

Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery

1. Introduction

State and territory health departments have asked the Australian Commission on Safety and Quality in Health Care (the Commission) to develop comprehensive guidance for consumers, clinicians and health services on the use of transvaginal mesh products for the treatment of both pelvic organ prolapse (POP) and stress urinary incontinence (SUI). One area of guidance required relates to the appropriate training and credentialing of clinicians who remove transvaginal mesh for those patients experiencing complications associated with the device.

The work being undertaken by the Commission to develop guidance complements work undertaken by a number of other organisations, including the Therapeutic Goods Administration and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) and the Urological Society of Australia and New Zealand (USANZ), aimed at improving the outcomes for women treated with transvaginal mesh implants.

It is important to note that on 28 November 2017 the Therapeutic Goods Administration (TGA) removed transvaginal mesh products whose sole use is the treatment of POP from the Australian Register of Therapeutic Goods (ARTG).

This followed a review by the TGA of the latest published international studies and an examination of the clinical evidence for each product included in the ARTG and supplied in Australia. Based on this new information, and since the publication by the TGA in 2014 of the [results of review into urogynaecological surgical mesh implants](#), the TGA is of the belief that the benefits of using transvaginal mesh products in the treatment of POP do not outweigh the risks these products pose to patients. The new conditions commenced 4 January 2018.

Furthermore, the TGA also announced that it considers that there is a lack of adequate scientific evidence for the safety and performance of the single incision mini sling devices for the treatment of stress urinary incontinence (SUI), and the risks to patients outweigh the benefits. These products have also been removed from the ARTG from 4 January, 2018. Mid-urethral slings remain on the ARTG.

On 17 January, 2018, the TGA issued further advice on its post-market review of urogynaecological mesh implants. It requires device sponsors of mid-urethral slings to include information about certain adverse events such as severe chronic pain, groin pain, and bladder perforation in the device Instructions for Use.

This Guidance has been developed in consultation with RANZCOG and the Royal Australasian College of Surgeons (RACS) for use by those hospitals (public and licensed non-government and private) responsible for credentialing senior medical practitioners to undertake transvaginal mesh removal surgery in their facilities. Separate Guidance is available in relation to transvaginal mesh surgery for SUI and POP.

The scope of transvaginal mesh removal surgery covered by this Guidance is elaborated upon in Section 3.

2. The Importance of Credentialing in Patient Safety

As stated in the Commission's 2015 publication, ***Credentialing health practitioners and defining their scope of clinical practice – a guide for managers and practitioners:***

“Credentialing and scope of clinical practice processes are key elements in ensuring the safety of consumers in health service organisations. The objective is to ensure that only health practitioners who are suitably experienced, trained and qualified to practise in a competent and ethical manner can practise in health service organisations. A practitioner’s scope of clinical practice is based on the individual practitioner’s skills, knowledge, performance and professional suitability in keeping with the needs and service capability of the organisation.”

All health service organisations should ensure a robust credentialing framework involving strong and transparent governance and clearly articulated policies. The Commission's 2015 Guide states:

“Health service organisations provide different types and levels of services in a variety of settings. They manage different levels of consumer need and complexity of care. They have different levels of resourcing and different technology and equipment available. They have different staffing levels and skill-mix and require practitioners to have different qualifications, skills and experience that are matched to the organisation’s capability and consumer demand.

Not all services or all levels of care can or should be delivered in all settings or facilities. Organisational and service needs and capabilities must be known (and appropriately documented) so that health practitioners’ skills, knowledge and qualifications can be matched to their scope of clinical practice.

Delineating the level and type of services to be provided within a health service is an essential component of determining scope of clinical practice for a practitioner.”

3. Context and Scope of this Guidance

Patients experiencing significant complications related to the implantation of mesh, trans-vaginally, particularly with regard to pain and the involvement of other organs, require careful assessment to determine an appropriate response, including whether substantial removal of the implant is indicated, as part of a multi-disciplinary treatment regimen to address the patient's symptoms and complications.

Substantial removal of transvaginal mesh requires a multi-disciplinary specialty team, which includes access to consultation with specialist urogynaecologist, urologist, colorectal surgeon, pelvic floor physiotherapists, diagnostic pelvic floor ultrasound capacity, comprehensive urodynamic testing, psychiatry, psychology and pain services). Consultation services may be achieved through networked or telehealth service provision.

Owing to the level of complexity involved with substantial removal, in terms of the procedure itself and that of the patients presenting with significant complications from transvaginal mesh surgery, specific credentialing for substantial removal of mesh which has been trans-vaginally implanted is warranted.

Substantial removal is to be distinguished from a procedure involving removal of smaller amounts of exposed mesh with the purpose of retaining it as a functioning device to improve its functionality and/or the patient experience associated with it.

This Guidance only applies to surgery involving the substantial removal of mesh which has been trans-vaginally implanted. It does not apply to any procedure involving initial adjustment of a mesh implant with the purpose of retaining it as a functioning device but improving its functionality and/or the patient experience associated with it.

