Issue date
1 February 2023

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, Managers and Staff of:
Gynaecology
Surgery
Nursing
Pain Services
Emergency
Mental Health Services
Physiotherapy Services
Medical Records Departments
Drugs and Therapeutics Committees

Expert Reference Group
Content reviewed by:
Office of the Chief Health Officer

Clinical Excellence Commission
Tel: 02 9269 5500
Email: CEC-Recalls@health.nsw.gov.au
Internet Website:
https://www.health.nsw.gov.au/sabs/Pages/default.aspx
Intranet Website:
http://internal.health.nsw.gov.au/quality/sabs/

Review date
February 2026

UPDATED: Transvaginal mesh implants for Pelvic Organ (Vaginal) Prolapse

What is updated in this Safety Notice from SN:018/22

The service and contact details for John Hunter Hospital have been added.

Situation

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) removed all transvaginal mesh products whose sole use was the treatment of pelvic organ prolapse, from the Australian Register of Therapeutic Goods (ARTG), effective 4 January 2018. Single incision mini-slings for the treatment of stress urinary incontinence were also 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*.

NSW Health has updated the information for patients with mesh implant for pelvic organ prolapse (also called vaginal prolapse)[a] and Transvaginal mesh[b] information for consumers, clinicians and health services was published in 2018 by the Australian Commission on Safety and Quality in Health Care (ACSQHC).

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 and 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 ACSQHC Treatment Options for Pelvic Organ Prolapse (POP) information for consumers[c]. 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.

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. Treatment options for complications of transvaginal mesh (including options for mesh removal) consumer information[d] is available and should be provided to patients.

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 offered virtual or consultation or referred to a local gynaecologist who can liaise with the specialist service.

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

- John Hunter Hospital - Phone 4921 3600
- Nepean Hospital - Phone 4734 1474 or 4734 2000
- Royal North Shore Hospital - Phone 9463 1377
- Royal Prince Alfred Hospital - Phone 9515 4526 or 0459 899 735, or RPA switch on 9515 6111
- St George Hospital - Phone 9113 2472 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 Management System (ims+).

Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians, clinical departments where contact with patients with transvaginal mesh implants are suspected or confirmed.
2. Include this Safety Notice in relevant handovers and safety huddles.
3. Report any incidents associated with transvaginal mesh implants into ims+ and TGA.

a. NSW Health (2020) Information for patients with mesh implant for pelvic organ prolapse (also called vaginal prolapse),
b. Australian Commission on Safety and Quality in Health Care, 2018, Transvaginal Mesh.
c. Australian Commission on Safety and Quality in Health Care, 2018, Treatment Options for Pelvic Organ Prolapse (POP).
d. Australian Commission on Safety and Quality in Health Care, 2018, Treatment options for complications of transvaginal mesh (including options for mesh removal)

Made Obsolete December 2023
Superseded by SN:042/23