AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

D19-2292

Commission work in regard to the Government Response to the Senate Inquiry *The number of women in Australia who have had transvaginal mesh implants and related matters* Recommendations

The Commission has completed work, appropriate to its role, for which it was recommended as a lead in the Senate Inquiry Report and the Government Response. This includes a range of guidance resources following an extensive consultation process, which have been published on the Commission's website and distributed to state and territory health departments, relevant colleges and specialty societies, primary health networks, health consumer councils and individual consumers.

State and territory health departments have responsibility for planning and delivering public health services and licencing private health care facilities. As such the states and territories have been actively collaborating with the Commission. Response and status of the Commission's work against the Recommendations is summarised below:

RECOMMENDATION 2: The committee recommends that the Therapeutic Goods Administration (TGA) and the Australian Commission on Safety and Quality in Health Care develop an information sheet to be provided to recipients of patient cards for implantable devices providing guidance on appropriate action to take in the event of an adverse event, including guidance on seeking appropriate treatment and support and on reporting the event.

RESPONSE AND STATUS:

Whilst the role proposed is not within the scope of responsibilities of the Commission, the Commission has worked with the TGA to provide comment on the development of patient cards and information sheets, specific to transvaginal mesh devices.

RECOMMENDATION 3: The committee recommends that the Australian Government prioritise consideration of the implementation of Recommendation 22 of the report of the Review of Medicines and Medical Devices Regulation recommending the establishment of a registry for all high-risk implantable devices, together with consideration of the feasibility of establishing such a registry on a cost recovery basis, and provide to the Senate by 29 November 2018 a progress report on work to date.

RESPONSE AND STATUS:

The Commission will continue to work with the Department of Health in regard to a strategy for clinical quality registries (CQRs).

RECOMMENDATION 6: The committee recommends that the Australian Commission on Safety and Quality in Health Care prepare guidance material on effective informed consent processes, with a view to ensuring that a dialogue between a medical practitioner and patient should:

- **clarify the rationale for the proposed treatment;**
- **discuss the range of alternate treatment options available and their attendant risks and benefits;**
- **discuss the likely success and potential complications of the recommended treatment as they relate to the individual patient;**
- **provide an opportunity for the patient to ask questions; and**
- **confirm that the individual patient has understood the information discussed.**

RESPONSE AND STATUS:

The Commission has completed the development of a suite of resources which support improved informed consent processes and dialogue between medical practitioners and patients. These include consumer information resources on treatment options for SUI, POP and mesh complications, hospital credentialing guidance for senior medical practitioners and care pathways. The guidance for consumers includes a series of questions to support women in these discussions.

These resources were developed in consultation with women who had mesh implanted ,health consumer organisations, clinicians, and state and territory health departments.

The guidance for hospital credentialing of senior medical practitioners includes reference to the need to ensure appropriate consent processes are undertaken. The care pathways for SUI, POP and mesh complications provide a resource to support doctors in discussions with individual patients about their options for treatment.

These resources are available at: https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/resources/

RECOMMENDATION 7: The committee recommends that treatment guidelines developed by the Australian Commission on Safety and Quality in Health Care should clearly indicate that transvaginal mesh implantation should only be undertaken with fully informed consent and as a last resort when other treatment options have been properly considered and determined unsuitable.

RESPONSE AND STATUS:

The care pathways for SUI, POP and mesh complications developed by the Commission describe the clinical considerations to be made when assessing treatment options for women with POP and SUI.

The pathways for POP and SUI have two components; the first section is predominantly for general practitioners, and the second supports specialists. The mesh complications pathway provides guidance for general practitioners. These pathways have been shared with Primary Health Networks and states and territories for integration into primary and acute care, as appropriate.

The specialised surgical elements of the pathways for POP and SUI use a traffic light approach (red, yellow, green) to identify pathways options for surgical treatments, based on the levels of evidence for each type of procedure.

The consumer resources provide information on treatment options to assist decision making, and in discussions with their healthcare provider. The care pathways and the consumer information resources have been developed in such a way as to support clinicians in discussing options for treatment with women and inform the consent process.

Non-surgical treatments are recommended as the first line of treatment by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Urological Society of Australia and New Zealand (part of the Royal Australasian College of Surgeons).

RECOMMENDATION 8: The committee recommends that the medical professional specialist colleges and societies ensure that processes are in place to draw their members' attention to the resources released by the Australian Commission on Safety and Quality in Health Care and implement arrangements which require members to consider the resources in their practice.

RESPONSE AND STATUS:

The Commission has distributed the resources to the following Colleges and Societies and recommend that they be widely promulgated: Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Royal Australasian College of Surgeons, Urological Society of Australia and New Zealand, UroGynaecological Society of Australasia, Colorectal Surgical Society of Australia and New Zealand, Royal Australian College of General Practitioners, and the Australian College of Nursing.

The Commission has also written to Australian Health Practitioner Regulation Agency regarding the credentialing guidance and care pathways.

RECOMMENDATION 9: The committee recommends that the Commonwealth, state and territory health Ministers require that guidance developed by the Australian Commission on Safety and Quality in Health Care for the credentialing of medical practitioners who perform transvaginal mesh procedures should underpin credentialing processes in all public hospitals and work with private hospitals to encourage the adoption of a similar requirement.

RESPONSE AND STATUS:

The Commission has issued the credentialing guidance to all Australian health departments, the Australian Private Hospitals Association and relevant surgical societies and colleges.

RECOMMENDATION 11: The committee recommends that Commonwealth, states and territory governments commission the Australian Commission on Safety and Quality in Health Care to undertake an audit of transvaginal mesh procedures undertaken and their outcomes since the introduction of transvaginal mesh devices for use in the Australian market.

RESPONSE AND STATUS:

The audits of procedures recommended by the Committee is a matter for state and territory health departments and private health service providers.

The Commission is working collaboratively with the states and territories to promote prospective data collection for women having mesh procedures now and into the future; improved data collection by senior medical officers being credentialed to undertake these procedures; and, the establishment of appropriate services for women experiencing complications following mesh procedures. States and territories have indicated, through the Inter-Jurisdictional Committee, that these activities have already commenced which will better support women who undertake these procedures.

RECOMMENDATION 13: The committee recommends that State and Territory governments continue to work with the Australian Commission on Safety and Quality in Health Care to review the provision of services for the use and removal of transvaginal mesh devices. In particular, the committee recommends that consideration be given to the establishment of:

- **information and helplines that women who have received transvaginal mesh implants can contact for advice on the availability of treatment and support services, including financial support programs, in their state;**
- **specialist counselling programs, to assist women who have sustained injuries following transvaginal mesh procedures;**
- **specialist multidisciplinary units for the assessment and management of complications associated with transvaginal mesh procedures, comprising:**
- **comprehensive diagnostic procedures, including relevant diagnostic imaging facilities and expertise;**
- **specialist pain management expertise; and**
- **high level expertise in the partial or full removal of transvaginal mesh;**
- **advice and practical assistance for women who are seeking to access their medical records; and**
- **the provision of further guidance for medical professionals on recording the use of implantable devices on medical records and reporting adverse events to the TGA.**

RESPONSE AND STATUS:

The Commission has completed a service model framework to support state and territory health departments in their planning for services for the use of transvaginal mesh devices and management of mesh-related complications.

The planning and delivery of health services, appropriate to the needs of the populations they serve, is the responsibility of state and territory health departments.