Te Kāwanatanga o Aotearoa
New Zealand Government

MANATŪ HAUORA
MINISTRY OF HEALTH

# National Credentialling Framework

## Pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures

**Version 1.1**

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# Acknowledgements

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Thank you also to the nine district health boards and the individual practitioners who participated in the June 2020 assessment of their approach and processes. This assessment focused on the surgeons who undertake urogynaecological surgical mesh procedures for stress urinary incontinence. The assessment was benchmarked against the credentialling guidance developed by the Australian Commission on Safety and Quality in Health Care.

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**Version history:**

- Version 1.0: Published initial version of the framework (May 2022)
- Version 1.1: Updated service configuration and tiers in Figure 3; updated Section 6: Procedure-specific credentialling for mesh revision and removal (November 2023)

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# Foreword

This framework was developed because we owe it to the people who have suffered significant avoidable harm through surgical procedures involving mesh to improve our health system and reduce the potential for future harm.

Whilst it is unusual to establish a credentialling process for a discrete set of procedures, it is not unique. This framework aligns with and builds on *The Credentialling Framework for New Zealand Health Professionals*, which is a national credentialling document first produced by the Ministry of Health in 2001 and updated in 2010. The principles incorporated in this 2022 framework are meant to be transferrable to other areas and will help us maintain the highest standards of care for our patients.

Among other responsibilities, credentialling must respond to the specific needs of Māori and acknowledge the government's responsibility under Te Tiriti o Waitangi to work in partnership to improve health outcomes for Māori. As such, cultural safety is identified as a specific tenet of this framework.

Critical to the delivery of modern health care is teamwork. The framework acknowledges this, and it is essential that credentialling encompasses individual surgeons and the wider team and environment in which they work. Credentialling brings together several processes involving multiple agencies to support quality health services and patient safety.

This current framework identifies the rationale for adopting a national credentialling standard, defines specific credentialling criteria and describes a process for the standard and criteria to be set in place. It identifies the structures needed to support individual practitioners and health services to achieve credentialled status. Most importantly, this credentialling framework should be viewed as a quality improvement opportunity rather than a compliance burden.

We intend to make this a living framework that will be updated when clinically relevant. A review will be conducted following the first round of credentialling, and any lessons learnt will be incorporated into a revised version and further revisions as necessary.

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# Executive summary

This national framework exists because women have suffered significant avoidable harm as a result of surgical procedures involving mesh.[1] We owe it to these women to improve our health system to reduce the potential for future harm.

The aim of this framework is to provide a national credentialling framework for pelvic floor reconstructive procedures, urogynaecological procedures and procedures for mesh revision and/or removal.

The framework supports principles of holistic models of care, assessing not only the health professional's technical ability but also their knowledge and judgement skills, the patient experience and the health team environment. Among other responsibilities, the framework aims to respond to the specific needs of Māori and acknowledges the government's responsibility under Te Tiriti o Waitangi to work in partnership with Māori to improve health outcomes for our tangata whenua. Cultural safety is identified as a specific tenet of this framework.

The framework has been developed in consultation with the Surgical Mesh Roundtable; the Pelvic Floor Reconstructive Medicine and Uro-gynaecological Procedures Credentialling Committee; The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG); the Urological Society of Australia and New Zealand (USANZ), which is a branch of the Royal Australasian College of Surgeons (RACS); and consumers.

We hope it will be used by all facilities (both public and private) within Aotearoa New Zealand that are responsible for credentialling senior medical practitioners and teams to undertake pelvic floor reconstructive procedures, urogynaecological procedures and procedures for mesh revision and/or removal.

Consumer input into the development of this framework was essential and will remain paramount in any future reviews of credentialling processes.

[1] Other terms used for mesh include tape, ribbon, scaffold, tension-free vaginal tape (TVT), trans-obturator tape (TOT), mid-urethral sling (MUS), sling, synthetic tissue, Mat (Dutch), graft and hammock.

# Section 1: Credentialling overview and principles

The Ministry of Health defines 'credentialling' as:
… a process used by health and disability service providers to assign specific clinical responsibilities to health practitioners on the basis of their education and training, qualifications, experience and fitness to practice within a defined context. This context includes the particular service provided, and the facilities and support available within the organisation.
The prime focus of credentialling is patient safety. It is also beneficial in terms of practitioner protection, provider accountability and consumer confidence in the health system.[2]

Currently, most credentialling in Aotearoa New Zealand is undertaken by individual service providers with minimal standardisation of credentialling criteria and processes. This framework looks to establish minimum criteria and quality standards for several specific procedures within a defined area of practice.

Having clear visibility and confidence in a practitioner's scope of practice will:

- ensure consumer safety and maintain quality of care provided to consumers
- promote transparency for consumers and the public
- support and embed the principles of best clinical practice.

The national credentialling framework as outlined in this document is a process that acknowledges competency and attainment of knowledge and skills that sit beyond regular training programmes. Rapid advances in medical technologies mean that recognition of appropriate ongoing training needs to be much more adaptable. A mechanism is required to recognise experience and competencies gained while the professional is qualified and operating within a vocational scope.

Credentialling provides this mechanism and assesses training, knowledge, skills, quality and consistency in areas that might not currently be part of postgraduate training. Whilst registration bodies recognise vocational scopes of practice, such bodies and training schemes have limited agility to identify and set care standards and ensure ongoing competence in the fast-changing field of medicine. One of the key features of the specific procedures identified in this framework is that currently none of them are formally taught or assessed in Australasian surgical vocational training programmes.

[2] Ministry of Health. 2010. *The Credentialling Framework for New Zealand Health Professionals*. Wellington: Ministry of Health, page 2. URL: **www.health.govt.nz/system/files/documents/publications/credentialling-framework-nz-health-professionals.pdf** (accessed 13 May 2022).

The General Medical Council in the United Kingdom recently developed a credentialling framework for areas where there have been risks to patient safety, albeit in more specific unregulated fields of practice.[3] Similarly, this framework responds, in part, to the significant safety concerns and poor outcomes for some consumers, and it is intended to help prevent future harm.

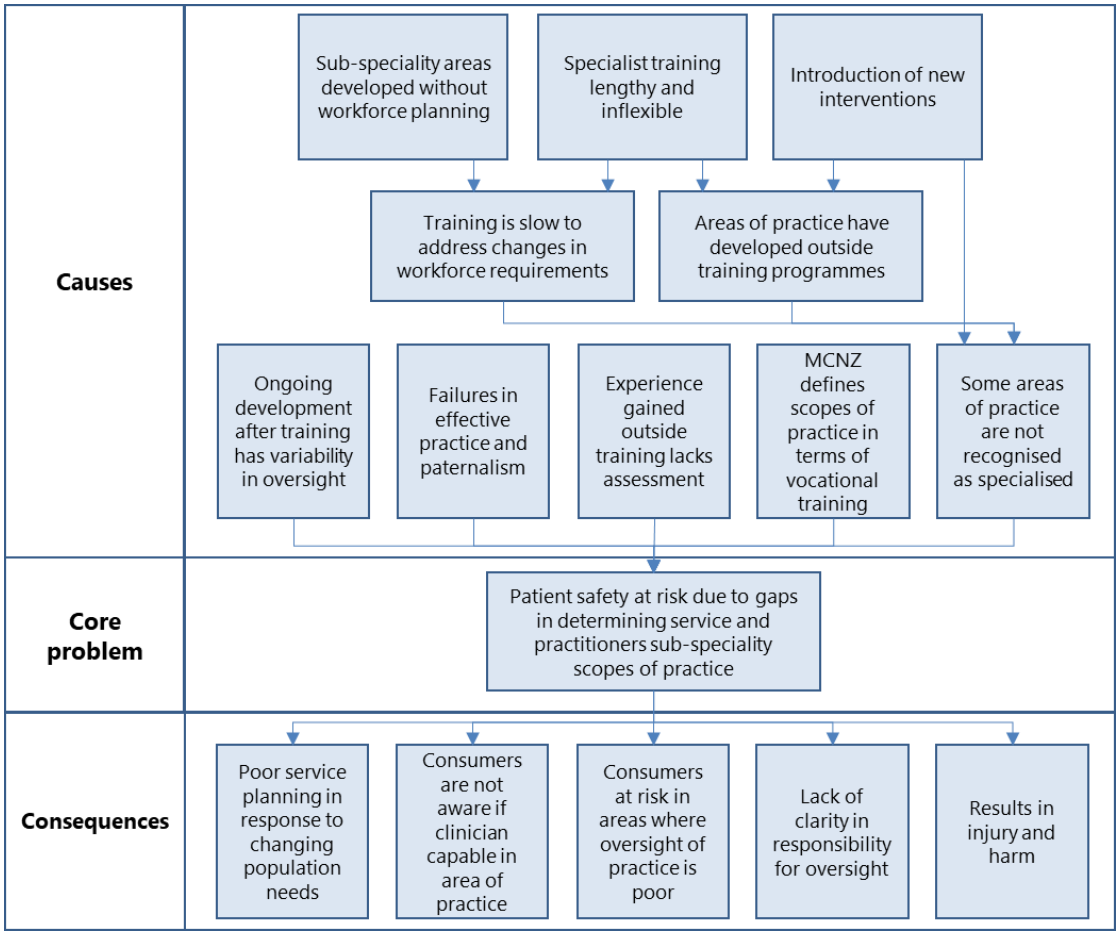
Credentialling can take different forms. Professional organisations such as the Royal Australasian College of Surgeons (RACS), supported by regulatory authorities such as the Medical Council of New Zealand (MCNZ), are intimately involved in credentialling through training and re-accreditation processes. The employing organisations are responsible for regular service credentialling to ensure that the local environment has the necessary supports to allow health practitioners to undertake their specified clinical responsibilities.

Although not recommended, from time to time, situations arise where medical therapies are used in practice once their safety and efficacy has been demonstrated in clinical trials but before they have been integrated into vocational training programmes. Ongoing rapid advances in medical technologies is exacerbating this trend. Setting credentialling standards at a national level provides an opportunity to ensure best practice standards are maintained in such situations. Credentialling frameworks for specific procedures should be reviewed at regular intervals as training curricula adapt to incorporate medical advances and national expertise is developed.

The factors outlined in figure 1's problem tree highlight the key issues this credentialling framework is trying to address.

[3] GMC. 2021. *Credentials for Doctors (2021).* URL: **www.gmc-uk.org/-/media/documents/gmc-credentialling-framework-2021_pdf-78983531.pdf** (accessed 13 May 2022).

**Figure 1: The problem to be solved**




The 2010 national credentialling framework document does not define a process for national credentialling for specific procedures or interventions, and whilst it does address the need for credentialling for new procedures and references regional credentialling, it does not discuss these to any great extent.[4]

Whilst, in this current framework, credentialling is focused on the individual practitioner, it also recognises the importance of the wider team and support services and structures. It is also explicit that the prime focus of credentialling is consumer safety. These aspects are particularly pertinent in the issue of pelvic floor reconstructive and urogynaecological procedures and mesh revision and removal procedures. The approach to credentialling these procedures is aligned with the principles outlined in the 2010 national credentialling framework.

This latest framework highlights that credentialling must take place in the context of the individual practitioner's workplace and acknowledge that practitioner's knowledge, experience and training with appropriate organisational supports and structures to deliver safe care and good consumer outcomes.

We also acknowledge that, while the principles and criteria that form the core of this document are immutable components of the framework, the process of undertaking

[4] Ministry of Health. 2010. *The Credentialling Framework for New Zealand Health Professionals*. Wellington: Ministry of Health. URL: **www.health.govt.nz/system/files/documents/publications/credentialling-framework-nz-health-professionals.pdf** (accessed 13 May 2022).

credentialling will, by necessity, vary between organisations. However, the national credentialling committee (the Pelvic Floor Reconstructive Medicine and Uro-gynaecological Procedures, Mesh Revision and Removal Credentialling Committee) will closely monitor these processes to ensure that a consistent, standardised, principles-based approach is followed. A nationally consistent, principles-based approach will confer key benefits that are identified in this national framework, including:

