

Chapter 1

Introduction

1.1 In the late 1990s, a supposedly innovative treatment for stress urinary incontinence (SUI) was introduced – transvaginal mesh surgery using the mid-urethral sling (MUS) or tension-free vaginal tape. As the use of surgical mesh in this way appeared to be equivalent to or better than existing procedures and involved shorter surgery and recovery time, it soon became the most frequently performed surgical procedure for the treatment of incontinence¹

1.2 Sling and tape devices first became available for clinical use in Australia in 1998 and the release of the results of randomised controlled trials (RCT) in 2002 and 2004 confirmed the benefits of this procedure over traditional surgical procedures.² Procedures using these devices quickly became the standard in the treatment of SUI.³

1.3 Apparent early success in the use of transvaginal mesh devices in the treatment of SUI led to their adoption in the treatment of pelvic organ prolapse (POP).⁴

1.4 Early published data was relatively supportive of the safety and efficacy of the use of mesh in the treatment of POP. However, there was a considerable lag before data from RCTs became available. The first RCTs on the use of mesh devices for the treatment of prolapse were not published until five to seven years after the devices came into use.⁵

1.5 While many women who have had a procedure using transvaginal mesh have experienced no difficulties, some women do and for some of those women the complications following their surgery have had a devastating impact on their lives. The prevalence and severity of problems associated with transvaginal mesh implants has risen since the first Australian adverse event was reported in 2006.⁶

1.6 Complications associated with mesh procedures can range from mild discomfort to debilitating pain and may be evident immediately or may not manifest for some years after surgery. The most severe symptoms of complication can range from: immediate symptoms during or after surgery, such as bleeding, perforation of

1 Associate Professor Christopher Maher, *Explaining the vaginal mesh controversy*, The University of Queensland, Faculty of Medicine, <https://medicine.uq.edu.au/article/2017/06/explaining-vaginal-mesh-controversy> (accessed 20 June 2017).

2 Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), *Submission 36*, p. 2; Department of Health (Department), *Submission 19*, p. 26.

3 Associate Professor Christopher Maher *Submission 154*, p. [1].

4 *Submission 154*, p. [5].

5 *Submission 154*, p. [5].

6 Department, *Submission 19*, p. 15.

organs and difficulty voiding; to medium or long-term symptoms such as persistent difficulty voiding, chronic pain, persistent or recurrent leakage; persistent infections and mesh exposure requiring surgery.⁷ A list of adverse events associated with urogynaecological meshes is provided on the Therapeutic Goods Administration's (TGA) website.⁸

1.7 Over the last two decades there has been a rise in the prevalence and severity of problems attributable to transvaginal mesh implants. Class actions have been initiated against manufacturers and suppliers of urogynaecological mesh devices in a number of countries, including the United States of America (United States), United Kingdom and Canada. Previous cases in the United States and Canada have awarded significant amounts to women who have suffered injuries as a result of mesh implants while other cases have been settled prior to a judgement being reached, without admission of liability.⁹

1.8 In recent years, new evidence has emerged that has highlighted questions around the regulation, marketing and use of transvaginal mesh devices, particularly for POP, and the adequacy of the response to women who have experienced adverse events.

1.9 Frustrated by the lack of recognition and support, women in a number of countries have successfully lobbied for reviews of the use of transvaginal mesh. In 2014, in response to petitions from women adversely affected by mesh devices, New Zealand and Scotland established independent inquiries into the safety of surgical mesh. The National Health Service (NHS) England established a Mesh Working Group to address concerns raised by patients and clinicians. New Zealand's Accident Compensation Corporation released its findings in March 2015 and released a retrospective update in October 2017.¹⁰ The Scottish Independent Review of Transvaginal Mesh Implants released its interim report in October 2015 and its final

7 Urogynaecology Units at the Mercy Hospital for Women and Monash Health, *Submission 44*, p. 3.

8 Department, Therapeutic Goods Administration, *Urogynaecological surgical mesh complications*, <https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications> (accessed 5 January 2018).

