RANZCOG™
Excellence in Women's Health

Te Kāhui Oranga ō Nuku

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Dr Robyn Carey
Chief Medical Officer
Manatū Hauora – Ministry of Health

Sent via email: Robyn.Carey@health.govt.nz

Tēnā koe Robyn

RANZCOG appreciated the opportunity to review the Final Draft of the National Mesh Credentialling Framework.

While we would be prepared to support the current version of the document, we believe it could be further strengthened and improved. This feedback is informed by comments from the RANZCOG fellows who you met with most recently.

1. General comments

Overall, we feel this document is an improvement over the previous version. We are very supportive of reference to indicative volumes rather than absolute volumes. There remain concerns however, that in practice volumes quoted, even though referenced as indictive, will in practice be interpreted as minimum volumes. The National Credentialing Committee has a responsibility to ensure that the principle behind the use of indicative volumes, that is to look at a single procedure within the broader context of the surgeons practice, is preserved.

The credentialing cycle is defined as every 2 years. Given the amount of work involved in the process we suggest, once the local committees are well set up and functioning, this should be increased to 3-yearly.

The document makes several recommendations with respect to the obligations on facilities that perform procedures referred to by this framework.

Facilities are required to: *ensure adequate staffing, building design, equipment, systems, and processes to provide a well-coordinated, best-practice environment for clinical care delivery.*

Credentialing reviews the environment and context in which the practitioner operates. Consequently, as part of the accreditation process, the facility and service (public or private) that are credentialing practitioners will be assessed as to whether they provide the supporting structures and systems to enable the individual practitioners and teams working within it to deliver best possible care. The development and promotion of a culture which supports consumer safety and consumer engagement with openness and transparency is paramount.

THE ROYAL AUSTRALIAN AND NEW ZEALAND
COLLEGE OF OBSTETRICIANS AND GYNAECOLOGISTS

NEW ZEALAND OFFICE
Level 6, Featherston Tower
23 Waring Taylor Street
Wellington 6011, New Zealand

Postal address:
PO Box 10611, The Terrace
Wellington 6143, New Zealand

tel +64 4 472 4608
email ranzcog@ranzcog.org.nz
web ranzcog.org.nz

We see this as being a critically important component of providing high quality care for women undergoing uro-gynaecology procedures. **Can you clarify where the responsibilities will sit in relation to facility compliance under the new health structures?**

We are also keen to ensure that the learning from mesh related procedures is more generally applied across the health system. We are encouraged to hear that the overall credentialing framework is likely to be reviewed by the CMO group sometime later this year. We feel it is important that it provides a framework to safely monitor new and emerging surgical procedures.

2. Evidence used to inform the document

We are concerned about the source of information used to inform the document, particularly with respect to complication rates. For example, references when provided include personal email correspondence and more obscure journals such as Int Braz J Urol. The use of systematic review evidence is limited.

3. Credentialing committees

We support the plan to transition from a national credentialing approach to one that is local, using a nationally consistent approach.

Eventually most credentialing for pelvic floor reconstructive and uro-gynaecological procedures will be undertaken locally or regionally. All organisations wishing to credential surgeons to undertake these procedures are required to have established appropriate clinical governance structures.

What resources will be made available to organisations/facilities who wish to undertake credentialing to ensure they establish appropriate clinical governance structures?

We believe the MOH needs to consider some specific assistance and guidance with respect to the selection of consumer representatives on the local credentialing committees. We are concerned that if this process is not robust, individuals with vested interests may undermine a fair process.

4. Data collection (*p.29*) and quality process

We remain concerned about the data collection process which is clearly critical to ensure a quality register to inform credentialing and, most importantly, quality care provision.

This document places responsibility on each practitioner and facility to collect and analyse an enormous amount of data. It does not provide guidance on how this data should be classified or structured to facilitate comparisons within a unit over time, and between units nationally and internationally. **Which classification system for complications should we use? Which validated instrument for sexual function or QoL?**

We agree that: *As the data in the Australasian Pelvic Floor Procedure Registry (APFPR) increases, Australasian trends regarding outcomes and complications will become more visible and will support the development of quality improvement targets in this area. As prospective data grows, and evidence of the true "local risk" of various complications emerges, this must be considered in regular review processes.* However, we are not reassured that the structures are in place to enable this to happen.

We understand from the recent briefings from Health New Zealand that there is recognition that data systems need to be strengthened. The move from 20 DHBs to a single entity will clearly reduce the complexities of gaining consensus around some of the system changes necessary to enable this improvement. We also understand that data systems, while important, are not listed as an immediate priority for HNZ.