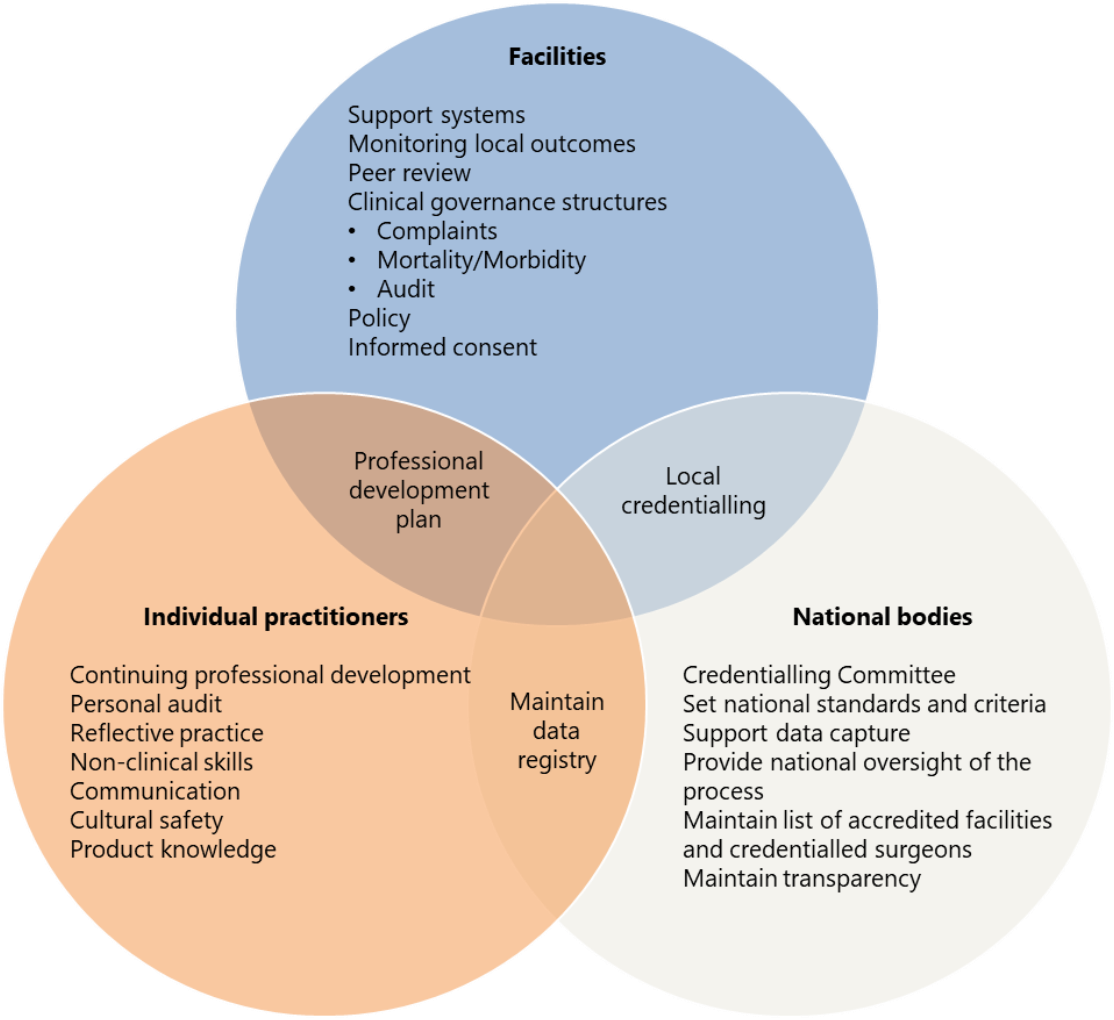
- protecting consumers and promoting consumer safety
- providing consumer-centric care
- providing equity of access and quality of care for Māori ***or*** achieving equity for Māori
- facilitating professional development among health practitioners
- improving risk management in provider organisations by ensuring clinicians are practising within their scope
- supporting quality improvement activities
- allowing some credentialling information to be accessible between organisations
- enabling the national credentialling committee to audit the system to ensure processes remain relevant and up to date
- improving public confidence in the health system.

The principles outlined in the 2010 national credentialling framework remain relevant and they underpin the intent of this latest procedure-specific credentialling framework. These principles are outlined in Appendix 2: Credentialling principles. However, local ownership, addressing specific clinical practice in a defined service setting, the involvement of multiple agencies and authorities and consumer input into this framework and future credentialling processes are essential.

# Credentialling responsibilities and accountabilities

Credentialling is a quality assurance and improvement activity. Each of the key parties involved will have defined roles and responsibilities, with some overlap. Figure 2 outlines the critical responsibilities.

**Figure 2: Responsibilities of individual practitioners, facilities and national bodies**




Individual practitioners are responsible for their ongoing professional development through appropriate continuing medical education. They should continually reflect on their practice, conducting regular personal audits and reviewing their personal registry or database information. They also need to develop their communication skills, practice in a culturally safe manner and have appropriate product knowledge.

Facilities must have established clinical governance structures in place to monitor quality assurance activities and review the collection of local, national and international outcomes data. They are required to establish local credentialling processes and report back to the national credentialling committee. Whilst the term 'credentialling' may also be used in the context of services and facilities, the construct of accreditation against a developed set of standards is seen as a more appropriate means of framing the assessment and endorsement of organisations within which procedures are carried out. All facilities and services within which these procedures are provided must be accredited to provide these procedures.

# Section 2: History of surgical mesh in Aotearoa New Zealand

Surgical mesh is a medical device that is used to provide additional support to weakened structures. It has been used extensively in the past in pelvic floor surgeries, such as for pelvic organ prolapse (POP) and stress urinary incontinence (SUI), and by general surgeons in the context of hernia repair. Mesh was initially introduced as earlier surgical methods had a high failure rate (estimated at 30 percent).[5]

The safety of transvaginal mesh implants for POP and SUI has been debated internationally for over 10 years.[6] The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) received its first adverse event report relating to surgical mesh devices in 2006.[7]

On 20 March 2014, a private petition was submitted to parliament requesting an independent inquiry into the use of surgical mesh in Aotearoa New Zealand. On 1 June 2016, the Health Select Committee presented a report to the House of Representatives with seven recommendations under three broad areas: the development of a surgical registry, improvement in medical practice and the role of the regulator in pre-market medical device approval. The Government accepted all the health committee's recommendations (see Appendix 1: The Health Select Committee and restorative justice actions), and implementation of the recommendations was devolved to the Ministry of Health (the Ministry).[8]

In December 2017, Medsafe, following similar moves by their Australian counterparts[9], removed from sale in Aotearoa New Zealand all surgical mesh products where sole use

[5] For more information, see the webpages Surgical mesh on the Ministry of Health website at: **www.health.govt.nz/our-work/hospitals-and-specialist-care/surgical-mesh** and Medical devices: Surgical mesh – safety information on the Medsafe website at: **www.medsafe.govt.nz/devices/Surgical%20Mesh/Landing.asp**

[6] For example, Ng-Stollmann N, Fünfgeld C, Gabriel B, et al. 2020. The international discussion and the new regulations concerning transvaginal mesh implants in pelvic organ prolapse surgery. *Int. Urogynecol. J. 31,* 1997–2002. DOI: **https://doi.org/10.1007/s00192-020-04407-0** (accessed 14 May 2022).

[7] Medsafe. 2019. *Adverse Event Reports Relating to Surgical Mesh Implants: Summary of data received by Medsafe, October 2019.* Wellington: Ministry of Health. URL: **https://medsafe.govt.nz/devices/Surgical%20Mesh/AdverseEventReportOctober2019.pdf** (accessed 14 May 2022).

[8] For more information, see the webpage Medical devices: Surgical Mesh Implants – Implementation of Government response to report of the health committee on petition 2011/102 on the Medsafe website at: **www.medsafe.govt.nz/devices/Surgical%20Mesh/Implementation.asp**

[9] The Therapeutic Goods Administration (TGA) is the medicine and therapeutic regulatory agency in the Australian Government's Department of Health.

was for the treatment of pelvic organ prolapse (POP) via transvaginal implantation and a single incision mini-sling product for the treatment of stress urinary incontinence.[10, 11]

The Accident Compensation Corporation (ACC) published *ACC Surgical Mesh Review: Analysis of Treatment Injury Claims 1 July 2005 to 30 June 2014* in March 2015 and an updated version in October 2018.[12] ACC is committed to reviewing declined surgical mesh claims made before 28 October 2020 and continues to receive new treatment injury claims regarding mesh.[13]

In 2018, the Director-General of Health Dr Ashley Bloomfield requested district health boards (DHBs) ensure that all practitioners using surgical mesh for urogynaecological procedures be credentialled against the Australian Commission on Safety and Quality in Health Care (ACSQHC) guideline.[14]

In 2019, as part of its Surgical Mesh Work Programme, the Ministry undertook a restorative justice process, listening to those negatively affected by surgical mesh. The Ministry published the findings of this work in December 2019 in the report: *Hearing and Responding to the Stories of Survivors of Surgical Mesh: Ngā kōrero a ngā mōrehu – he urupare*.[15] The Ministry committed to facilitating a total of 19 actions resulting from the report (see Appendix 1: The Health Select Committee and restorative justice actions). The actions relevant to this framework are:

- Action 9 – strengthening credentialling:
  'Establish a credentialling committee by the end of January 2020 to recommend national standards for individual practitioners and services commencing with urogynecology procedures. Minimum standards for insertion, renewal, repair and removal surgery and native tissue repair will be included.'[16]
- Action 10 – technical expertise:
  'The Ministry of Health will lead, supported by ACC, interdisciplinary education and build the capability of the required technical skills to prevent future harm, and reduce the severity of existing harm. This action intends to also support the provision of removal surgery.'[17]

[10] This regulation does not currently preclude health practitioners importing mesh products.

[11] For more information, see the webpage Safety information: Surgical mesh implants on the Medsafe website at: **www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp** (accessed 14 May 2022).

[12] ACC. 2015. *ACC Surgical Mesh Review: Analysis of Treatment Injury Claims 1 July 2005 to 30 June 2014*. Wellington: Accident Compensation Corporation (ACC). URL: **www.acc.co.nz/assets/provider/surgical-mesh-report.pdf** (accessed 14 May 2022); ACC. 2018. *ACC Treatment Injury Claims: Surgical mesh-related claim data, from 1 July 2005 to 30 June 2018*. Wellington: Accident Compensation Corporation (ACC). URL: **www.acc.co.nz/assets/provider/surgical-mesh-data-2005-2018.pdf** (accessed 14 May 2022).

[13] For more information, see the webpage Reassessing declined surgical mesh claims on the ACC website at: **www.acc.co.nz/surgical-mesh** (accessed 14 May 2022).

[14] For more details about the guidelines, see the webpage Resources for consumers, clinicians and health service organisations – transvaginal mesh on the ACSQHC website at: **www.safetyandquality.gov.au/our-work/transvaginal-mesh/resources/** (accessed 14 May 2022).

[15] Wailling J, Marshall C, Wilkinson J. 2019. *Hearing and Responding to the Stories of Survivors of Surgical Mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health)*. Wellington: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington. URL: **www.health.govt.nz/system/files/documents/publications/responding-to-harm-from-surgical-mesh-dec19.pdf** (accessed 14 May 2022).

[16] Ibid, page 44.

[17] Ibid, page 45.

In January 2020, the Ministry established the Pelvic Floor Reconstructive Medicine and Urogynaecological Procedures Credentialling Committee (the Credentialling Committee).[18] One of the Credentialling Committee's tasks was to develop this national female pelvic floor reconstructive and urogynaecological procedures credentialling framework, including the insertion and removal of surgical mesh.

[18] For more information, see the webpage Surgical mesh: Terms of reference on the Ministry of Health website at: **www.health.govt.nz/our-work/hospitals-and-specialist-care/surgical-mesh/surgical-mesh-terms-reference** (accessed 14 May 2022).

# Section 3: Credentialling of pelvic floor reconstructive, uro-gynaecology and mesh revision and removal procedures – general principles

## The credentialling process

The credentialling process described here applies to all surgeons and services and facilities wishing to undertake pelvic floor reconstructive surgery, urogynaecological procedures and mesh revision and removal procedures. This includes practitioners who:

- are newly qualified
- currently perform procedures in their existing setting or facility
- have lapsed credentials
- want to undertake these procedures in a new setting or facility.

Practitioners need to be credentialled for each service within which they work – services and facilities often vary markedly in terms of support and ancillary services available (examples include critical care services, equipment levels, range and experience levels of support staff) with resultant impacts on the nature and complexity of the procedures that the practitioner can undertake in any specific setting.

Reciprocity of credentialling across services and facilities can occur but should sit within the context of a formal memorandum of understanding between organisations.

Credentialling will take place on a two-yearly (biennial) cycle. Individuals or facilities may need to be credentialled more frequently if additional criteria are applied to their status.

The national Credentialing Committee, overseen by the Ministry, will have oversight of the whole credentialling process. The committee will work with RACS/USANZ, RANZCOG, other relevant international colleges and societies and consumers to maintain a group of experts that will form part of the committee and will be appointed where appropriate to local and regional credentialling panels.

The committee will undertake the initial credentialling of all practitioners undertaking pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures.[19]

Public (lay) members of the credentialling committee will be accorded the same rights of protection as practitioners and tasked with the same responsibility to maintain confidentiality.

The role of the external experts appointed by the national committee is two-fold. Primarily they will provide independent advice to the credentialling committee. This independence, in tandem with sector-wide knowledge will help with benchmarking, quality assurance and sharing of quality improvement opportunities. The external experts will also undertake an assessment of the credentialling process and ensure the standards outlined in this framework are met.

The committee will have oversight of national outcome data and will regularly review that data. They will also review and ratify service and facility accreditation and credentialling reports and maintain a list of accredited services, facilities and credentialled surgeons.

Eventually, most credentialling for pelvic floor reconstructive and urogynaecological procedures will be undertaken locally or regionally. The credentialling of mesh revision and removal procedures will continue to be undertaken by the national Credentialling Committee.

All organisations wishing to credential surgeons to undertake pelvic floor reconstructive and urogynaecological procedures will be required to have appropriate clinical governance structures in place. They will be responsible for a credentialling policy and procedures that specify sign-off and reporting requirements within the service or organisation and to the Credentialing Committee.

The local clinical governance structure will be responsible for appointing a credentialling panel that will also include a consumer representative and external experts appointed by the Credentialing Committee. Clinical governance oversight will be in accordance with the six credentialling domains (see Credentialling domains below) and will include regular monitoring of outcomes, quality assurance and consumer safety activities, including review of complications, complaints and broader

[19] The initial credentialling will be undertaken with assistance from international experts until such time as we have our own credentialled experts for these procedures available. We will select such experts based on their credentialled status within their own jurisdictions.

clinical skills, such as processes used for obtaining informed consent, communicating with both the consumer and other appropriate health practitioners, and cultural safety.

The Ministry will hold the list of credentialled surgeons and accredited services, and this list will be publicly available.

