of Carmel Berry and Charlotte Korte, and recommendations from restorative justice process facilitated by Victoria University in 2019. The core workstreams include:
    a. establishment of specialist multi-disciplinary services for those who experience mesh complications and/or require removal of their mesh; led by HNZ.
    b. ongoing implementation of a specific New Zealand credentialing framework covering urogynaecological procedures, to strengthen credentialing processes to ensure surgeons have the appropriate skills and training to undertake procedures involving mesh; currently lead by the Ministry.
    c. development and deployment of an interdisciplinary education programme to build capability of the required knowledge and technical skills to prevent future harm and reduce the severity of existing harm; led by the Health Quality and Safety Commission.
    d. establishment of a registry for procedures involving surgical mesh.
8. The Mesh Roundtable (MRT) provides oversight and monitoring of the surgical mesh work programme and provides advice and recommendations to the Ministry and Health New Zealand on the delivery of the work programme.
9. In 2017, Medsafe used regulatory action available to it via Section 38 of the Medicines Act 1981 to request information on the safety of urogynaecological mesh devices from the suppliers of mesh for pelvic organ prolapse (POP).
10. After Medsafe's inquiry, all suppliers of pelvic organ prolapse mesh advised Medsafe that their products would no longer be available on the New Zealand market. Pelvic organ prolapse mesh is not legally banned in New Zealand but has not been available since 2018. In 2019, the USA Food and Drug Administration (FDA) ordered mesh manufacturers to stop selling devices for transvaginal repair of pelvic organ prolapse.

11. In August 2023, with some evidence of ongoing harm from mesh, and key safeguards still to be implemented, the Director-General of Health recommended a time-limited pause on the use of mesh for the treatment of stress urinary incontinence (SUI) be adhered to immediately.
12. Conditions to lift the pause reflect the incomplete actions within the core workstreams from the Restorative Justice process (i.e. credentialling of surgeons, establishment of multidisciplinary meetings etc.).
13. The Ministry is responsible for developing system safeguards that are required during the period of the pause. Based on international experience, these safeguards have been identified as providing high vigilance guidance for practitioners using non-mesh surgical procedures and providing an exception process for patients for whom mesh is the only viable treatment option. Interim high vigilance guideline for Non-Mesh Stress urinary incontinence surgery were published on the Ministry of Health website in December 2023 and the exception process is currently being finalised with the exceptions committee.
14. The MRT retains oversight of the mesh workstreams and will evaluate when the conditions have been met to lift the pause.

Stakeholders

15. There are several interested stakeholders involved with surgical mesh. There has been formal engagement from the listed below stakeholders in various committees, such as MRT, credentialling, and external advocacy.

Consumers

16. Consumer engagement has been an integral part of the mesh work programme and governance, with a minimum of one consumer representative within each forum. The Ministry also meets regularly with engaged consumers ahead of the Mesh Roundtable meeting to give opportunity to discuss any emerging or ongoing issues across work programmes.
17. Throughout the years, there has been a core group of mesh injured consumers who have engaged with the Ministry and HNZ. Many have been involved in the advocacy group Mesh Down Under, co-founded by Ms Charlotte Korte and Ms Carmel Berry, and in petitioning the Government to address surgical mesh harm through the Select Committee process. Consumer advocates are well organised and have shared stories of their mesh injury and failure by the health system to the media and will speak publicly on emerging issues.
18. More recently, in September 2022, Sally Walker presented a petition with over 1,000 signatures, requesting the House suspend the implantation of mesh sling for stress urinary incontinence. This was heard before the Health Select Committee in May 2023. As previously noted, there is currently a time limited pause on the use of mesh for SUI in New Zealand.

Professional Colleges

19. The Royal Australian College of Surgeons (RACS) and the Royal Australian College of Gynaecologists (RANZCOG) have an interest in mesh, as their Fellows, urologists and gynaecologists, are the surgeons implanting urogynaecological mesh and managing the complications when these occur.

20. RACS is a non-profit organisation training surgeons and maintaining surgical standards in Australia and Aotearoa New Zealand

21. RANZCOG trains and accredits doctors in the specialties of obstetrics and gynaecology so that they can provide the highest standards of healthcare.

22. The Ministry has had discussions with RACS and RANZCOG regarding development of a joint training programme for pelvic surgery. Conversations are ongoing.

Health System Quality and Safety Commissioners

23. The Health and Disability Commissioner (HDC) and the Health Quality and Safety Commission (HQSC) have an interest in ensuring the public is kept safe when accessing and receiving treatment and care for their health. Both are represented on the MRT.

