

Guidance for Hospital Credentialing of Senior Medical Practitioners to Undertake Transvaginal Mesh Surgery for Stress Urinary Incontinence

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 mesh devices for the treatment of SUI.

The work being undertaken by the Commission to develop guidance complements work undertaken by a number of other organisations, including the Royal Australian, 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.

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 (TVM) surgery for SUI in their facilities. Separate Guidance is available in relation to transvaginal mesh surgery for POP and the removal of transvaginal mesh.

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

On 28 November 2017 the Therapeutic Goods Administration (TGA) 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 SUI, and the risks to patients outweigh their benefits. These products have been removed from the Australian Register of Therapeutic Goods (ARTG) from 4 January 2018. Mid-urethral slings remain on the ARTG.

On the 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.

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 and Scope of this Guidance

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

- (i) the role of primary operator in transvaginal mesh surgery for SUI is the province of those medical practitioners who are accredited gynaecologists or urologists.
- (ii) there is robust evidence nationally and internationally to support the use of traditional mid-urethral slings (MUS) for SUI in appropriate cases.
- (iii) the introduction of new devices, delivery systems or technologies involving transvaginal mesh implants for SUI such as Single Incision Slings should only occur within the context of a formal clinical trial, until there is sufficient data to support their efficacy.

- (iv) the greater the level of experience of the operator the lower the complication rate for this procedure.
- (v) the performance of transvaginal mesh surgery for SUI should generally occur in the context of assessment and treatment decisions, when conservative treatment has been unsuccessful.

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.

Medical practitioners should only be credentialed to perform transvaginal mesh procedures for SUI which involve new or other devices, systems or technologies not listed on the ARTG subject to the regimen of a clinical trial approved by an eligible Human Research Ethics Committee (HREC), being a HREC which either has certification in a relevant category from the National Health and Medical Research Council, or one which is designated by a jurisdiction.

This Guidance has been developed to be consistent with, and to support the implementation of, these essential elements for undertaking transvaginal mesh surgery for SUI safely and efficiently, and in cases where this procedure is 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 SUI, 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 Stress Urinary Incontinence.

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

4.1 A senior medical practitioner who has not previously independently performed TVM surgery for SUI (***the procedure***) should only be credentialed to independently perform the procedure if he or she satisfies the following criteria:

4.1.1 the medical practitioner:

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

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

4.2 To satisfy 4.1.2, a senior medical practitioner must be:

4.2.1 a RANZCOG certified urogynaecologist and/or authorised by the MBA to use the title “specialist urogynaecologist; ***or***

4.2.2 a specialist urologist who has at least 1 years’ post fellowship (or similar) training in the specific area of female and functional urology; ***or***

4.2.3 a medical practitioner authorised by the MBA to use either the title “specialist urologist” or “specialist obstetrician and gynaecologist”:

- (i) who can demonstrate specific supervised and documented training in the procedure under the supervision of a senior medical practitioner who is fully credentialed to perform the procedure; and
- (ii) who must as part of that supervised training undertake as many surgeries as necessary to satisfy section 4.3 below, in order to demonstrate he or she can independently undertake the procedure safely and efficiently, and in cases where it is appropriately indicated.

4.3 To satisfy 4.2.3 (ii), 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;
- (vi) the capacity to track outcomes and complications.

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

5. Transitional provision - Senior medical practitioners who currently independently perform transvaginal mesh surgery for SUI

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

- 5.1 For a senior medical practitioner who currently independently performs TVM surgery for SUI (**the procedure**), in order to be credentialed, or continue to be credentialed, to perform the procedure, he/she should satisfy the following criteria:
- 5.1.1 (i) the medical practitioner is a fellow of the RANZCOG and/or is registered by the Medical Board of Australia (MBA) in the specialty of obstetrics and gynaecology, and is authorised by the MBA to use the title “specialist obstetrician and gynaecologist” or “specialist urogynaecologist”; or
- (ii) the medical practitioner is a fellow of the RACS and/or is registered by the MBA in the specialty of surgery, and he/she is a RACS certified urologist and/or authorised by the MBA to use the title “specialist urologist”; and
- 5.1.2 he/she **also** has demonstrated requisite surgical skills and experience in the performance of the procedure as set out in 5.2 and 5.3; and
- 5.1.3 he/she **also** has demonstrated requisite knowledge and understanding in the treatment of SUI, including both mesh and non-mesh surgical treatments and other non-surgical treatments, and when each such treatment is appropriately clinically indicated, as set out in 5.2 and 5.3; and
- 5.1.4 he/she is **also** familiar with the relevant clinical care pathways Guidance issued by the Commission.
- 5.2 To satisfy 5.1.2 and 5.1.3 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 Credentials Committee requires, which demonstrates he or she can undertake the procedure safely and efficiently, and in cases where appropriately indicated.
- 5.3 Where the relevant Credentials Committee considers it necessary, in addition to the documentation submitted in accordance with 5.2, the Committee should require the medical practitioner to undergo further proctorship in order to determine if the medical practitioner can undertake the procedure safely and efficiently, and in cases where it is appropriately indicated.

