

June 2018

Transvaginal mesh: the Victorian response



GLOSSARY

ACSQHC	Australian Commission on Safety and Quality in Health Care
MBA	Medical Board of Australia
MBS	Medicare Benefits Schedule
POP	pelvic organ prolapse
RACS	Royal Australasian College of Surgeons
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
SCV	Safer Care Victoria
SUI	stress urinary incontinence
TGA	Therapeutic Goods Administration

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Introduction

This document seeks to summarise actions taken at both a national and Victorian level to support women affected by complications from transvaginal mesh, and to help health services provide safe, high-quality care.

It also details the actions Safer Care Victoria (SCV) and the Department of Health and Human Services (the department) have taken and will take in response to recommendations made by the Australian Commission on Safety and Quality in Health Care (ACSQHC) and the Australian Government Senate Community Affairs Reference Committee.

ABOUT TRANSVAGINAL MESH

Transvaginal mesh is a synthetic net-like substance that provides extra support to repair weakened or damaged internal tissue. The mesh has holes in it to allow the body's own tissues to grow into it. It is intended to be permanent and so it may not be able to be fully removed if complications arise.

Transvaginal mesh products, including mid-urethral slings, are used to treat stress urinary incontinence (SUI) usually when non-surgical treatments have been unsuccessful. It is only one of the surgical options available.

Until recent actions were taken to address concerns raised about the use of transvaginal mesh, it was also previously used in the treatment of pelvic organ prolapse (POP). This involved surgery to repair conditions such as bladder, bowel or uterine prolapse. In 2018, transvaginal mesh products used to treat POP were withdrawn from general use in Australia by the Therapeutic Goods Administration (TGA). Transvaginal mesh may still be used under special access schemes and, where approved, within research trials.

Complications

While transvaginal mesh is successful in helping many women, about 10 per cent of women may experience significant complications. Women can experience such complications immediately after their operation or years later.

Complications may range from mild discomfort to debilitating pain, including:

- irregular vaginal bleeding or discharge
- pelvic pain or swelling
- discomfort during sex
- bladder and bowel problems like infection and incontinence
- prickling feeling or sharp stabbing pain in the vagina, which may become worse with exercise
- abdominal, buttock or leg pain.

A more complete list of complications that may arise from the use of transvaginal mesh implants is available at www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications.

BACKGROUND

In August 2014, the TGA published a review of transvaginal surgical mesh implants. It found the evidence to support the use of transvaginal mesh for pelvic organ prolapse repair was not well established. It also found adverse events involving mesh implants are likely to be under-reported.

Between July 2012 and 1 June 2016, the TGA received 99 adverse event reports involving transvaginal mesh.

On 15 February 2017, the Senate referred the issue of transvaginal mesh to the Senate Community Affairs Reference Committee. The Committee called for public submissions during 2017 and the final report was released on 28 March 2018.

A timeline of national and state actions can be found at **Appendix 1**.

Media attention and public comment have focused on the significant impact and adverse events associated with the procedure. There was also a perception that there were no clinicians in Australia able to remove the mesh and provide remedial repair surgery.

Consumer bodies such as the Health Issues Centre strongly advocated for women impacted by transvaginal mesh and amplified their concerns by challenging perceptions, specifically in relation to the severity of the problem being framed in terms of 'the good outcomes of the many outweighing the unfortunate experiences of the few'.

KEY FINDINGS IN THE SENATE REPORT

The Senate Community Affairs Reference Committee report, *Number of women in Australia who have had transvaginal mesh implants and related matters*¹ acknowledged the extensive impact of mesh on affected women. The committee made the following key findings:

- There are differences in complications for SUI and POP. Complications following mesh surgery for POP are both more common and more severe than those associated with surgery for SUI. For many women the complications of transvaginal mesh are extremely debilitating and have an immense impact on their lives emotionally, financially and socially.
- There was evidence that the patient consent processes for mesh surgery may have been inconsistent or inadequate.
- There is a lack of reliable data on how many women have had mesh procedures and the number of women adversely affected by mesh. This is because there is no mechanism for mesh device tracking. There is some administrative data on mesh procedures, such as Medicare Benefits Schedule (MBS) data, ICD-10 coding and urogynaecological registries. These indicate that 150,000 Australian women are likely to have undergone transvaginal mesh procedures. However, the lack of data on adverse outcomes was highlighted as a serious concern.
- It was noted that many mesh affected women felt that the process of reporting complications was difficult due to unclear reporting mechanisms and perceived lack of appropriate response from clinicians.
- There was evidence of a lack of appropriate responses to women presenting with mesh complications.

