AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

D18-4388

Senate Community Affairs References Committee – Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters

Australian Commission on Safety and Quality in Health Care Update

Status of Commission Guidance

The Commission is finalising a number of Guidance documents to improve health care for women considering the use of transvaginal mesh for pelvic organ prolapse (POP) and stress urinary incontinence (SUI), and for removal of transvaginal mesh.

The Guidance includes:

1. Patient information resources
2. Care pathways for POP and SUI
3. Training and credentialing of clinicians to implant and remove mesh for treatment of POP and SUI

The Guidance documents result from detailed consideration of the peer-reviewed evidence and consultation with consumers, clinicians, relevant colleges and surgical specialty societies, state and territory health departments, the Australian Government Department of Health and the Reference Group that was convened to support this work.

The Commission's Guidance documents have taken into account recent changes by the Therapeutic Goods Administration (TGA) to the registration of a number of transvaginal mesh devices on the Australian Register of Therapeutic Goods (ARTG). While registration for transvaginal mesh products for treatment of POP has been cancelled, there is still potential for clinicians to use these devices with the necessary approvals. For this reason, the Commission has continued to produce Guidance documents for POP.

The Commission will release the resources progressively between March and June 2018. Final approval processes are under way for the SUI and POP resources.

1. Patient information on treatment of POP and SUI and removal of mesh

The resources have been developed following extensive consultation with women affected by complications of transvaginal mesh.

The resources will explain the symptoms of POP and SUI, the range of treatment options – doing nothing, non-surgical and surgical treatments – and their risks and benefits. They will also include information about changes made by the TGA to remove transvaginal mesh products from the ARTG whose sole use is the treatment of POP via transvaginal implantation and single incision mini-slings for treatment of SUI, and advice that use of these mesh products in Australia now requires special approval.

Each resource will also include information on complications of transvaginal mesh treatment and where to find more detail about them and a list of questions which women might consider asking their doctor, prior to these procedures.

The Commission has commenced work on an information resource for women considering removal of transvaginal mesh following complications.

2. Care pathways for POP and SUI

These pathways describe the clinical considerations to be made when assessing women with POP and SUI. The pathways provide clinicians with an evidence-based approach to first line management, specialised surgical and non-surgical care and the types of medical specialists who may be involved in providing care.

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

These pathways provide an opportunity for alignment with the pathways used by a number of Primary Health Networks to also guide the discussions between women and their general practitioners.

The pathways are heavily based on the work of the International Collaboration on Incontinence, and the Commission acknowledges the contribution of this group in the development of the Commission's versions of the resources. The pathways are being developed as an interactive web version to allow easier access for clinicians reviewing treatment options and also in explaining various pathways to women considering treatment.

Final approval processes for the care pathways are under way. The Commission is also working on the development of a care pathway for removal of transvaginal mesh following complications.

3. Training and credentialing of senior medical practitioners who implant transvaginal mesh for treatment of POP and SUI and for mesh removal

Credentialing is the process used by public and private hospitals to ensure that only suitably experienced, trained and qualified medical practitioners provide particular types of services. Credentialing is essential to ensure the safety of patient care.

Guidance for credentialing and training of senior medical practitioners who implant transvaginal mesh for treatment of POP and SUI, and also for the removal of transvaginal mesh, was developed in consultation with the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Urological Society of Australia and New Zealand, the Reference Group and state and territory health departments.

The Guidance describes the experience and qualifications that senior medical practitioners need to be credentialed to implant and remove mesh for treatment of POP and SUI. It also includes recommendations on device specific training, the requirements for maintaining skills, monitoring and reporting on patient outcomes, the types of specialty supports services hospitals should have if they offer implantation and removal of transvaginal mesh and the requirement for post-operative follow-up.

The states and territories will use the Guidance in their local credentialing processes. The private sector also undertake credentialing processes, and the Commission will be working with the private sector to promote the use of these Guidance for credentialing across private hospitals.

States, territories and private health services
The use and removal of transvaginal mesh is of great importance to both public and private health services in Australia. Each state and territory is reviewing the provision of these services, and some have developed specific information resources and support services – for example, dedicated telephone information and referral services and improved coordination and designation of services to promote a more integrated means for women to access services.

The Commission is also finalising a service model framework which will describe the key elements of an optimal service for removal of transvaginal mesh. This resource will also bring together information on the services available in each jurisdiction.

The Commission will provide copies of the Guidance as they become available over the coming months.