## Configuration of services

Application of the national credentialling framework to pelvic floor reconstructive, urogynaecology and mesh revision and removal procedures entails tiers of service configuration (with appropriate accreditation) and individual practitioner credentialling. This is one way of ensuring that health practitioners who are working across several health facilities deliver a consistent standard of safety and effectiveness by facilitating peer review and supporting best practice. Its implementation within services may include:

- designing an efficient means of credentialling practitioners or teams working in more than one organisation and across different levels of service (secondary and tertiary)
- designing an efficient means of accrediting several organisations that contribute to a single regional service
- ensuring that organisations can contribute to the credentialling processes of another organisation where the two organisations share clinical responsibility.

Credentialling services may sit within either the public or private sector or combine components from both sectors.

Tiers of service provision will support the concept of procedure-specific credentialling. To ensure the provision of safe and comprehensive services across Aotearoa New Zealand for these procedures, we have defined three credentialling tiers: tier 3 (national), tier 2 (regional) and tier 1 (local). Pelvic floor reconstructive and urogynaecological procedure credentialling will occur across all three tiers, whereas mesh revision credentialling will occur at tier 2 only, and mesh removal procedure credentialling will occur at tier 3 only.

There will be one national specialist mesh complications service (tier 3) provided in two centres across the country.[20] These highly specialised centres will be the ideal hubs for building regional networks and ultimately overseeing much of the credentialling activity.,

There may be more than one tier 2 accredited service within a specific region and any number of tier 1 services.

Acute procedures for mesh revision or removal represent an area of overlap and details as to where such procedures may be undertaken are covered under the acute procedures section below and within table 2: Pelvic mesh revision and removal procedures for each tier of service provision.

[20] We expect that the national service will be established during the second half of 2022.

Tier 1 services may be provided in all hospitals by clinicians and facilities that are able to meet the credentialling criteria outlined in this framework. Cases will be of low complexity.

As case complexity increases, the treatment options and challenges for interventions require increasing multidisciplinary team involvement and are therefore likely to be provided at tier 2 and 3. Credentialling requirements for each tier are outlined below.

## The determinants for procedures requiring tier 3 credentialling

- Services are highly specialised.
- Multiple specialty colleges and professional bodies are involved in standard setting.
- The interventions are new/emerging.
- Significant safety concerns have been identified.
- The case is very complex.

## The determinants for procedures requiring tier 2 credentialling

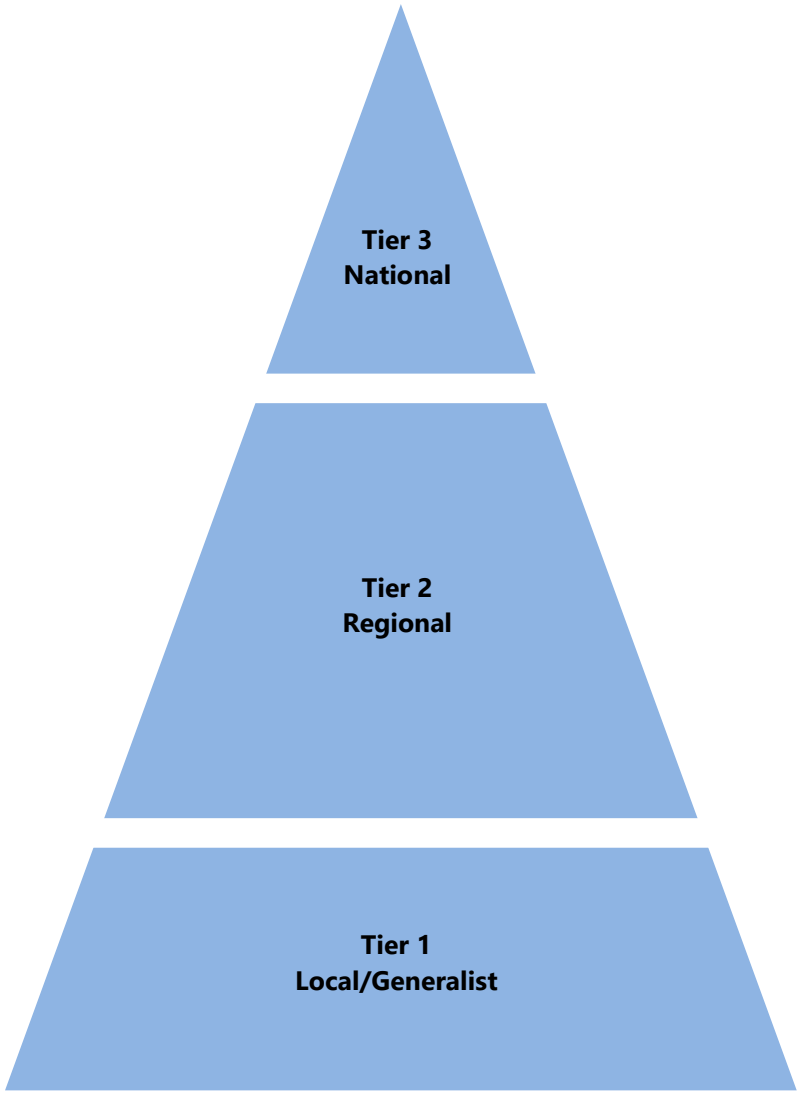
- Multidisciplinary teams are involved.
- The case is moderately complex (including recurrent prolapse or the need for more than one intervention following all urogynaecological procedures, for example, recurrent stress urinary incontinence, ).
- Procedures considered for tier 2 credentialling may be referred to tier 3 credentialling as indicated.

## The determinants for procedures requiring tier 1 credentialling

- The case is for a woman with low-complexity urogynaecological symptoms treated with or without surgical intervention.
- The case is for surgical management of a prolapse, with referral to tiers 2 or 3 credentialling when indicated.

Note: Some of the determinants for allocating procedures to specific tiers may change over time.

**Figure 3: Service configuration: Updated in November 2022**




| | |
|---|---|
| • Highly specialised<br>• Multi-specialty<br>• New or emerging procedures<br>• Very complex / significant safety issues | • Removal of retropubic mid-urethral sling (MUS) (partial (vaginal) or complete), orphan arms<br>• Removal of trans-obturator MUS (partial (vaginal) or complete), orphan arms<br>• Removal anterior/posterior vaginal prolapse mesh, body and arms, orphan arms<br>• Removal sacrocolpopexy vaginal attachment mesh<br>• Complete removal rectopexy mesh/bowel repair[21]<br>• Removal of orphan arms<br>• Removal of mesh from bladder, urethra, ureter, or bowel<br>• Reconstruction following mesh removal<br>• Removal of bulking agents<br>• Autologous sling removal<br>• Trans-obturator MUS (insertion of) |
| • Multidisciplinary teams<br>• Moderately complex cases (including recurrent prolapse or SUI)<br>• Referral to tier 3 may be indicated | • MUS (mesh sling) – retropubic<br>• Sacrocolpopexy, Sacrohysteropexy<br>• Sacrospinous hysteropexy (with permanent sutures)<br>• Autologous sling (for example, pubovaginal fascial sling, fascia lata)<br>• Burch colposuspension (open or laparoscopic)<br>• Urethral bulking agents<br>**Revision:**<br>• Acute loosening of sling for voiding dysfunction (mesh and autologous slings)<br>• Acute division of sling for voiding dysfunction (mesh and autologous slings)<br>• Vaginal division of MUS for obstruction<br>• Trimming (excision) of <1 cm exposed vaginal mesh |
| • Low complexity cases<br>• Surgical management of prolapse with referral when indicated | • High uterosacral ligament suspension (transvaginal or laparoscopic)<br>• Non-mesh apical suspension (without permanent sutures)<br>• Sacrospinous fixation/hysteropexy (without permanent sutures)<br>• Acute Non-Mesh Revision<br>• Repair of wound dehiscence along suture line<br>• Treatment of haematoma and infection |

[21] It is not expected [under the current Framework] that urologists and gynaecologists are required to credentialled for this procedure.

Note: From November 2022 the following changes have been made to service configuration and tiers in Figure 3 of the Framework:

**Tier 3**:

- Removal of orphan arms added to tier 3
- Removal of bulking agents added to tier 3
- Insertion of trans-obturator MUS added to tier 3

**Tier 2:**

- Sacrospinous hysteropexy (with permanent sutures) added to tier 2
- Autologous slings moved from tier 1 to tier 2
- Burch colposuspension moved from tier 1 to tier 2
- Urethral bulking agents moved from tier 1 to tier 2

**Tier 1:**

- Change from 'acute revision' to 'acute non-mesh revision'.
- High uterosacral ligament suspension (transvaginal or laparoscopic) moved from tier 2 to tier 1
- Non-mesh apical suspension moved from tier 2 to tier 1 with the addition of 'without permanent sutures'

# Credentialling domains

For each of the procedures and areas identified as being carried out in the tiers, explicit credentialling criteria are proposed that fall under the following six broad domains.

- Knowledge
- Skills (surgical and broader clinical)
- Outcomes
- Peer review
- Support systems
- Facilities/Services (to enable and support credentialling of both surgeons and services).

Whilst most criteria sitting within these domains will be applicable to all the procedures covered by this framework, there are some material differences in considering procedure-specific credentialling for pelvic floor reconstructive procedures and urogynaecological procedures in contrast to those procedures for mesh revision and removal. These differences are explored and described within this framework.

Acute (less than six weeks after surgery) mesh revision and removal procedures are an area of overlap between the two major categories of surgery covered in this framework, and credentialling for these procedures will generally be a component of credentialling for pelvic floor reconstructive procedures and urogynaecological procedures.

Credentialling reviews the environment and context in which the practitioner operates. Where multiple facilities are involved within a service, the efficacy of the clinical network also needs to be reviewed.

The term credentialling may also be used in the context of services and facilities. However, accreditation against a developed set of standards is a more standard means of framing the assessment and endorsement of organisations within which procedures are carried out, similar to how organisations are accredited by regulatory bodies to provide training programmes and providers are certified against the Ngā Paerewa Health and Disability Sector Standards (2020).

# Credentialling outcomes

There are three potential outcomes from the credentialling process that relate to either the surgeon or the facility. These are as follows.

- All criteria met – credentialled
- Criteria substantially met – credentialled with recommendations or conditions
- Criteria not met – not credentialled, therefore cannot perform procedures or must be supervised.

Recommendations will be progressed against agreed timelines, with a designated local body responsible for monitoring progress and communicating this to the national credentialling committee.

Where the credentialing process results in an alteration to a practitioner's credentialed scope of practice, the employing organisation will support those applicants that are credentialed with conditions or recommendations, and those who do not achieve credentialed status with the requisite upskilling and/or activities, such as proctoring,[22] where appropriate. For those practitioners practising in private only, an arrangement will be facilitated by the national Credentialling Committee. Where the practitioner and the Credentialling Committee disagree over a credentialling outcome, an appeals process will be available and governed by due processes clearly specified by the practitioners employer and professional organisation.[23]

The Credentialling Committee has advisory powers only, with no statutory authority to enforce their recommendations. They will send a copy of each credentialling report to relevant staff and facilities for consideration. Where the committee has concerns regarding a practitioner's competence or conduct within that practitioner's scope of practice, a member of the committee may notify the MCNZ within the terms of the Health Practitioners Competence Assurance Act 2003. The Credentialling Committee may also send a copy of this notification to the relevant professional body (RACS or RANZCOG), in case the practitioner approaches the professional body for support/advice.

The Health and Disability Commissioner protects the rights of health consumers and disability services consumers. Every consumer has the right to services of an appropriate standard. Services must be provided with reasonable care and skill, and they must comply with legal, professional, ethical and other relevant standards. As such, in  investigation of complaints from consumers about the standard of care provided by surgeons undertaking pelvic floor reconstructive, urogynaecological and mesh revision and removal procedures in future, an important consideration for the Health and Disability Commissioner will be whether the practitioner is credentialled. If the practitioner has not undertaken a credentialling process or if they are working contrary to their credentialling process recommendations, the Health and Disability Commissioner may decide that individual is in breach of the Code of Health and Disability Services Consumers' Rights.

# Device-specific credentialling

Practitioners must undergo training specific for each kind of device, technology or delivery system they propose to use. To achieve credentialled status, they must fulfil all the credentialling criteria outlined in this framework.

[22] Sachdeva A.K., Russell T.R. (2007). Safe introduction of new procedures and emerging technologies in surgery: education, credentialling, and privileging. *Surg Clin North Am. 87*(4): 853-–vii. DOI: **www.doi.org/10.1016/j.suc.2007.06.006** (accessed 16 May 2022).