9 Shine Lawyers, 'Manufacturers face multiple actions for faulty implants worldwide', <https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action/manufacturers-face-multiple-actions-for-faulty-implant/> (accessed 21 July 2017); Hannah Devlin, *The Guardian*, 'Senior doctors call for public inquiry into use of vaginal mesh surgery in UK', 19 July 2017, <https://www.theguardian.com/society/2017/jul/18/senior-doctors-call-for-public-inquiry-into-use-of-vaginal-mesh-surgery-in-uk> (accessed 21 July 2017); CTV News, 'Canadian women reach transvaginal mesh settlement', 2 April 2016, <https://www.ctvnews.ca/canada/canadian-women-reach-transvaginal-mesh-settlement-1.2842781> (accessed 21 July 2017).

10 Accident Compensation Corporation (ACC), *ACC Surgical Mesh Review, Analysis of Treatment Injury Claims 1 July 2005 to 30 June 2014*, 13 March 2015; ACC, *ACC treatment injury claims: Surgical mesh-related claim data from 1 July 2005 to 30 June 2017*, 18 October 2017.

report in March 2017.¹¹ The NHS Mesh Working Group released an interim report in December 2015 and its final report in July 2017.¹²

1.10 In 2016, the latest update of the Cochrane systematic review of clinical publications of evidence on the use of mesh for POP was published and concluded that mesh 'might be useful for particular individual women, who might be willing to accept the risks, but that there was limited information regarding the benefits and risks and more research was needed.'¹³

1.11 In January 2017, the results of the 'PROSPECT' trial demonstrated no treatment benefit in using a mesh device over native tissue repair in women undergoing initial surgical treatment for POP. The trial concluded that the use of mesh introduced the potential for mesh-related complications that are not present in native tissue repair surgery.¹⁴

The purpose of this inquiry

1.12 The purpose of this inquiry is to:

- identify how many women in Australia have been adversely affected following transvaginal mesh surgery;
- consider the information and support provided to women undergoing transvaginal mesh procedures;
- consider the information provided to doctors and surgeons who recommend and undertake transvaginal mesh procedures; and
- examine the role of the TGA in approving and monitoring urogynaecological mesh devices for use in Australia.¹⁵

11 Scottish Government, *Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Interim Report*, 2 October 2015; Scottish Government, *Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women: Final Report*, 27 March 2017.

12 NHS England, Mesh Working Group, *Interim Report*, December 2015; NHS England, *Mesh Oversight Group Report*, 25 July 2017.

13 Department, *Submission 19*, p. 20.

14 The PROlapse Surgery: Pragmatic Evaluation and randomised Controlled Trials (PROSPECT) comprised two large randomised trials in 35 hospitals in the United Kingdom. It compared various types of mesh devices to native tissue repair for pelvic organ prolapse in women having their first surgical repair for pelvic organ prolapse. *Submission 19*, p. 20.

15 The terms of reference for the inquiry are available at Appendix 1 and on the committee's website:

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Terms_of_Reference.

Conduct of the inquiry

1.13 Since this matter was referred to the committee for inquiry and report,¹⁶ the committee has been struck by the extent to which women who have had adverse experiences following transvaginal mesh surgery have struggled to be heard as they have sought to raise concerns about their symptoms. More than 500 women wrote to the committee during the inquiry. The vast majority of these have experienced adverse events following surgery to implant surgical mesh and the majority of these have struggled to find assistance and support. Many of these women consider that the medical professionals they approached simply did not have sufficient awareness or knowledge of symptoms of adverse events after a surgical mesh implant. Some women were told that their symptoms were imagined. Others were led to believe that they were the only person who had reported any negative consequences following a transvaginal mesh procedure. Many women have waited extensive periods, sometimes years, to receive recognition and treatment to address their symptoms, all the while suffering debilitating pain, physical limitations, social isolation and financial and emotional stress.

1.14 The committee has sought to place these women at the forefront of this inquiry. At hearings in Melbourne, Perth, Sydney and Canberra the committee has provided opportunities for individual women to speak directly to the committee about their experiences.¹⁷ The committee has also accepted written personal accounts from over 500 women throughout the inquiry. The committee is indebted to each of these women for bravely coming forward to discuss these deeply private and frequently traumatic experiences.