In the meantime, the responsibilities sit with the facilities. Section 5: Service accreditation and credentialing (*p.40*), lists supporting *and facilitating participation in the designated registry and consequent long-term follow up or an alternative database in the interim,* as a facility requirement.

We have several questions/concerns:

- **Who will provide the oversight to ensure these resources are available?**
- **What will happen if the data is unavailable?**
- **Do the data systems need to be in place before the credentialing process can start**?

5. Procedure specific credentialing for pelvic floor reconstructive procedures and uro-gynaecological procedures

Uro-gynaecological procedures for stress urinary incontinence (p.21)

This section of the document presents the skills and approach that practitioners need to follow in order to offer/perform SUI procedures.

All practitioners performing SUI procedures must -

- *provide a comprehensive evaluation of urinary incontinence including history and pelvic examination*
- *identify the index from the non-index patient and identify high risk factors for treatment failure and complication*
- *accurately interpret urodynamics including pressure-flow studies*
- *recognize and manage complications of treatment, intra-operatively and post operatively*
- *have experience and training in performing intraoperative cystoscopy to evaluate for bladder and ureteral integrity.*

It is unclear what is meant in the highlighted section by index and non-index patient. The reference for this recommendation (https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/06/evaluation-of-uncomplicated-stress-urinary-incontinence-in-women-before-surgical-treatment) uses the term index only in relation to Incontinence Severity Index (USI). This needs to be clarified.

We believe that in looking at surgical competencies the document should consider the surgeons role in empowering woman's rights to choose the treatment that is best for them. In addition to the competencies described above, surgeons have a responsibility to ensure women are well informed and offered the full range of interventions appropriate to their diagnosis (not just those available in their local community), including non-surgical and surgical (both mesh and non-mesh). Women should be enabled/supported to travel beyond their local community should they feel that the best option for them is a procedure not available locally.

6. Comments relevant to Assessment Criteria

Acute procedures (p.19)

The document lists indications for acute procedures done by surgeon at a Tier 1 and 2 facilities as:

For acute procedures to be done by the implanting surgeon at Tier 1, the indications for surgery are:

- *wound dehiscence, infection, or haematoma.*

The acute procedures able to be undertaken in a Tier 1 environment are:

- *repair of wound dehiscence along suture line*
- *treatment of haematoma and infection*

For acute procedures undertaken at Tier 2 the indications for surgery are:

- *urinary retention within 14 days post-surgery*
- *voiding dysfunction without pain or haematuria*

The procedures form part of the credentialing framework in *Table 2, p.34*. However, complications listed should also be captured as procedure complications in *Table 1 (p.24 & 25) under* early complications. Only wound infection is included in the early complication list.

Assessment Criteria (including indicative volumes and complication rates) for pelvic floor reconstructive procedures and uro-gynaecological procedures (Table 1, p.24)

All procedures relevant to the credentialing process should be included in *Table 1*. For example, only sacrocolpopexy is included from the prolapse procedures.

The indicative volumes are listed for a two-year period, presumably to align with proposed credentialing frequency. We feel these would be better listed as annual indicative volumes.

7. Required qualifications *(p.27)*

The document states:

Vocationally registered with the Medical Council of New Zealand and are:

- *a RANZCOG certified uro-gynaecologist (CU), or*
- *a specialist urologist who has at least one year post fellowship (or similar) training in the specific area of female and functional urology, or…*

All three categories must demonstrate requisite knowledge and understanding in the treatment of SUI and POP, including both mesh and non-mesh surgical treatments and other non-surgical treatments, and when such treatment is appropriately clinically indicated.

Our fellows are concerned that this suggests equivalency of qualifications between a RANZCOG certified uro-gynaecologist and a specialist urologist with one year post fellowship training. We do not agree that these training are comparable. The CU qualification is 3 years and has an exit exam, whereas urology fellowship can vary in their rigor.

For fellows who do not have above training the document suggests that the surgeon: *demonstrates the experience to independently undertake the procedures safely and efficiently, and in cases where*

they are appropriately indicated. This will involve a detailed evaluation of patient journeys and appropriate outcomes, including the management of complications.

We would argue that these are competencies that all surgeons, regardless of their training should demonstrate.

8. Table 2: Pelvic mesh revision and removal procedures for each Tier of service provision *(p.34)*

The rigid timeframes within this table are potentially problematic. **What if there is critical sepsis more than 6 weeks post sling insertion? Does a sick patient have to travel?** A complication similar to this led to HDC concerns according to one of our fellows. Some flexibility with timeframes will help avoid unintended consequences.

If you need further information on any of our comments please contact me through Catherine Cooper, RANZCOG New Zealand Manager at ccooper@ranzcog.org.nz.

Ngā mihi

Dr Susan Fleming