

# Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Surgery for Pelvic Organ (Vaginal) Prolapse

## 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 implant and remove mesh for treatment of POP.

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 for POP.

On 28 November 2017 the Therapeutic Goods Administration (TGA) announced the intention to remove transvaginal mesh products whose sole use is the treatment of POP from the Australian Register of Therapeutic Goods (ARTG). These products were removed from the ARTG from 4 January, 2018.

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 has determined that the risks of using transvaginal mesh products posed to patients in the treatment of POP outweigh the benefits. The new conditions commenced on 4 January 2018.

This Guidance has been developed, having regard to the revised regulatory context, 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 surgery for POP in their facilities. Separate Guidance is available in relation to transvaginal mesh surgery for SUI and the removal of transvaginal mesh.

## 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.”*

The key elements of credentialing frameworks that hospitals and other relevant health service organisations should establish are set out in the 2015 Guide:

- “• *establishing credentialing committees (however named or constituted) with clearly delineated terms of reference, and ensuring that committee members understand their responsibilities and have the required knowledge and skills to fulfil their responsibilities*
- *providing human resource support for the purposes of undertaking routine appointment and re-appointment processes such as issuing appointment letters (or contracts), developing or reviewing position descriptions, and conducting criminal record and working with children checks as required*
- *establishing mechanisms for the exchange of information between human resources and those with responsibility for credentialing and determining the scope of clinical practice, particularly when matters of concern with practice are identified*
- *identifying positions within the organisation that are to be the subject of formal credentialing and scope of clinical practice processes, and informing staff in those roles of their responsibilities*
- *engaging the highest level of clinical leadership to guide the credentialing processes and informing staff responsible for determining the scope of clinical practice of their responsibilities*
- *documenting the processes for modifying a health practitioner’s scope of clinical practice. This might be necessary if an organisational or individual practitioner’s capabilities change or if (for example) practice restrictions are placed on a health practitioner by a registration board or a service is ceased*
- *informing those responsible for credentialing and determining the scope of clinical practice of the relevant jurisdictional requirements*
- *establishing an appropriate system to review and validate the processes for credentialing, defining and managing scope of clinical practice and ensuring these are diligent and effective.”*

### 3. Context for this Guidance

There is a strong consensus both in Australia and internationally that:

- (i) the role of primary operator in transvaginal mesh surgery for POP is the province of those medical practitioners who are accredited gynaecologists or urologists, although other specialists such as colorectal surgeons also play a role in specific types of cases.
- (ii) the performance of mesh surgery for POP requires specific training and experience over and above core specialist training in gynaecology or urology and should be the subject of specific credentialing.

- (iii) the greater the level of experience the lower the complication rate for these procedures.
- (iv) the performance of transvaginal mesh surgery for POP should occur in the context of careful patient selection, and assessment and treatment decisions involving a multi-disciplinary team, unit or formally established network.

Given the current lack of clinical evidence supporting the use of mesh devices for POP and the prevailing regulatory framework for mesh intended for implantation transvaginally for the treatment of POP, medical practitioners should only be credentialed to perform transvaginal mesh procedures for POP subject to the regimen of a formal clinical trial approved by an eligible Human Research Ethics Committee (HREC), being either a HREC which has certification in a relevant category from the National Health and Medical Research Council, or one which is designated by a jurisdiction.

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 has been developed consistent with, and to support the implementation of, these essential elements for undertaking transvaginal mesh surgery for POP safely and efficiently, and in cases where appropriately indicated.

A procedure involving initial adjustment of a mesh implant for the purpose of retaining it as a functioning device but improving its functionality and/or the patient experience associated with it is to be distinguished from a procedure involving substantial removal of trans-vaginally implanted mesh.

This Guidance covers credentialing for a procedure involving both the implantation of mesh trans-vaginally for POP, or any subsequent procedure involving an initial adjustment of such a mesh implant for 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.

This Guidance does not cover substantial removal of transvaginally implanted mesh. The **Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery** applies to clinicians seeking to perform substantial mesh removal or second or further adjustments of transvaginal mesh.