1.15 The committee commenced its inquiry in February 2017 and invited written submissions by 31 May 2017. The committee continued to accept submissions after this date. The committee received 555 submissions.¹⁸ The committee is grateful to all those who provided evidence to the committee.

16 The Senate referred the matter to the committee on 15 February 2017 for inquiry and report by 30 November 2017. On 16 November 2017, the Senate granted an extension of time for reporting until 14 February 2018, on 14 February 2018 the Senate granted an extension until 20 March 2018 and on 20 March 2018 the Senate granted a further extension until 27 March 2018. See *Journals of the Senate*:

https://www.aph.gov.au/Parliamentary_Business/Chamber_documents/Senate_chamber_documents/Journals_of_the_Senate.

17 The committee held the following public hearings: 3 August 2017 in Melbourne, 25 August 2017 in Perth, 18 September 2017 in Sydney, 19 September 2017 in Canberra and 6 February 2017 in Canberra. The list of witnesses who provided evidence at the public hearings is available at Appendix 2.

18 A list of submissions received by the committee is available at Appendix 3 and on the committee's website:

https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/Submissions.

Types of devices and procedures

1.16 Throughout the inquiry, the committee heard a range of evidence advocating for, or critical of, specific mesh devices and surgical procedures using mesh. The committee does not pretend to have the expertise to evaluate the relative merits of specific devices or procedures. The committee has approached its task by focussing on the processes that those tasked with regulating and prescribing such devices and procedures have followed.

1.17 The committee has also been mindful of current class actions and matters before the Administrative Appeals Tribunal and has avoided commentary on matters under active consideration.

Class actions and the committee's inquiry

1.18 On 4 July 2017 a class action against Johnson & Johnson Medical Pty Ltd and Ethicon was commenced in the Federal Court of Australia.¹⁹ The committee notes that class action against another manufacturer and supplier of urogynaecological mesh products is being investigated.²⁰

1.19 In a submission to the inquiry, Maurice Blackburn Lawyers advised the committee that it had been instructed to commence legal action on behalf of three women in relation to a specific mesh product.²¹

1.20 This Senate committee inquiry is a separate process from any class action. Throughout the inquiry, the committee has sought to exercise care in canvassing matters that witnesses may subsequently be questioned on in court. The protection of parliamentary privilege means that witnesses at committee hearings cannot be questioned in court on information they have provided to the committee.

Report structure

1.21 This report is presented in five chapters:

- This first chapter provides background to the committee's inquiry and an overview of the use and regulation of urogynaecological mesh in Australia.
- Chapter 2 examines the experiences of women who have had transvaginal mesh implants, including the types and incidence of health problems they have experienced, and the impact these experiences have had on their lives.
- Chapter 3 considers the sources of data available to assist in determining the number of women in Australia who have had transvaginal mesh implants and the number of women who have experienced adverse side effects.

19 Shine Lawyers, *Johnson & Johnson/Ethicon Class Action*, <https://www.shine.com.au/service/class-actions/johnson-johnson-ethicon-class-action/>.

20 Shine Lawyers, *American Medical Systems Mesh Class Action*, <https://www.shine.com.au/service/class-actions/american-medical-systems-mesh-class-action/>.

21 *Submission 45*, p. 4.

- Chapter 4 considers the information and support provided to women prior to and following their surgery, regarding possible complications and side effects and the options available to women who are experiencing side effects.
- Chapter 5 considers the responses of regulators, the medical profession and device manufacturers and presents the committee's conclusions and recommendations.

What is transvaginal mesh?

1.22 Transvaginal mesh is a form of urogynaecological mesh that is implanted in a surgical procedure via an incision in the vagina to address pelvic floor conditions.²² It is a synthetic (polypropylene) net-like substance that is designed to provide extra support to repair weakened and damaged internal tissue. The mesh has holes in it to allow the body's own tissues to grow into the mesh.²³

1.23 Urogynaecological mesh devices are used to treat SUI and POP. These are common but different medical conditions that affect a significant number of women and can result in a reduced quality of life for many women. One in three women experience urinary incontinence after childbirth.²⁴ Up to 50 per cent of women who have given birth will have some prolapse present.²⁵ These conditions may present independently or together.

