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National Credentialing Framework: Pelvic Floor Reconstructive Procedures Urogynaecological Procedures Mesh Revision and Removal Procedures

RANZCOG appreciates the opportunity to provide feedback on the draft *Mesh Credentialing Framework*.

We acknowledge the pain and distress suffered by many New Zealand women who have experienced complications arising from pelvic mesh implants, particularly those where mesh has been used for the treatment of vaginal prolapse. We remain committed to ensuring women are given evidence-based guidance and are offered an appropriate range of treatment options, in line with their own goals and values.

RANZCOG supports the idea of setting broad credentialing standards at a national level, particularly in a country as small as Aotearoa New Zealand. We agree that credentialing frameworks generally, and for specific procedures, should be reviewed at regular intervals and as new issues emerge.

We acknowledge the time and effort it has taken to develop the draft *Mesh Credentialing Framework* and the sense of urgency at the Ministry of Health to ensure a transparent and robust monitoring and credentialing approach is in place. However, after consultation with Te Kāhui Oranga ō Nuku (RANZCOG's Aotearoa New Zealand committee) and discussions with those involved in the process RANZCOG is unable to support the proposed credentialling framework as it currently stands.

Recommended changes to the draft framework

RANZCOG is concerned that in focusing on managing and restricting uro-gynaecological practice the draft framework does not sufficiently consider the burden of incontinence and prolapse, and the impact the framework could have on the ability to provide surgical options to women around Aotearoa New Zealand.

There are a few key areas that RANZCOG would like to see addressed to be able to support the credentialing framework.

1. *Non-mesh prolapse procedures are not included in the framework*

The draft framework goes beyond mesh related procedures to include non-mesh related procedures for management of stress urinary incontinence (SUI) and pelvic organ prolapse (POP). While we support the inclusion of other SUI procedures in the framework, we believe it is not appropriate that routine gynaecological procedures such as sacrospinous fixation following hysterectomoy are included in the framework.

We recommend that non-mesh repair of prolapse, including sacrospinous fixation, be removed from the framework and that pages 26-27 be amended to reflect this.

2. *Broader approach to surgical expertise*

RANZCOG endorses the principles that surgeons need to be appropriately trained in the procedures they perform, perform the procedures regularly enough to maintain skills, offer women a range of treatment choices (particularly non-surgical and non-mesh), monitor their outcomes and provide evidence of good outcomes, engage in relevant CME and have access to appropriate support mechanisms such as medical investigations and multidisciplinary teams.

RANZCOG agrees that surgeons need to operate sufficiently often to maintain their skills across the range of procedures for which they are credentialed. While the framework document specifies six credentialing domains and within the domain of 'skills', 'volume/case mix' is only one of five areas for review, in our view there remains risk that credentialing under the framework will give unreasonable emphasis to surgical numbers.

As the framework acknowledges, procedure specific volume is not an isolated measure and needs to be viewed in the context of a surgeon's broader surgical practice and experience. The framework recognises that cross recognition of skills is important. In addition, many surgeons will have extensive experience of performing procedures over many years, building up a large case volume, although many have seen their caseloads decline in recent years. We think this experience should also be recognised in the framework.

Even with commentary in the document acknowledging cross recognition of skills and extensive experience, we are concerned that there is risk that credentialling focus will remain on the most obvious and measurable of factors – surgical volumes.

Table 1 Assessment Criteria (on page 27) specifies 'Acceptable Volumes' over two years for procedures. This seems to imply minimum volumes and does not make reference to consideration of the surgeon's whole scope of practice (page 19) or their experience.

The volume requirements for each procedure, as outlined in Table 1, would be unachievable for most surgeons. We understand that review of surgical numbers across New Zealand DHB's confirmed this. Aotearoa New Zealand has a small and widely distributed population. This means that most obstetric and gynaecological care is delivered by generalists. It is common and necessary within smaller centres for specialists within a service to develop special areas of interest to ensure that women can access most of the care they need in their local communities. We are concerned that even with a concentration of urogynaecology skills in the hands of those with a special interest, surgeons will struggle to achieve the numbers proposed. This will impact the provision of care to women in smaller centres.

We also note that outcome measures for small, individual data sets will be statistically problematic. Uncommon or rare adverse outcomes may heavily impact the unlucky surgeon.