6. Device specific training

- 6.1 It should be a condition of the scope of practice/clinical privileges granted, that medical practitioners permitted to perform transvaginal placement or adjustment of surgical mesh for SUI, must undergo training specific to each kind of device, technology or delivery system they propose to use in these procedures. In order to demonstrate specific knowledge of a particular device, technology or delivery system, practitioners should:
- (i) read the manufacturer's instructions for use;
 - (ii) observe steps involved in the procedure via animation, video or live surgery;
 - (iii) undergo hands on experience with the procedure using simulated models, animal or cadaveric models or other accepted learning models;
 - (iv) consider specific intraoperative and postoperative complications that may be unique to that procedure or device and the steps necessary to manage those complications;
 - (v) be familiar with the clinical care pathways guidance issued by the Commission;
 - (vi) be familiar with the requirements for adequate informed patient consent, including the ability to clearly and accurately explain and document the alternative treatments available;
 - (vii) except in the context of a formal clinical trial applying to new and/or unapproved devices technologies or delivery systems not listed in the ARTG, be proctored on as many procedures as necessary, to 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 new and/or unapproved devices, technologies or delivery systems involving transvaginal mesh implants for SUI, including Single Incision Slings, not listed in the ARTG, should be subject to the regimen of a formal 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 yearlyⁱ documentation of:
- (i) annual continuing professional development (CPD) in the treatment of female stress urinary incontinence in each of those years;
 - (ii) having undertaken a minimum of 10ⁱⁱ surgeries for SUI (either mesh or non-mesh) each year over that period; and
 - (iii) routine participation in prospective tracking of his or her patients' outcomes, which is transparent and clearly documented in accordance with specified criteria, which has been subject to independent clinical audit and which demonstrates the practitioner can continue to perform these procedures safely and efficiently.
- 7.2 Where the medical practitioner has done less than 10 procedures each year in accordance with 7.1 (ii), or where the relevant Credentials Committee (however called) otherwise considers it necessary after reviewing the submitted documentation, the Committee should require the medical practitioner to undergo further 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 Maintaining quality assurance after the implementation phase for this Guidance through regular internal audits, at the local departmental, institutional level and/or statewide or national registry level, should be required of all medical practitioners performing the procedure.
- 8.2 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, for new and/or unapproved mesh devices not listed in the ARTG, medical practitioners must meet all data collection and reporting requirements under the conditions of a formal clinical trial which has been approved by an eligible HREC.
- 8.3 At as minimum patient outcomes from undergoing TVM surgery for SUI 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 over a minimum six month period including:
- Patient reported level of improvement and satisfaction
 - Objective measures of incontinence, if appropriate
 - Urinary retention
 - Over active bladder
 - Persisting groin or pelvic pain.
- (ii) any of the following events, at whatever point they come to the medical practitioner's attention:
- Recurrent urinary tract infection
 - Injury to the pelvic organs or major blood vessels
 - Blood loss > 500 ml for procedure
 - Documentation of mesh erosion, extrusion or exposure
 - New onset vaginal pain lasting longer than 6 weeks
 - New onset or worsening dyspareunia
 - Persistent neurologic injury or groin or pelvic pain lasting longer than 6 weeks.
 - Over active bladder
 - Retreatment for recurrent incontinence including further surgery
 - Readmission and re-operation for complications related to continence surgery
 - Sepsis
 - Death from all causes, with cause recorded.

9. Local institutional role and facilities

Any hospital that credentials medical practitioners to perform TVM surgery for SUI 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.

Where new and/or unapproved mesh devices not listed in the ARTG, are proposed to be used hospitals should ensure this only occurs subject to the regimen, including the data collection and reporting requirements, of a clinical trial which has been approved by an eligible HREC.

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.

ⁱⁱ See Mowat A, Maher, Ballard E, Surgical outcomes for low volume vs high volume surgeons in gynecology surgery: a systematic review and meta-analysis, *American Journal of Obstetrics & Gynecology*, July 2016; 21 – 32; See Welk B, Hana'a A, Winick N, Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence, 9 September 2015 ; *JAMA Surg.*2015;150 (12):1167 – 1175