The use of transvaginal mesh in the treatment of pelvic floor dysfunction

1.24 Throughout the inquiry, witnesses have emphasised that SUI and POP are different conditions and that, while both conditions are often present in the same woman and can be treated concurrently, each condition requires separate assessment and treatment.²⁶ Similarly, while mesh devices for the treatment of SUI and POP are usually made from the same material, the procedures to implant them are different and each has unique risks and benefits.²⁷

Stress urinary incontinence

1.25 SUI refers to the involuntary loss of urine which occurs with physical activity such as coughing, sneezing, running or heavy lifting. It is caused by a lack of support of the urethra and reduced function of the urethral sphincter. It can result from the

22 Dr Michelle Atherton, *Submission 98*, p.1.

23 Victoria State Government, Better Health Channel, Transvaginal mesh, <https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/Transvaginal-mesh> (accessed 31 January 2018).

24 RANZCOG, *Submission 36*, p. 2.

25 Department, *Submission 19*, p. 11.

26 Monash Health, *Submission 44*, p. 1; RANZCOG, *Submission 36*, p. 1.

27 RANZCOG, *Submission 36*, p. 1; RANZCOG Communique, *Use of mesh for the surgical treatment of vaginal prolapse and urinary incontinence*, updated 29 October 2017: <https://www.ranzcog.edu.au/news/Use-of-mesh-for-the-surgical-treatment-of-vaginal> (accessed 17 January 2017).

weakening of the tissues and pelvic floor muscles that support the urethra as a result of pregnancy and childbirth, obesity, chronic cough, constipation and age.²⁸

1.26 While SUI is a very common condition, affecting up to a third of women, the committee heard that it can impact significantly on quality of life and the psychological and psychosocial wellbeing of people who experience it.²⁹ Management of the condition can become progressively burdensome and costly.³⁰ For some women, the need to plan their daily activities so as to minimise embarrassment impacts on their work, their ability to participate in social and physical activities, and their family and intimate relationships.³¹

1.27 SUI can be treated by non-surgical and surgical treatments. Non-operative treatment options for SUI include general lifestyle changes, pelvic floor muscle rehabilitation with a pelvic floor physiotherapist and continence devices. Non-surgical treatment may be effective for women with minor degrees of SUI.³² Those women who continue to have symptoms may require surgery.

1.28 There are a number of different types of surgical procedures used in the treatment of SUI. The committee heard that the most commonly used surgery uses MUS to support the urethra or bladder neck. MUS are narrow tapes made from polypropylene. Once inserted, scar tissue forms around the tape, holding it in place and acting like a sling to support the urethra during increased abdominal pressure.³³

1.29 There are three different insertion methods used to insert MUS:

- Retropubic (RPR) involving incisions in the vagina and just above the public bone;
- Transobturator (TOR) involving incisions in the vagina and in the groin area; and
- Single incision (SIS) involving an incision in the vagina only.³⁴

1.30 Throughout the inquiry the committee heard from medical practitioners that the use of MUS for the treatment of SUI 'is established as a safe and effective

28 Urogynaecological Society of Australasia (UGSA), Information Sheet, Stress Urinary Incontinence, *Submission 32, Attachment 1*, p. 2.

29 Continence Foundation of Australia, *Submission 35*, p. [1].

30 UGSA and RANZCOG, Position statement on midurethral slings, *Submission 32, Attachment 7*, p. 2.

31 See, for example: Name withheld, *Submission 56*, p. 5; Dr Darren Gold, *Submission 145, Attachment 1*, p. 1, Name withheld, *Submission 418*, p. 8; Name withheld, *Submission 463*, p. 1; Name withheld, *Submission 519*, p. 5.

32 International Urogynaecological Association, Stress Urinary Incontinence, A Guide for Women, *Submission 32, Attachment 8*, p. [2].