However, any second or subsequent adjustment of a mesh device involving an individual patient, regardless of the amount of mesh to be removed or the time interval between adjustment procedures, is to be considered a “substantial removal” for the purposes of this Guidance. This is irrespective of whether the same or different medical practitioners undertook the initial implantation and/or the initial adjustment of the device.

It is also noted that legal and professional obligations of medical practitioners and hospitals require adequate documentation and record keeping of the information provided to patients in obtaining consent to medical treatment, as well as reasonable details of the medical treatment provided and the progress of the patient as a consequence of that treatment.

This Guidance should be read in conjunction with the ***Guidance for Hospital Credentialing of Medical Practitioners to undertake Transvaginal Mesh surgery for Pelvic Organ (Vaginal) Prolapse*** and ***Guidance for Hospital Credentialing of Medical Practitioners to undertake Transvaginal Mesh surgery for Stress Urinary Incontinence***, which cover both implantation of mesh trans-vaginally, as well as adjustment of mesh implants to improve functionality and/or patient experience.

4. Core training and experience for senior medical practitioners who have not previously independently performed transvaginal mesh removal surgery as the primary operator

4.1 Removal of mesh which has been trans-vaginally implanted (***the procedure***) should only be performed by a senior medical practitioner, as primary operator, who satisfies the following criteria:

4.1.1 the medical practitioner has requisite knowledge, surgical skills and experience in female pelvic reconstructive surgery encompassing a thorough understanding of female pelvic anatomy as follows:

(i) he/she is a fellow of the RANZCOG and/or registered by the Medical Board of Australia (MBA) in the specialty of obstetrics and gynaecology, and he/she is a RANZCOG certified urogynaecologist and/or is authorised by the MBA to use the title “specialist urogynaecologist”;

or

(ii) he/she is a fellow of the RANZCOG and/or registered by the MBA in the specialty of obstetrics and gynaecology who is authorised to use the title “specialist obstetrician and gynaecologist”, and:

(a) he/she has successfully completed the RANZCOG advanced training module for pelvic floor surgery; and

(b) following completion of the module, he/she has undertaken a further period of at least one year’s audited practice in pelvic floor surgery;

or

(iii) he/she is a fellow of RACS and/or registered by the MBA in the specialty of surgery and:

(a) he/she is a RACS certified urologist and/or is authorised by the MBA to use the title “specialist urologist”; and

(b) he/she has at least 1 year’s post fellowship (or similar) training in the specific area of female and functional urology which has included training in vaginal prolapse surgery;

or

- (iv) he/she is a fellow of RACS and/or registered by the MBA in the specialty of surgery and:
 - (a) he/she is a RACS certified general surgeon and/or is authorised by the MBA to use the title “specialist general surgeon”; and
 - (b) he/she has undergone at least one year’s post fellowship (or similar) training in colorectal surgery which has included a significant focus on female pelvic floor related surgery and direct training in rectocele repair;

4.1.2 the medical practitioner **also** has specific supervised and documented training in the removal procedure as set out in 4.2 below.

4.2 To satisfy 4.1.2 above, a medical practitioner should be able to demonstrate specific supervised and documented training in the procedure under the supervision of a medical practitioner who is fully credentialed (in accordance with this Guidance) to perform the procedure, comprising as many surgeries as necessary, to demonstrate the *supervised* practitioner can independently perform the procedure safely and efficiently, and in cases where it is appropriately indicated.

The *supervising* practitioner should be able to perform an independent evaluation of the trainee and that evaluation should be clearly documented.

4.3 In respect of a specialist general surgeon who satisfies paragraphs 4.1.1 (iii) and 4.2, his/her scope of practice/clinical privileges in relation to the procedure is to be limited to the removal of mesh related to rectocele repair and must involve specific case consultation with at least one other medical practitioner who is either a specialist urogynaecologist or a specialist urologist, who is also credentialed to perform the procedure.

5. Transitional provision – senior medical practitioners who currently independently perform transvaginal mesh removal surgery as primary operator

Note: *This section applies to those senior medical practitioners who have been independently performing the procedure as primary operator at the time this Guidance is implemented in the hospital in which they are performing the procedure*

5.1 Removal of mesh which has been trans-vaginally implanted (**the procedure**) should only be independently performed by a medical practitioner, as primary operator, who satisfies the following criteria:

5.1.1 the medical practitioner has requisite knowledge, surgical skills and experience in female pelvic reconstructive surgery encompassing a thorough understanding of female pelvic anatomy as follows:

- (i) he/she is a fellow of the RANZCOG and/or registered by the Medical Board of Australia (MBA) in the specialty of obstetrics and gynaecology, and he/she is a RANZCOG certified urogynaecologist and/or is authorised by the MBA to use the title “specialist urogynaecologist”;
or
- (ii) he/she is a fellow of RACS and/or registered by the MBA in the specialty of surgery and:
 - (a) he/she is a RACS certified urologist and/or is authorised by the MBA to use the title “specialist urologist”; and

