Safety Notice 015/17

Transvaginal mesh implants for Pelvic Organ (Vaginal) Prolapse

20 December 2017

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance

We recommend you also inform:

- Directors of Gynaecology
- Directors of Surgery
- Directors of Nursing
- Directors of Pain Services
- Directors of Emergency
- Managers of Mental Health Services
- Managers of Physiotherapy Services
- Medical Records Departments
- Drugs and Therapeutics Committees

Expert Reference Group

Content reviewed by:

- Office of the Chief Health Officer
- Transvaginal Mesh Clinical Network
- Transvagainal Mesh Taskforce

Clinical Excellence Commission

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Background

Severe complications following the use of transvaginal mesh to surgically treat pelvic organ (vaginal) prolapse have been reported by women in Australia and overseas. Although most women who receive the procedure have good results, complications occur in 8 to 15% of cases. Most complications are minor or temporary, however, a number of women experience severe complications.

The Therapeutic Goods Administration (TGA) has announced that all transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse, will be removed from the Australian Register of Therapeutic Goods (ARTG), effective 4 January 2018. Single incision mini-slings for the treatment of stress urinary incontinence will also be removed.

Please note that these actions **do not** affect standard mid-urethral slings for the treatment of stress urinary incontinence.

Recommendations for NSW Health facilities

Use of transvaginal mesh for pelvic organ prolapse

Mesh products

From 4 January 2018, mesh products removed from the ARTG must be quarantined and can only be lawfully supplied to patients through special access arrangements under the *Therapeutic Goods Act 1989*. Device sponsors will communicate directly with customers. For a full list of affected mesh products see the TGA alert

https://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants

All patients receiving a transvaginal mesh implant for pelvic organ prolapse under special access arrangements should have the device's product name and batch number included in their surgical record and discharge summary.

Patient selection and surgeon experience

NSW Health recommends that transvaginal mesh for pelvic organ prolapse should only be used in carefully selected patients with a high risk of recurrence under special access arrangements. A comprehensive diagnostic assessment should be made pre-operatively. The procedure should only be performed at high volume units by an experienced pelvic surgeon in consultation with a urogynaecologist.

Informed consent

Surgeons should comprehensively discuss the potential risks and benefits of the procedure with patients, including any alternative approaches. All patients considering the procedure should be provided with the NSW Health information sheet (see Resources on page 2). Further input into patient management may be sought from another specialist or from a multidisciplinary team arrangement.

Doctors who have a financial relationship with a mesh company are expected to declare any conflict of interest as recommended by *Good Medical Practice: A Code of Conduct for Doctors in Australia*. This includes informing patients when the doctor has an interest that could affect, or could be perceived to affect, patient care.

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Management of possible mesh-related complications

Accessing medical records

Patients who have had a transvaginal mesh procedure may seek access to their medical record. Patients should be assisted to access their medical record if requested. Where health information sought relates to continued treatment and/or future management, no charge should be raised, as per NSW Health policy directive *Health Records and Medical/Clinical Reports – Charging Policy* (PD 2006_050).

Information and referral to specialist services

Patients who have had a transvaginal mesh procedure may present with symptoms they are concerned could be mesh-related. Information sheets are available and should be provided to these patients (see Resources below).

In addition, patients should be supported to access multidisciplinary specialist services for the assessment and management of mesh complications.

Mesh removal should only be considered at specialist centres with the appropriate multidisciplinary model in place, including a qualified urogynaecologist as the lead. The unit should have comprehensive diagnostic procedures in place, including someone experienced in performing and interpreting pelvic floor ultrasound.

Supporting disciplines should be pain services, pelvic floor physiotherapists, and psychology. There should also be urology and colorectal units available for consultation.

If a patient cannot travel to one of the specialist services, they should be referred to a local gynaecologist who can liaise with the specialist service.

Specialist multidisciplinary services with an experienced urogynaecologist are available in NSW at:

- Nepean Hospital (Phone: 4734 1474 or 4734 2000)
- Royal North Shore Hospital (Phone: 9463 2377)
- Royal Prince Alfred Hospital (Phone: 9515 4526 or 0459 899 735)
- St George Hospital (Phone: 9113 2272 or 9113 1588)
- Westmead Hospital (Phone: 8890 7668)

Reporting adverse events

Suspected adverse events from medical devices or medicines must be reported to the Therapeutic Goods Administration. Any incidents, near-misses or complaints should be entered in the Incident Information Management System (IIMS).

Resources

1. Information for Patients Considering a Mesh Implant for Pelvic Organ Prolapse (also called Vaginal Prolapse)
2. Information for Patients with Mesh Implant for Pelvic Organ Prolapse (also called Vaginal Prolapse)
3. Information for General Practitioners regarding Mesh Implant for Pelvic Organ Prolapse

The Australian Commission on Safety and Quality in Health Care are currently developing national information resources. These will be disseminated when available, and will complement the NSW Health resources

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant staff.
2. Review and revise local protocols in line with this Safety Notice.