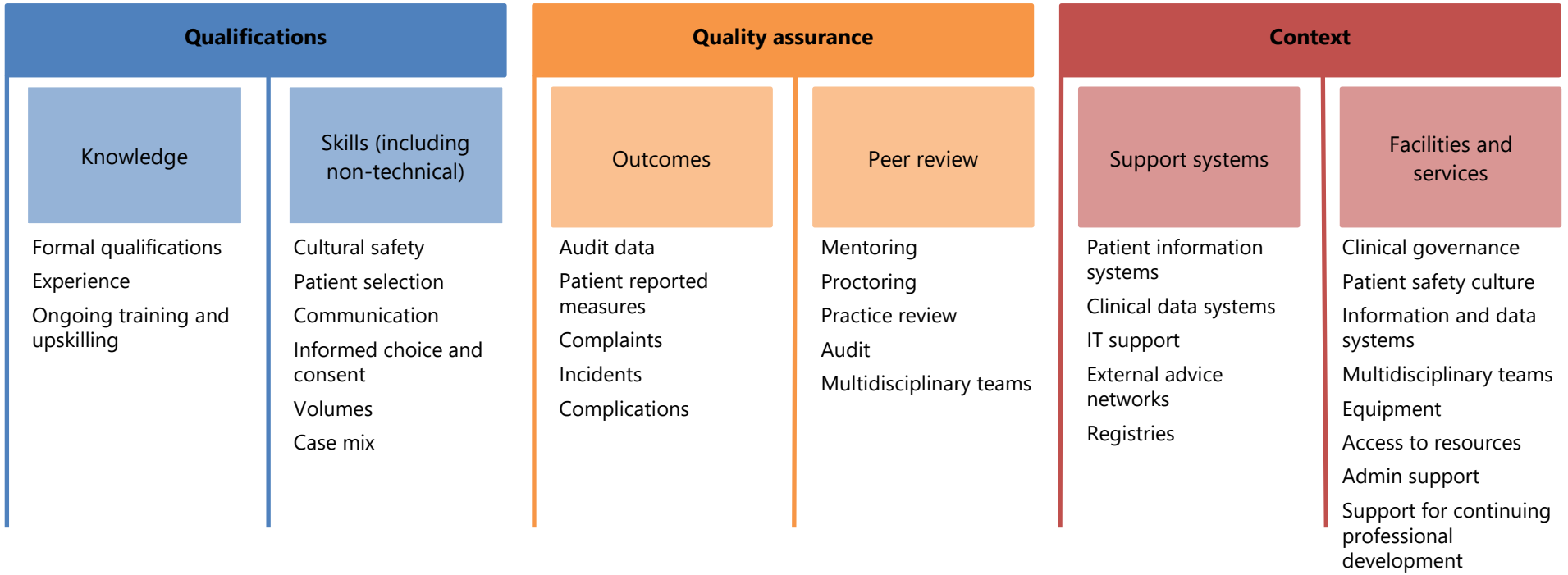
[23] Ministry of Health. 2010. *The Credentialling Framework for New Zealand Health Professionals*. Wellington: Ministry of Health, page 2. URL: **www.health.govt.nz/system/files/documents/publications/credentialling-framework-nz-health-professionals.pdf** (accessed 13 May 2022).

# Section 4: General principles for procedure-specific credentialling

The principles of credentialling apply to all the major categories of surgical procedure covered in this framework. There are many similarities in the configuration and accreditation of services and facilities in which these surgical procedures take place. However, there are some material differences in procedure-specific credentialling for pelvic floor reconstructive and urogynaecological procedures compared with the procedures for mesh revision and removal. Therefore, these matters are considered separately in sections 5 and 6 respectively.

For each of the procedures and areas identified as being carried out in the tiers, there are explicit credentialling criteria proposed falling under three areas and six broad domains as outlined in figure 4: Procedure-specific credentialling domains. These domains define requirements for knowledge, skills, quality assurance activities and the support systems to enable and support credentialling of practitioners and accreditation of services.

**Figure 4: Procedure-specific credentialling domains**



# Generic procedure-specific credentialling domains

## Qualifications

### Knowledge

Required formal qualifications and levels of experience are specified within the procedure-specific sections 3 and 4 that follow this section of the document.

#### Continuing professional development

The individual practitioner is responsible for their own ongoing professional development, attaining appropriate continuing medical education as specified by their professional colleges or associations and in keeping with the requirements of the MCNZ.

Practitioners must demonstrate at credentialling evidence of their continuing professional development for the procedure categories and groupings in which they are working and wish to remain credentialled for. Their practice should be reflective and involve audit and registry information and presentation at peer review. Where audit outcomes lead to changes and reflections in clinical practices (for example, practice visits, mentoring, attending accredited international courses), records should be kept and should be available at credentialling. Professional development must include broader clinical skill development, including communication, training in trauma-informed care and cultural safety components. Contributions to the service, such as quality initiatives, teaching and planned service extensions, should also be presented.

### Skills (including non-technical)

The credentialling process will include review of the following.

#### Cultural safety

Practitioners must meet the cultural safety standards as outlined by the MCNZ.[24] Practitioners must also commit to achieving health equity for Māori.[25]

#### Patient selection

An important component of the credentialling process will be consideration of the quality of decision-making around preferred treatment options (patient selection and patient choice), use of appropriate investigations, multidisciplinary decision-making and the quality of the informed consent process. It is expected that such decision-making will be guided by and consistent with accepted international guidelines, such

[24] For more information, see the webpage Cultural safety on the Medical Council of New Zealand website at: **www.mcnz.org.nz/our-standards/current-standards/cultural-safety** (accessed 16 May 2022).

[25] MCNZ. 2019. *He Ara Hauora Māori: A pathway to Māori health equity.* Wellington: Medical Council of New Zealand (MCNZ). URL: **www.mcnz.org.nz/assets/standards/6c2ece58e8/He-Ara-Hauora-Maori-A-Pathway-to-Maori-Health-Equity.pdf** (accessed 16 May 2022).

as the National Institute for Health Care and Excellence (NICE) NG123 guideline: *Urinary Incontinence and Pelvic Organ Prolapse in Women: Management*.[26]

Practitioners must demonstrate to the credentialling committee their knowledge and experience of accurately interpreting urodynamic studies. Wider discussion with the multidisciplinary team is expected.

### Communication

Good consumer-centric communications and cultural safety are core clinical skills, and individual practitioners should provide evidence that this is a component of their ongoing professional development. Facilities must incorporate in their clinical governance structures a process to enable assessment of these skills, such as through peer review, complaints or compliments and audit. Measures of the quality of this should be reflected in patient-reported experience measures (PREMs) questionnaires.

### Patient information and consent and informed choice

Informed consent and choice processes are expected to be consistent with the MCNZ published standard: Informed Consent: Helping patients make informed decisions about their care.[27] This process must be supported with the use of appropriate consumer information, such as the co-designed 2019 booklet published by the Ministry, *Considering Surgical Mesh to Treat Stress Urinary Incontinence? Using permanent polypropylene (plastic) mesh tape in mid-urethral sling (MUS) operations*.[28]

The following are integral to information and consent processes, and the credentialling process will assess that they have been addressed adequately.

- The practitioner explains the various treatment options available (including conservative, medical and surgical options) thoroughly and accurately, with the risks and benefits of each clearly explained to the women. There must be an honest and open conversation with consumers about the individual practitioner and proposed team's skill set and experience, results from previous similar procedures and complications linked to the suggested procedure. Women must be aware and understand that resolution of their symptoms after the procedure is not guaranteed. Clear and transparent treatment plans must be in place.
- Comprehensive, informed choice discussions with women include clearly identifying the steps involved in surgery, how any risks will be mitigated, potential referral to other teams, management of intra- and post-operative complications, and discussion of post-operative sequalae.
- The consumer should take an active role in the informed choice process, and decisions regarding treatment must be made with the women. Obtaining consent will be a multi-step process, with the women given ample time to consider the

[26] NICE. 2019.*Urinary Incontinence and Pelvic Organ Prolapse in Women: Management* NICE guideline [NG123]. London: National Institute for Health and Care Excellence (NICE). URL: **www.nice.org.uk/guidance/ng123** (accessed 17 May 2022).

[27] MCNZ. 2021. *Informed Consent: Helping patients make informed decisions about their care.* Wellington: Medical Council of New Zealand (MCNZ). URL: **www.mcnz.org.nz/assets/standards/79e1482703/Statement-on-informed-consent.pdf** (accessed 17 May 2022).

[28] Ministry of Health. 2019. *Considering Surgical Mesh to Treat Stress Urinary Incontinence? Using permanent polypropylene (plastic) mesh tape in mid-urethral sling (MUS) operations*. Wellington: Ministry of Health. URL: **www.health.govt.nz/system/files/documents/publications/considering-surgical-mesh-to-treat-stress-urinary-incontinence-aug2019.pdf** (accessed 17 May 2022).

verbal and written information provided. They must have an opportunity to discuss options at the consultation appointment; the opportunity to reflect beyond the clinical setting before being expected to reach a final decision; and be able to change their decision at any time before the surgery.

### Volumes and case mix

The indicative volumes described in this framework provide guidance for practitioners in terms of what will be expected for credentialling. Higher surgical volumes and associated favourable outcomes have been demonstrated across a variety of surgical specialities, including gynaecology and urogynaecology.[29, 30, 31] However, the evidence associating volumes with outcome regarding surgical mesh revision and removal is sparse and potentially contradictory, partly because these procedures are recent and rapidly evolving.[32] As the credentialling process' primary focus is competency, high volumes will not automatically equate to proficiency. The Credentialling Committee will take account of situations where surgeons may have extensive experience in performing procedures over many years, building up a large case volume with outcomes within expected ranges, although their caseloads may have declined more recently. The committee will also consider how surgeons in smaller centres can maintain competence with lower volumes of procedures.

The detail specific to procedures is included in sections 5 and 6 below.

### Cross recognition of skills and prior experience

Credentialling recognises that some knowledge and skills are transferable between procedures, including anatomical knowledge, technical expertise and communication skills. Assessment for credentialling purposes should consider the whole scope of a surgeon's practice. The Credentialling Committee acknowledges that cross-recognition of skills is both nuanced and subject to inconsistent application, and therefore, the committee will need to develop principles-based guidelines.

# Quality assurance

## Outcomes

Patient outcomes and complication rates will be guided by international guidelines, local institutional and relevant professional organisation requirements, consumers, and Credentialling Committee opinion (inclusive of international experts). 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. At the same time, evidence of

[29] Mowat A, Maher C, Ballard E. 2016. Surgical outcomes for low-volume vs high-volume surgeons in gynecology surgery: a systematic review and meta-analysis. *American Journal of Obstetrics & Gynecology. 215*: 1; 21–33. DOI: **http://dx.doi.org/10.1016/j.ajog.2016.02.048** (accessed 17 May 2022).

[30] Barnes HC, Shim SPR, Whiteside JL. 2021. Follow the Evidence 9/21 – Physician operative volume and patient outcomes for hysterectomy. *Int. Acad. Pelvic Surg.*

[31] AUGS-IUGS. 2020. Joint position statement on the management of mesh-related complications for the FPMRS Specialist. AUGS-IUGS joint publication. *Female Pelvic Med Reconstr Surg, 26*; 4: 219–32. URL: **www.augs.org/assets/1/6/Joint_Position_Statement_on_the_Management_of.1.pdf** (accessed 17 May 2022).

[32] Ibid.

the true 'local risk' of various complications will emerge, and this must be considered in regular review processes and strongly influence discussions and information provided to consumers who are considering mesh removal. Recognition will be accorded to the statistical bias that may accompany outcome measures for small, individual data sets.

More detailed descriptions of expectations for considering outcomes, as a part of credentialling for procedure groupings, are provided in sections 5 and 6 below. However, key areas to be included are:

- audit data
- patient-reported outcome measures (PROMs) and PREMs
- functional outcomes, including:
  - sexual function
  - effect on daily life
  - severity of complications to daily life
  - years lived with disability (YLD)
  - ability to return to exercise
  - effects on relationships
- complaints
- incidents
- complications.

### Peer review

Required peer review includes:

- mentoring
- proctoring (used here in the sense of monitoring, observing and supervising as opposed to invigilating)
- practice review – including college-based processes that contribute to recertification programmes
- audit – individual, team and unit review mechanisms for both cases and accumulated data relating to outcomes, complications, incidents and clinical process reviews (includes mortality and morbidity meetings)
- multidisciplinary meetings (in both public and private practices or combined)
- learning from other disciplines.

## Context

### Support systems

The required support systems include:

- service-specific documentation requirements, including care plans
- patient information systems
- clinical data collection systems
- information technology (IT) support

- external advice networks
- national and international registries.

## Facilities and services

Credentialling 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 credentialling practitioners will be assessed as to whether they provide the supporting structures and systems to enable the individual practitioners and multidisciplinary teams working within it to deliver the best possible care. The development and promotion of a culture that supports consumer safety and consumer engagement with openness and transparency is paramount.

Where multiple facilities are involved within a service, the efficacy of the clinical network also needs to be reviewed.

Standards used in assessing for accreditation should include:

- measures to ensure demonstration of the principles of Te Tiriti o Waitangi, including equity of access and quality of care for Māori and ensuring the health care environment supports the cultural safety of all women and whānau
- commitment to developing and promoting a culture that supports consumer safety and engagement with openness and transparency
- clinical governance and administration of local credentialling processes, including established reporting channels to the national Credentialing Committee
- ensuring adequate staffing, building design, equipment, systems and processes to provide a well-coordinated, best-practice environment for clinical care delivery
- facilitation of a multidisciplinary approach to the care and treatment of women and their whānau presenting with complex clinical needs and with complications
- establishment and support for multidisciplinary meetings and teams (such as radiologists, specialist continence nursing, specialist pelvic health physiotherapy, pain specialist services, psychologists)
- supporting and facilitating clinical data collection systems, including registries, where these have been established
- robust local clinical governance structures to monitor and administer all quality assurance activities, including those relevant to complaints, Health and Disability Commissioner investigations, Accident Compensation Corporation (ACC) treatment claims, risk of harm notifications, case reviews (via mechanisms such as mortality and morbidity reviews, the Health Quality and Safety Commission New Zealand's (HQSC's) serious adverse event reviews, etc) and broader data and outcome audit mechanisms
- providers supporting and enabling appropriate professional development, including continuing medical education, for practitioners in their specific fields of clinical practice and procedures
- review of clinical networks in terms of jointly agreed guidelines and pathways, referral guidelines and protocols, guidelines and protocols for patient follow-up – short, medium and long term.

All facilities have a responsibility to support individual practitioners, by providing a service within their facility, to meet the credentialling criteria. However, there are aspects of the criteria within private facilities where the practitioner takes the lead and provide evidence at credentialling. These include:

- demonstrating the provision of a wraparound service for the women they operate on in private facilities
- taking a multidisciplinary approach to the care and treatment of women and whānau presenting with complex clinical needs and with complications
- engaging in multidisciplinary meetings within their private and/or public practices
- demonstrating access to the multidisciplinary team (such as radiologists, specialist continence nursing, specialist pelvic health physiotherapy, pain specialist services, psychologists) as required
- demonstrating their ongoing professional development, including continuing medical education in their specific fields of clinical practice and procedures.

