ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

RACS Response to Australian Government's response to the Senate Community Affairs Reference Committee Urogynaecological Mesh Inquiry

Date: **19 December 2018**

Established in 1927, the Royal Australasian College of Surgeons (RACS) is the leading advocate for surgical standards, professionalism and surgical education in Australia and New Zealand. The College is a not-for-profit organisation representing more than 7,000 surgeons and 1,300 surgical trainees and international medical graduates.

RACS and its affiliated Specialty Surgical societies are the peak bodies for training surgeons and setting high standards of surgical care. Their focus is on maintaining standards with an expectation that all Fellows will actively participate in continuing medical education throughout their lifetime of surgical practice.

This response to the Senate Inquiry and recommendations from the Commonwealth Health Minister and Chief Medical Officer represents a consensus from the Royal Australasian College of Surgeons with and on behalf of the specialty groups with whom many Fellows of RACS identify, including the Urological Society of Australia and New Zealand (USANZ), the Colorectal Surgical Society of Australia and New Zealand (CSSANZ), and General Surgeons Australia (GSA) ("the Specialty Surgical Societies"). The majority of surgeons implanting Urogynaecological mesh are not members of RACS and consideration should be given to undertaking research into principles for reducing risk of implantation of foreign materials as it relates to Urogynaecological mesh.

In response to the Australian Government's recommendations, we support the following:

1. Priority be given to the establishment of a national Clinical Quality Registry (CQR) for mesh implants on a cost recovery basis
2. A CQR be established and funded for mesh removal procedures which are recognised to be high risk surgical procedures
3. An audit of mesh that has already been implanted be undertaken to allow for service planning over the next 2-5 years
4. Review the online reporting process for adverse events to the Therapeutic Goods Administration (TGA), with an emphasis on reducing the time and administrative burden in reporting this data
5. Medical education should include reporting of adverse events that arise from pharmaceuticals and prosthetic devices.
6. RACS surgeons to trial the TGA's new online learning module for reporting adverse events
7. An online, real-time and streamlined tool to record prostheses at the time of implantation should be established, with hospitals responsible for the notification to the TGA
8. Further research be undertaken into principles for reducing risk of implantation of foreign materials as it relates to Urogynaecological mesh
9. The Presidents USANZ and CSSANZ (in association with RACS) to promote to their members the use of the Care Pathways for Pelvic Organ Prolapse and Stress Urinary Incontinence created by Australian Commission on Safety and Quality in Healthcare (ACSQHC).
10. Promulgation of the Credentialing guidelines formed by the ACSQHC and future review of these as experience is gained with the guidelines.
11. Improved access for patients to records of their previous mesh surgery via the implanting surgeon or hospital.
12. Implementation of patient information cards as standard for those who receive a Urogynaecological mesh implant

    Development of multi-disciplinary teams including surgical expertise, pain specialists, physiotherapists, psychologists and experienced radiologists at sites specialising in mesh removal surgery

Resources provided to these teams to provide the labour-intensive care that is required.

INTRODUCTION

RACS and the Specialty Surgical Societies are broadly supportive of the recommendations from the Senate Inquiry into the number of women in Australia who have had transvaginal mesh implants and related matters. We recognise and commend the bravery of the women who drew the Federal Government's attention to the complications associated with pelvic mesh used for pelvic organ prolapse and stress urinary incontinence.

The Senate Inquiry has raised the national awareness of these problems which are serious in some women. Several senior RACS Fellows and members of the Specialty Surgical Societies have contributed to the deliberations of the Australian Commission on Safety and Quality in Health Care *(*ACSQHC*)* Transvaginal Mesh Reference Group and support the materials developed by that group in conjunction with its consumer representatives.

We acknowledge that the mesh related problems affecting Australian women are not unique to Australian women but are part of a global health problem. We are also aware that many women have been travelling to other countries for services to address complications resulting from mesh surgery that are available in Australia.

