

24 September 2018

All DHB Chief Executives

Surgical mesh devices and ensuring patient safety

In May 2018 the Acting Director-General, Stephen McKernan, wrote to update you on developments and actions relating to surgical mesh.

Since then, both England and Scotland have instigated an immediate pause of the use of vaginally-inserted surgical mesh for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) procedures. The pauses are non-regulatory measures taken to reduce the risk to women undergoing these procedures.

Here, Medsafe took regulatory action in 2017, resulting in the withdrawal of all surgical mesh products used for POP via transvaginal implantation, and one single incision mini-sling for SUI.

Other surgical mesh devices continue to be supplied in New Zealand. This means that there is still the potential for risk of harm to some patients. The Ministry of Health is working with a Surgical Mesh Roundtable on actions to reduce this risk. Members of the Roundtable include the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the Royal New Zealand College of General Practitioners, ACC, Health and Disability Commission and Mesh Down Under. Current work includes developing guidance for credentialing surgical mesh services and surgeons; and developing information about potential risks arising from mesh use so that patients can make more informed decisions.

In the meantime, I am seeking your support to undertake urgent collective action in two areas to minimise the risk to patients. At this stage there is a particular focus on urogynaecology as other surgical mesh procedures, such as hernia repair, are considered lower risk.

- i. Assess those surgeons undertaking urogynaecological surgical mesh procedures in your DHB against credentialing guidance developed by the Australian Commission on Safety and Quality in Health Care. This can be accessed at: www.safetyandquality.gov.au/our-work/transvaginal-mesh/resources/
- ii. Ensure rigorous informed consent processes that include understanding of the associated risks.

If you are not satisfied that your services or surgeons meet these standards, surgeries involving surgical mesh should not take place.

I would appreciate it if you could please advise the Ministry's Chief Medical Officer, Dr Andrew Simpson, by 8 October 2018 that you have completed the above actions, and whether your facility intends to continue to undertake urogynaecological surgeries involving surgical mesh. Dr Simpson is available to discuss this issue with you or your clinical staff on 021 418 705 or Andrew_Simpson@moh.govt.nz.

The Ministry will also be asking DHBs to hold and maintain local registers to collect information about surgeries involving surgical mesh. This follows completion of a cost benefit analysis on a national surgical mesh registry which is available on the Ministry's website (www.health.govt.nz/publication/surgical-mesh-registry-cost-benefit-analysis). While a national registry remains under consideration, local registers are a more immediate step we can take to identify and monitor surgical mesh use and is supported by the Surgical Mesh Roundtable. You will receive more information from the Ministry about this in due course.

I appreciate your support to help minimise the risk of patient harm. Mesh-related complications are a significant women's health issue, and it is critical that we do everything possible to minimise the risks associated with the use of surgical mesh.

Thank you for your attention to this important patient safety matter.

Yours sincerely



Dr Ashley Bloomfield
Director-General of Health

Cc DHB Chief Medical Officers

Chair, New Zealand Committee, Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Chair, New Zealand Office, Royal Australasian College of Surgeons

New Zealand Section Representative, Urological Society of Australia and New Zealand