**This Guidance should be read in conjunction with the Commission Guidance on Clinical Care Pathways for the treatment of POP.**

#### 4. Core training and experience for senior medical practitioners who have not previously independently performed transvaginal mesh surgery for POP

4.1 A medical practitioner who has not previously independently performed transvaginal placement of surgical mesh for Pelvic Organ (vaginal) Prolapse (***the procedure***) should only be credentialed to perform the procedure independently as the primary operator subject to the regimen of a formally registered clinical trial, with approval of an eligible HREC, and only if he or she satisfies the following criteria:

4.1.1 the medical practitioner is:

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

**or**

(ii) 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) who has successfully completed the RANZCOG advanced training module for pelvic floor surgery; and
- (b) who, following completion of the module, has undertaken a further period of at least one year’s audited practice in pelvic floor surgery;

**or**

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

- (a) who is a RACS certified urologist and/or is authorised by the MBA to use the title “specialist urologist”; and
- (b) who 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) a fellow of RACS and/or registered by the MBA in the specialty of surgery and:

- (a) who is a RACS certified general surgeon and/or is authorised by the MBA to use the title “specialist general surgeon”; and
- (b) who 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 requisite knowledge, surgical skills and experience in pelvic reconstructive surgery encompassing a thorough understanding of female pelvic anatomy, **and**
- (i) in respect of a specialist obstetrician and gynaecologist or specialist urologist, experience and competence in non-mesh vaginal repair of prolapse including anterior compartment repair, posterior compartment repair, and vaginal apical support, and experience in performing intraoperative cystoscopy to evaluate for bladder and ureteral integrity, **or**
  - (ii) in respect of a specialist general surgeon, experience and competence in rectocele repair;
- 4.1.3 the medical practitioner **also** has specific supervised and documented training in the transvaginal mesh (TVM) procedure, as set out in 4.2 and 4.3 below.

4.2 To satisfy 4.1.3 above, specific supervised and documented training in the TVM procedure should comprise the performance of as many surgeries as necessary under the supervision of a medical practitioner who is fully credentialed (in accordance with this Guidance) to independently perform the procedure as the primary operator, to demonstrate the *supervised* practitioner can independently perform the procedure as the primary operator safely and efficiently, and in cases where it is appropriately indicated.

4.3 At the conclusion of the supervised training in the procedure, the *supervised* practitioner must demonstrate **all** of the following:

- (i) familiarity with the clinical care pathways guidance issued by the Commission;
- (ii) the ability to diagnose and select patients who are appropriate to undergo the procedure;
- (iii) the ability to explain the procedure, potential outcomes and potential complications at the time of obtaining the patient's informed consent, including the ability to clearly and accurately explain and document the alternative treatments available;
- (iv) the knowledge of appropriate pelvic anatomy and potential areas of safety/risk associated with the procedure;
- (v) the ability to perform the actual procedure safely and efficiently; and
- (vi) the capacity to track outcomes and complications.

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

4.4 In respect of a medical practitioner who is a specialist general surgeon, the scope of practice/clinical privileges related to the transvaginal placement of mesh is to be limited 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 surgery for POP as the primary operator**

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

5.1 For a medical practitioner who already independently performs transvaginal placement of surgical mesh for POP (**the procedure**) as the primary operator, he/she should only be credentialed, or continue to be credentialed, to perform the procedure subject to the regimen of a formally registered clinical trial, with approval from an eligible HREC and should also satisfy the following criteria:

5.1.1 the medical practitioner is:

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

**or**

(ii) a fellow of RACS and/or registered by the MBA in the specialty of surgery and:

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

(b) who 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) a fellow of RACS and/or registered by the MBA in the specialty of surgery and:

(a) who is a RACS certified general surgeon and/or who is authorised by the MBA to use the title “specialist general surgeon”; and

(b) who 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 he/she **also** has demonstrated requisite knowledge, understanding, surgical skills and experience in female pelvic reconstructive surgery, including both mesh and non-mesh vaginal repair, as set out in 5.2 below;

5.1.3 he/she is **also** familiar with the clinical care pathways Guidance issued by the Commission.

5.2 To satisfy 5.1.2 above:

5.2.1 the senior medical practitioner should provide to the relevant Credentials Committee (however called), a record detailing 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;

- 5.2.2 the record should include details of the performance of any mesh and non-mesh vaginal repairs of prolapse, demonstrating experience and competence in female pelvic floor surgery, including:
- (i) in the case of a specialist obstetrician and gynaecologists or specialist urologist, anterior compartment repair, posterior compartment repair, and vaginal apical support, and experience in performing intraoperative cystoscopy to evaluate for bladder and ureteral integrity; **or**
  - (ii) in the case of a specialist general surgeon, rectocele repair;
- 5.2.3 the record should demonstrate the medical practitioner can undertake the TVM procedure safely and efficiently, and in cases where appropriately indicated.