ESTABLISHMENT OF A CLINICAL QUALITY REGISTRY (CQR)

The Senate Inquiry has highlighted the importance of prioritising the establishment of a Clinical Quality Registry (CQR) for mesh implants and the need for a CQR for mesh removal procedures going forward. Though hindsight will not change the past for women who have already suffered, it is appropriate to reflect that a CQR may have enabled systematic early detection by the profession of any emerging problem. A CQR provides the best quality post marketing surveillance for this group of therapeutic goods.

Audit is an important function of any surgeon's practice. Participation in an annual peer reviewed audit of practice is a compulsory requirement within the RACS Continuing Professional Development program and we note that audit is included under Recommendation 10. The power of an audit to lead to change depends on the type, accuracy and completeness of data collected. Audit data compiled in a national CQR can increase the quality of individual efforts, with data from the entire group benchmarking surgeon and implant performance. The CQR experience with joint replacement (i.e. Australian Orthopaedic Association National Joint Replacement Registry) and breast implants (i.e. Australian Breast Device Registry) has been extremely helpful in this respect enabling detection of outliers (surgeons and devices) and supporting institutions to take appropriate steps to remedy any problems identified.

For a registry to offer data that improves practice, it needs to have several characteristics which are detailed in the attached letter of Professor John McNeil, leader of the Clinical Registries group at Monash University's Department of Epidemiology and Preventive Medicine to the Chair of Safer Care Victoria (Appendix A). Substantial progress has already been made towards implementing such a register, with several RACS members participating with Urogynaecology colleagues to establish the Pelvic Mesh Registry. In establishing a registry, we acknowledge and support the need for this to be done on a 'cost recovery basis' as outlined in Recommendation 3, with data routinely collected which provides ongoing 'risk adjusted, benchmarking to clinicians on their clinical performance'. A cost recovery model will ensure the registry is funded by a 'fee for service' model to a level which ensure it can be successfully administered.

In conjunction with establishing a CQR, while there are well-established principles for reducing the risk of implantation of foreign materials, the extent to which these principles have been studied in surgery associated with Urogynaecological mesh is unclear. The majority of surgeons implanting Urogynaecological mesh are not members of RACS and consideration should be given to undertaking research into the principles for reducing risk of implantation of foreign materials as it relates to Urogynaecological mesh.

THERAPEUTIC GOODS ADMINISTRATION (TGA) AND ADVERSE EVENT REPORTING

While the TGA have had a process for reporting adverse events, the number of adverse events reported has been relatively low. This is likely linked to the inherent difficulty involved in using the online reporting process. The process has been time consuming and very often the clinician managing the complication is different from the clinician who has the details of what surgery was performed, when and which products were involved. Many of the women who have had mesh implants are not aware that they have had mesh implanted as part of their prolapse surgery. Consistency of the information being collected has also been limited as the requirements for recording of intra-operative events have not been standardised.

The liaison between TGA and the medical profession to improve processes has been greatly appreciated and we support continued efforts by the TGA to improve the quality and standardisation of reporting. This will require on-going communication between the TGA and hospitals regarding appropriate recording about surgical products that have been used. We are supportive of systems that are sustainable and tested by the professions so as to 'reduce the administrative burden' on healthcare professionals. In this regard we would be willing to trial the on-line learning module for reporting adverse events developed by the TGA to ensure it is user friendly and to optimise the quality of reporting going forward.

Compulsory online recording of prostheses implanted by hospital employees at the time of the surgery would support and enhance any reporting system going forward. The surgeon would be expected to participate in a CQR (ideally recorded at the time of surgery). Reporting of adverse events could become a mandatory part of medical education for both pharmaceuticals and devices. Simplification of any reporting is key to gaining support from professionals who are already time poor and under pressure from an ever-increasing administrative burden.

CREDENTIALING OF SURGEONS – AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE (ACSQHC) GUIDANCE

The ACSQHC has recently published and widely distributed guidance for hospitals on credentialing of senior practitioners who implant and remove transvaginal mesh. The development of credentialing guidance by an agency is a departure from existing processes where typically the profession – in conjunction with the Australian Medical Council (AMC) – outline the terms of its credentialing processes. We support promulgation of these guidelines. Because of the arbitrary nature of some of the details we would recommend that a review of this process with Specialty Surgical Societies take place at a future point to ensure the process is beneficial. CQR data, the new item numbers of Urogynaecological procedures and tighter reporting to the TGA by hospitals and clinicians should help to inform the ongoing credentialing process.

