Te Kāwanatanga o Aotearoa
New Zealand Government

MANATŪ HAUORA
MINISTRY OF HEALTH

Interim High Vigilance Guideline for Non-Mesh Stress Urinary Incontinence Surgery

December 2023

The interim high vigilance (HV) guideline applies to all surgical procedures undertaken for female stress urinary incontinence (SUI), whether primary or revision. Examples of SUI procedures include, but are not limited to:

- fascial slings
- burch colposuspension
- peri-urethral bulking agents

We[1] recommend this guideline[2] for best practice based on available evidence and expert consensus. This guideline should apply at all facilities where practitioners perform the listed high vigilance procedures.

This guideline is an interim measure that will remain in place until the required system safety steps for female pelvic floor surgery (eg, formalised multidisciplinary meeting are in place.)

While there is a pause on stress urinary incontinence (SUI) mesh procedures, there could be a shift to non-mesh SUI procedures. For this reason, we need a high vigilance guideline similar to the UK guideline that was put in place after the 2018 pause in SUI and pelvic organ prolapse mesh procedures[3].

The purpose of this guideline is to ensure that:

1. There is a documented peer review for all patients scheduled for high vigilance procedures through an appropriately constituted multidisciplinary meeting (MDM).
2. Practitioners inform patients of all suitable treatment options using written patient decision aids to guide shared decision-making.

[1] The group included representation or consultation with Te Aka Whai Ora, Te Whatu Ora, the NZ Private Surgical Hospitals Association, mesh-injured consumers, and the relevant medical colleges (RACS and RANZCOG).

[2] A guideline provides non-prescriptive advice on a subject. For example, see *How NICE Clinical Guidelines Are Developed: An Overview for Stakeholders, the Public and the NHS* on the National Institute for Health and Care Excellence (NICE) website: URL: **www.nice.org.uk/process/pmg6/resources/how-nice-clinical-guidelines-are-developed-an-overview-for-stakeholders-the-public-and-the-nhs-2549708893/chapter/nice-clinical-guidelines** (accessed 22 November 2023).

[3] British Society of Urogynaecology. [2018]. *Recommendations of the Mesh Pause Clinical Advisory Group to Medical Directors and Surgical Teams.* URL: **bsug.org.uk/budcms/includes/kcfinder/upload/files/info-leaflets/SUBMITTED-Mesh-Clinical-Advisory-Group---advice-FINAL-20thJulyPM.pdf** (accessed 23 November 2023).

Practitioners should meet the following requirements before they undertake the listed procedures:

1. The operating surgeon should demonstrate that they are appropriately skilled to perform the procedure. For example, the operating surgeon is credentialled within the surgical facility to perform the planned surgery or operating with a supervising credentialled surgeon[4] [5].

2. Unless the patient has demonstrated strong coordinated pelvic floor activity on assessment by a specialist and is unlikely to receive additional benefit by undergoing further supervised pelvic floor exercises, they should have a trial of supervised pelvic floor muscle training that lasts at least 12 weeks[6] [7].

3. The patient should have a full preoperative assessment that includes performance of urodynamic studies, where clinically indicated[8] [9], and interpretation by an appropriately skilled clinician.

4. The patient should have participated in a shared decision-making and informed consent process consistent with the Code of Rights[10] that includes the use of a patient decision aid, for example, National Institute for Health and Care Excellence (NICE) or the Australian Commission on Safety and Quality in Health Care[11] [12], until the Aotearoa New Zealand tool is available.

5. Practitioners should advise the patient that they will share their information with an appropriately constituted multidisciplinary meeting, in which there will be a discussion and review of the proposed care plan.

[4] Surgeons are encouraged to follow the indicative volume guidance for each of these three procedures provided in Table 1, page 31 of the New Zealand National Credentialling Framework: URL: **www.health.govt.nz/publication/national-credentialling-framework-pelvic-floor-reconstructive-urogynaecological-and-mesh-revision** (accessed 22 November 2023).

[5] Local credentialling should continue by current and existing local processes until further direction from the National Credentialling Committee.

6 National Institute for Health and Care Excellence. 2016. Urinary Incontinence in Women: The management of urinary incontinence in women. URL: **bpac.org.nz/guidelines/2/#recommendations-1-3** (accessed 23 November 2023).