¹ The Senate and Community Affairs Reference Committee (2018) *Number of women in Australia who have had transvaginal mesh implants and related matters*, Commonwealth of Australia, March 2018.

Recommendations

The Senate Community Affairs Reference Committee report made 13 key recommendations. SCV has undertaken the following actions and provided advice in relation to next key steps.

Key Senate report recommendation	Endorsed?	SCV's response	Lead	Timeframe
<p>That the Australian Government, in consultation with states and territories and The Medical Board of Australia (MBA) review the current system of reporting adverse events to the TGA to:</p> <ul style="list-style-type: none"> ● implement mandatory reporting of adverse events ● provide guidance to consumers and clinicians on what constitutes an adverse event ● improve awareness of the reporting system ● examine options to simplify the reporting process 	✓	SCV notes that internal notification mechanisms to the TGA are already well established in Victoria. The department and SCV will continue to ensure health services and clinicians are aware of the need to notify the TGA of adverse events.	SCV Department	Ongoing
That the TGA and ACSQHC develop an information sheet to be provided to recipients of patient cards for implantable devices providing guidance on appropriate action to take in the event of an adverse event, including guidance on seeking appropriate treatment and support on reporting the event.	✓	SCV will support the development and distribution of information sheets.	SCV	As required
That the Australian Government prioritise consideration of the implementation of Recommendation 22 of the report of the Review of Medicines and Medical Devices Regulation recommending the establishment of a registry for all high-risk implantable devices, together with consideration of the feasibility of establishing such a registry on a cost recovery basis, and provide to the Senate by 29 November 2018 a progress report on work to date.	✓	SCV will work with clinicians to develop a business case in support of the establishment of a prospective clinical registry for implantable devices.	SCV	TBA
That the MBS Taskforce prioritise the report of the Gynaecological Clinical Committee.	✓	SCV will work with the department to facilitate the distribution of MBS notifications and decisions as required.	Department	As required
That the Australian Government prioritise the establishment of a more comprehensive post-market monitoring scheme and provide to the Senate by 29 November 2018 a progress report on work undertaken to date.	✓	SCV will work with the department to facilitate and support post market monitoring in collaboration with other jurisdictions and the Commonwealth.	Department	As required

Key Senate report recommendation	Endorsed?	SCV's response	Lead	Timeframe
<p>That the ACSQHC prepare guidance material on effective informed consent processes, with a view to ensuring that a dialogue between a medical practitioner and patient should:</p> <ul style="list-style-type: none"> • clarify the rationale for the proposed treatment • discuss the range of alternate treatment options available and their attendant risks and benefits • discuss the likely success and potential complications of the recommended treatment as they relate to the individual patient • provide an opportunity for the patient to ask questions • confirm that the individual patient has understood the information. 	✓	<p>There are existing mechanisms in place to distribute guidance on informed consent to health services.</p> <p>SCV will continue to promote best practice in relation to informed consent, particularly through the improvement projects led by the clinical network teams.</p>	SCV	As required
<p>That the ACSQHC ensure treatment guidelines are available indicating transvaginal mesh should only be undertaken with fully informed consent present and only as a last resort.</p>	✓	<p>There are existing mechanisms in place to distribute guidance to health services. SCV will facilitate the distribution and promotion of any guidance on treatment guidelines to health services.</p>	SCV	As required
<p>That the medical professional specialist colleges and societies ensure that processes are in place to draw their members' attention to the resources released by the ACSQHC and implement arrangements which require members to consider the resources in their practice.</p>	✓	<p>There are existing mechanisms in place for clinicians to access resources developed by the ACSQHC.</p>	SCV Department	As required