## Summary credentialling decision tree

The credentialling decision tree for procedure-specific credentialling of practitioners is represented in figure 5 below and should be used as the basis for structuring credentialling processes across all tiers and in all services and facilities.

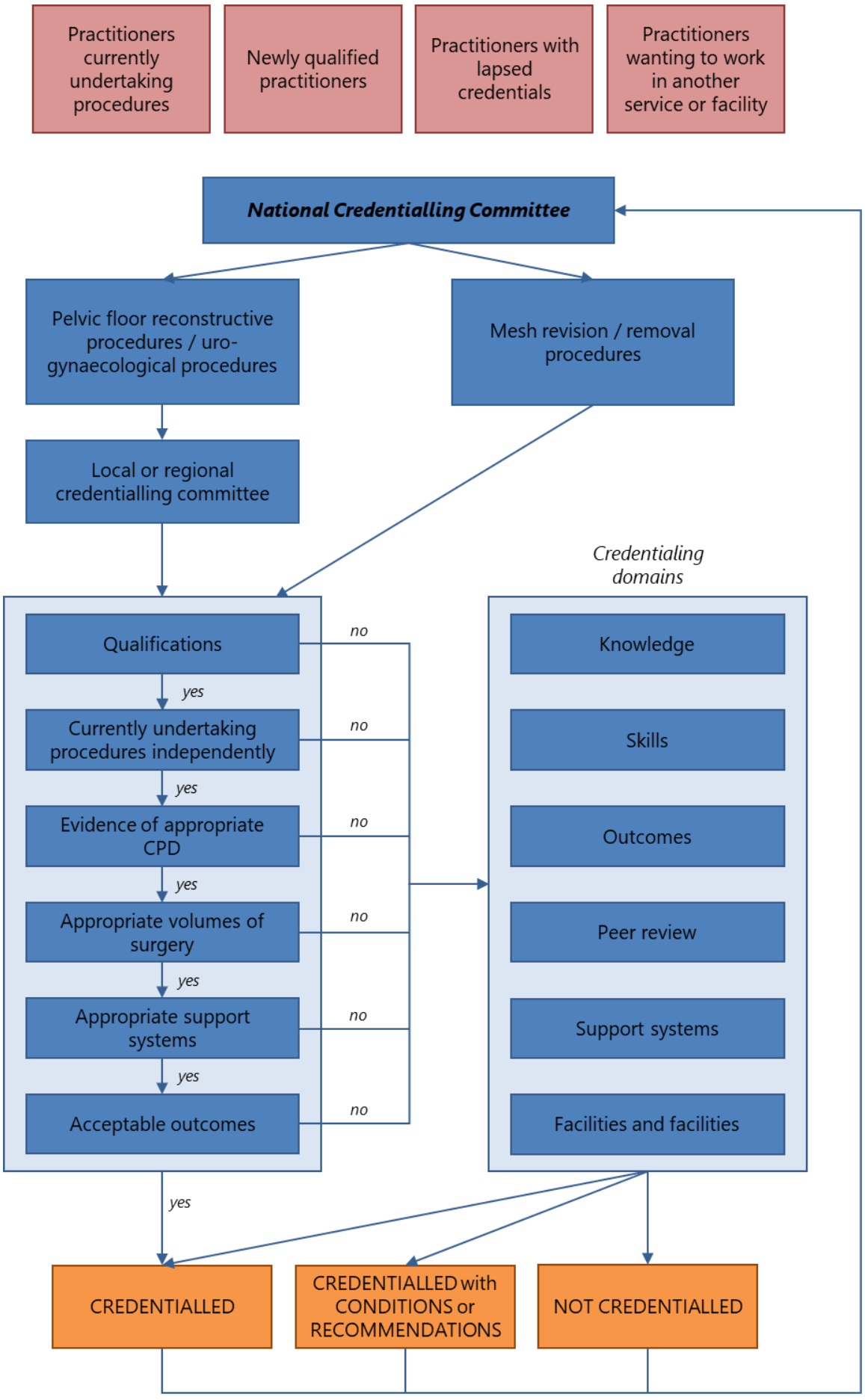
The Credentialing Committee will identify extra credentialling requirements for those applicants that are credentialled with conditions or recommendations and those who do not achieve credentialled status. The nature of these extra requirements will be determined on an individual basis and could include:

- educational activities (including online)
- non-technical skills workshop
- proctoring
- peer mentoring and supervision
- practice reviews
- access to structured multidisciplinary meetings
- input and review of data
- access to resources, support and IT systems.

Ownership of the process by the facility, together with evidence of ongoing monitoring of outcomes and issues, will ensure that emerging problems are identified and mitigated early.

As noted above under ‘The credentialling process’ in section 3, credentialling will initially take place on a two-yearly cycle. Individuals or facilities may need to be credentialled more frequently if additional criteria are applied to their status.

**Figure 5: Decision tree for procedure-specific credentialling of practitioners**



# Acute procedures

Acute mesh revision or removal procedures (for the purposes of this framework considered to be less than six weeks after surgery) are an area of overlap between the two major categories of surgery covered in this framework. Such procedures are delineated in table 2 Pelvic mesh revision and removal procedures for each tier of service provision

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 after surgery
- voiding dysfunction without pain or haematuria.

The acute procedures able to be undertaken at tier 2 are:

- MUS loosening
- MUS division
- MUS trimming < 1 cm (retropubic slings only).

Multidisciplinary team input must be sought from the tier 3 national Specialist Mesh Complications Service before there is any intervention at tier 2 (regionally).

If a sling loosening or division is undertaken at tier 2 (regionally) for voiding dysfunction, a referral to the Specialist Mesh Complications Service for follow-up is required.

Any consumer with ongoing residual symptoms following an acute procedure undertaken at either tier 1 or tier 2 is to be referred to the Specialist Mesh Complications Service.

Outcome measures to be collected following these procedures include:

- PROMs and PREMs
- flow rate.

# New and innovative procedures, including robotic procedures

It is self-evident that, over time, new assessment and treatment procedures and modalities will be developed for managing women with gynaecological and urological conditions, and there will be continued evolution of existing procedures and modalities. A current example is the application of robotic surgery for mesh removal, which is in its early stages in the Aotearoa New Zealand setting.[33] It is expected that robotic surgery will be delivered at tier 2 or 3 as it applies to this framework.

Effective governance of all new procedures before implementation is essential to ensure confidence in and benefit from the advances in health care science. It is essential for consumer and public safety that robust risk-management policies, processes and ethical standards are in place.

A new surgical procedure is defined as one that has not previously been used in that hospital or health service, that is, no previous use or local experience, and represents a significant departure from previous practice. This includes new techniques, new nonsurgical treatment modalities, new equipment and technologies, and new implants.

All new procedures, including significant changes to existing procedures, must be rigorously assessed and approved before they are introduced into clinical practice, with practitioners having undergone procedure-specific training and services/facilities accredited to provide the new procedures.

The essential considerations as well as guidance for organisations and individual practitioners are well delineated in the RACS document *General Guidelines for Assessing, Approving and Introducing new Surgical Procedures into a Hospital or Health Service RACS-ASERNIPS-S*.[34] Once a new procedure has been introduced it must be subject to the audit requirements detailed in the RACS guidelines and to all the principles and processes described in this framework.

Consumer safety is paramount as, in the case of surgical mesh, historically harm has followed the unregulated introduction of new clinical procedures and products.

[33] Rice MK, Hodges JC, Bellon J, et al. 2020. Association of mentorship and a formal robotic proficiency skills curriculum with subsequent generations' learning curve and safety for robotic pancreaticoduodenectomy. *JAMA Surg. 155*(7): 607–15. DOI: **http://doi.org/10.1001/jamasurg.2020.1040** (accessed 17 May 2022).

[34] RACS, ASERNIP-S. *General Guidelines for Assessing, Approving and Introducing new Surgical Procedures into a Hospital or Health Service RACS-ASERNIPS-S*. Roayl Australasian College of Surgeons / ASERNIP-SURL: **www.surgeons.org/-/media/Project/RACS/surgeons-org/files/position-papers/rea_ase_3103_p_general_guidelines_for_assessing_approving_introducing_new_surgical_procedures_into_a.pdf?rev=45633c22bd9941129d471fc98e300083&hash=BB63DA90EEB5CA3A8B491CCCC0FFA185** (accessed 17 May 2022).

# Section 5: Procedure-specific credentialling for uro-gynaecological and pelvic floor reconstructive procedures

## Urogynaecological procedures for stress urinary incontinence

The procedures relevant to this section include all procedures performed for the indication of SUI, including, but not limited to:

- MUS mesh
  - retropubic
  - trans-obturator – indications for this procedure are specific and limited and must be discussed in the tier 3 specialist mesh complications multidisciplinary or peer review forum (see note below)
- autologous sling (for example, pubovaginal fascial sling, fascia lata)
- burch colposuspension (open or laparoscopic/robotic)
- urethral bulking agents.

These procedures are not included in standard training programmes, and additional training is required. The RANZCOG advanced training module, urogynaecology fellowship or urology fellowship covering female and reconstructive procedures, provides evidence of training, however, all other criteria must be met for credentialling.

SUI surgery should only be performed by specialists who are able to offer a range of surgical options and provide informed choice for all options and can demonstrate they fulfil all the credentialling criteria. This may include procedures they do not offer themselves, in which case, they should refer to appropriate surgeons or providers elsewhere.

Note: The use of the trans-obturator procedure is no longer supported except for very specific and limited indications and in exceptional circumstances.[35] The specialist mesh complication service multidisciplinary team must be consulted, and a collective decision made in these circumstances.[36, 37]

All practitioners performing SUI procedures must:

- provide a comprehensive evaluation of urinary incontinence, including history and pelvic examination
- identify complicated from uncomplicated (index from non-index) stress urinary incontinence patients[38] and high-risk factors for treatment failure and complication
- accurately interpret urodynamics, including pressure-flow studies
- recognise and manage complications of treatment, intra- and post-operatively
- have experience and training in performing intraoperative cystoscopy to evaluate for bladder and ureteral integrity.

# Pelvic floor reconstructive procedures for complex pelvic organ prolapse

The procedures relevant for POP include all procedures[39] for post-hysterectomy vaginal vault prolapse and all uterine-preserving apical prolapse procedures, including, but not limited to:

- sacrocolpopexy
- sacrospinous fixation
- sacrospinous hysteropexy
- high uterosacral ligament suspension (transvaginal or laparoscopic/robotic)
- non-mesh apical suspension.

[35] Ministry of Health, RANZCOG, USANZ. 2020. *Surgical Mesh Roundtable: Position statement on the use of the transobturator approach in incontinence surgery*. Wellington: Ministry of Health. URL: **www.health.govt.nz/system/files/documents/pages/position_statement_on_the_use_of_the_transobturator_approach.pdf** (accessed 18 May 2022).

[36] Gomes CM, Carvalho FL, Bellucci CHS, et al. 2017. Update on complications of synthetic suburethral slings. *Int Braz J Urol. 43*(5): 822–34.

[37] Ministry of Health, RANZCOG, USANZ. 2020. *Surgical Mesh Roundtable: Position statement on the use of the transobturator approach in incontinence surgery*. Wellington: Ministry of Health. URL: **www.health.govt.nz/system/files/documents/pages/position_statement_on_the_use_of_the_transobturator_approach.pdf** (accessed 18 May 2022).

[38] ACOG. 2014. Evaluation of uncomplicated stress urinary incontinence in women before surgical treatment. *Committee Opinion, 603.* URL: **www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2014/06/evaluation-of-uncomplicated-stress-urinary-incontinence-in-women-before-surgical-treatment** (accessed 18 May 2022).

[39] Including the use of mesh and non-mesh procedures.

These procedures are not included in standard training programmes and additional training is required. The RANZCOG advanced training module, urogynaecology fellowship or urology fellowship covering female and reconstructive procedures, provides evidence of training, however, all other criteria must also be met for credentialling.

Note: Vaginal hysterectomy (with or without uterosacral pedicle plication procedures), anterior vaginal wall repair (colporrhaphy), posterior vaginal wall repair (colporrhaphy) or colpocleisis are *not included* in this framework. Credentialling for these procedures will continue to occur within the existing credentialling processes for specialist gynaecologists and urologists.

Pelvic floor reconstructive procedures should be performed by specialists who are able to offer a range of surgical options and provide informed choice for all options and can demonstrate they fulfil all the credentialling criteria. This may include procedures they do not offer themselves, in which case, they should refer to appropriate surgeons or providers elsewhere.

Surgeons planning to perform apical prolapse procedures in their practice must demonstrate previous experience and current practice in providing vaginal-approach pelvic organ prolapse surgery.

Table 1 identifies acceptable assessment criteria, indicative volumes and complication rates, which credentialling committees should use for benchmarking purposes only. They are acknowledged criteria, volumes and complication rates from published papers and, when such criteria are unavailable, expert consensus.[40, 41, 42, 43, 44, 45]

We acknowledge that the volumes and rates may well alter over time as further evidence and expert commentary come to hand and that volumes alone are only one component considered for credentialling.

[40] Blaivas JG, Purohit RS, Benedon MS, et al. 2015. Safety considerations for synthetic sling surgery. *Nat Rev Urol. 12*: 481–509.

[41] Brazzelli M, Javanbakht M, Imamura M, et al. 2019. The effectiveness and cost-effectiveness of surgical treatments for women with stress urinary incontinence: An evidence synthesis, economic evaluation and discrete choice experiment (ESTER). *Health Technol Assess 23*: 1–306.