33 UGSA, Information Sheet, Mid-urethral Slings, *Submission 32, Attachment 3*, p. [1].

34 UGSA, *Submission 32, Attachment 3*.

treatment, and regarded as the "gold standard" for SUI surgery.³⁵ It is described as minimally invasive surgery, performed under general anaesthesia, and often as day surgery, with a relatively short recovery time.³⁶

1.31 The committee heard that prior to the introduction of the MUS, standard incontinence procedures required major abdominal surgery with several days hospitalisation, a prolonged recovery period and the risk of major complications.³⁷ The Urological Society of Australia and New Zealand (USANZ) told the committee that, compared to traditional incontinence procedures, such as a fascial sling or a Burch Colposuspension, the MUS 'reduces the need for an abdominal incision and as such is associated with a faster rate of recovery and can be placed in patients who are older and have more complex health issues.'³⁸

Pelvic organ prolapse

1.32 POP is a common condition of weakness of the supporting ligaments and muscles of the vagina and uterus. The symptoms of POP are varied and can range in severity from symptoms that can be managed conservatively through pelvic floor exercises, diet and lifestyle changes to symptoms requiring surgical intervention. Symptoms can result in functional changes affecting the bladder and bowel, as well as sexual function.³⁹

1.33 If left untreated, POP can have significant health, social and psychological outcomes. There are a number of surgical procedures available for the treatment of POP. POP can be treated by implanting surgical mesh to reinforce the weakened vaginal wall supports. This surgery can be done through the abdomen (trans-abdominal) or through the vagina (trans-vaginal).

1.34 The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) advised the committee that transvaginal mesh was introduced for the treatment of POP with the aim of better success rates than are achieved with traditional native tissue repairs, which have a recognised failure rate and commonly require repeat surgery.⁴⁰

Regulation of the introduction and use of transvaginal mesh in Australia

1.35 Regulatory responsibility for the introduction and use of transvaginal mesh devices in Australia sits across a number of entities, principally: the TGA, the medical colleges and the ACSQHC, under the oversight of the Council of Australian Governments Health Council.

35 RANZCOG Communique, *Use of mesh for the surgical treatment of vaginal prolapse and urinary incontinence*, updated 29 October 2017.

36 UGSA Information Sheet, Mid-urethral Slings, *Submission 32, Attachment 3*, p. [1].

37 UGSA, *Submission 32*, p. 1; Dr Darren Gold, *Submission 145*, p. [3].

38 RANZCOG, *Submission 42*, p. 2.

39 *Submission 36*, p. 2.

40 *Submission 36*, p. 2.

Regulation of medical devices

1.36 Regulation of medical devices, including urogynaecological meshes, is the responsibility of the TGA. The regulatory framework for medical devices comprises pre-market and post market requirements. Pre-market, manufacturers of all medical devices supplied in Australia must demonstrate compliance with safety and performance requirements (known as Essential Principles). High risk classified devices (Class III) undergo further mandatory pre-market assessment prior to inclusion of the device into the Australian Register of Therapeutic Goods (ARTG). Devices included on the ARTG are subject to ongoing post market monitoring.⁴¹

1.37 The TGA employs a risk-based approach to the regulation and the level of regulatory oversight increases with the risk of the device. Evidence provided at the time of application for registration of a device is reviewed in light of evolving evidence from clinical studies and practical experience.⁴² Urogynaecological mesh devices are currently classified as Class IIB (medium to high risk). In July 2017, The TGA released a consultation paper seeking comment on measures to align regulation of these products with European regulatory requirements.⁴³

1.38 Because the majority of medical devices supplied in Australia are imported, the Australian regulatory framework is closely aligned with that in Europe. This means that the Australian market authorisation process relies significantly on regulatory assessment work undertaken in the European Union. Sponsors seeking to supply a device in Australia, including devices manufactured in Australia, can provide conformity assessment certification issued to the manufacturer by a European Notified Body in support of their application.⁴⁴

1.39 In 2008 the TGA undertook its first post market review of urogynaecological meshes in response to a United States Food and Drug Administration safety alert. Since then the TGA has undertaken a series of postmarket reviews.⁴⁵ The TGA's post market monitoring is summarised in the chronology at Appendix 4. The response of the TGA to evidence regarding the risk associated with transvaginal mesh devices will be discussed further in Chapter 4.