24. The HDC and HQSC have been vocal in the past about their concerns of ongoing harm from surgical mesh, and the pace in which action is being taken to address the Restorative Justice recommended actions. Since the recommendation for a time limited pause on the use of mesh for SUI in August 2023, both agencies appear to be more confident in the system's ability to address the safeguards needed to minimise ongoing harm.

Private Surgical Hospital

25. The New Zealand Private Surgical Hospital Association (NZPSHA) was established represent the interests of private surgical hospitals. They connect the private surgical hospital sector, represent on collective issues within the New Zealand health sector and promote excellence. Most of mesh procedures have been done in a private facility.

The Public Health System

26. Health New Zealand and the Ministry of Health work closely together to understand their roles and responsibilities in delivering and monitoring the recommended actions. Health New Zealand is responsible for service delivery (including commissioning decisions) and any operational matters. The Ministry of Health as system stewards are responsible for monitoring the progress of the mesh work programme and ensuring system safeguards are in place before lifting the pause on mesh.

Accident Compensation Corporation

27. The Accident Compensation Corporation (ACC) is interested in mesh as they support those who experience female pelvic mesh injuries caused by treatment or failure to provide the right treatment.

28. ACC have a dedicated cover assessment team to guide people through the pelvic mesh injury claim process. Claims declined before 28 October 2020 can be reassessed under the current criteria. Reassessments are based on the latest evidence and understanding of mesh injuries.

Specialist centres

29. Establishment of the New Zealand Female Pelvic Mesh Service (NZFPMS) to assess and treat women with complications associated with female pelvic surgical mesh insertion. As of 20 February 2024, 285 referrals have been received. This has been enabled by a communication campaign with primary care providers, specialists, and consumers. Support has been provided

to district hospital women's health and urology teams to gain access to e-referral systems that enable referrals outside their region in a coordinated effort to move away from traditional paper and email referrals to a specified surgeon.

30. Two Consumer Advisors have been recruited and retained to work with the NZFPMS to ensure that all aspects of development that impact the patient pathway are patient centric and in keeping with the ethos of restorative justice.

31. All referred patients have engaged with the Navigators and Clinical Nurse Specialists and are accepting the support being provided.

On-going risks related to the surgical mesh programme

32. A number of stakeholders, notably mesh injured consumers and the HDC and HQSC, welcomed the Director-General of Health's recommendation to pause the use of mesh in treating SUI in August 2023.

33. However, there have been ongoing challenges for the professional college RANZCOG, as the pause has altered their Fellows ability to perform some procedures, and in some instances, financial gain in their private practice. The Ministry engages regularly with RANZCOG on the matters of credentialling and upskilling of surgeons, to maintain RANZCOG's support in the principle of creating a safer system.

34. To the best of our knowledge credentialling of individual surgeons by procedure type has never been done in New Zealand before. The National Credentialling Framework requires surgeons wishing to perform the listed procedures to undergo an assessment of their evidence to be credentialed.

35. There are some polarised views on how the credentialling process ought to be carried out and the fairness of it. Concerns regarding the stainability and scalability of the current process design has also been raised. The National Credentialling Committee is tasked with overseeing the process of credentialling and addressing these concerns as they arise.

36. There is ongoing concern amongst a small number of consumers that women experiencing mesh complications associated with the insertion of mesh for rectal prolapse (as part of the Pelvic Organ Prolapse procedural group) are not included in the Specialist Service for mesh complications and are therefore not receiving equitable care and treatment to women with SUI or female only Pelvic Organ Prolapse (POP) mesh complications. Health New Zealand Surgical Mesh Specialist Services has made an agreement to revisit this decision, and it is tabled for discussion in April 2024.

37. During the restorative justice process, consumers raised concerns regarding harm from hernias used in abdominal surgery. This will be raised at future MRT for discussion later in 2024.

Surgical Mesh Restorative Justice and Work Programme

38. The surgical mesh work programme entails both the oversight, facilitations (and where appropriate) the delivery of the 19 actions from the 2019 Restorative Justice Report, and the

oversight and ownership of the pause on the use of mesh for stress urinary incontinence (SUI) as recommended by the DG in August 2023.

39. There has been significant progress towards addressing the 19 actions over the last 5 years including, specialist service design, development of the National Credentialling Framework: Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures, and developing education resources for primary care providers.