[42] Gomes CM, Carvalho FL, Bellucci CHS, et al. 2017. Update on complications of synthetic suburethral slings. *Int Braz J Urol. 43*(5): 822–34.

[43] Imamura M, Hudson J, Wallace SA, et al. 2019. Surgical interventions for women with stress urinary incontinence: systematic review and network meta-analysis of randomised controlled trials. *BMJ; 365*: 1,842.

[44] Scottish Government. 2017. *Transvaginal Mesh Implants Independent Review: Final report.* Edinburgh: Scottish Government. URL: **www.gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711** (accessed 18 May 2022).

[45] Brosche T, Kuhn A, Lobodasch K, et al. 2021. Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence. *Neurourology and Urodynamics; 40*: 502–508. DOI: **https://doi.org/10.1002/nau.24589** (accessed 18 May 2022).

**Table 1: Assessment criteria (including indicative volumes and complication rates) for pelvic floor reconstructive procedures and urogynaecological procedures[46]**

| | MUS with mesh (retropubic) | Pubovaginal fascial sling | Sacrocolpopexy | Colposuspension | Peri-urethral bulking[47] |
|---|---|---|---|---|---|
| Indicative volumes (2 years) | 20 | 20 | 20 | 20 | - |
| **Outcome measures** | | | | | |
| PROMs | Outcome 3 and 12 months through to 5 years | | | | |
| PREMs | | | | | |
| Functional outcomes | *See Data collection below for the list of outcomes* | | | | |
| PGI-I | PGI-I scoring 1 and 2 >70% plus and 6 and 7 <10% | | | | |
| Overactive bladder (new onset) | 5–20% | 5–20% | 1% | 5–20% | Rare |
| Voiding difficulty or retention | 8% | 5–10% | 2–5% | 5–10% | Rare |
| **Complications and reported rates** | | | | | |
| *Early* | | | | | |
| Injury to the genitourinary tract (bladder injury, ureteric obstruction/ damage) | 6–8% | 1–2% | 2–5% | 2–5% | <3% |
| Injury to other GI and vascular organs | 2% | Rare | <1% | <1% | |
| Blood loss> 500 mL | Rare | 1–2% | 5–10% | 2–5% | |
| Hospital length of stay | <2 nights | <3 nights | <3 nights | <3 nights | <1 night |

[46] No specific volumes have been stated for sacrospinous fixation, sacrospinous hysteropexy, high uterosacral ligament suspension (transvaginal or laparoscopic/robotic) or non-mesh apical suspension, however, evidence of satisfactory outcomes, including PROMs, and audits are required.

[47] No indicative volumes are listed for this procedure, however, practice will still be assessed as part of the overall credentialling process.

| | MUS with mesh (retropubic) | Pubovaginal fascial sling | Sacrocolpopexy | Colposuspension | Peri-urethral bulking[47] |
|---|---|---|---|---|---|
| Wound infection | <1% | 5–10% | 5–10% (open)<br><1% (lap) | 5–10% (open)<br><1% (lap) | |
| Death from all causes within 30 days | Rare | Rare | Rare | Rare | Rare |
| *Late* | | | | | |
| New-onset vaginal or pelvic pain lasting longer than 6 weeks | 3% | <1% | <5% | 10–15% | 4% |
| Erosion into another organ | 1–3% | N/A | 1% | 1% | 2% |
| Dyspareunia | 5% | Rare | 1% | <5% | |
| Re-treatment for recurrent incontinence, including further surgery | <5% | <5% | N/A | 10% | |
| Mesh exposure | 2–4% | N/A | 5% | N/A | N/A |
| Recurrent urinary tract infection | 5–10% | 5–10% | 2–5%[48] | 5–10% | Rare |

[48] Sacrocolpopexy UTI rates 2% without incontinence procedure, 5% with concomitant incontinence procedure.

# Further commentary on credentialling domains

Generic credentialling domains are described earlier in this framework and are to be applied to all processes used for pelvic floor reconstructive surgery and urogynaecological procedures. Further commentary and details on credentialling for these specific procedures are discussed below and should be applied during assessment. These include:

- required qualifications
- medical practice in accordance with Te Tiriti o Waitangi and its principles
- diagnostic skills – anatomy; lower urinary tract function; urodynamics; pelvic radiology, including ultrasound; computerised tomography (CT); magnetic resonance imaging (MRI) when indicated
- experience of pelvic floor reconstructive and urogynaecological procedures to help with selecting the appropriate procedure
- operative experience with outcomes within the expected range, including PROMs and PREMs
- recognition and management of intra- and post-operative complications
- documentation of multidisciplinary meeting to show individual treatment plans have been provided that involve the wider multidisciplinary team – physiotherapy, pain, psychology, nursing, radiology, other surgical disciplines
- continuing professional development (CPD) specific to pelvic mesh reconstructive and urogynaecological procedures within the last two years
- clinic and operation theatre availability (service)
- IT support for outcome data (service)
- availability of an appropriate registry (service).

# Required qualifications

The practitioner must be vocationally registered with the MCNZ and:

- a RANZCOG certified urogynaecologist (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
- a Fellow of RANZCOG or RACS who does not have the above qualifications but who can demonstrate:
  - a substantially similar level of post FRANZCOG or FRACS supervised and documented training in each specific procedure (demonstrated through logbooks, review of case log and review of case scenarios)
  - 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.

All three of the above 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, as well as when such treatments are appropriately clinically indicated.

# Non-mesh surgical treatments

Given the predominance of the use of mesh (representing more than 98 percent of procedures since the mid-2000s), there has been minimal training and recency of experience in non-mesh SUI procedures, for example, burch colposuspension, autologous slings.[49]

Therefore, all practitioners with the required qualifications, as listed above, who are undertaking non-mesh SUI, will be required to:

- demonstrate supervised and documented training in each specific non-mesh procedure (for example, through logbooks, including volumes and case review of patients) or
- be proctored by a qualified surgeon with currency of experience in specific procedures and
- demonstrate the ability to successfully treat the complications of non-mesh procedures.

# Logbooks and care plans

Applicants for credentialling must send the Credentialling Committee their operative logbooks for procedures, including indication for surgery, examination findings, diagnostic results, pre-operative PROMs, operation notes, complications and clinical and patient-reported outcomes at six months (for initial credentialling purposes only, while the medium- to longer-term measures are being defined). We expect longer-term outcome capture to start as soon as possible.

The individualised treatment care plans created with the women and the multidisciplinary team will be presented to the Credentialing Committee or designated committee as evidence of effective management.

# Volumes

The indicative volumes listed in table 1 provide guidance for practitioners in terms of what will be expected for credentialling. We recognise that high volumes do not automatically equate to proficiency. Therefore, the Credentialing Committee will consider applications from practitioners with less than the indicative volumes listed,

[49] Withington J, Hirji S, Sahai A. 2014. The changing face of urinary continence surgery in England: a perspective from the Hospital Episode Statistics database. *BJU Int. Aug;114*(2): 268–77. DOI: **http://doi.org/10.1111/bju.12650** (accessed 18 May 2022). Epub 2014 May 22. PMID: 24512557.

provided the outcomes from such procedures are within the expected range. We will also take into consideration overall volumes of more than one procedure, that is, cross-recognition of skills. Volumes from both public and private practices may be combined.

No specific volumes have been stated for sacrospinous fixation, sacrospinous hysteropexy, high uterosacral ligament suspension (transvaginal or laparoscopic/robotic) or non-mesh apical suspension, however, evidence of satisfactory outcomes, including PROMs and audits, is required.

# Data collection

The collection of, and access to, appropriate data is essential to support credentialling. Service providers need to facilitate and readily support data collection to enable quality assurance, benchmarking, and quality improvement. The data outlined in table 1 above should be collected 'at arms-length' from the operating surgeon. A mechanism to support long-term patient follow up needs to be established. Until an appropriate registry is in place in Aotearoa New Zealand other means of collecting data must be established to capture the minimum data suggested in the table above.

## Outcome data

Further work is required to refine the medium- to longer-term outcome datasets. In the interim, outcome data reviewed at credentialling will utilise the minimum dataset developed, which will be held by an appropriate registry. Data to be captured includes:

- previous surgery and mesh type
- indications for treatment and outcome: urinary incontinence, dyspareunia, persistent pelvic and associated pain, recurrent urinary tract infections, voiding or storage dysfunction of bladder or bowel, PROMs – minimum dataset symptoms
- measures of pelvic floor status pre- and post-operatively, examination, urodynamics (UDS), radiology
- intraoperative complications – blood loss >500mL, sepsis
- risk factors with modifying effects on surgical outcomes – BMI, smoking, diabetes and menopausal status
- additional complications, such as unintentional organ injury, for example, injury of the bladder, and nerve injury
- return to theatre < 30 days
- post-operative PREMs – see below
- functional outcomes, for example, PROMs:
  - loss of sexual function
  - pain
  - urinary tract function
  - effect on daily quality of life
  - severity of complications on daily life
  - years lived with disability (YLD)

- ability to return to exercise
- effects on relationships.

## Patient-reported measures (outcomes and experience)

PROMs must be collected at baseline (before the surgical procedure) and then 6 and 12 months after surgery and annually thereafter for up to five years, or longer if indicated. The measures to be collected include:

- the Patient Global Impression of Improvement (PGI-I) instrument
- the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS), a questionnaire for evaluating female lower urinary tract symptoms and impact on quality of life
- the Pelvic Organ Prolapse / Urinary Incontinence Sexual Questionnaire, IUGA-revised (PISQ-IR), which is a validated evaluation tool to assess female sexual function (FSF)
- SF 12 general health questionnaire that assesses the impact of health on everyday life.[50]

PREMs should be utilised as they become available from the appropriate registry (once it is in place). A 360 multisource feedback tool for patients will be utilised in the interim.

# Continuing professional development

At credentialling, practitioners must demonstrate evidence of annual CPD in substantial pelvic floor reconstructive and urogynaecological procedures. A record of ongoing CPD will be reviewed at credentialling.

# Multidisciplinary teamwork

Multiple options are available to treat SUI and POP. A multidisciplinary team approach facilitates access to more treatment choices for patients presenting with these conditions. The health care provider must ensure that the patient has access to all members of the multidisciplinary team as appropriate.

[50] These measures may change with further refinement of the datasets.

# Section 6: Procedure-specific credentialling for mesh revision and removal

The procedures discussed in this section include:

- vaginal loosening of MUS for voiding dysfunction
- vaginal division of MUS for voiding dysfunction and/or obstruction
- trimming (excision) of < 1 cm exposed vaginal mesh
- removal of retropubic MUS (partial (vaginal) or complete)
- removal of trans-obturator MUS (partial (vaginal) or complete)
- removal anterior/posterior vaginal prolapse mesh, body and arms
- removal sacrocolpopexy vaginal attachment mesh
- complete removal rectopexy mesh / bowel repair
- removal of mesh from bladder, urethra, ureter or bowel
- reconstruction following mesh removal.

The removal of pelvic mesh is generally considered a more complex procedure than insertion, warranting specific credentialling, and should be undertaken only in specialty centres that have access to a multidisciplinary specialty team, including subspecialist post-Fellowship urogynaecologists and post-Fellowship urologists.[51] As the removal of mesh is a subspecialty practice, practitioners undertaking this procedure must have completed specific subspecialty training before doing so.

Acute procedures (less than six weeks after surgery) are an area of overlap between the two major categories of surgery covered in this framework. Credentialling for these procedures will generally be a component of credentialling for pelvic floor reconstructive procedures and urogynaecological procedures (see section 5 above).

Reported success rates of mesh removal surgery vary widely, and additional surgery may be required after either partial or complete mesh removal.[52] The risk of

[51] Australian Commission on Safety and Quality in Health Care. nd. *Guidance for Hospital Credentialling of Senior Medical Practitioners to Undertake Transvaginal Mesh Implant Removal Surgery*. URL: **www.safetyandquality.gov.au/sites/default/files/migrated/Credentialling-of-Senior-Medical-Practitioners-to-Undertake-Transvaginal-Mesh-Implant-Removal-Surgery.pdf** (accessed 19 May 2022).

[52] Carter P, Fou L, Whiter F, et al. 2019. Management of mesh complications following surgery for stress urinary incontinence or pelvic organ prolapse: a systematic review. *BJOG; Sept*. DOI: **http://doi.org/10.1111/1471-0528.15958** (accessed 19 May 2022).

complications from SUI and POP mesh removal procedures is increased in relation to associated increased comorbidity, variation in device characteristics, the complex technical nature of the surgical solutions, low volumes of specific procedures and surgeon expertise.

Examples of complications from partial or full mesh removal surgeries include injury to:

- bowel, bladder or urethra
- intra-operative haemorrhage
- infection
- urinary retention or incontinence
- fistula formation
- abscess
- ureteric obstruction.[53]

Late complications include:

- mesh exposure
- chronic pain
- nerve damage
- orphaned arms.

Complication rates for SUI and POP mesh removal procedures have yet to be defined and accepted nationally or internationally. The United Kingdom is currently developing credentialling standards for these two procedures that may provide guidance.

The most appropriate response to mesh complications is using a trauma-informed, patient-centred approach that must be determined in the context of a multidisciplinary treatment regimen addressing the woman's symptoms and emotional wellbeing. Adherence to comprehensive, informed choice processes is essential, with full documentation of the choice and ensuing consent process, the medical treatment provided and the subsequent progress of the woman. We expect providers to use resources such as the NICE patient decision aid for mesh removal in the context of treating mesh complications.[54]

The process and sequelae of removal of pelvic mesh requires a multidisciplinary team and includes specialist urogynaecologists, urologists, a radiologist with expertise in female pelvic floor and reconstructive medicine, potentially colorectal and orthopaedic surgeons, specialist continence and urology nurses, a specialist in pain management with pelvic floor expertise, pelvic health physiotherapists, diagnostic pelvic floor ultrasound capacity, comprehensive urodynamic testing, psychology psychosexual support and consumer advocacy.