(b) he/she has at least 1 year's post fellowship (or similar) training in the specific area of female and functional urology which has included training in vaginal prolapse surgery;

or

(iii) he/she is a fellow of RACS and/or registered by the MBA in the specialty of surgery and:

(a) he/she is a RACS certified general surgeon and/or is authorised by the MBA to use the title "specialist general surgeon"; and

(b) he/she has undergone at least one year's post fellowship (or similar) training in colorectal surgery which has included a significant focus on female pelvic floor related surgery and direct training in rectocele repair;

5.1.2 the medical practitioner **also** has demonstrated requisite knowledge, surgical skills and experience in transvaginal mesh removal, as set out in 5.2.

5.2 To satisfy 5.1.2 above, the senior medical practitioner should provide to the relevant Credentials Committee (however called) documentation evidencing his/her relevant surgical experience, continuing professional development and patient outcomes, covering at least the immediately prior 2 year period, or such longer period as the relevant Credential Committee requires.

The documentation should demonstrate the medical practitioner can undertake the procedure safely and efficiently, and in cases where appropriately indicated.

5.3 In respect of a specialist general surgeon who satisfies paragraphs 5.1.1 (iii) and 5.2, his/her scope of practice/clinical privileges in relation to the procedure is to be limited to the removal of mesh related to rectocele repair and must involve specific case consultation with at least one other medical practitioner who is either a specialist urogynaecologist or a specialist urologist, who is also credentialed to perform the procedure.

6. Skills maintenance and review

6.1 Subject to 6.2 below, a medical practitioner should only continue to be credentialed to perform the removal procedure as primary operator if he/she provides at least two yearly¹ documentation of:

(i) annual continuing professional development (CPD) in substantial mesh removal surgery in each of the years; **and**

(ii) routine participation in prospective tracking of his or her patients' outcomes, which is transparent and clearly documented in accordance with specified criteria, and which demonstrates the practitioner can continue to perform these procedures safely and efficiently, and in cases where it is appropriately indicated.

6.2 Where the relevant Credentials Committee (however called) considers it necessary, the Committee should require the medical practitioner to undergo further proctorship in order to determine if the medical practitioner can continue to independently undertake the procedure safely and efficiently, and in cases where it is appropriately indicated, as primary operator.

7. Patient Outcome Monitoring and Reporting

7.1 Maintaining quality assurance after the implementation phase of this Guidance, through regular internal audits, at the local departmental, institutional and/or statewide or national registry level, should be required of all medical practitioners performing the procedure.

- 7.2 Medical practitioners should follow their patients postoperatively and comply with any local institutional and relevant professional organisations' requirements concerning patient outcomes, and the audit thereof.
- 7.3 Patient outcomes from undergoing transvaginal mesh removal surgery should be clearly recorded through properly maintained logbooks or other suitable documentation, citing the medical record number for each patient undergoing the procedure and including the following information:
- (i) the results of post-operative monitoring of the patient over a minimum 6 month period including:
 - Documentation of residual mesh erosion, extrusion or exposure and level of retained mesh
 - patient reported level of improvement and satisfaction
 - Persisting groin or pelvic pain.
 - (ii) any of the following events, at whatever point they come to the medical practitioner's attention:
 - Injury to the pelvic organs or major blood vessels
 - Injury to the gastro-intestinal tract
 - Blood loss > 500 ml for procedure
 - New or worsening vaginal, pelvic or groin pain
 - New onset or worsening dyspareunia
 - Persistent neurologic injury.
 - Readmission/re-operation for complications related to removal surgery
 - Sepsis
 - Death from any cause, with cause recorded.

8. Local institutional role and facilities

Access to multi-disciplinary expertise

- 8.1 Substantial removal of transvaginal mesh should only be undertaken in those hospitals which have a multi-disciplinary specialty service (including access to consultation with specialist urogynaecologist, urologist, colorectal surgeon, pelvic floor physiotherapists, diagnostic pelvic floor ultrasound capacity, comprehensive urodynamic testing, psychiatry, psychology and pain services). These services may be obtained through networking or telehealth service models.

Documented process for post-operative follow up

- 8.2 Any hospital that credentials medical practitioners to perform the procedure as part of their scope of practice/clinical privileges should ensure that it has in place a transparent and well-documented process that those undertaking the procedures should adhere to for post-operative follow up of patients. Such hospitals should also ensure there is regular audit of this data, undertaken at arms-length from the relevant medical practitioner, which can be relied on by the hospital when reviewing the medical practitioner's scope of practice/privileges for these procedures.

This guidance will be reviewed periodically to ensure it is consistent with the latest evidence.

ⁱ Given current concerns surrounding both the clinical safety of transvaginal mesh devices, and the complexity of their removal, a period of 2 years is considered appropriate. This period may increase depending on future evidence concerning the clinical safety of procedures relating to transvaginal mesh.