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MTAA Submission to the Social Development Committee, Parliament of South Australia:

Surgical Implantation of Medical Mesh in South Australia

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Contents

1. Executive Summary

This MTAA submission is in response to the invitation by the Social Development Committee, a Standing Committee of the South Australian Parliament, to provide comments into issues related to the Surgical Implantation of Medical Mesh in South Australia.

The Committee has been tasked to consider:

(a) the number of people in South Australia adversely affected following the implantation of medical mesh;
(b) the benefits of establishing a South Australian register of mesh implant recipients, including a prospective and retrospective audit, which includes the public and private hospital sectors;
(c) identifying the current role of South Australian medical practitioners in reporting medical mesh associated adverse outcomes and the consequences of nonmandatory reporting;
(d) assessing the usefulness of current patient information provided prior to surgery, including options for non-surgical treatment, possible adverse outcomes and fully informed consent;
(e) the credentialing of medical practitioners conducting implantation and removal of medical mesh;
(f) identifying the extent to which there exists a need for physical and psychological support, including family members, following adverse outcomes; and
(g) any other related matter.

A previous inquiry into transvaginal surgical meshes was conducted in 2017 by the Commonwealth Senate MTAA believes that a Commonwealth response is the appropriate action for improving patient outcomes. We question whether a state-based inquiry is going to achieve meaningful new data or drive change in addition to the Commonwealth inquiry and subsequent actions.

In the next sections we provide specific feedback to the South Australian Social Development Committee inquiry which reiterates our position in relation to surgical meshes.

2. Number of patients adversely affected

In 2017 the Commonwealth Senate referred a similar inquiry to the Community Affairs References Committee which subsequently released its report *Number of women in Australia who have had transvaginal mesh implants and related matters*[1]. The report made 13 recommendations[2]. In response to these recommendations MTAA provided a response in which we broadly welcomed the report's recommendations.

Individual companies have also made submissions to the Senate Committee[3] outlining the adverse event reporting process which is part of a company's quality management system. Adverse event reporting is mandatory for medical device manufacturers and sponsors. Reporting is voluntary for surgeons, other healthcare professionals and patients. MTAA agrees with suggestions to strengthen the adverse event reporting and address current underreporting by making reporting by surgeons mandatory.

The transvaginal (urogynaecological) meshes that were the subject of the Senate inquiry are part of a mesh category intended for treating pelvic organ prolapse (POP). Surgical meshes intended for POP have also been used to treat serious and complex conditions. In 2017, the TGA cancelled the approval of specific types of transvaginal mesh devices, and these devices can no longer be supplied in Australia.[4]

Surgical meshes intended for the treatment of stress urinary incontinence (SIU) are the gold standard for SUI, as acknowledged in the Senate report. Many patients experience very good outcomes from procedures involving these devices.

This latest inquiry by the South Australian Parliament covers surgical mesh in general, not just transvaginal mesh, and the patients affected include both men and women.

The MTAA does not hold adverse event data. This information is typically found in the following databases and information repositories:

- Database of Adverse Event Notifications (DAEN)[5]

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[1] Parliament of Australia – Report: Number of women in Australia who have had transvaginal mesh implants and related matters, 28 March 2018: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report

[2] Parliament of Australia – Report: Number of women in Australia who have had transvaginal mesh implants and related matters, 28 March 2018 - List of recommendations: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report/b01

[3] Parliament of Australia, Parliament Business, Submissions: https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions

[4] TGSA Transvaginal (urogynaecological) surgical mesh hub: https://www.tga.gov.au/hubs/transvaginal-mesh

[5] TGA Database of Adverse Event Notifications (DAEN): https://www.tga.gov.au/database-adverse-event-notifications-daen

- Medibank data
- Health Issues Centre (HIC) data

Manufacturers and sponsors are required to report the details of events associated with their device(s) that have resulted, or could have resulted, in serious injury or death. Events associated (caused or partially attributable) with the use (or misuse) of a medical device are categorised as medical device adverse events. They include faults that may affect the quality, timeliness and cost-effectiveness such as problems with getting the device to operate, repeated repairs, device design and difficulty to use.

Adverse event reporting is a condition of inclusion in the Australian Register of Therapeutic Goods (ARTG). The reporting timelines for manufacturers and sponsors are:

- Within 2 days of becoming aware of an issue of serious public health that will require prompt action to reduce hazard;
- Within 10 days of becoming aware of a death or serious injury;
- Within 30 days of becoming aware of an event that might have led to serious injury or death.

However not all incidents are medical device adverse events, and they do not need to be reported if they are:

- The issue was found by the user prior to using the device.
- The adverse event was caused solely by patient conditions.
- The adverse event occurred after the medical device reached its end-of service life.
- The device protection against a fault functioned correctly.
- There is a remote likelihood of occurrence of death or serious injury.
- The adverse event represents an expected and foreseeable side effect that is documented in manufacturer's Instructions for Use or labelling.
- The adverse event is described in an advisory notice
- TGA has granted a reporting exemption.

None of the above exemption from reporting obligations apply if:

- TGA identified the adverse event as an issue that requires close monitoring; or
- A change in trend (usually an increase in frequency) or pattern is identified; or
- The adverse event is associated with user error, which indicated that the manufacturer's Instructions for Use may require improving.