Key Senate report recommendation	Endorsed?	SCV's response	Lead	Timeframe
That the Commonwealth, state and territory health Ministers require that guidance developed by the ACSQHC for the credentialing of medical practitioners who perform transvaginal mesh procedures should underpin credentialing processes in all public hospitals and work with private hospitals to encourage the adoption of a similar requirement.	✓	<p>There are existing mechanisms in place that govern credentialing and scope of practice assessment and approval in Victoria.</p> <p>The department and SCV will inform health services of the new requirements and create additional mechanisms to ensure that the guidelines for credentialing in relation to insertion and removal of mesh have been implemented and adhered to.</p> <p>The department and SCV will monitor any impact of credentialing on tertiary referral and regional services and consider action if required.</p> <p>The department and SCV are supportive of collaborative arrangements that will support clinicians to meet the revised credentialing requirements for insertion and removal of mesh.</p>	Department SCV	From July 2018
The committee recommends that medical professional colleges and specialist societies implement governance arrangements for transvaginal mesh procedures which require that their members have adequate training and skills in the use of the specific device, are monitoring, recording and reporting patient outcomes and work within multi-disciplinary teams.	✓	SCV and the department will await advice for any necessary action at a state level.	SCV Department	TBA
That the Commonwealth, states and territory governments commission the ACSQHC to undertake an audit of transvaginal mesh procedures undertaken and their outcomes since the introduction of transvaginal mesh devices for use in the Australian market.	✗	<p>The availability of current data relating to procedures and outcomes is not consistent and is problematic.</p> <p>Any retrospective audit will require a manual process and would be time consuming and require significant resources. The benefit of such an investment is not clear.</p> <p>SCV is very supportive of prospective data collection and monitoring of outcomes. SCV supports the creation of a device registry so all new cases can be logged. Women may also voluntarily register themselves for previous surgeries (similar to the Australian Breast Device Registry).</p> <p>SCV will await further guidance from the ACSQHC and the Commonwealth.</p>	SCV	Ongoing

Key Senate report recommendation	Endorsed?	SCV's response	Lead	Timeframe
<p>That the Department of Health work with the Medical Technology Association of Australia and the MBA to review the systems in place within the device manufacturing industry and the medical professions to support consistent, high ethical standards, with specific emphasis on systems in place to prevent the payment of inducements to medical professionals and teaching hospitals.</p>	✓	<p>SCV and the department will await advice for any necessary action at a state level.</p>	<p>SCV Department</p>	<p>TBA</p>
<p>That state and territory governments continue to work with the ACSQHC to review the provision of services for the use and removal of transvaginal mesh devices. In particular, the committee recommends that consideration be given to the establishment of:</p> <ul style="list-style-type: none"> ● information and helplines that women who have received transvaginal mesh implants can contact for advice on the availability of treatment and support services, including financial support programs, in their state ● specialist counselling programs, to assist women who have sustained injuries following transvaginal mesh procedures ● specialist multidisciplinary units for the assessment and management of complications associated with transvaginal mesh procedures, including: pain management expertise, expertise in removal of transvaginal mesh and comprehensive diagnostic services ● advice and practical assistance for women who are seeking to access their medical records ● the provision of further guidance for medical professionals on recording the use of implantable devices on medical records and reporting adverse events to the TGA. 	✓	<p>SCV has established a range of services to support women impacted by mesh. These include a helpline, consumer/clinician (GP) information, peer support groups and tertiary referral centers.</p>	<p>SCV Department</p>	<p>Ongoing for 2018</p>
<p>SCV and the department will continue to support these services for the foreseeable future and will continue to monitor and review the demand and efficacy of these services in the coming months.</p>				

Summary of the Victorian response

Led by SCV, the Victorian Government responded quickly to issue information to health services and clinicians, and provide support and referral pathways for Victorian women and their families.

Our response was informed by:

- a SCV working group with representatives from all stakeholder groups, including women living with the complications of transvaginal mesh and consumer advocates
- recalls and guidance issued by the TGA in October and November 2017
- international responses to mesh complications, including credentialing guidelines issued by the ACSQHC and national in March 2018.

Many of these activities in Victoria pre-emptively addressed recommendations made by the Senate Community Affairs Reference Committee.

MESH ADVISORY STEERING COMMITTEE

Helping to guide the Victorian response, the Mesh Advisory Steering Committee included consumer representatives, advocates and senior expert clinicians.

The committee's key recommendations included:

- establishing health service referral centres
- providing guidance on setting up a help line
- forming a peer support group for women
- developing consumer and primary care resources.

SCV thanks all the Committee members for their time and contribution.

Consumer representatives: Linda Schultz, Danny Vadasz (Health Issues Centre), Dora Vasiliadis, Joanne Villardi, Janice Wise

Clinical representatives: Dr Oliver Daly (Urogynaecologist, Western Health), Dr Khai Mohamed-Noor (Gynaecologist, The Royal Women's Hospital), Donna Smith (Physiotherapy Manager, The Royal Women's Hospital), Dr Alison D'Souza (Urogynaecologist, Monash Health), Dr Christine Tippet (Consultant Obstetrician and Gynaecologist)

Agency representatives: Katy Fielding (the department), Louise McKinlay (SCV), Sarah McPherson (Victorian Managed Insurance Authority), Meagan Ward (SCV), Brigid Clark (SCV), Shannon Storey (SCV)

SPECIALIST HOSPITAL PROGRAMS

Victoria's main urogynaecology centres at public hospitals have established programs for women experiencing complications with transvaginal mesh.