40. There are four remaining pieces of work that require completion before the 19 Restorative Justice actions have been satisfied and there are sufficient safeguards in the system to lift the pause on the use of mesh for SUI. Activity to address all four actions is underway and are at varying stages of completion.

    1. Credentialling of surgeons
    2. Multidisciplinary meeting for cases (MDM)
    3. Pelvic floor registry
    4. Consumer education support resources

Credentialling

41. Progressing credentialling is a priority to ensure New Zealand has an adequate number of appropriately credentialled surgeons able to deliver urogynaecological pelvic floor surgery women suffering with stress urinary continence, where mesh is the preferred treatment option.
42. The Ministry has completed a second round of credentialling for pelvic floor reconstructive, urogynaecological and mesh procedures in February 2024. The first round focused on credentialling clinicians for Tier 3 procedures[1] and this second round expanded to focus on Tier 1 and 2 credentialling. There was a sufficient number of clinicians credentialled in the first round to service the New Zealand Female Pelvic Mesh Service (NZFPMS).
43. Discussions have recently commenced with HNZ representatives to transfer responsibility for operating the credentialing process.

Registry

44. The establishment of a mesh registry was not included in the Restorative Justice but has been acknowledged by consumers, and stakeholders as a required action to include in the work programme. The MRT has oversight for the progress against the establishment of a mesh registry.
45. Transfer of mesh registry accountability and work programme from the Ministry to Health New Zealand occurred late 2023. The Australasian Pelvic Floor Procedure Registry (APFPR), Monash University has been identified as the preferred platform.
46. Work is underway to agree a Statement of Work and a formal contract to purchase the access rights to the APFPR with Monash University
47. The operating model for implementation has been agreed. Work is underway to establish a contract with a New Zealand based health data and outcomes provider who has a pre-existing Monash University registry remit and experience.

48. The establishment of a clinical and data advisory committee to shape the processes has occurred. The initial focus for these committees is on data alignment and access, security, development of a governance framework, and privacy impact assessment and data sovereignty for the Registry.

Patient decision aid

49. The Health Quality and Safety Commission (HQSC) are responsible for the publication of patient informed consent decision tools. The surgical pathway patient decision resource tool is soon to be published, with work ongoing on the non-surgical pathway document.

Regional SUI Multidisciplinary Meetings (MDMs)

50. A project working group made up of gynaecologists, urologist, urogynaecologists and pelvic health physiotherapist commenced in October 2023 with a remit to develop governance processes in public and private sector including Regional MDM Terms of Reference, Referral and outcome processes and forms, including safe data and digital sharing option. The focus is on achieving uniformity in the MDM processes and monitoring and reporting between the regions and specialists.

51. A trial of the form and process is being tested in Taranaki in February 2024. Work to refine and test with a wider audience to ensure solutions are scalable will occur in late March, with the intent to trial in a larger centre in April.

52. An initial plan to roll out the MDM process to the remaining regions in early 2024 is not achievable due to complexity with digital connections preventing safe sharing of patient clinical information outside their district hospital clinical software remit. Solutions are being worked through to ensure safe transfer of patient information.

Broader considerations for support of the mesh work programme

Funding - Budget 24

53. Modelling undertaken as part of the development Surgical Mesh Specialist Service Model of Care has informed the level of funding required deliver the service, however in the absence of actual volumes for a sufficient period of time it is difficult to have a set budget. s 9(2)(f)(iv) [redacted] e intend to confirm a budget for 2024 and ensuing years later in the year once volumes and conversion rates to surgery are clearer.

Oversight and monitoring of surgical mesh

54. The Ministry, as system stewards and for clinical quality and safety, will retain sector leadership of the MRT, as Chair, for the duration of the time required to achieve the restorative justice outstanding actions.

55. Function changes under the Pae Ora Act 2022, has already resulted in changes to the lead agency responsible for work stream delivery (e.g., transfer of specialist service delivery from the Ministry to HNZ). Further transfers of operational tasks are expected from the Ministry to HNZ over the next 3-6 months.

56. The conditions to lift the pause in the use of mesh for SUI also encompass the remaining actions to be completed in the Restorative Justice process. Lifting of the pause, once conditions have been met will be the natural terminus for MRT in its current function and a review of the Terms of Reference will be required.

Next steps

57. Dr Joe Bourne, Chief Medical Officer, will meet with you on 27 March 2024 to discuss this programme of work.
58. Should there be any updates or risks within this work program, the Ministry will keep your office up to date.

ENDS.

Minister's Notes