Surgical Training and Scope of Practice

Each surgical specialty has a standard scope of practice and multiple advanced scopes of practice. Within Urology surgery there is an advanced scope of practice in female urology (similar scope to Urogynaecology but with the standard scope of Urology surgery). Urology as an example of surgical training requires 6 years in the Surgical Education and Training (SET) program to which entry is gained typically after 3-5 years of surgical training preparation.

At the end of the 6th year of SET, entry to a career in Female and Functional Urology is associated with 1-2 years of additional Fellowship training. Training in SET involves assessment of competencies rather than numbers of operations. At each 3 month assessment the RACS competences which include non-technical competencies such as Collaboration and Teamwork, Communication, Health advocacy, Professionalism and Ethics. Scholarship and Teaching are assessed formally for each trainee and signed off by the training supervisor. Towards the end of the SET program formal exit examinations are held. Trainees are not fit to enter independent practice until they are signed off for SET 6 and have passed their exit examinations.

The ability to perform major open pelvic surgery is an essential skill which underpins SET training in both Colorectal Surgery and Urological Surgery. Both surgical specialties also train to an advanced standard in endoscopic and laparoscopic surgery. Diagnostic skills for evaluating bladder and bowel disorders include advanced training in the interpretation of imaging modalities (ultrasound, CT and MRI) and these skills permit identification of mesh complications. Mesh complications present with a wide range of symptoms and surgeons who do not have advanced training in Female Urology will still be identifying mesh eroded into the bladder, urethra, mesh extruded through the vaginal wall and potentially involving other organs rather than identifying it at an early stage on imaging.

Pelvic Mesh Removal and Multidisciplinary Teams

Pelvic mesh removal requires multi-disciplinary care, including clinicians who can assist with pelvic pain. Multi-disciplinary meetings are a routine and integral component of Urological and Colorectal care, particularly in the care of patients with cancer. We support the States and Territories in developing sites where pelvic mesh removal surgery can be supported by multi-disciplinary care involving the relevant surgical expertise – high quality imaging, Urology, Urogynaecology, Colorectal surgery, pain specialists, physiotherapists and psychology.

Patients who have already had mesh removal may have ongoing functional disturbance that may not require surgery. Each State and Territory is likely to have one or more specialist multi-disciplinary units for mesh removal, though it may be preferable for women to travel than seek treatment via a limited regional service. The potential for harm with pelvic mesh removal is significant because normal structures such as the bowel, bladder, urethra and ureters can easily be harmed in the process of removing mesh. CQR for mesh and mesh removal will be important going forward and would provide an example of how the Commonwealth could lead cross-jurisdictional response and interact with the professions to achieve the best outcome for patients. The jurisdictions will also have greater capacity to track morbidity due to the new MBS item numbers. Importantly, the clinical work to support women with complex pain and ongoing severe health problems, requires resources and is labour intensive. Provisions for these resources must be found.

ACSQHSC RESOURCES FOR MEDICAL PRACTITIONERS

The materials that were developed by the ACSQHC and by a multi-disciplinary group which included RACS members, other professionals and importantly, consumer representatives are of a high quality and supported by RACS and the Surgical Specialty Societies. We also support the use of the Care Pathways for Pelvic Organ Prolapse and Stress Urinary Incontinence.

To draw member's attention to these resources, we support the recommendation of the Commonwealth Chief Medical Officer for the President of RACS, USANZ and CSSANZ in writing (letter and electronic) to members highlighting the resources of the ACSQHC and the expectation that these will be used when counselling patients.

PATIENT INFORMATION RESOURCES

The informed consent principles detailed by the Senate Inquiry are broadly supported. The requirement that clinicians 'confirm that the individual patient has understood the information discussed' (pg. 9) will be difficult to implement in practice as it implies that the patients' retention of information will be interrogated in some way. In doing so, this process may cause undue anxiety and will be difficult to achieve for the less health literate members of the public. In this regard, we would recommend using existing informed consent processes that are guided by established principles (RACS Informed Consent Position Paper).