To avoid undue emphasis on surgical numbers relative to the other credentialing criteria outlined on pages 18 to 21, we believe there needs to be specific and clear guidance for credentialling committees and surgeons on how surgical volumes will influence the determination of whether a surgeon will be credentialled.

We recommend that:

- **the wording in Table 1 on page 27 be amended from 'Acceptable Volumes' to 'Indicative Volumes'**
- **that a section is added to the skills credentialing domain information on pages 18-19 specifying consideration of a surgeon's experience as well as current volumes**
- **that consideration is given to how surgeons in smaller centres can maintain competence with lower volumes of procedures**

Wider recommendations

Establishment of dedicated centres of excellence for the management of mesh complications

RANZCOG agrees that highly specialised skills are required to manage mesh complications. This is acknowledged in the framework and these skills described as part of the Tier 3 service responsibilities. We think it is essential that national centres of excellence dedicated to the management of mesh complications are established with urgency.

Implementation of a database/registry with centralised prospective data collection and surgical outcome monitoring

RANZCOG supports the recommendation for strong clinical governance that includes regular monitoring of outcomes, review of early and late complications, review of complaints, monitoring of procedure specific surgical volumes and collection of patient subjective outcomes – for all types of surgery.

The framework puts responsibility for audit on individual practitioners and facilities. We believe that it is necessary to develop a database or registry with centralised prospective data collection and surgical outcome monitoring. Such a system is crucial to the ongoing workability of the proposed framework, which relies on the long-term reporting of surgical outcomes and complications.

We believe it is vital that there is national leadership of the development of an appropriate data collection system and/or collaboration on the use of existing approaches. We note that an Australasian Pelvic Floor Procedures Registry (APFPR) was set up in 2019 to collect outcomes relating to SUI/POP diagnosis, comorbidities, surgery, and complications including revision and mesh removal details.

Finding a solution to data collection and monitoring is complex and not unique to mesh surgery. Reliable national surgical outcomes data that includes outcomes beyond the immediate surgical period and includes a patient perspective (PROMS and PREMS) is lacking for all surgery. There is great variability across Aotearoa New Zealand in the collection of local immediate surgical data. RANZCOG recommends that attention is given to New Zealand's information systems that are unable to provide the level of information required to assess performance of surgeons, units and of the health system generally.

Strengthening credentialing framework for all surgical procedures

RANZCOG supports the idea of setting broad credentialing standards at a national level. We agree that, given the level of concern and patient harm associated with the use of mesh, the Ministry of Health has an obligation to ensure a transparent and robust monitoring and credentialing approach is in place to ensure ongoing safety of use. Our preferred approach to credentialing for mesh and uro-gynaecological procedures would be to see this embedded within a broader National Credentialing Framework that incorporates lessons learnt since the introduction of the 2010 national framework.

We are concerned that the focus on mesh, pelvic floor and urogynaecological procedures is a lost opportunity to prevent a similar problem with a new procedure or technology in the future. While the report acknowledges the need to provide a formal framework to guide the introduction of new procedures into clinical practice, its detailed recommendations are not more broadly applicable. Our strong recommendation is for mesh solutions to be ultimately embedded in a more generic approach with wide applicability across all surgical specialties.

RANZCOG believes that the system lessons arising from our mesh experience are relevant to the introduction of all new surgical treatments.

In summary

RANZCOG is supportive of the principles of credentialling. We recognise the changing nature of practice, in particular that it is not realistic for all surgeons to perform all procedures, or for all hospitals to provide all types of services. We endorse the principles that surgeons need to be appropriately trained in the procedures they perform, perform the procedures regularly enough to maintain skills, offer women a range of treatment choices (particularly non-surgical and non-mesh), monitor their outcomes and provide evidence of good outcomes, engage in relevant CME and have access to appropriate support mechanisms such as medical investigations and multidisciplinary teams.

RANZCOG is happy to continue to work with the Ministry to refine the proposed framework to ensure this is a workable and effective process for the benefit of women in Aotearoa New Zealand. We also hope that longer term the focus will move to better IT systems for surgical outcome monitoring and a credentialing framework that is applicable across all surgical specialties.

If you need further information on any of our comments please contact me through Catherine Cooper, RANZCOG's Head of Aotearoa New Zealand Office on ccooper@ranzcog.org.nz.

Ngā mihi

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