3. Mesh implant registry

MTAA is supportive of establishing a national surgical mesh registry in Australia, provided it is set up and operated as a Clinical Quality Registry; it enables appropriate and fair access to data; it provides transparency on both devices and surgeons; and its funding is spread equitably among the main beneficiaries.

MTAA believes that registries should be established on a national rather than State level and should be set up and operated in accordance with the principles, guidelines and standards for Australian Clinical Quality Registries[6]. Any prospective and retrospective auditing should be nationally harmonised to ensure that best practice is implemented across Australia, and appropriate resources should be budgeted for this activity.

Appropriate and fair access to data and transparency on both devices and surgeons is essential to ensure accurate assessment of safety outcomes. Funding of registries should recognise they provide benefits to a range of stakeholders, including hospitals and patients. All those that benefit should pay for it – including regulators, healthcare professionals, insurers, hospitals and policy makers.

It is well known that clinical quality registries are extremely costly to set up and manage. Careful consideration needs to be given to prioritise areas of high risk for selection and implementation of a registry. In a widely referenced 2015 report to the U.S. FDA the Medical Device Registry Task Force & the Medical Devices Epidemiology Network proposes 11 priority areas for establishing device registries, including for surgical meshes[7]:

1. Hip replacement devices
2. Knee replacement devices
3. Vascular procedures/devices (includes peripheral, AAA, carotid and vascular access/catheters)
4. Spine surgery procedures/devices
5. Cardiac valve replacement
6. Atrial fibrillation ablation procedures/devices
7. ICD/cardiac resynchronization therapy (CRT) implantation
8. Coronary stents
9. Robotic and other less invasive surgery
10. Ophthalmic procedures/devices
11. Surgical mesh

[6] Australian Commission on Safety and Quality in Health Care website, accessed on 19 August 2018: https://www.safetyandquality.gov.au/publications/framework-for-australian-clinical-quality-registries/

[7] Recommendations for a National Medical Device Evaluation System, A Report from the Medical Device Registry Task Force & the Medical Devices Epidemiology Network, August 20, 2015, p.81: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM459368.pdf

4. Adverse event reporting by medical practitioners

Adverse event reporting is an essential part of post-market safety monitoring of therapeutic goods, because it provides important information on the nature and magnitude of the problem, and reassess, if necessary, the risk profile of the therapeutic good. Early signal detection enables minimising harm to patients.

While mandatory for sponsors of medical devices[8], adverse event reporting is optional for medical practitioners. Unless the obligation to report is extended to medical practitioners, some adverse events will always go unreported.

Incidents involving implanted medical devices can have various causes: device malfunction or failure; inappropriate patient selection; sub-optimal surgical skill; patient comorbidities and lifestyle. As TGA noted: "Importantly, an adverse event is not always caused by the therapeutic good itself. An adverse event could be a result of incorrect user interaction or other circumstances such as two properly functioning devices that do not operate as intended when used in combination. The occurrence of an adverse event does not necessarily mean that there is something wrong with the therapeutic good."[9]

MTAA supports making adverse event reporting mandatory for medical practitioners to improve the rate of incident reporting. The definitions and guidelines for what constitutes an adverse event and the statutory timelines should be aligned with requirements applicable to industry.

Consumers and patients should be encouraged to report adverse events, and appropriate educational programs should be put in place to assist them with understanding the reporting framework.

5. Patient information leaflets and implant cards

MTAA is supportive of the recently introduced requirements for patient information materials to be supplied with implantable and active implantable medical devices in Australia – patient information leaflets (PIL) and patient implant cards (PIC).[10]

The PIL are intended to assist patient doctor discussions prior to surgery, to facilitate understanding of the type of medical device being considered and the type of medical condition the device is used for.

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[8] Therapeutic Goods (Medical Devices) Regulations 2002, Regulation 5.7 Conditions applying automatically—period for giving information about adverse events etc. (Act s 41FN): https://www.legislation.gov.au/Details/F2018C00292

[9] TGA website Reporting adverse events, accessed on 19 August 2018 - https://www.tga.gov.au/reporting-adverse-events

[10] TGA website Medical device patient information leaflets and implant cards, accessed 19 August 2019 - https://www.tga.gov.au/publication/medical-device-patient-information-leaflets-and-implant-cards

The PIC are user-friendly, small, portable cards intended to be provided to patients following surgery who have received either a permanent implantable medical device or an active implantable medical device.

MTAA has been supportive of this initiative and we have provided specific and detailed feedback to TGA to improve and streamline the PIL/PIC requirements, such as the option to provide PIL in electronic format on company's website and PIC as an app on patients' mobile phone.

6. Medical practitioners credentialing

Appropriate training and credentialing of medical practitioners by the medical colleges is essential for ensuring successful outcomes of any implantation procedure. As mentioned earlier in this document, inappropriate patient selection and sub-optimal surgical skill can be at the root cause of adverse events just like medical device malfunction or failure.

MTAA strongly agrees that the medical colleges and specialist societies need to take responsibility for the professional development of specialist doctors and senior medical practitioners and establish documented credentialing procedures. Specialist training might include targeted device training by manufacturers.

7. Post-surgery patient support

Post-surgery patient support, both physical and psychological, should be provided in all situations where serious adverse events occur. In our opinion, this is a matter for the relevant medical colleges and the Australian Commission of Safety and Quality in Health Care to address.