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

## **6. Device specific training**

- 6.1 The scope of practice/clinical privileges granted to medical practitioners permitted to perform transvaginal placement of surgical mesh for POP, must include initial training specific to each kind of device, technology or delivery system they propose to use in these procedures. This must be achieved subject to the regimen of a formal clinical trial approved by an eligible HREC. For any device, technology or delivery system involving the transvaginal placement of mesh for POP, practitioners should meet the requirements of the TGA with regard to unregistered devices and:
- read any manufacturer’s instructions for use;
  - observe steps involved in the procedure via animation, video or live surgery;
  - undergo hands on experience with the procedure using simulated models, animal or cadaveric models or other accepted learning models;
  - consider specific intraoperative and postoperative complications that may be unique to that procedure or device and the steps necessary to manage those complications;
  - be familiar with the clinical care pathways guidance issued by the Commission;
  - be familiar with the requirements for adequate informed patient consent including the ability to clearly and accurately explain and document the alternative treatments available;
  - demonstrate they can independently perform the procedure using the newly adopted device, technology or delivery system safely and efficiently, and in cases where it is appropriately indicated.
- 6.2 The introduction or use of any new or unapproved devices, technologies or delivery systems involving transvaginal mesh implants for POP should be subject to the regimen of a formally registered clinical trial, with an eligible HREC’s approval, until there is sufficient data to support their efficacy and subsequent regulatory approval.

## **7. Skills maintenance and review**

- 7.1 Any medical practitioner who is credentialed to perform the procedure should provide at last two yearly<sup>j</sup> documentation of:
- (i) annual continuing professional development (CPD) in female pelvic medicine and pelvic floor surgery in each of the years; **and**
  - (ii) practice that includes a significant component of pelvic floor surgery each year; **and**
  - (iii) 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 is able to perform these procedures safely and efficiently, and in cases where it is appropriately indicated.
- 7.2 Where the relevant Credentials Committee (however called) considers it necessary, the Committee should require the medical practitioner to undergo proctorship in order to determine if the medical practitioner can undertake the procedure safely and efficiently, and in cases where it is appropriately indicated.

## **8. Patient Outcome Monitoring and Reporting**

- 8.1 Medical practitioners should follow their patients postoperatively and comply with any national reporting of device use and adverse events, as well as adhering to any local institutional and relevant professional organisations' requirements concerning patient outcomes, and the audit thereof.

In addition medical practitioners must meet all data collection and reporting requirements under the conditions of a formally registered clinical trial which has been approved by an eligible HREC.

- 8.2 At a minimum, patient outcomes from undergoing transvaginal mesh surgery for POP 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:
    - Patient reported level of improvement and satisfaction
    - Objective measures of prolapse
    - 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
    - Blood loss > 500 ml for procedure
    - Recurrent urinary tract infection
    - Documentation of mesh erosion, extrusion or exposure
    - New onset vaginal pain lasting longer than 6 weeks
    - Groin or pelvic pain lasting longer than 6 weeks
    - Fistula formation
    - New onset or worsening dyspareunia
    - Persistent neurologic injury
    - Retreatment for recurrent prolapse including further surgery and/or pessary use



- Readmission and re-operation for complications related to prolapse surgery
- Sepsis
- Death from any cause, with cause recorded.

## 9. Local institutional role and facilities

### *Access to multi-disciplinary expertise*

9.1 Transvaginal mesh procedures for POP should only be undertaken in those hospitals where the following criteria are satisfied:

9.1.1 any such procedure is only performed subject to the regimen of a formal clinical trial, with an eligible HREC's approval; **and**

9.1.2 one of the following applies:

- (i) the hospital has a high volume multi-disciplinary specialty service (including specialist urogynaecologist, urologist, colorectal surgeon and pelvic floor physiotherapists) treating pelvic organ (vaginal) prolapse; **or**
- (ii) any medical practitioner credentialed by the hospital to perform these procedures has confirmed access to an established multi-disciplinary network (including specialist urogynaecologist, urologist, colorectal surgeon and pelvic floor physiotherapists), and members of the network are involved as appropriate; having regard to the Commission clinical care pathways Guidance, in patient diagnosis, selection and pre-operative assessment of patients being considered for these procedures.

### *Documented process for post-operative follow up*

Any hospital that credentials medical practitioners to perform the TVM 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 as part of a formally registered clinical trial with an eligible HREC's approval.

Such hospitals should also ensure there is 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.**

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<sup>i</sup> Given current concerns surrounding both the clinical safety of trans vaginal 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.