These specialist, multi-disciplinary programs are contact points for women wanting to discuss their surgical options in Victoria. Their focus was to provide women with timely assessment by senior clinicians, multi-disciplinary care planning in consultation with the woman, and remedial surgery where needed.

SCV continues to work with these health services to ensure a sustainable and responsive model of care that is consumer driven.

SCV supports governance arrangements for these services in conjunction with the department. SCV has provided advice for these services to promote information sharing and consistency of guideline application. Ongoing governance and support for the established mesh complication referral centres will be reviewed in late 2018 and ongoing support and governance requirements will be assessed. This review is recommended to include examination of funding models and how these services can be best possible assisted to meet the senate report requirements, such as auditing requirements and the possible establishment of a mesh registry.

VICTORIAN MESH INFORMATION LINE

The Victorian mesh information line provides an initial contact point for women who are:

- concerned they may be experiencing complications from mesh surgery
- unsure if they have had mesh surgery
- are considering mesh surgery.

Callers can speak with registered nurses about their clinical options, and access to treatment and surgery in Victoria.

Between December 2017 and May 2018, 223 phone calls were received and 101 women accessed the advice and supports offered via the helpline. Of the calls, 81 per cent were from women who had undergone mesh surgery.

KEY CONTACTS FOR VICTORIAN WOMEN

Specialist hospital programs

- Royal Women's Hospital 8345 3143
- Mercy Hospital for Women 8458 4500
- Monash Health 9928 8588
- Western Health 0481 908 118

Victorian mesh information line

Call 1800 55 6374 (1800 55 MESH) during business hours.

Peer support network

Contact tvmeshsupport@whv.org.au or visit www.whv.org.au.

More information

www.betterhealth.vic.gov.au.

PEER NETWORK

The peer network seeks to connect women with others who have similar experiences, allowing them to share their experiences and practical information. Facilitated by a qualified health professional, the peer support group has met twice, with 12 women attending each session.

SCV will continue to fund and support both the help line and the peer group for the remainder of 2018. The services will then be reviewed in conjunction with the department.

OTHER MATERIALS

Developed with Jean Hailes for Women's Health, consumer information was published on the Better Health Channel and promoted through social media.

The ACSQHC has since released standard guidance for consumers on the use of transvaginal mesh products to treat both POP and SUI, also referenced through the Better Health Channel.

HEALTH SERVICE INFORMATION

As a key contact point for health services, SCV sent all health service CEOs a letter outlining the issue when it first emerged. The correspondence detailed the work underway and highlighted the need for health services to remain abreast of the issue and to ensure they were aware of their obligation to ensure consumers have full access to information including procedure risks and benefits. SCV will continue in this role, providing health services with information on updates and clinical service implications as required.

INFORMATION FOR GENERAL PRACTITIONERS

SCV worked with Jean Hailes for Women's Health to develop a GP referral pathway regarding support for mesh-affected women and women considering mesh surgery. Detailing potential complications and patient options, this information sheet was sent to all Victorian GPs in February 2018.

The referral pathway is available at safercare.vic.gov.au.

TGA RECALLS AND GUIDANCE

Eight products (45 devices) have been recalled by the TGA.

Transvaginal mesh for POP may still be used for purposes approved under the TGA's special access or authorised prescriber schemes. For more information, go to www.tga.gov.au.

Mesh may also still be used for other surgical procedures.

The ACSQHC is in the process of developing standard guidance for clinicians and health services on the use of transvaginal mesh products to treat both POP and SUI.

Credentialing guidelines

One of many actions commissioned by the ACSQHC, the national agency released credentialing guidelines on the insertion and removal of transvaginal mesh in March 2018. SCV was consulted on and supported the development of the guidelines.

Requirements include:

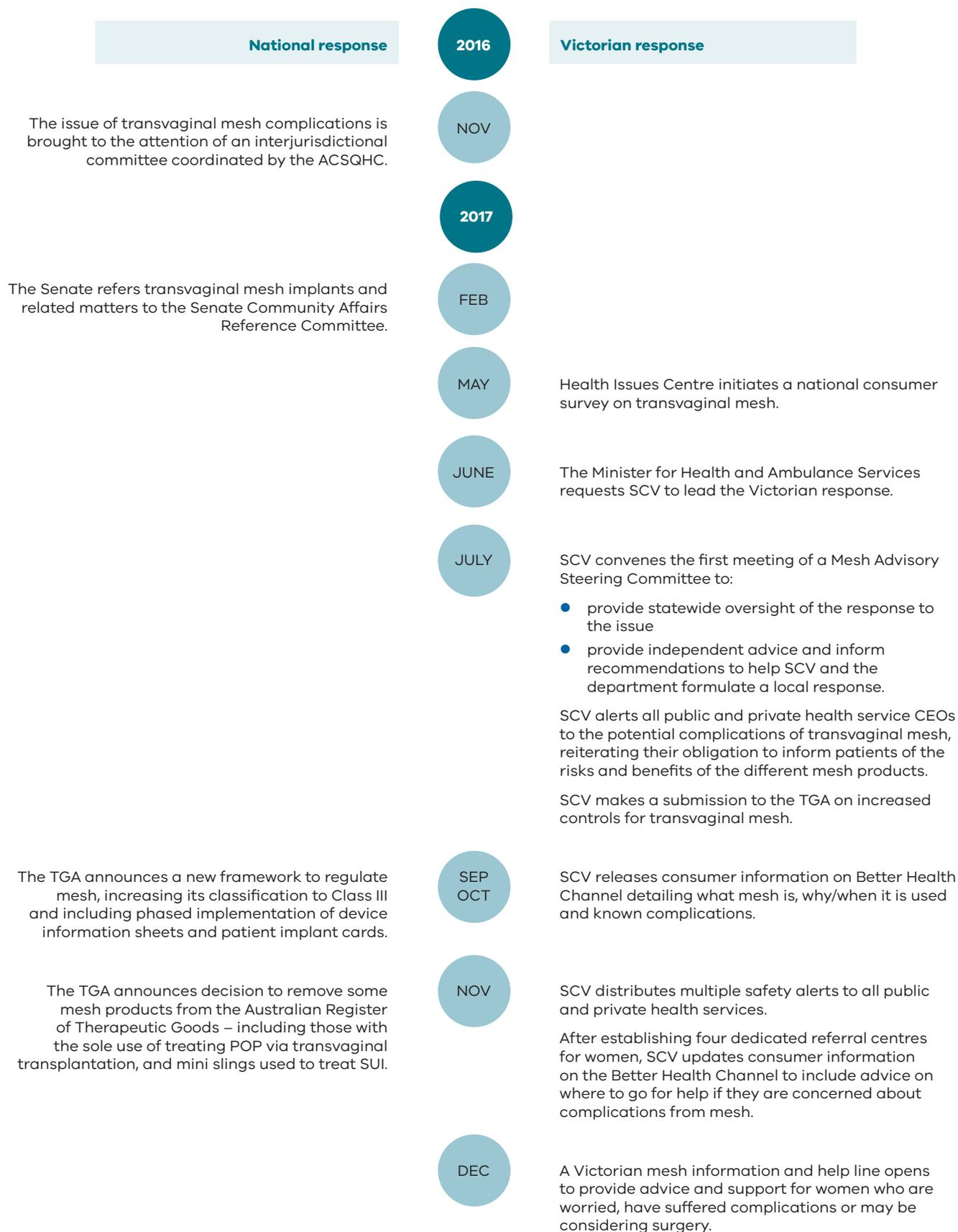
- a minimum of 10 SUI procedures to be undertaken each year to allow for ongoing credentialing in mesh-related SUI procedures
- clinicians to be a member of Royal Australasian College of Surgeons (RACS) or the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG)
- clinicians and health services to monitor and report on patient outcomes related to mesh and associated procedures.

Following the release of the guidelines, RANZCOG raised concerns about the number of procedures required for ongoing SUI credentialing, endorsing a lower threshold of five supervised procedures. RANZCOG also expressed concerns about the impact on rural and regional women who may have reduced access to SUI procedures due to this requirement.

SCV continues to work with health services and clinicians who are inserting and removing mesh products for POP and SUI to support the implementation of the credentialing guidelines. We are also working with the department and health service executives to limit any potential impact on rural and regional women needing to access mesh and associated procedures, and respond to any emerging issues.

Appendix 1

TIMELINE



National response

2018

Victorian response

FEB

Victorian peer support program starts connecting women across the state.

Tailored clinical pathway resources are launched and distributed to all GPs.

MAR

The Senate Community Affairs Reference Committee tables its final report, *Number of women in Australia who have had transvaginal mesh implants and related matters* in Parliament.

ACSQHC releases credentialing guidelines on the insertion and removal of transvaginal mesh.

MAY

ACSQHC releases patient information on transvaginal mesh.

Victorian clinical leaders meet to discuss the Senate Committee recommendations, credentialing guidelines and the Victorian response.