[53] Bergersen A, Hinkel C, Funk J, et al. 2019. Management of vaginal mesh exposure: A systemic review. *AJU*, *17* (1): 40–48. URL: **www.ncbi.nlm.nih.gov/pmc/articles/PMC6583711/** (accessed 19 May 2022).

[54] NICE. 2021. *Treating Complications from Mesh Used for Stress Urinary Incontinence: Options for women referred to specialist centres: Patient decision aid.* National Institute for Health and Care Excellence (NICE). URL: **www.nice.org.uk/guidance/ng123/resources/treating-complications-from-mesh-used-for-stress-urinary-incontinence-options-for-women-referred-to-specialist-centres-patient-decision-aid-pdf-6725286117** (accessed 19 May 2022).

# Credentialling process

This framework relates to credentialling of the gynaecologist, urologist or urogynaecologist providing care to the women and the multidisciplinary team as a whole, as well as accreditation of the facility or facilities within which the care takes place. Individual credentialling of other members of the team, such as the colorectal surgeon (refer to tier 3 in table 2), orthopaedic surgeons, radiologists, physiotherapists, nurses, psychologists and pain specialists, is through their own credentialling processes and systems.

The Credentialling Committee will review any concerns raised about the care provided by any of the members of the multidisciplinary team and will address those concerns in their recommendations. The credentialling process must also consider the efficacy of clinical network arrangements, including the quality and clarity of referral guidelines and the compliance of local and regional centres with agreed guidelines and protocols.

The credentialling for mesh revision and removal procedures will be overseen by the national Credentialling Committee facilitated by the Ministry. The credentialling process will include a standardised committee with at least one external surgical expert from a recognised overseas mesh removal centre, an expert from Aotearoa New Zealand with appropriate surgical experience and acceptable outcomes (once credentialled themselves), consumer representation and Māori health clinical expertise.[55] The external experts and consumers will be appointed by the national Credentialing Committee. Credentialling for mesh revision and removal and other pelvic floor and urogynaecological procedures may occur simultaneously.

All Aotearoa New Zealand specialty centres engaging in mesh removal must participate in the designated registry once it has been implemented. Until an appropriate registry is in place, other means of collecting data such as local databases must be in place to capture the minimum data suggested in this framework.

Facility accreditation as per this framework will be required for these procedures, and for the contract(s) to provide the national specialist mesh complications service.

Table 2 indicates which procedures should occur at each tier of service.

[55] Ministry of Health. (2010). *The Credentialling Framework for New Zealand Health Professionals*. Wellington: Ministry of Health, pages 20–21.

**Table 2: Pelvic mesh revision and removal procedures for each tier of service provision**

| Service provider | Generalist secondary services | Regional services | National specialist mesh complications service |
|---|---|---|---|
| **Tier** | **Tier 1** | **Tier 2** | **Tier 3** |
| Revision or removal of implanted mesh | Adverse event within six weeks of surgery[56]<br>Acute | MUS vaginal loosening/division/trimming of < 1 cm (retropubic only)<br>More than six weeks after implantation | Trans-obturator and retropubic MUS<br>Anterior and posterior vaginal prolapse mesh<br>Sacrocolpopexy mesh<br>Rectopexy mesh |
| Indications for surgery | Wound dehiscence, infection, haematoma | Urinary retention within 14 days of surgery<br>Voiding dysfunction without pain or haematuria<br>Recurrent prolapse or SUI | Mesh vagina exposure<br>Voiding dysfunction<br>Pelvic or leg pain<br>Mesh within bladder, ureter, urethra, bowel |
| Multidisciplinary team meeting | Local or regional or Specialist Mesh Complications Service | Specialist Mesh Complications Service | Specialist Mesh Complications Service |
| Procedures | Repair of wound dehiscence along suture line<br>Treatment of haematoma and infection<br>Acute non-mesh revision | Acute loosening of sling for voiding dysfunction<br>Acute division of sling for voiding dysfunction<br>Vaginal division of MUS for obstruction and excision of <1 cm for measurement and histology | Removal of retropubic MUS (partial (vaginal) or complete), orphan arms<br>Removal of trans-obturator MUS (partial (vaginal) or complete), orphan arms<br>Removal anterior/posterior vaginal prolapse mesh, body and arms, orphan arms<br>Removal sacrocolpopexy vaginal attachment mesh<br>Complete removal rectopexy mesh/bowel repair<br>Mesh removal from bladder, urethra, ureter, bowel<br>Reconstruction following mesh removal<br>Removal of bulking agents |

[56] There may be some flexibility with this timeframe to ensure acute care is received in a timely manner. However, management, including for procedures beyond the six weeks, must be undertaken in discussion with a tier-3 service.

| Service provider | Generalist secondary services | Regional services | National specialist mesh complications service |
|---|---|---|---|
| **Tier** | **Tier 1** | **Tier 2** | **Tier 3** |
| Outcome measures<br>(use registry dataset or other approved databases) | PROMs/PREMs<br>Residual symptoms referred to Specialist Mesh Complications Service<br>Flow rate | PROMs/PREMs<br>Histology/measurement mesh 1x1 cm / photos<br>Residual symptoms<br>Perineal ultrasound<br>Referral to Specialist Mesh Complications Servicemultidisciplinary team | PROMs/PREMs<br>Histology or photo measurement of mesh<br>Approved databases |

# Indicative volumes

The following are indicative for procedures that appear in tier 3 of table 2.

**Table 3: Indicative volumes for mesh revision or removal procedures**

| Procedure | Volumes |
|---|---|
| Partial or complete removal of retropubic MUS (partial (vaginal) or complete) | Five or more cases of a single procedure in one year |
| Partial or complete removal of trans-obturator MUS (partial (vaginal) or complete) | Five or more cases of a single procedure in one year |
| Complete removal of anterior or posterior vaginal portion of mesh | Five or more cases of a single procedure in two years |
| Complete removal of sacrocolpopexy vaginal attachment mesh | Five or more cases of a single procedure in two years |
| Removal of mesh from bladder, urethra, ureter, (urologists only). | Five or more cases of a single procedure in two years |
| Reconstruction following mesh removal | Five or more cases of a single procedure in two years |

Some surgeons may only be credentialled for one surgical procedure group. Surgeons will choose which grouping(s) they wish to be credentialled for.

Rectopexy mesh removal or removal of mesh from the bowel is not included as a group as this procedure sits within the colorectal domain of practice, and urogynaecologists and urologists will not be credentialled for this procedure. There will be circumstances where the removal of rectopexy mesh or mesh in the bowel will be incorporated with other pelvic mesh removal procedures. In these circumstances, a colorectal surgeon will be in attendance leading this component of the removal procedure.

Any practitioner who wishes to continue or commence mesh removal procedures is expected to put themselves forward for credentialling. The Credentialling Committee will review all applications and progress credentialling based on volumes and outcome data supplied.

# Further commentary on credentialling domains

Generic credentialling domains are described earlier in this framework and are to be applied to all processes used for mesh revision and removal procedures. Below we provide further commentary and details on credentialling for these specific categories of procedures that must also be applied during assessment. The categories include:

- required qualifications
- medical practice in accordance with Te Tiriti o Waitangi and its principles
- diagnostic skills – anatomy; lower urinary tract function; urodynamics; pelvic radiology, including ultrasound, CT, MRI
- experience of complete mesh removal to help with selecting the appropriate procedure
- operative experience with good outcomes, including PROMs and PREMs
- reconstructive skills post-mesh removal
- recognition and management of intra- and post-operative complications
- documentation of multidisciplinary meetings to show provision of individual treatment plans involving the wider multidisciplinary team – physiotherapy, pain, psychology, nursing, radiology and other surgical disciplines
- CPD within the last two years specific to pelvic mesh removal
- robust processes for ensuring consumer-informed choice of management and treatment
- clinic and operation theatre availability (service)
- IT support for outcomes data (service)
- availability of the mesh removal register (service).

The required information (including the adequacy of the facilities) should be submitted in advance for consideration by the Credentialling Committee. Provision will be made for the committee to make a site visit and for individual practitioner interviews, which will provide an opportunity to discuss issues around patient selection, informed choice and consent processes, volumes, complications, patient feedback and experience, accuracy and comprehensiveness of record keeping, audit information, reporting of adverse events, equity of access, etc. During the site visit, the committee should be able to review and discuss any issues, including facility recognition and provision for Māori health needs, and a member of the committee should be given the chance to observe a multidisciplinary team meeting.

# Required qualifications

The practitioner must be vocationally registered with the MCNZ and:

- a RANZCOG certified urogynaecologist, or
- a specialist urologist who has at least one year post-fellowship training in the specific area of female and functional urology.

There may be exceptional circumstances where the Credentialling Committee could consider credentialling a senior medical practitioner who does not have the qualifications specified but has been independently performing mesh removal surgery as the primary operator at the time this guidance is implemented and can demonstrate high-quality outcomes. The committee will base its considerations on documented knowledge, skills and experience, evidence of peer support and outcomes. Furthermore, if the committee credentials such a practitioner, that practitioner will be subject to the same ongoing requirements for practice review as specified in this framework, including any limitations as the committee sees fit.

# Logbooks and care plans

Applicants for credentialling must send operative logbook(s) of the procedures completed to the Credentialing Committee, including indication for surgery, examination findings, diagnostic results, pre-operative PROMs, operation note, complications and clinical and patient reported outcomes at six months (for initial credentialling purposes only, whilst the medium- to longer-term measures are being defined). We expect that longer-term outcome capture will start as soon as possible. The practitioner will also present the individualised treatment care plans that have been created with the women and multidisciplinary teams to the Credentialling Committee as evidence of effective management.

# Volumes

The indicative volumes in table 3 above provide guidance for practitioners around what will be expected for credentialling. The evidence associating volumes with outcomes for surgical mesh revision and removal is sparse and potentially contradictory partly because these procedures are more recent and rapidly evolving.[57] As the number of mesh procedures for prolapse has declined markedly over time, it is expected that there will be correspondingly less call for mesh removal procedures.

The Credentialling Committee will consider applications from practitioners with less than the indicative volumes listed in table 3 provided the outcomes from such procedures are acceptable. Overall volumes of more than one procedure will also be

[57] AUGS-IUGS. 2020. Joint position statement on the management of mesh-related complications for the FPMRS specialist. AUGS-IUGS Joint Publication. *Female Pelvic Med Reconstr Surg* 202026; 4: 219–32. URL: **www.augs.org/assets/1/6/Joint_Position_Statement_on_the_Management_of.1.pdf** (accessed 17 May 2022).

taken into consideration. Volumes from both public and private practice may be combined.

# Continuing professional development

At credentialling, practitioners must demonstrate evidence of annual CPD in substantial mesh revision or removal.

# Outcome data

Further work is required to refine the medium- to longer-term outcome datasets.

In the interim, outcome data reviewed at credentialling will utilise the minimum dataset developed (and this data will be transferred into the designated registry once the registry is adopted). Data to be captured includes:

- previous surgery and mesh type
- indications for treatment and outcome: urinary incontinence, dyspareunia, persistent pelvic and associated pain, recurrent urinary tract infections, voiding or storage dysfunction of bladder or bowel, PROMs – minimum dataset symptoms
- measures of pelvic floor status pre- and post-operatively, examination, UDS, radiology
- intraoperative complications – blood loss > 500 mL, sepsis
- risk factors with modifying effect on surgical outcomes – BMI, smoking, diabetes and menopausal status
- additional complications, such as unintentional organ injury, for example, injury of the bladder, and nerve injury
- return to theatre < 30 days
- post-operative PREMs – see below
- Functional outcomes, for example, PROMs:
  - loss of sexual function
  - pain
  - urinary tract function
  - effect on daily quality of life
  - severity of complications on daily life
  - years lived with disability (YLD)
  - ability to return to exercise
  - effects on relationships.

Any information not captured in the designated registry should be presented to the Credentialling Committee, once available, using similar parameters to those listed

above. Once again, practitioners will be expected to provide their logbooks to the Credentialling Committee with the above data or similar for initial credentialling.

The follow-up and management of mesh removal sequalae is the responsibility of both the service provider (ensuring resource and equipment access and availability) and the wider specialist team.

Follow-up will include consideration of non-mesh techniques for managing recurrent stress urinary incontinence; third-line therapy for an overactive bladder, such as sacral neuromodulation, intravesical botulinum toxin, percutaneous tibial nerve stimulation and surgical and non-surgical management of recurrent vaginal prolapse.

## Patient-reported outcomes and experience measures

PROMs will be collected at baseline (before the surgical procedure) and then 6 and 12 months after surgery and annually thereafter for up to five years, or longer if indicated. Specialist removal centres will be required to use the PROMs consistent with the designated registry once it is in place. In the meantime, centres are encouraged to use the PROMs developed by the Australasian Pelvic Floor Procedure Registry, which at the time of writing was based on:[58, 59]

- the Patient Global Impression of Improvement (PGI-I) instrument
- the International Consultation on Incontinence Questionnaire Female Lower Urinary Tract Symptoms Modules (ICIQ-FLUTS), a questionnaire for evaluating female lower urinary tract symptoms and impact on quality of life
- the Pelvic Organ Prolapse / Urinary Incontinence Sexual Questionnaire, IUGA-revised (PISQ-IR), which is a validated evaluation tool to assess female sexual function (FSF)
- SF 12 general health questionnaire that assesses the impact of health on everyday life
- the Brief Pain Inventory (BPI), the Pain Catastrophizing Scale (PCS) and the Pain Self-Efficacy Questionnaire (PSEQ) for assessing pain.

