MINISTRY OF HEALTH
MANATŪ HAUORA

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Dear Health Sector Chief Executive

Surgical Mesh Update

Surgical mesh remains an important clinical issue for consumers, healthcare professionals, the Ministry of Health and the health system. It is important that we all work together to ensure New Zealanders receive the best information, clinical care and pre and post-operative support for procedures that utilise surgical mesh. In recent months there have been a number of developments relating to surgical mesh that have an impact on the services provided within your hospital. This letter provides you with an update on these developments and the actions we would ask you and your surgical teams to take in response to this information.

Recent key actions include:

- Regulatory action was taken which resulted in four suppliers of surgical mesh implants used in urogynaecological surgery removing some or all of their products from supply in New Zealand. I would be grateful if you could ensure that your heads of surgery and gynaecology are aware of these product withdrawals and have acted on the changes in indication of the remaining surgical mesh products used in urogynaecological procedures.

- A roundtable meeting was held in October 2017 involving the relevant colleges, HDC, ACC and the consumer group Mesh DownUnder (MDU). At this meeting it was agreed that representatives from MDU and the professional colleges were to meet to co-design patient information leaflets and consent forms. These documents are close to being finalised and the Ministry will contact you on their release seeking assurance that they will be utilised at all appropriate surgical clinics and theatres in your DHB.

- The Ministry also agreed at the roundtable meeting that it would undertake a cost-benefit analysis of the utility of creating a surgical mesh registry for urogynaecological and abdominal surgery. This project has commenced and the Ministry will get back to you following its completion should any changes in clinical practice be required should a decision to establish a registry be made in response to the report of this project.

- The Australian Senate Inquiry into surgical mesh has released its report (refer: www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Report). The Senate report recommendations align very closely with the recommendations made by the Health Committee in New Zealand in 2016. An update on progress against the recommendations from the New Zealand

Health Committee inquiry into the use of surgical mesh which were released in 2016: www.medsafe.govt.nz/devices/surgical-mesh-recommendations-implementation.asp

- The Royal Australasian College of Surgeons (RACS) and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) have also issued guidelines and resources to support members in the use of surgical mesh. This guidance includes training expectations which covers skills appropriate to insertion and removal of surgical mesh. In addition, RANZCOG has published patient information sheets on the use of mesh and mesh removal that can be used in the interim while the new consent documents are completed in partnership between the Colleges and Mesh Downunder.

Further regulatory information on surgical mesh is available on Medsafe's website: www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp

I would be grateful if you could ask the heads of surgery and gynaecology in your hospitals to raise awareness of this information to their colleagues and to ensure that the Colleges' guidelines are being used on the risks and benefits of surgical mesh, and of its alternatives, when seeking informed consent from all patients. I also ask that you seek assurance from the relevant surgical services that they are actively discussing how to provide the best care for women who have suffered adverse events as a consequence of use of surgical mesh, and whether there is a need to establish an expert internal referral service within your service to ensure that women requiring mesh removal are managed by the clinicians with the most experience in this surgical technique.

Yours sincerely

Stephen McKernan
Acting Director-General of Health