While it has been standard practice for recipients of some prostheses to receive patient information cards, this has not been the standard for Urogynaecological mesh. We are very supportive of the move by the TGA to mandate information be given in plain language to patients receiving Urogynaecological (or any significant implant) going forward and acknowledge the timelines for this initiative. The information card will also assist primary care doctors – many who have not been provided with or do not have accurate surgical records of previous operations – with the validity of information they maintain on their patients. We also acknowledge that this could be complemented by the new 'My Health Record' available to Australian citizens, which may help to keep track of any operation they have undergone and any associated prostheses that may have been implanted.

MEDICARE BENEFITS SCHEDULE CHANGES IN CONTEXT

The changes to the MBS which came into effect on the 1st of July 2018 are appropriate and timely. These changes will enable the Commonwealth to track the number of Urogynaecological mesh cases in the future. The lack of such administrative tracking has been a key barrier to quantifying mesh related surgery. Medicare data, new TGA reporting combined with jurisdictional data on hospital admission, will permit analysis of readmission rates, transfusion rates, ICU admission, and possibly sepsis rates. We would like to bring to the Commonwealth's attention that whilst the codes are regarded as Urogynaecological, in practice we would expect removal and to a lesser extent ongoing implantation, to involve RACS surgeons. The CQR data will complement such MBS and hospital-based data to enable risk to be adequately monitored going forward.

PREVIOUS MESH CASES – AUDIT AND SUPPORT FOR WOMEN GOING FORWARD

While RACS is supportive of this recommendation and the benefit it could have in service planning, it does present significant implementation challenges. Many patients who have had mesh placed as part

of a Pelvic Organ Prolapse (POP) repair may not be aware that mesh was placed. Primary care doctors may need to be encouraged to support patients in obtaining operating reports from their original surgeon or hospital if they have persistent pelvic symptoms with a history of POP or SUI surgery. Pelvic pain, dyspareunia, recurrent urinary infection, increasingly severe urge incontinence, poor bladder emptying, vaginal discharge and bowel symptoms may be manifestations of a mesh complication and may require further investigation. Studies of bladder and bowel function, ultrasound, and specialised MRI may help to demonstrate inflamed or problematic mesh.

Often the hospitals hold a copy of the relevant operating report if the doctor no longer does. The obstacles to implementing recommendation 11 are detailed in the Australian Government's report. We do not have the data yet to predict how many cases we expect will require removal surgery. The Commission may work with the jurisdictions to coordinate an audit of mesh that has already been implanted. Without such an audit service planning will be more difficult.

It is likely that the profession, hospitals and jurisdictions will have a major project to perform mesh removal surgery aiming to minimise collateral morbidity. With the cessation of mesh POP implant surgery and the growing awareness of the risks of mesh and the alternatives it is likely that the number of mesh removal cases will rise significantly in the next few years and taper off by 5 or so years. The jurisdictions have moved to develop services for use and removal of mesh utilising a model of service developed by the Commission as informed by the professions and consumers.

There has been a significant down turn in the use of transvaginal mesh worldwide. The risk may be reduced by only highly skilled surgeons who use sound foreign body surgical principles with appropriate credentialing in mesh implantation to perform this surgery going forward. The risks of mesh removal surgery cannot be under-estimated. Better mechanisms are in place to track cases and jurisdictional identification of centres to offer multi-disciplinary care have been identified. Resourcing for the management of patients who have complex pain disorders as a result of previous and ongoing complex surgery to remove mesh must be found.

INTERACTIONS WITH MEDICAL TECHNOLOGY ASSOCIATION OF AUSTRALIA (MTAA)

RACS supports the Australian Consensus Framework for Ethical Collaboration in the Australian Healthcare Sector and we are in agreement with the Chief Medical Officer that the profession needs to uphold high ethical standards and have appropriate systems in place to prevent unethical payment of inducements. We also recognise that MTAA members are bound by a Code of Practice to ensure that healthcare providers are not influenced by financial or other inducements.

The RACS Code of Conduct – which is based on long standing ethical and professional principles - also requires members to ensure informed consent (including financial) is obtained prior to surgery.