[7] Dumolin C, Cacciari LP, Hay-Smith EJ. 2018. Pelvic Floor Muscle Training Versus No Treatment, or Inactive Control Treatments, for Urinary Incontinence in Women. *Cochrane Database Syst Rev*. DOI: 10.1002/14651858.CD005654.pub4 (accessed 23 November 2023).

[8] Kobashi KC, Vasavada S, Bloschichak A et al. 2023. Updates to Surgical Treatment of Female Stress Urinary Incontinence (SUI): AUA/SUFU Guideline. *J Urol* 209(6): 1091-1098. URL: **www.auanet.org/guidelines-and-quality/guidelines/stress-urinary-incontinence-(sui)-guideline#x4496** (accessed 23 November 2023).

[9] American College of Obstetricians and Gynaecologists. 2014. Evaluation of Uncomplicated Stress Urinary Incontinence in Women Before Surgical Treatment. Committee Opinion No. 603. *Obstetrics and Gynaecology* 123: 1403-7.URL: **www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/06/evaluation-of-uncomplicated-stress-urinary-incontinence-in-women-before-surgical-treatment** (accessed 23 November 2023).

[10] Health & Disability Commissioner. The Code and Your Rights. URL: **www.hdc.org.nz/your-rights/the-code-and-your-rights** (accessed 23 November 2023).

[11] National Institute for Health and Care Excellence. 2019. Urinary Incontinence and Pelvic Organ Prolapse in Women: Management. *Guideline NG123.* URL: **www.nice.org.uk/guidance/ng123/resources/patient-decision-aids-and-user-guides-6725286109** (accessed 23 November 2023).

[12] Australian Commission on Safety and Quality in Health Care. 2018. *Treatment Options for Stress Urinary Incontinence*. URL: **http://www.safetyandquality.gov.au/publications-and-resources/resource-library/treatment-options-stress-urinary-incontinence-sui** (accessed 23 November 2023).

6. We recommend the following minimum structure should be in place for a multidisciplinary meeting, which can be held either in person or virtually:
    a. Multidisciplinary meeting participants should consist of:
        i. Two surgeons, ideally a gynaecologist/urogynaecologist (RANZCOG) and urologist (RACS/USANZ)[13]
        ii. Two continence advisors, eg, clinical nurse specialist or female pelvic floor physiotherapist.
    b. Multidisciplinary meeting participants should minute the outcomes and document recommendations in the patient's notes and provide these to the patient in writing for their agreement and consent for implementation, including an appropriate follow-up plan[14].
7. Patient data, including patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs)[15] should be recorded in a database pending availability of the Australasian Pelvic Floor Procedure Registry.
8. There should be regular structured peer review of the local database[16].

Where there are complex cases[17] that require additional input or advice, referrals can be made to Te Whatu Ora Female Pelvic Mesh Service. Practitioners who refer a patient to this service should attend and present their patient, as indicated by the multidisciplinary meeting chair and participate in the ensuing discussions. To make a referral, email the New Zealand Female Pelvic Mesh Service at **nzfpms@tewhatuora.govt.nz** with the subject line 'Attention MDM Coordinator-High Vigilance SUI MDM request'. The multidisciplinary meeting coordinator will guide the practitioner on information requirements and identify a mutually agreeable time to attend the meeting.

December 2023
HP 9054

[13] We recognise that this may not always be possible and therefore may consist of two surgeons from the same college.

[14] Where a patient requests to attend the multidisciplinary meeting this should be accommodated where circumstances allow.

[15] We note that there are different PROMS and PREMs in use in female pelvic floor surgery and at this stage there is no single consensus on the which set to use in Aotearoa New Zealand, however, we advise the use of PROMS that measure urinary symptoms and their impact on quality of life (QoL), measures of pelvic pain symptoms and QoL, and a global improvement score following surgery.

[16] Surgeons should refer to their relevant college's guidelines on audit standards.

[17] Referrals should be considered where the local multidisciplinary meeting has been unable to reach a consensus agreement on the preferred course, revision surgery, and/or where the patient has requested a referral to the Te Whatu Ora Female Pelvic Mesh Service multidisciplinary meeting.