In Confidence	*Terms of Reference*	MINISTRY OF HEALTH MANATŪ HAUORA

Surgical Mesh Roundtable

Introduction

The Ministry of Health is leading a surgical mesh work programme which aims to support those who have been harmed by surgical mesh and minimise the risk to patients who may be considering its use.

The use of surgical mesh, especially in urogynaecological procedures, has been a matter of local and international concern for some years.

In 2014 Carmel Berry and Charlotte Korte petitioned Parliament for an inquiry into the use of surgical mesh in New Zealand. The Health Committee's report on this petition, with seven recommendations, was presented to the House in 2016.

In December 2019 the Ministry released a report prepared by the Diana Unwin Chair of Restorative Justice at Victoria University, *Hearing and Responding to the Stories of Survivors of Surgical Mesh*. This report included a number of actions agreed to by stakeholder representatives in response to the harms and needs heard, and identified the Surgical Mesh Roundtable as 'an appropriate group to oversee the delivery of the workstreams'.

Purpose and function

The Roundtable will be responsible for:

- providing oversight and monitoring of the surgical mesh work programme, including the actions and recommendations arising from the Health Committee and Restorative Justice reports (refer Appendix 1),
- providing advice and recommendations to the Ministry of Health on the delivery of the work programme, and
- ensuring a collaborative, people-centred approach, with issues considered from a patient perspective, and guided by the Treaty of Waitangi, with a focus on delivering equitable health outcomes.

Whilst recognising the wider use and impact of surgical mesh, the work of the Ministry and Roundtable will in the first instance be focussed on the use of surgical mesh within urogynaecological surgery as this is associated with the greatest risk. Lessons from this will be subsequently considered and applied for other uses of surgical mesh.

Membership

Up to two members will be nominated by each of the following stakeholder organisations and groups to participate in the Roundtable:

- Royal Australian and New Zealand College of Obstetricians and Gynaecologists
- Royal Australasian College of Surgeons
- the Urological Society of Australia and New Zealand

- Royal New Zealand College of General Practitioners
- Nursing
- ACC
- Health and Disability Commission
- New Zealand Private Surgical Hospitals Association
- Consumer
- Ministry of Health (ex-officio)

Requests for proxies to attend meetings will be considered on a case-by-case basis.

Meetings

The Roundtable will meet for up to two hours, every two months. Meetings will be based across Auckland and Wellington, with tele- and video- connections.

The Ministry of Health will provide the secretariat and administrative support for the Roundtable. This will include the preparation of reports to, and on behalf of, the Roundtable.

Payment and expenses

It is not normal for the Ministry to pay representatives from the publicly funded sector for meeting attendance. Consumers will be reimbursed. The Ministry may remunerate other parties by mutual agreement.

Managing interest

Members must perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to a conflict of interest.

From time to time, a member may find themselves in a position where they may have competing duties, responsibilities or interests to their membership of the Roundtable. In this situation members should document their conflicts of interests and identify any conflict of interest prior to a discussion of a particular issue. The Roundtable can ask a member to withdraw or limit participation in the event that the member has a conflict of interest.

Accountability and communications

The Roundtable is accountable and reports to the Ministry of Health.

Members are not agents of the Ministry of Health and cannot speak on behalf of the Roundtable. This doesn't restrict members from making statements relating to their own expertise in an individual capacity.

The Roundtable will agree on any key messages from meetings and provide these to the Ministry of Health.

Appendix 1

Recommendations to Government from the Health Committee report:

- that it work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry
- that a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications
- that it suggest that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures
- that it encourage health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored
- that it encourage utilisation of the adverse events reporting system as applicable to medical devices
- that it endorse the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery
- that it consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand

Agreed actions in the Restorative Justice report:

- The severity of the harm from surgical mesh should be acknowledged when the report is released publicly.
- The Ministry of Health was identified as the coordinating agency for each workstream.
- A collaborative approach is required to respond to harm from surgical mesh, and groups that should collaborate, were identified for each workstream.
- The HDC will promote the visibility of their national advocacy service.
- Attendees will share the final report with their professional members/within agencies.
- 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.
- Consumers will be reimbursed when participating in the co-design of each workstream.
- 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.
- 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.
- 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.

- Professional colleges will inform and educate their members about their role in preventing and reducing harm from surgical mesh.
- 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.
- ACC will explore the potential to provide support services, such as counselling, while cover decisions are pending.
- 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.
- 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.
- 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.
- 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.
- 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.
- The Ministry of Health will identify the actions and supports required to meet the need for a collaborative approach to safety systems and culture.