PREMs should be utilised as they become available on the appropriate registry. A 360 multisource feedback tool for patients should be used in the interim.

[58] APFPR Communique, Edition 2, February 2021

[59] These might change with further refinement of the datasets.

# Section 7: Service/facility accreditation and credentialling

As part of the accreditation or credentialling process, facility assessment should include the provision of supporting structures and systems to enable the centre, and practitioners within it, to deliver best possible care. Where multiple facilities are involved, the Credentialling Committee will review the efficacy of the clinical network.

Necessary criteria to be considered in service assessment are listed above under Credentialling domains. Further criteria specific to mesh revision and removal includes:

- ensuring adequate staffing, building design, equipment, systems and processes to provide a well-coordinated, best-practice specialist centre in mesh removal
- facilitating a multidisciplinary approach to women presenting with complications from mesh insertion
- providing support for all members of the multidisciplinary team, such as specialist continence and urology nurses, pelvic health physiotherapist, pain medicine specialist and psychologist
- reviewing clinical networks in terms of jointly agreed guidelines and pathways, referral guidelines and protocols, guidelines and protocols for patient follow-up
- supporting and facilitating participation in the designated registry and consequent long-term follow-up or an alternative database in the interim
- providing robust local clinical governance structures around complaints, Health and Disability investigations, ACC treatment injury claims, case review (via mechanisms such as mortality and morbidity reviews, HQSC's serious adverse event reviews, etc)
- supporting professional development in mesh revision and removal – technical and broader clinical skills
- assisting with two-yearly credentialling, for example, providing administrative support for activities such as 360 multisource feedback tools and overseeing logistical arrangements for committee members
- ensuring robust documentation – record keeping from entry into until exit from the specialist mesh complications service.

All facilities have a responsibility to support the credentialling criteria that individual practitioners providing a service within their facility must meet. However, there are aspects of the criteria within private facilities where the practitioner must take the lead and provide evidence at credentialling that shows them:

- providing a wrap-around service for their patients who they have operated on in private facilities
- taking a multidisciplinary approach to the care and treatment of women and whānau presenting with complex clinical needs and complications
- engaging in multidisciplinary meetings within their private and/or public practice
- accessing the multidisciplinary team (such as radiologists, specialist continence nursing, specialist pelvic health physiotherapy, pain specialist services, psychologists) as required
- taking part in ongoing professional development and medical education in their specific fields of clinical practice and procedures.

# Appendix 1: The Health Select Committee and restorative justice actions

## Recommendations to Government from the 2014 Health Select Committee report

- That it work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry
- That a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications
- That it suggest that the colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures
- That it encourage health providers to ensure that coding for mesh surgery is consistent (This should include a system to allow patients with mesh complications to be identified and monitored.)
- That it encourage utilisation of the adverse events reporting system as applicable to medical devices
- That it endorse the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery
- That it consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in Aotearoa New Zealand.

# Agreed actions in the 2019 restorative justice report[60]

- The severity of the harm from surgical mesh should be acknowledged when the report is released publicly.
- The Ministry of Health was identified as the coordinating agency for each workstream.
- A collaborative approach is required to respond to harm from surgical mesh, and groups that should collaborate, were identified for each workstream.
- The HDC will promote the visibility of their national advocacy service.
- Attendees will share the final report with their professional members/within agencies.
- The Surgical Mesh Round Table is considered an appropriate group to oversee the delivery of the workstreams. To restore trust, there was an expectation of transparent reporting and regular public updates to communicate progress.
- Consumers will be reimbursed when participating in the co-design of each workstream.
- Specialist multi-disciplinary centre(s) are required. A group will meet in January 2020 to advise: the number of specialist centres required to ensure equity of access, the model of care and team required. This may be informed by learning from successful models elsewhere.
- Establish a credentialling committee by the end of January 2020 to recommend national standards for individual practitioners and services commencing with uro-gynaecology procedures. Minimum standards for insertion, renewal, repair and removal surgery and native tissue repair will be included.
- The Ministry of Health will lead, supported by ACC, interdisciplinary education and build capability of the required technical skills to prevent future harm, and reduce the severity of existing harm. This action intends to also support the provision of removal surgery.
- Professional colleges will inform and educate their members about their role in preventing and reducing harm from surgical mesh.
- ACC will partner with consumer representatives to design an approach for looking back through declined mesh-related treatment injury claims. Recognising that claim outcomes may not change; the process will also aim to learn where improvements can be made to the consumer experience.
- ACC will explore the potential to provide support services, such as counselling, while cover decisions are pending.

[60] Wailling, J., Marshall, C., & Wilkinson, J. (2019). Hearing and responding to the stories of survivors of surgical mesh: Ngā kōrero a ngā mōrehu – he urupare (A report for the Ministry of Health). Wellington: The Diana Unwin Chair in Restorative Justice, Victoria University of Wellington. URL: **https://www.health.govt.nz/publication/hearing-and-responding-stories-survivors-surgical-mesh** (accessed 12 May 2022).

- ACC recognises the complex and sensitive nature of mesh claims and intends to use an approach that ensures mesh injured clients are matched to case owners with appropriate background, experience and skills.
- ACC will continuously improve the collation and sharing of information on injuries caused by surgical mesh with key stakeholders and agencies under its risk of harm reporting framework to support prevention of future harm.
- National standards of practice and the code of rights for informed consent are already in place. Credentialling and training will support these to be embedded in everyday clinical work.
- National information resources for mesh related procedures should be created with consumers and include informed consent processes. Information should incorporate the product safety profile, outcomes and risks, alternative treatments available, and the informed consent process.
- The Ministry of Health and Medsafe will support the Government in modernising the regulation of medical devices in New Zealand, including the development of new legislation (Therapeutic Products Bill) to improve device safety.
- The Ministry of Health will identify the actions and supports required to meet the need for a collaborative approach to safety systems and culture.

# Appendix 2: Credentialling principles

**Principle 1**

Credentialling is a process used by all health and disability service providers to promote the provision of quality health care.

The ultimate responsibility for credentialling lies with the governing body of an organisation – the chief executive and the board, or equivalent. The governing body must ensure that agreed credentialling policies and procedures are documented and adhered to and that due process is followed. In practical terms, credentialling is a quality assurance process owned by the service provider, and clinical governance structures need to be established to undertake and coordinate the process.

Practitioners' confidence in the process and their willing participation are essential: effective credentialling requires **ownership** of the process by practitioners and **partnership** between practitioners and employers based on trust and mutual respect. More robust and transparent systems are seen where credentialling is viewed as a quality improvement opportunity.

**Principle 2**

Credentialling is focused on the competence of health practitioners to perform specific clinical responsibilities within a designated service environment.

Credentialling is focused on the individual practitioner. However, no practitioner works alone, and the wider context of the clinical team and the whole service is important in credentialling discussions. A panel is convened to apply a credentialling process to a group of practitioners within a particular service at one time and reviews the facility or service as part of that process.

All practitioners and services/facilities whose practice is in some way specialised and not subject to routine supervision should be credentialled. The criteria and processes by which this occurs has historically been relatively subjective. However, it has become evident there is a need for a more systematic and objective approach to credentialling in some areas of clinical practice.

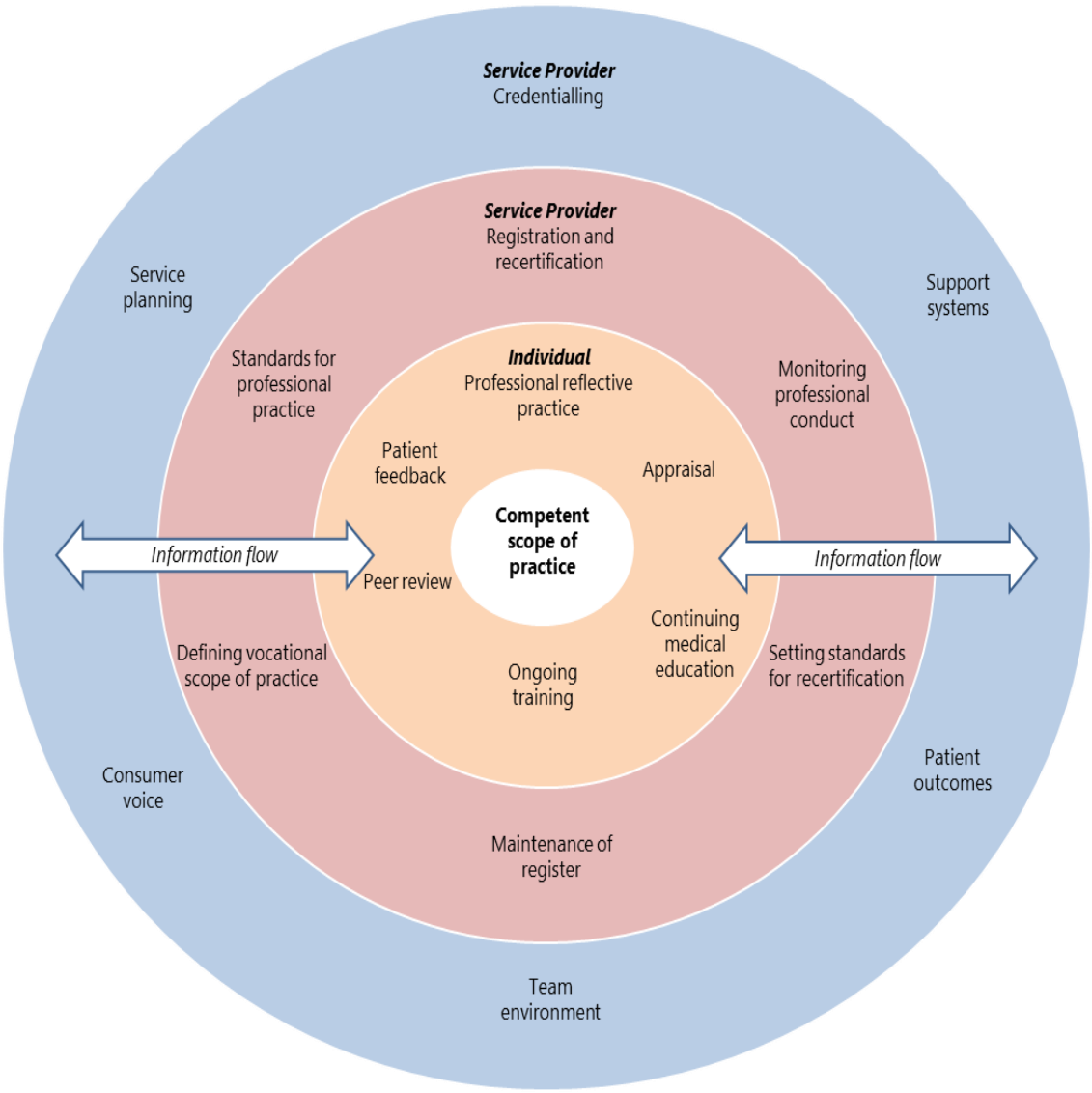
**Principle 3**

Professional bodies, employers and individual health practitioners have essential roles in credentialling that are distinct and complementary.

There is considerable overlap between the key authorities overseeing and monitoring practitioner's professional practice. The regulatory authorities' responsibilities include defining the scope of practice based on vocational training, ensuring practitioners are competent and fit to practice and managing recertification as a mechanism for ensuring ongoing competence.

Professional colleges and societies provide expertise into defined areas of specialist practice, and unions address employment issues by working with service providers and practitioners to ensure facilities and supporting resources meet the requirements for safe practice. However, credentialling is the only process that looks at competency and performance in the context of the health environment in which the practitioner is providing care, taking into account each of these areas.

**Figure 6: Essential roles in credentialling**




## Principle 4

Consumer input is a requirement of the credentialling process.

The primary purpose of credentialling is to improve health outcomes for patients, who therefore should play a critical role in the process. Among other responsibilities, credentialling must respond to the specific needs of Māori and acknowledge the government's responsibility under Te Tiriti o Waitangi to work in partnership to improve health outcomes for Māori. The role of the consumer is extensively covered in the national credentialling framework.

## Principle 5

Credentialling is a regular, ongoing, responsive process that commences on appointment and continues for the period of employment.

The national credentialling framework emphasises that credentialling is a continuous process and introduced the term 'credentialling review' to replace 'recredentialling'. The process is well described in this framework. Importantly, it identifies that further credentialling processes should be in place to respond to the non-routine situations that practitioners face from time to time, such as with the introduction of a new technology.

### Principle 6

Credentialling processes must be fair, transparent and robust.

A commitment to quality patient care and objective professional standards provides the foundation for an unbiased credentialling system. Two other concepts are equally important in the development of credentialling policies: due process and equal protection. 'Due process' entails two aspects: **substantive** due process refers to the duties, rights and responsibilities of practitioners and managers (in other words, agreed policy) and **procedural** due process refers to the processes by which the policy is maintained (for example, required procedures to be followed and records kept). The national credentialling framework indicates what a local credentialling framework policy must incorporate.

### Principle 7

Credentialling processes accommodate a variety of practice settings and practitioner working arrangements.

The credentialling processes should be the same for both public and private providers, with common credentialling processes developed for both public and private service providers. Some areas already accommodate this principle to a certain degree in respect to credentialling practitioners who have dual appointments and between district health boards (DHBs). All private providers should also have a credentialling process in place.

Credentialling teams and services is essential to ensure that collectively health services and facilities provide a safe service in which consumers and practitioners alike are protected. This principle also ensures that adequate support services are provided where appropriate.

A regional credentialling system provides a mechanism to ensure the safe delivery of services in which components are provided across different organisations: for example, services dealing with a low volume of consumers, services requiring a high level of expertise or small services relying on larger organisations for more specialist backup.