Regulation of clinical practice

1.40 The TGA has no regulatory role with respect to clinical practice. Responsibility for the quality of clinical practice rests with the individual medical practitioner, assisted by codes of conduct, guidelines and policies issued by the relevant professional college.

41 Adjunct Professor John Skerritt, Deputy Secretary, Department of Health, *Submission 19*, p. 3.

42 *Committee Hansard*, 3 August 2017, p. 50.

43 Therapeutic Goods Administration, *Consultation: Alignment with European medical device regulatory framework*, 28 July 2017, <https://www.tga.gov.au/consultation/consultation-alignment-european-medical-device-regulatory-framework> (accessed 16 March 2018).

44 Department, *Submission 19*, p. 4.

45 *Submission 19*, pp. 5-6.

1.41 The framework for regulation of medical practitioners and the services they provide is complex and responsibilities are shared by the Commonwealth, state and territory governments, professional organisations, independent statutory bodies and public and private hospitals.

1.42 However, under the *Therapeutic Goods Act 1989* (Cth), the TGA does have a role in regulatory oversight of the information that the sponsors of devices must provide for all medical devices, known as Instructions for Use.

1.43 Professional colleges, such as RANZCOG and the Urogynaecological Society of Australasia (UGSA), influence the standard of care delivered by practitioners through education and training, the provision of guidance for the management of clinical conditions in women's health and standards for professional behaviour and research.⁴⁶

1.44 However, while the colleges can guide and advise, they have no regulatory role in relation to standards of clinical practice, outside auditing doctors' compliance with continuing professional development. Credentialing of individual doctors is the responsibility of credentialing committees within individual hospitals.⁴⁷

Safety and quality in health care

1.45 Responsibility for leadership and coordination of improvements in safety and quality in health care at a national level rests with the ACSQHC. The ACSQHC is jointly funded by all governments and its work program is developed in consultation with the Australian, state and territory Health Ministers. The ACSQHC works in partnership with patients, consumers, clinicians, managers, policy makers and healthcare organisations.⁴⁸

1.46 In June 2016, the Queensland Department of Health raised issues with the ACSQHC concerning complications experienced by women who had undergone transvaginal mesh procedures. Following a subsequent request from state and territory health department representatives, the ACSQHC commenced an examination of the safety and clinical aspects of the use of transvaginal mesh products for the treatment of pelvic organ prolapse.⁴⁹

1.47 This work was informed by a literature review, and close consultation with clinicians and with affected women through consumer forums between January and March 2017.⁵⁰ Adjunct Professor Picone told the committee:

46 RANZCOG, *Committee Hansard*, p. 19, Urogynaecological Society of Australia, *Committee Hansard*, 18 September 2017, p. 14.

47 Professor Stephen Robson, President, RANZCOG, *Committee Hansard*, 19 September 2017, p. 19.

48 Australian Commission on Safety and Quality in Health Care, *Governance*, <https://www.safetyandquality.gov.au/about-us/governance/> (accessed 8 October 2017).

49 Adjunct Professor Debora Picone, Chief Executive Officer, Australian Commission on Safety and Quality in Health Care, *Committee Hansard*, 3 August 2017, p. 39.

50 Prof Picone, *Committee Hansard*, 3 August 2017, p. 39.

The great majority of women who participated in the forums were physically and/or psychologically impacted following the procedure and, in our view ... they have been very significantly affected. It was not minor complications but very significant complications.⁵¹

1.48 The ACSQHC is currently developing a number of guidance documents to improve health care for women and to guide practitioners in the use of transvaginal mesh for POP and SUI and for the removal of transvaginal mesh.⁵² The work of the ACSQHC will be discussed further in Chapter 5.

51 Prof Picone, *Committee Hansard*, 3 August 2017, p. 39.

52 *Additional Information*, Australian Commission on Safety and Quality in Health Care update, received 6 February 2018, p. 1.

